DECISION-MAKING IN THE HUMAN SUBJECTS REVIEW SYSTEM

A Dissertation
Presented to
The Academic Faculty

By

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In Partial Fulfillment
Of the Requirement for the Degree
Doctor of Philosophy in Public Policy

Georgia Institute of Technology

January 2005

DECISION-MAKING IN THE HUMAN SUBJECTS REVIEW SYSTEM

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For my children,

Eoin, Graeme and Niamh

Your love of learning has been my inspiration.

ACKNOWLEDGEMENT

A journey such as this could never be made alone, without the support and encouragement of family and friends. So many individuals made personal sacrifices to enable me to complete this journey and I am grateful to each of them.

The members of my committee—Drs. Richard Barke, Roberta Berry, Ann Bostrom, Barry Bozeman and Mary Frank Fox—provided me with just the right blend of challenging questions and supportive guidance. I am grateful to each of them for giving their time and energy to me, for their interest in my research, and for their confidence in my ability to succeed. I am particularly grateful to my advisor, Dr. Richard Barke, for his mentorship and friendship. From the beginning, his wisdom and knowledge have guided and taught me what it is to be a truly great teacher.

While working on this dissertation, I spent two years as a research assistant working with the Georgia Tech Institutional Review Board (IRB). I owe many thanks to both the IRB staff and IRB members for allowing me that opportunity to develop a better understanding of the system about which I would eventually study for this dissertation. In particular, I am grateful to Barbara Henry, Alice Basler, and Jilda Garton for making this opportunity possible.

I would also like to thank those whom I interviewed for this research. Confidentiality does not permit me to directly acknowledge each of them or their affiliated universities. With their participation and their willingness to allow me inside the human subjects decision-making system, my research became possible. I would also like to acknowledge the National Science Foundation for generous support of this research via a Dissertation Improvement Grant (SES-0240394).

Among the many friends I have come to know over the past few years, I am so grateful to those who began this journey with me, especially my peers in the School of Public Policy at Georgia Tech. From the beginning, it was clear that we would become both colleagues and friends. Their support throughout every phase of this process has been invaluable to me. Through the ABD Moms group, I have enjoyed the "virtual" support of other women across the U.S. whose encouragement and willingness to share

"their dissertation story" with strangers often helped me to regain perspective and to continue moving forward. I am grateful for many other friends, who never lost faith in me in spite of the many times my dissertation obligations had to take precedence over friendship.

Most of all, I am indebted to my family for their love and support throughout this endeavor. My sister, Dara O'Neil, who is completing her own dissertation at this time, has been an amazing sounding board and patient listener. Particularly during the early stages of my thinking about this research, she allowed me to ask many "stupid questions" without smirking or laughing. From a very early age, my parents—Dr. Daniel O'Neil and Betty Noone O'Neil—cultivated the love of learning that not only led me to embark on this journey, but also sustained me throughout the past five and a half years during which time they selflessly gave of their time, doing whatever was necessary to enable my progress with this dissertation. Words cannot express how much gratitude I have for their role in helping me to achieve this goal. My children—Eoin, Graeme, and Niamh—also deserve my deepest acknowledgements. One by one they joined me along this path, listening to me read and talk aloud before they were old enough to even speak, patiently waiting for me to finish "one more thing" before getting my attention, and eventually sitting alongside me and "writing" their own "dissertation".

Last, but never least, I am most grateful to my husband, James Lane, for his unconditional love and self-sacrifice. He put his own career on hold to be both father and mother to our three children on countless weekends, nights, and even occasionally taking vacation from work just to help me realize this dream. He had faith in me when I most needed it, gave me strength when I could not find my own, and patiently allowed me to express every emotion one could possibly feel during an endeavor such as this. It is with great pleasure that I can finally write these words and fully share in our future together.

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GLOSSARY

Human Subjects Research Definitions[1]

45 CFR Part 46: Code of Federal Regulations covering protection of human subjects. 45 CFR 46 is divided into four subparts: A, B, C, and D. Subpart A, also known as the Common Rule, governs human subject research for most federal agencies; subparts B, C, and D address special areas.

Anonymized: Refers to information or data where identifiers (and codes that are linked to identifiers) have been removed, as well as other values that would enable individuals to be identified by inference. Close correlation with values in additional datasets, or unique values, or cells containing few data points, for instance, could support such inferences. A dataset, therefore, must at least have been thoroughly de-identified in order to be anonymized. For all practical purposes, anonymized data cannot be linked to the individual.

Belmont Report: Statement of ethical principles for human subjects research issued by the National Commission for the Protection of Human Subjects in 1978.

Beneficence: Ethical principle stated in the Belmont Report, stating an obligation to protect people from harm by not doing harm and by maximizing benefits and minimizing risks.

Child/Minor: A person who has not attained the legal age for consent to treatments or procedures involved in the research

Clinical Trial: Human subjects term indicating a prospective study of human subjects designed to answer questions about biomedical or behavioral interventions, e.g., drugs, treatments, devices, or new ways of using known treatments to determine whether they are safe and effective.

- Phase I tests a new intervention in 20-80 people for an initial evaluation of its safety, e.g., to determine a safe dosage range and identify side effects.
- Phase II studies an intervention in a larger group of people, usually several hundred, to determine efficacy and further evaluate safety.
- Phase III studies the efficacy of an intervention in large groups of several hundred to several thousand subjects by comparing it to other standard or experimental interventions, while monitoring adverse events and collecting information that will allow safe use.
- Phase IV is a study done after an intervention has been marketed to monitor its effectiveness in the general population, and collect information about adverse effects associated with widespread use.

[1] The definitions on the following pages are excerpted directly from the federal regulations on human subjects research: Department of Health and Human Services regulations 45 CFR 46, Food and Drug Administration regulations 21 CFR (parts 50 and 56).

Common Rule: The central federal policy adopted “in common” by 16 federal departments and agencies (and concurred, with some modifications, by the FDA) that support and/or conduct research involving human subjects. The adoption of the federal policy in 1991 implements a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that all federal departments and agencies "adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services (codified at 45 CFR 46, Subpart A, Protection of Human Subjects).

Compensation: Payment or other benefits that are provided to participants in research.

Confidentiality: Act of not divulging information disclosed in a relationship of trust without permission, including fulfilling the expectation that it will remain private.

Conflict of Interest (COI): Financial, career, or other such interest, including interests of family members, that could be advanced by the conduct of a research project.

Continuing Review: Research that has been approved will undergo review until the completion or termination of the research, including scheduled continual reviews of research that will occur at least annually

Data: Refers to information that is collected for analysis or used to reason or make a decision

Deferral: Refers to the status of a protocol that cannot be approved without additional information about the research. Several situations can lead to a deferral, including if the protocol does not contain enough information to allow the IRB to fully review and understand the nature of the research; and, if the IRB feels it does not have enough expertise to assess a specific portion of the protocol.

De-Identified: Refers to information or data where direct identifiers such as name and address have been removed. Typically this refers to data where it may still be possible to identify individuals by inference or through codes held by the investigator or a third party. Thus data that is de-identified may not be anonymized because it may still permit at least probabilistic re-identification when analyzed in conjunction with other datasets.

Department of Health and Human Services (DHHS): Federal government department to which the National Institutes for Health (NIH) belong whose mission is to protect the health of Americans and provide essential human services.

Exempt: Human subjects research that is excluded from 45 CFR 46. You do not need documentation that your research is exempt; you only need the signatures of the applicant and signing official on the face page of the PHS 398.

Exemption Categories: Human subjects term indicating six research categories exempt from human subjects regulations:

1. Research conducted in educational settings involving normal educational practices, such as research on instructional strategies, techniques, curricula, or classroom management methods.
2. Research using cognitive, diagnostic, aptitude, and educational achievement tests, or surveys, interviews, or observations of public behavior, unless human subjects are identifiable, and disclosure of responses could put them at risk of liability, or damage to their reputations or financial standing.
3. Research using cognitive, diagnostic, aptitude, and educational achievement tests, or surveys, interviews, or observations of public behavior, unless subjects are public officials or candidates for public office, or federal statutes require that the confidentiality of identifiable information will be maintained.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the sources are publicly available, or the information is recorded so subjects cannot be identified.
5. Research and demonstration projects conducted or approved by agency heads to study public benefit or service programs, procedures for obtaining benefits or services, or other changes to those programs.
6. Taste and food quality evaluation and consumer acceptance studies in a) wholesome foods without additives or b) food containing a food ingredient at or below a level and use found to be safe, or an agricultural chemical or environmental contaminant at or below a level deemed safe by the following agencies: Food and Drug Administration, Environmental Protection Agency, and the U.S. Department of Agriculture.

Expedited Review: Review of a research project by a designated voting member or members rather than an entire IRB. Expedited review is allowed for some low- risk research and minor changes in approved research.

Experimental: Therapy unproved or not yet scientifically validated for safety and efficacy. A procedure may be considered "experimental" without necessarily being part of formal research.

Federalwide Assurance (FWA): Online form that every institution conducting human subjects research must file with the Office for Human Research Protections. The federal regulations stipulate that institutions performing research covered by 45 CFR 46 must provide written assurance that it will comply with the requirements set forth in 45 CFR 46.

Food and Drug Administration (FDA): Department of Health and Human Services (DHHS) agency that reviews clinical research to regulate the marketing of foods, drugs, devices, and cosmetics.

Full Board Review: Review meeting of a quorum (or majority) of IRB members, including at least one nonscientific member. To gain IRB approval, a majority of members present at a meeting must agree.

Gender: Human subjects term indicating a classification of research subjects into women and men. In some cases, gender cannot be accurately determined, e.g., for pooled blood samples.

Human Subject: A living person with whom an investigator directly interacts or intervenes or obtains identifiable, private information private information. Regulations apply to human organs, tissues, body fluids, and recorded information from identifiable people.

Informed Consent: A person's voluntary agreement, based upon adequate knowledge and understanding, to participate in research or to undergo a medical procedure. In giving informed consent, a human subject may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

Institution: Any public or private entity or Agency (including federal, state, and other agencies).

Institute of Medicine (IOM): A multidisciplinary organization that examines the use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health care services to increase knowledge and understanding of the structure, processes, and effects of health services for individuals and populations.

Institutional Review Board (IRB): Committee set up by a research institution to ensure the protection of rights and welfare of human subjects. IRBs make an independent determination to approve, modify, or disapprove research protocols based on the adequate protection of human subjects, as required by federal regulations and local institutional policy. IRBs must register with the Office for Human Research Protections (OHRP).

IRB Approval: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

Justice: Ethical principle stated in the Belmont Report that requires that the benefits and burdens of research be distributed fairly.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Nonaffiliated Member: An IRB member who "is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution" (45 CFR 46.107).

Nonscientist Member: An IRB member "whose primary concerns are in nonscientific areas" (45 CFR 46.107).

Nuremberg Code: Code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

Office for Human Research Protection (OHRP): DHHS office that oversees human subjects protection for DHHS-supported research (formerly the NIH Office of Protection from Research Risks).

Peer Review Criteria: Basis for assessing the scientific merit of (typically funded) research grant applications:

- Significance – Is the topic important? Will it advance scientific knowledge?
- Approach – Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed?
- Innovation – Does the proposal involve new ideas or methods?
- Investigator – Do the investigators have the training and experience to do the work?
- Environment – Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities?

Principal Investigator (PI): Qualified person designated by an applicant institution to direct a research project or program. The research project or program may or may not be supported by a federal agency or other funding body. PIs oversee scientific and technical aspects of a grant and the day-to-day management of the research. PIs do not have to be employees of a grantee organization; however, these parties must have a written agreement specifying their relationship.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (such as a medical record).

Protocol: Formal design for research involving human subjects that an investigator submits to an IRB for review for human subjects research. A protocol generally has an objective, rationale, design, eligibility requirements, treatment regimen, and a description of research and data analysis methods.

Quorum: A majority of IRB members (required for IRB decisions), including at least one nonscientist member.

Research: Systematic investigation, including research development, testing, and evaluation, to develop generalizable knowledge.

Respect for Persons: Ethical principle stated in the Belmont Report that involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

Risk: Probability of harm or physical, psychological, social, or economic injury resulting from participation in a research study.

Scientific Misconduct: Fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted in the scientific community for conducting or reporting research.

Scientist Member: A person whose "primary concerns are in scientific areas" (45 CFR 46.107).

Serious Adverse Event: Adverse event that results in death, life-threatening experience, hospitalization or prolongation of hospitalization, significant disability, or a birth defect. Investigators must file serious adverse event reports with a sponsor and the IRB, which reports them to the appropriate federal oversight body (either OHRP or FDA).

Subject: Historically, a subject was defined as a healthy person or patient who participates in a clinical investigation either as a recipient of an investigational drug or as a control. This term is also used to describe any human research participant, regardless of the nature of the research study.

Subpopulations: Human subjects term indicating a group further defined by geographic origins, national origins, or cultural differences. Subpopulation data can be defined and reported by self-reporting or other means. Mixed racial or ethnic descent also applies to subpopulations, and such combinations may have biomedical or cultural implications for the science.

Waiver of Informed Consent: The Common Rule specifies that an IRB can alter or waive the requirement to obtain informed consent if it finds and documents that the research involves no more than minimal risk to the subjects, the waiver or alteration will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

SUMMARY

Issues involving the use of human subjects converge at the intersection of research in engineering, science, ethics, medicine, and technology and society. Ultimately, questions arise about risks and benefits to research participants and society, and the governance of science. By law, research organizations must establish an institutional review board (IRB) to decide whether to approve research protocols with human participants. Approximately 6600 IRBs exist in the U.S. Previous research on IRBs, mostly quantitative, has not studied the relationship between member characteristics (such as role and gender) and member perceptions of the IRB process. In this research I draw primarily on participatory democratic theory to frame the central research questions and the resulting analysis. I examine IRB members' roles, participation, and expertise on the IRB and how these relate to their perception of the IRB decision-making processes at seven leading U.S. research universities.

Policymakers and researchers alike increasingly are focusing on the adequacy of the existing system that oversees research studies involving human participants. As tension continues to mount over the applicability of the current guidelines to all research involving human participants, federally funded or not, it is timely to examine this oversight system to increase our understanding of how these committees actually decide whether to approve or disapprove human subjects research in their organizations.

In this study, data are collected from personal interviews with scientist, nonscientist and nonaffiliated members serving on IRBs at each of the participating universities, and from observation of an IRB meeting in session at each site. The findings of this research provide a scientific assessment of the relationship between IRB member composition and members' perceptions of the IRB process. This research contributes to our understanding of the decision-making process that takes place within IRBs. Furthermore it utilizes the IRB as a mechanism for expanding our understanding of larger questions about the interfaces of science and policy and science and society. By questioning who are the experts and how do different members attribute value to a research protocol on an IRB, we can begin to address broader issues of expertise and public understanding of science and research.

1.0 INTRODUCTION

1.1 Background to the research

Dr. Smith: Okay, we have a quorum now. Let's get this meeting started. Who's got #04-067? Mary, I believe you were primary reviewer on that one. John, you were secondary reviewer, right?

Mary: Yes, that was me. Let's see, Mr. White wants to ask students in the SOC401 class about their sexual behavior, beliefs and attitude. He's hypothesizing that young adults from single parent households have more liberal views towards sexual behavior. Looks like the lit review is decent but he didn't cite Doe's work, which I think is important to what he expects to find. There's a consent form included in the protocol and it seems to cover the key elements of informed consent according to our IRB checklist.

John: What department is White from?

Mary: He's a student in my department but I don't know him personally. Morgan signed off as his advisor. John, do you have anything to add?

John: Yes. Actually, I have two problems with this one. First, I wonder whether it should be coming to the board at all. If this is a class project then it could be classified as non-research and therefore, we don't need to see it. Second, if it is research for his thesis or something like that, I'm concerned about how this will look if the study results hit the front page of the local paper, especially if something negative comes out of it and that's entirely possible given the nature of the study. Does the university really want that kind of exposure?

Michael: I don't have the full IRB package. Did he give us any information on the types of questions he's planning to ask?

Kathy: I have a real problem with student research like this. I mean, there are some potentially big problems with a student asking his peers sensitive questions on sexuality. Is White in this class or is he a TA for the class? Can't someone else collect the data on his behalf? What if someone was sexually abused and some of the questions trigger a painful memory for him or her? What if he finds out that one of the students in the class sexually assaulted another student on campus? Then what will he do? I am not at all comfortable with this research and especially not with the student collecting the data from his peers.

Jones: I'm not as concerned about that but I think this research design is awful. How could Morgan have signed off on this junk? It makes me wonder if he even read it before giving it his approval. What is White comparing his sample group to? How can he get the information he's looking for with this kind of a design? Has the survey instrument been validated? It is also not clear to me what benefit will come of this research?

Ann: Could we step back for a moment, because I am still not sure whether it is within our purview to review the scientific merit of studies? This is a student project and there may be no real direct benefit to society. But if this is part of the learning process for the student to become a good researcher, doesn't that ultimately benefit society?

Miss Regs: Ann brings up a good point but let me remind the committee that technically speaking we are charged with the responsibility of making sure that the risks are minimized in a research protocol. So, if the study design compromises the participants' safety, then we ought to consider the design in our decision. In fact, we're obliged to review the scientific merit and research design according to 45 CFR 46 so it is well within the IRB's purview to do so.

Mary: As we are discussing this, I'm just looking over the survey instrument again and the questions look fine to me. They are all validated measures. This is standard in our field.

Dr. Smith: Well, do we have enough information on this one to make a motion?

Kathy: I think we need to table this until we get more information about how he will handle the issue of data collection and confidentiality. I'm still not comfortable with this in its current form.

Dr. Smith: If we push this off another month, it's going to delay his research. We have to think about that and make sure that we're tabling it for good reasons. Our priority is to protect the potential participants, but we don't want to be an obstacle to the research getting done either.

John: I'm satisfied. I don't think it's as big of a deal as Kathy does. I move to approve the protocol on the condition that we receive written clarification on the PI's status, justification for performing the study, and revisions to the consent form satisfactory to the chair. Dr. Smith, is that okay with you?

Ann: I second.

Dr. Smith: That's fine with me. Miss Regs will include these specific required revisions in the letter that goes out to the PI. All in favor say "aye". All opposed say so.

Kathy: Opposed

Mary: I abstain because he's from my department.

Dr. Smith: Kathy, would it make you feel better to also see the revisions before final approval? (Kathy agrees.)

Reverend Carter: Can I ask a question? What if the parents of these students find out about their participation in this study, especially if the results reflect negatively on single parents?

Dr. Smith: You raise a good point Reverend Carter. Miss Regs, could you add these concerns to the PI letter? Kathy and I will review the revisions prior to final approval. Reverend Carter, would you also like to see the revised protocol again? (Carter agrees.) Okay, White is approved with aforementioned conditions subject to approval of the Chair, Kathy, and Reverend Carter.

There are many issues at play in this hypothetical institutional review board (IRB) scenario that invite in-depth examination about the role of the IRB, how members determine the potential risks and level of risk in the study, the ways in which IRB members make decisions about whether to approve or disapprove a research protocol and how (or whether) these decisions are affected by the composition of members and their participation in the IRB discussion. The scenario is not intended to represent a specific factual case or all IRB meetings; yet, it combines many of the elements and issues observed while conducting this research at seven U.S. research universities. Moreover, it provides a point of departure for dissecting the human subjects review system and for answering more challenging questions about expertise and democratic governance of science.

The task of protecting human research participants requires balance among risk minimization, concern for public values, and a desire to advance scientific knowledge. In the U.S., IRBs were conceived as a means to protect human research participants by promoting ethical and responsible conduct of research. The pursuit of this balance is built into the composition of an IRB via the current federally mandated requirement that all IRBs must include at least one scientist member, one nonscientist member and one nonaffiliated member on a committee of at least five members[1] "with varying backgrounds to promote complete and adequate review of research activities" (45 CFR 46, Protection of Human Subjects, Section 107). In theory, this composition is intended

[1] Where necessary and depending on the nature of the research project, members from or representing vulnerable populations should also be included in the IRB review process (e.g., prisoners or prisoner advocates, child advocates, elderly populations or representatives of such populations, and patients or patient advocates).

to ensure that the board is diverse, sufficiently qualified, and sensitive to issues including community attitudes. Yet, little is actually known about how IRBs actually function, or more specifically about how member characteristics relate to the group decision-making process and outcomes of the IRB. Most IRB research (for example, Bell et al., 1998; Gray et al., 1978; Goldman and Katz, 1982; Barber et al., 1973) treats the IRB decision-making process as a "black box", primarily using quantitative methods to characterize it and mostly measuring inputs and outputs. They do little to reveal the decision-making process of an IRB itself.

The policy problem that emerges from the regulation of human subjects research is ensuring that human participants in research are granted three basic ethical rights—justice, beneficence, and respect for persons—while continuing to advance scientific knowledge. The conflict over how this should be achieved is indicative of an underlying intellectual challenge that lies at the heart of current debates on the issue. Because the answers to the policy and intellectual problems are so closely intertwined, this study attempts to dissect the system that oversees human subjects research by focusing on the arena where novel (and often more risky) research is most prevalent—the research university.

1.2 Research problem and research questions

It is uncertain whether the regulatory objective of a diverse composition of IRB members actually results in the most effective decision-making processes or yields quality decision outcomes regarding a research proposal. It is also unclear what "most effective" and "quality outcomes" mean in a decision system that blends scientific and public values criteria. Is a decision most effective if it allows the investigator to conduct the research as long as no risk is inflicted upon the research participants? Is the best decision outcome one that provides value-added to the scientific merit or study design of the research? Or is it best to disapprove a study outright if it is poorly designed or has more than minimal risk? Is a most effective decision one that permits a mediocre student project with little or no benefit to anyone but the student researcher? Are these outcomes even the outcomes we should be using to measure the effectiveness of the IRB system? These are difficult questions that cannot be answered solely by tallying outputs such as

counting how many protocols an IRB approves, modifies, defers, or disapproves. Such "bricks and mortar" analyses cannot fully explain the IRB decision-making process or determine the quality of IRB review provided. These questions cannot be adequately addressed without probing deep into the group decision-making process that takes place behind the doors of the university IRB meeting. This dissertation represents the first phase of what will be a longer-term study of IRB decision-making at the group level.

To increase our understanding of the IRB decision-making process (and more broadly decision-making at the boundary of science and society) in depth systematic research is needed at the local level to examine specifically how university IRBs assess risk, how members come to the determination that a study should be approved or disapproved, and how or whether board composition (i.e., membership characteristics) impacts these decision outcomes. In the IRB setting, what matters more is the quality of the decision—that is, the extent to which issues such as risks and benefits, and public values and concerns are discussed during protocol review—rather than what decision (approve, approve with modifications, defer, or disapprove) is taken. A more comprehensive treatment of potential risks and benefits, discussion about the contribution of the research to knowledge, and so forth contributes to the richness of the group history associated with a particular decision that, in the IRB setting, is applicable to future decisions. This information is available in the group repertoire and can used again in future decision-making about similar human subjects issues that other wise may not benefit from such deliberation.

Thus, the problem addressed in this research is, "**what is the relationship between IRB member characteristics and members' experiences and perceptions of the IRB process**?" To expand our understanding of this problem, I examine the relationship between the member perceptions of the IRB decision-making process and characteristics of IRB members and their committees. More specifically, I examine the relationship of member role in the different IRB settings of public and private universities and IRBs that review all types of human subjects research compared with those that review primarily biomedical or social and behavioral human subjects research.

Since 2000, federal funding has been suspended at several U.S. research universities[1] because of violations of regulations governing safety and ethical standards in human subjects research. In response, the National Bioethics Advisory Committee and some members of Congress have recommended an increase in the proportion of nonscientists and nonaffiliated members that serve on IRBs. But empirical evidence is lacking as to whether these failures and other IRB issues are directly attributable to various board characteristics. To date, no published systematic research has examined the influence of board composition on university IRB decision-making processes and associated decision outcomes. Thus, this research study seeks to examine that relationship between IRB composition—the types of members that serve on an IRB—and IRB behavior by asking a series of research questions: **How do IRB members make decisions about whether to approve a human subjects research protocol—that is, about risk-benefit ratio, scientific merit, research design, and adequacy of informed consent? What is the relationship between members' roles on the IRB and their level of expertise as these characteristics relate to their experiences and perceptions of the IRB process?**

These research questions are driven by a gap in our understanding of how IRBs function in practice and by a transdisciplinary call for overhauling the human subjects research oversight system. They also arise from the observation that IRBs are being thrust directly into the crossfire of researchers' fight for academic freedom on the one hand and a push to expand public governance of science on the other. Furthermore, answering these research questions provides entrée into more complex questions about how membership characteristics specifically affect the quality of the decision outcome. Thus, owing to the nature of my research objective and questions, I will not formally state or test hypotheses about the research questions in this dissertation. Rather, based on my

[1] Due to the death of gene therapy volunteer Jesse Geslinger all gene therapy programs at the University of Pennsylvania were suspended in January 2000. In July 2000, federally funded medical research was suspended at the University of Oklahoma because of concerns about the safety of a vaccine to treat melanoma. Though there has been no confirmed link to the study, 26 of the participants in the melanoma study died over the course of the study. At the University of Washington's Hutchinson Cancer Research Center, 80 of the 82 patients who participated in a failed blood-cancer trial between 1981 and 1993 have died. Ellen Roche, a healthy volunteer in a Johns Hopkins asthma study, died in 2001. Also in 2001, Johns Hopkins University was accused of purposely misleading volunteers in a lead-based paint study about the risks of exposure to lead and withholding important medical information from the study participants.

review of the literature, pilot study results, and my experience working closely with one IRB for two years, several preliminary propositions will guide my research about the relationship between IRB composition and members' perceptions of the IRB decision-making process. More specifically I examine whether: *Characteristics of IRB members are related to participation in the IRB decision-making process, such that (1) nonaffiliated members and nonscientist members participate in the process differently, and perhaps less, than scientist members, and (2) female members participate differently than male member in the group discussion, regardless of expertise.* I will refer to this the "member characteristic proposition". I also expect that the IRB is not immune to group behaviors, such as deference, that are evidenced in studies of small group decision-making. However, I have no a priori expectations about how these behaviors specifically manifest themselves among the convened group of IRB members.

Other explanations for why nonscientist and nonaffiliated IRB members, and female members participate in different ways compared with their scientist, and male member counterparts could be due to the type of IRB (biomedical, social and behavioral, or comprehensive) and whether it is located at a public or private university. For example, members who serve on biomedical IRBs may participate differently in the decision-making process than their social and behavioral IRB counterparts, specifically with regard to the issues they emphasize in protocol reviews. Or, members on IRBs at public universities may approach their review of the issue of scientific merit differently by virtue of the mission of a public university. Thus, either or both of these "IRB characteristics" might instead explain the differences in the relationship of IRB member composition and the IRB decision-making process. I will refer to these alternative explanations as the "IRB culture proposition".

The results of this research will contribute to theory and to policy and practice. It is expected that this research will inform the debate over public participation in technical decision-making and contribute to our understanding of difficult questions about what it means to be an expert in the science policy process. Furthermore, by providing universities with knowledge that will relate to the selection of members to serve on an IRB, this research will also inform policy and decision-makers for improving human subjects research policies at the local level.

1.3 Justification for the research

Research on IRBs is varied and what does exist focuses primarily on the bureaucratic functions of the research oversight process. Studies have examined the workload of IRBs (e.g., Gray et al, 1978; Bell et al, 1998), the perceptions that research investigators have of the review process (e.g., Cleary, 1987; Ferraro et al., 1999), and various elements of the IRB protocol such as issues of informed consent (e.g., Barber et al., 1973). Yet, the actual process by which the members on an IRB arrive at their decision to approve, defer, or disapprove a research protocol has been virtually neglected. No studies that I have discovered have examined the characteristics of IRB members in the context of the federal guidelines that each committee must have three types of member: a scientist, a nonscientist, and a nonaffiliated member. None of the earlier studies of IRBs have sought to use the IRB as a mechanism to inform our understanding of the role of the lay public in technical decision-making or governance of science. And, no studies on IRBs have employed the IRB decision-making process as a lens by which to examine what it means to be an expert in technical decision-making.

During the past 25 years, studies have attempted to characterize IRB operations by examining features such as the workload, types of research reviewed, and general operating procedures. Those studies were contextually driven by our limited knowledge about the development of IRBs in response to the early federal regulations. Little is reflected in the published literature about how IRBs formed after the promulgation of the 1966 U.S. Public Health Services policy requirement for all recipients of federal funding to establish an IRB (see McCarthy, 1998). Subsequent studies examined various components of IRB legislation such as the requirement for informed consent and consent process in general, or they attempted to understand how the oversight process from the research investigators perspective (for example, Gray et al., 1978; Goldman and Katz, 1982; Bell et al., 1993).

This study differs from prior research in that it attempts to relate IRB members' perceptions of the decision-making process to the composition and participation of these members on the IRB and thereby draw conclusions about the impact of composition on the resulting decision outcomes and human subjects oversight system. This research is

also unique in that the IRB decision-making process is examined via participatory democratic theory, which suggests that nonscientists and lay people ("nonexperts") can participate in political decision-making that is obviously dependent on the knowledge of experts (Dewey 1927, cited in Fischer 2000). The examination is further informed by research on small group decision-making, which suggests that groups exhibit a bias toward discussing only shared knowledge.

Participatory democratic theory implies that maximum input (participation) is required by the public, and that output includes not just policies (decisions) but also the development of the social and political capacities of each individual involved in the process (Pateman, 1970). Participatory democratic theory, therefore, suggests that in the ideal IRB setting, the required composition of scientists, nonscientists, and nonaffiliated members should contribute to broad discussion about research protocols, and not only should this participatory discussion lead to a quality decision (e.g., Phillips, 1995) about the research protocol but it should also improve the decision-making capacity of each member in subsequent discussions about future research protocols. Yet, evidence from research on small group decision-making suggests that groups do not necessarily incorporate knowledge that is held by only a few individuals (Stewart, 1998). As it relates to nonscientist or lay participation in human subjects decision-making, this evidence suggests that unless these members and scientist members share beliefs or knowledge about protocol-relevant information or public values, such information is not necessarily reflected in the IRB decision process or outcome.

At the broadest level, I apply participatory democratic theory to IRB decision-making—that is, to decision-making about scientific research involving human participants. Against this framework, I consider the relationship between individual member decision processes and the overall group level discussion. By examining the relationship between IRB composition and IRB decision-making at a sample of top ranking research universities I offer explanations about what it means to be a scientist versus a nonscientist (the expert-nonexpert distinction) on the IRB and how these characteristics may ultimately influence the quality of the decision outcome of the committee. I employ IRBs as a lens through which to examine the expert-nonexpert distinction at the interface of science and society. Additionally, by investigating the

considerations they take into account during this decision-making process, I aim to further clarify our understanding of how IRB committee members arrive at a decision of whether to approve research with human participants. It is expected that this research will contribute to the identification of a solution to the intellectual dilemma (protect human subjects while advancing scientific knowledge) and inform the policy question posed by how to best regulate research involving human participants.

In summary, this research attempts to (1) examine how IRB members determine whether to approve a human subjects research protocol, and (2) investigate how member composition on the IRB is related to members perceptions about the IRB decision-making process. While it is beyond the scope of this dissertation to directly examine the quality of IRB decisions, I use the results of this research to speculate on the relationship between IRB characteristics and the quality of IRB decision outcomes.

1.4 Methodology

This research employs qualitative analysis and case study methodology to characterize the research oversight system in seven top ranking U.S. research universities and to articulate a theory of IRB decision-making. A qualitative research approach was selected for its ability to investigate IRB attributes and behaviors that are not easily quantifiable, but necessary to explain IRB decision-making and improve upon it. Interview data are analyzed at the IRB level at each university and then compared via cross-case analysis across all participating universities. The methodological approach is detailed and justified in Chapter 4.

1.5 Organization of the dissertation

In Chapter 2, the reader is oriented with the historical context of human subjects research and the development of related policies that impact human subjects research in the U.S. In Chapter 3, the study of member participation in the decision-making process on IRBs is framed in terms suggested primarily by participatory democratic theory but also by small group decision-making theory. Given the limited empirical research on IRB decision-making I pay particular attention to areas where further research will enhance our understanding of governance of science and decision-making at the boundaries

between science and society. The theoretical framework plays close attention to the participatory culture on university IRBs and their relationship with those they serve in the context of a regulatory environment of science. It also illuminates the challenges in defining concepts such as participation, risk, public values, and expertise. In Chapter 4, I describe and discuss the data sources and methodological inquiry employed in this research.

The empirical chapters of this dissertation are organized in two sections. Chapter 5 provides a brief overview of the participant demographics. Chapter 6 investigates the human subjects review system at the individual case level of each university IRB and sets the context for subsequently examining participation and decision-making across the cases in Chapter 7. A cross-case analysis is presented in Chapter 7, in which I compare and contrast IRB decision-making across the seven universities. In Chapter 8, I offer conclusions about both the general research problem and the specific research questions that guide this study. Additionally, I consider implications for the theories that frame my analysis and human subjects research policy and practice. Finally, Chapter 8 addresses limitations of the research and offers more general comments on the problems and possibilities of studying IRBs in other contexts (such as hospitals, private research centers, developing countries, and so forth). The interview protocols and codebooks for obtaining and analyzing the data may be found in the Appendices.

1.6 Definitions

In order to examine prevailing beliefs of and challenges to oversight of human subjects research, it is necessary to clarify terms that will be frequently used throughout this dissertation. A complete list (adapted from federal sources[1]) of common terminology in human subjects research and IRB review is provided at the front of this dissertation.

For purposes of this research the following operational definitions are used. *Decision-making* or the *decision-making process* is the course of action taken by the individual member, or the IRB committee as a whole, as it relates to determining whether a protocol is approved or not. Generally IRB members receive protocols for review in

[1]Definitions were obtained from regulatory guidelines from the Office of Human Research Protections (OHRP) and Food and Drug Administration (FDA). (available at: www.hhs.gov/ohrp/policy/index.html and www.fda.gov/oc/ohrt/irbs/default.htm)

advance of the IRB meeting. Members are asked to review the protocols and identify potential problems or issues that may prevent IRB approval at the convened meeting. Typically IRB members independently review these protocols prior to the actual IRB meeting, and then discuss their concerns as a group at the convened IRB meeting. Thus, I define the decision-making process as the procedures by which members, both independently and as a group, judge the risks and benefits of the proposed research, the scientific merit of the study, the appropriateness of the sample selection, and the adequacy of the consent process. The decision-making process is also assessed via the meeting agenda, available meeting minutes, and correspondence with research investigators and other participants in the study via emails, letters or other forms of communication.

Participation means different things to different people. In this study there are two contexts in which I consider and discuss participation: participatory democratic theory and actual participation on an IRB. Participation in the context of *participatory democratic theory* refers to the normative process of shared decision-making and governance between government (decision-makers) and citizens (see Dahl et al., 2003). In the context of this study, this concept is situated amidst the decision-making process on the IRB that involves scientists and nonscientists, experts and nonexperts, elites and lay citizens. I distinguish the normative definition of participation from *participation on an IRB,* which I envision occurs at two different levels: either the member's active involvement (talking about or asking questions about a protocol) in the discussion at IRB meetings, or the member's involvement in the overall IRB process external to the actual meeting. Examples of the latter type of involvement may occur at multiple levels that are not necessarily equal (in the sense that all members do not necessarily review all protocols or in the same manner), including attendance at the meeting, contribution to the discussion, active review of protocols, service as a liaison between the IRB and the research investigators, or holding or participating in campus-wide IRB workshops. Participation level in this study is measured qualitatively in two ways: (1) self reported by the IRB member during the in-depth interview, and (2) independently observed at the in-session IRB meeting. Henceforth, these will be distinguished as "self-reported" and "observed" participation.

The federal guidelines for IRB membership—that is, the types of members who are required to serve on an IRB—as laid out in the Common Rule (45 CFR 46),[1] are not overly specific. Specifically 45 CFR 46.107 describes a *scientist* and a *nonscientist* vaguely as a "member whose primary concerns are in scientific areas" and a "member whose primary concerns are in nonscientific areas," respectively. Per the Common Rule (45 CFR 46.107), the *nonaffiliated member* is characterized not by his or her educational background, but rather by his or her affiliation with the research institution. To be considered "nonaffiliated," a member may not have any connection to the university which the IRB serves and may not be part of the immediate family of a person who is affiliated with the institute. Many IRBs refer to the nonaffiliated member as "the community member" since s/he is typically chosen from the surrounding community. Often (but not always) these members are ministers, local business owners, retired doctors, lawyers, retired teachers, or homemakers. The nonaffiliated member may be further classified as a scientist or a nonscientist depending on their educational training and experience. And in fact, it is not unusual in some organizations for the nonaffiliated member to possess a similar background in education and experience to the scientist members on the committee.

1.7 Delimitations of scope and key assumptions

Several limitations are purposefully imposed upon this research. First, the sampling frame was limited to top ranking research universities because the vast majority of federally funded and nonfederally funded human subjects research is performed in these organizations. While this means that the sample group at the university level is somewhat homogenous in certain areas (research expenditure, breadth of undergraduate and graduate programs, organizational structure), it can be expected to differ from other types of colleges and universities and from non-educational research organizations (hospitals, specialized research institutions) where human subjects research is also conducted. Second, the sample size is relatively small, though consistent with that

[1] The Common Rule (or 45 CFR 46) receives its name by virtue of the fact that its core requirements upheld by more than a dozen U.S. federal agencies that conduct or fund human subjects research. 45 CFR 46 includes three basic requirements: (1) compliance by research institutions, (2) assurance that researchers will obtain and document informed consent, and (3) the establishment of certain obligations for IRBs including membership, function, operations, review of research, and record keeping.

typically seen in qualitative research studies. Seven universities participated in this research, which yielded interviews with 37 IRB members. The current composition of members on each IRB further dictated which type of member participated in the study by virtue of the fact that some universities fulfill the nonscientist and nonaffiliated roles with the same person, thereby reducing the number of potential participants from these member categories. For example, at one participating university in this study all of the affiliated members are scientist members while the nonaffiliated members satisfy the nonscientist member requirement simultaneously.

1.8 Summary

This chapter laid the foundations for the dissertation. It introduced the research problem and the research questions that guided the study and influenced the choice of research methods. A justification for this research was provided, definitions and terms were presented, the methodology was briefly described, the study was outlined, and the limitations of the research were stated. The following chapters will expand upon these ideas and in further detail.

2.0 A Brief History of Human Subjects Research

In order to formulate a theoretical perspective to inform our understanding of IRB decision-making, it is helpful understand why IRBs exist at all. Prior to World War II, the ethics of research was seldom mentioned or rarely documented for several reasons: (1) clear standards of research ethics were not systematically taught in medical schools or research centers at that time; (2) only a very small portion of the federal budget was allocated to human subjects research and those studies did not attract much attention from Congress or the media; (3) neither the public nor scientists clearly distinguished between "research" and "care"; and (4) physicians enjoyed a high level of public trust and thus, the ethics of their research was seldom criticized by patient subjects (McCarthy, 1998).

But history has shown that some human subjects research never should have occurred. McNeill (1993) provides a broad account of unethical human experimentation dating as far back as Hippocrates and the Ptolemies. However, until the 1940s the concept of "research ethics" was not one of widespread concern (Rothman, 1987). It was during this time that funding of research significantly increased in the U.S., much of it with the intention of benefiting soldiers coping with war-related diseases (McNeill, 1993). The Nazi medical experiments on prisoners during World War II represent a trigger event in research ethics and the need to protect human research participants, and ultimately led to the development of the Nuremberg Code (1949)—ten guiding principles for conducting permissible medical research on human participants. Twenty-three German doctors and scientists were tried for various crimes including placing prisoners in low pressure chambers and observing their deaths; exposing prisoners to freezing air and water; infecting prisoners with typhus and malaria to test various drugs; sterilization and castration by various means; and murdering prisoners (including children) for parts of their anatomy (Alexander, 1949).

But the catalysts that forced ethical standards into the practice of clinical research were a series of exposés in the 1960s and early 1970s that made headlines (Rothman, 1998). In the 1960s, a study at the Willowbrook State School in New York deliberately exposed children to hepatitis to observe the course of the disease. In the mid-1960s, a study at the Jewish Chronic Disease Hospital in Brooklyn, New York involved injecting

elderly and senile patients with live cancer cells to observe how the health system of chronically ill patients reacted to foreign cells (Evans, 1982). In 1966, Henry Beecher's (a physician-researcher himself) infamous article in the *New England Journal of Medicine* in 1966 was published, citing 22 examples of ethically deficient and questionable health-threatening experiments performed on humans without informed consent. In the 1970s, the Tuskegee syphilis study (1932-1972) was made public. The Tuskegee study participants were black men with syphilis who were purposefully left untreated, even though a treatment for syphilis was available, in order to observe the course of the disease if left untreated. Even as recently as the early 1990s, the Johns Hopkins University conducted a research study on lead paint exposure, in which landlords of lead-contaminated housing were encouraged to rent to families (with otherwise healthy young children) who were told the homes had been abated of lead paint (Kaiser, 2001). Those families were subsequently recruited to participate in a study in which blood testing of the children would be done; however, families were not informed that blood lead testing was to be part of the study.

Not all of the studies that led to the current human subjects policies were conducted in the medical sciences, however. In the 1950s, a University of Chicago study involved bugging federal juries and led to Congressional hearings and legislation. During the same period, Milgram's famous psychology experiment on obedience led to significant controversy among social scientists.

These and other human subjects research studies conducted during the 20th century prompted the federal government in the U.S. and other countries to develop human subjects protection policies that have evolved during the past 50 years. The first federal document requiring committee review was issued in 1953 but applied only to intramural research at the newly opened Clinical Center at the NIH (Levine, 1981). In 1964, the World Medical Association developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving humans (World Medical Association, 2002). In 1966, the U.S. National Advisory Health Council issued Policy and Procedure Order 129 (PPO 129), which required Public Health Service (PHS) grantee institutions to:

> …provide prior review of the judgment of the principal investigator or program director by a committee of his institutional associates. This review should assure an independent determination (1) of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation.

Thus the institutional review board (IRB) was born. The PHS policy has been expanded and revised several times since 1966. But from the beginning the premise behind the policy was that the government would demand accountability while implementation would be local (McCarthy, 1998). Two key requirements missing from earlier versions of PPO 129 were subsequently added in 1981: (1) informed consent in cases where the reviewing committee found no risk to subjects, and (2) a justice provision that would require equitable distribution of the burdens and benefits of biomedical research throughout society (McCarthy, 1998). During this early period of regulatory policy, the division of NIH that was responsible for overseeing the new human subjects research protection policy was very small and quickly became overwhelmed. Early compliance with PPO 129 was dispersed and inconsistent across research institutions in part because so little specific guidance was available for institutions required to comply with the policy.

The issuance of PPO 129 was not the final solution to human subjects abuses. As noted above, research on the Tuskegee Syphilis Study continued for five years *after* PPO 129 was originally issued, and ultimately was the impetus for passing the National Research Act of 1974 (Public Law 93-348: National Biomedical Research Fellowship, Traineeship, and Training Act). The National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and further strengthened legislative oversight of human subjects research. This commission was charged with the task of identifying the basic ethical pillars of biomedical and behavioral research involving humans and with developing guidelines which institutions could follow to assure that human subjects research was conducted in accordance with such ethical principles. Over the course of four years, the 11-member committee deliberated on such topics as informed consent, risk/benefit ratios, selection of

research subjects, the use of fetuses and vulnerable populations, and other issues (Greenwald, 1982).

The National Commission responded by preparing the Belmont Report in 1979, which set forth three fundamental ethical principles for research involving humans: (1) respect for persons, (2) beneficence, and (3) justice. *Respect for persons* involves recognition of the personal dignity and autonomy of individuals, and advocates special protection of people with diminished autonomy. The principle of respect for persons is achieved via the informed consent process in which potential participants are presented with comprehensible information in a manner that allows them to make an informed decision about whether or not to participate in a research study. The principle of *beneficence* is embedded in the ethical tradition of medicine via the Hippocratic Oath to "help, or at least to do no harm" (Levine, 1981) and involves the obligation to protect participants from harm by maximizing anticipated benefits and minimizing possible risks of harm. The principle of beneficence is achieved through a careful analysis of the risks and benefits ensuring that the expected benefits outweigh the risks, and that the risks are minimized. Finally, the principle of *justice* requires that the benefits and risks of research are distributed equally over the population and that participants are not chosen simply because they are conveniently accessible.

In 1981, the U.S. Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) issued regulations based on the Belmont Report (see McCarthy, 1998). Known as the Common Rule (i.e., 45 CFR 46), these regulations provide guidance for researchers on the appropriate ways to involve human participants in research projects. The Common Rule (so called because its core requirements have been adopted by more than a dozen U.S. federal agencies that conduct or fund human subjects research) includes three basic requirements: (1) compliance by research institutions, (2) assurance that researchers will obtain and document informed consent, and (3) the establishment of certain obligations for IRBs including membership, function, operations, review of research, and record keeping.

IRBs are formally designated groups of people that review and monitor research involving human participants, with the primary obligation to protect the rights and

welfare of human research participants. Today, every organization[1] that performs federally funded research must submit its research protocols involving humans for IRB approval. Federal guidelines require IRBs not only to evaluate the potential risks and benefits to research participants, but also to judge the scientific merits of the study (because even minimal risk is not permissible if the project is methodologically flawed). The IRBs source of authority and its credibility within the research community is reflected within the process of appointing IRB members (Ryan, 1982).

Peer review and ethical review are key components of the human subjects research monitoring system (Dunn and Chadwick, 1999). Both the Nuremberg Code and the Declaration of Helsinki stipulate that research should be designed in a manner to justify the performance of the experiment (Nuremberg 3) and that basic biomedical research on human subjects must conform to generally accepted scientific principles and a thorough knowledge of the scientific literature (Helsinki, I.1) (Levine, 1981). The process of peer review ensures that sound research design and methods are employed (Dunn and Chadwick, 1999). Poorly designed research will not yield benefits, thus making it difficult if not impossible to uphold the principle of beneficence. Likewise, if one agrees to participate in research they are entitled to something of value because of their participation. Poorly designed research wastes the time of the participant and consequently violates the principle of respect for persons (Levine, 1981).

Ethical review ensures that risks are minimized or are reasonable with respect to benefits; selection of subjects is equitable; informed consent is sought and documented appropriately; where appropriate, that data monitoring provisions are adequate; and, that additional safeguards are in place if any participants are from vulnerable populations.[2] Federal guidelines (45 CFR 46) grant the IRB autonomy in the interpretation of

[1] Many types of organizations conduct research involving humans and thus have IRBs associated with them—universities, state and federal agencies, hospitals, and research foundations (National Academy of Sciences, 2000). The number of federal wide assurances on file at OHRP totals more than 6,600 (email correspondence with OHRP on March 31, 2004). External and private IRBs are also included in this number. These independent IRBs provide for-hire services to accommodate those institutions that have research activities but either do not have their own IRB (perhaps because they cannot justify the cost of a full-time IRB) or desire to supplement existing local IRBs.

[2] Vulnerable populations include groups such as children, prisoners or wards of the state, and the elderly (45 CFR 46).

regulations. Each IRB is asked to apply its own discretion when deciding how a research proposal will be judged to meet the ethical criteria laid out in the federal guidelines.

The Common Rule delineates three categories under which research with human subjects can be classified: exempt, expedited and full board review. But before a protocol is classified it must be deemed to be "research". The term "research" usually refers to a class of activities designed to develop or contribute to generalizable knowledge. Per the federal guidelines (specifically 45 CFR 46.102) "research" is defined as:

> …a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Research is distinct from the "practice" of medicine or behavior therapy which are activities designed solely to enhance a patient's or client's well-being (Levine, 1981). Generally the determination of whether a study is "research" according to this definition is made initially by the IRB administrator and staff, and sometimes with input of the IRB chair. Occasionally, a protocol makes it to the fully convened IRB where its classification as "research" may be questioned by IRB members during the decision-making discussion.

The federal guidelines provide additional assistance to aid in the determination of whether the research is then "exempt" from or "expedited" through the full IRB review process. To be considered "exempt" from the full board review process, a research study must fall under one or more of six "exempt" categories (45 CFR 46.101b):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the

research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If research cannot be classified as “exempt”, the next category of IRB review is “expedited” review. Expedited review does not necessarily mean that the research will move quickly through the system. Rather, it suggests that the research can be classified in either or both of the following ways (45 CFR 46.110):

1. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
2. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

The specific categories under which a research protocol may qualify for expedited IRB review are:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (under specific conditions as noted in the regulations).

3. Prospective collection of biological specimens for research purposes by noninvasive means.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened IRB as follows: where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2-8 do not apply

> but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The Common Rule stipulates that "under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB…(who) may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research" (45 CFR 46.110). If the expedited review procedure is used, IRBs must have a formal process for keeping all IRB members informed of research proposals which have been approved under the procedure. Generally this is achieved by presenting a list of such protocols to the full committee at the next IRB meeting for final approval.

If a research protocol does not qualify for IRB review under either the exempt or expedited review process, it must be reviewed by the full committee at a convened IRB meeting at which it will undergo the review process that is a primary focus of this dissertation, i.e., the IRB decision-making process at the convened IRB meeting. In accordance with federal policies, an IRB has the authority to approve and disapprove research protocols based not only on the potential for the study to impart risk to subjects, but also on the scientific merit of the study. These IRB actions are deemed essential in assuring that the rights and welfare of human research participants are protected at all times throughout a research study.

The IRB accomplishes its goal of protecting the rights and welfare of human research participants through the peer review and ethical review of informed consent documents and procedures, determining whether risks are reasonable in light of expected benefits, and judging that the risks and benefits of research are equitably distributed across the population (Belmont Report, 1979). It is assumed that IRBs use a group process to evaluate research protocols and related materials, such as informed consent documents, before a study is approved and throughout the duration of an approved research study. Thus, the IRB must make decisions at two levels: (1) whether a research protocol is approvable and, (2) whether the risk involved is significant or nonsignificant risk. To achieve this goal the IRB must make judgments about four key areas of the research protocol:

- scientific merit
- research design
- risk-benefit ratio, and
- adequacy of informed consent.

The federal guidelines do not provide specific criteria about all of these key areas. Rather, each committee is left to autonomously decide how to interpret the baseline regulations and in fact, is encouraged to use the flexibility of the regulations where appropriate.

The Common Rule provides minimal guidance about the regulatory basis for approving a research protocol. Per Section 46.111 of the Common Rule, IRBs are asked to ensure that protocols address seven points within the context of the four review areas above. First, risks to subjects should be minimized. This is determined by evaluating the research design of a study to verify that the research is consistent with sound research design and that participants are not being subjected to unnecessary risk. Second, risks to participants should be reasonable in comparison to expected benefits. The IRB is told to consider *only* those risks and benefits that may result from the research (as compared with those risks or benefits that participants may experience if they were receiving a treatment regardless of participation). Third, sample selection should be equitable and not limited to a specific group. In such cases where targeted research is being done, such as research on the elderly or children or prisoners, it must be justified and special considerations for vulnerable populations must be incorporated into such settings. Fourth, informed consent should be sought from each participant or his or her legal guardian, unless justification for a waiver can be provided. Fifth, the process of informed consent must be documented. Sixth, where appropriate, data monitoring procedures must be explained and provided. And finally, IRBs should consider whether provisions for participant confidentiality are adequate in the context of the research risks.

Other than these seven general guidelines for review, the Code of Federal Regulations does not state exactly *how* IRBs ought to arrive at a decision to approve or disapprove human subjects research. Rather IRBs and their members are left to independently judge the adequacy of submitted research protocol. In July 2002, OHRP issued a statement that outlines the required elements set forth in 45 CFR 46. This document summarizes requirements of the Common Rule in lay terms by specifically

stating *what* the IRB must do; however, nowhere does it explain *how* the IRB members should arrive at their decision. For example, the July 2002 letter states that:

> Unless a primary reviewer system is used, all members should receive a copy of the complete documentation. These materials should be received by members sufficiently in advance of the meeting date to allow review of this material. If the IRB uses a primary reviewer system, the primary reviewer(s) should do an in-depth review of all pertinent documentation. All other IRB members should at least receive and review a protocol summary (of sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111), the proposed informed consent document, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects.[1]

The federal regulations do not provide IRBs or members with specific information about what constitutes an "in-depth review". Upon joining the IRB, members are typically introduced to the IRB process via one of the publicly available Internet courses on human subjects protection, a training manual, or a workshop designed in-house at their research organization. During this introductory training, IRB members learn about the basic principles of ethical research, history of human subjects research, elements of informed consent and so forth. However, OHRP does not actually require IRBs to formally train their members. Instead,

> OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subject research.[2]

Greenwald (1982) observes that one of the most perplexing problems facing IRB members is the relationship between the ethical components of IRB review and the

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[1] Office of Human Research Protections (OHRP), "OHRP Guidance on Written Procedures," July 11, 2002, Department of Health and Human Services (available at: www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm; visited on October 12, 2004)

[2] U. S. Department of Health and Human Services, Office for Human Research Protections, Federalwide Assurance of Protection for Human Subjects, March 20, 2002 (available at: www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm; visited on October 12, 2004)

scientific aspects of the study. In most organizations, a large number of IRB members are likely to be nonexperts in the field of the study. Furthermore, the consensus among lawyers, clergy, community representatives and others typically serving in the nonaffiliated or nonscientist role is that they feel unqualified to judge the scientific merits of a protocol (Greenwald, 1982). Yet, the 1979 version of the Federal regulations explicitly required IRBs to evaluate research design to determine whether the methods are appropriate to the objectives of the study and such that the risks are minimized via sound research design. Though the final regulations published in 1981 softened this requirement somewhat by focusing primarily on the requirement that "risks to subjects are minimized by using the safest procedures with sound research design" (Greenwald, 1982), IRBs are required nonetheless to review both the research design and scientific merit of human subjects research protocols.

The flexibility in the federal guidelines is intended to allow IRBs to reflect local values (Azar, 2002), and this also holds true for committee composition. Except for minimal requirements, IRBs are free to choose which individuals will participate on the committee. At a minimum IRBs must be comprised of at least five members, including a chair, a scientist, a nonscientist, and a person not affiliated with the university.[1] The definition of each type of committee member is somewhat vague. The Common Rule states only that each IRB must include one member whose "primary concerns are in scientific areas" (i.e., the scientist member) and one member whose "primary concerns are in nonscientific areas" (i.e., the nonscientist member). Similarly, each IRB must also include at least one member who is "not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution" (i.e., the nonaffiliated member). Additionally, IRBs are required to make every effort to ensure that a committee is not composed entirely of members from one profession or entirely of men or entirely of women, as long as "no selection is made to the IRB on the basis of gender" (45 CFR 46.107). Where appropriate (depending on the research studies reviewed by the organization), IRBs must include representation of vulnerable populations such as prisoners, children, and the elderly either in the form of a voting

[1] IRBs often refer to the nonaffiliated member as the community member.

member who represents one of these groups or, if members do not possess this expertise in-house, by obtaining additional expertise from a consultant as needed.

3.0 LITERATURE REVIEW

3.1 Introduction

Chapter 3 identifies and reviews the conceptual dimension of the literature and provides theoretical justification for the research questions that inform this study. In the previous chapter, the reader was acquainted with the research subject via a brief history of the evolution of IRBs, which provided the historical context of and rationale for why IRBs exist at all. In this chapter, the research problem is first situated in the extant literatures of participatory democratic theory and decision-making theory (particularly as it relates to small group settings). The specific field of the research problem—decision-making in science and technology—is then discussed within the boundaries of university research and more specifically, in the context of university IRBs. This is followed by a summary of previous empirical studies on IRBs. Ultimately, two key research questions emerge, where methodological weaknesses and knowledge gaps exist in our current understanding of human subjects decision-making, and these questions guide and shape this dissertation research.

3.2 Theoretical framework

The theoretical framework for this research is anchored primarily in the participatory democratic theory literature, but is also informed by research on small group decision-making. Human subjects review is a political process as much as it is an ethical process because it is about balancing the interests of science and scientists against the interests of human research participants (McNeill, 1993). A participatory model of decision-making is, therefore, useful for examining IRB decision-making because the Common Rule requirement for IRB composition implies that better (higher quality) decisions will result if the IRB decision-making process includes the perspectives of scientists and nonscientists, affiliated and nonaffiliated members (from the community), and where necessary, members from or representing vulnerable populations (prisoners, children, elderly, patients). Research on small group decision-making theory lends further opportunity to understand and begin to explain the *actual* dynamics of the IRB decision-making "black box".

3.2.1 Decision theory

Decision theory is about how decisions are made. Most decision theories are either normative (how decisions *should* be made) or descriptive (how decisions are *actually* made). In the normative sense, decision theory tells the (rational) decision-maker how to achieve a particular objective. But, how decision-makers *ought* to make decisions is not necessarily how decisions *actually* get made. To answer the latter, several major models have evolved to explain decision-making processes in the policy environment at the individual, group, and institutional levels.

Building on earlier efforts of Koopman and Pool (1991), Beach (1997) outlines some of the major decision-making models. The classical economics model or the rational comprehensive model assumes that the decision-maker is able to identify the problem, that his goals, values, and objectives are clear and ordered according to their importance, that other ways of addressing the problem are considered, that the advantages and disadvantages of each option are investigated, that alternatives and their outcomes can be compared with other alternatives, and that the decision-maker will choose the option that maximizes the achievement of his or her goals, values, and objectives. Simon's (1955) bounded rational model, sometimes referred to as the information model (Beach, 1997), suggests that decision-makers develop a minimum acceptable level for each criteria; that is, they satisfice, or settle on a decision that is "good enough". Incremental decision-making or "muddling through" (Lindblom, 1959) suggests that the choice of goals and objectives is intertwined with the analysis of the problem. In other words the means and ends are not distinct from one another. In this "structural model" of decision-making new options may evolve over the course of the decision-making that were not clear at the time the original decision was being made (Beach, 1997). A fourth model—the garbage can model—portrays organizations as "organized anarchies" (Cohen et al., 1972) that have unclear or inconsistent goals. They rely on decisions made by members who are inconsistent participants (Beach, 1997). This model of decision-making portrays the organization as a garbage can in which collections of problems, solutions, participants, and choices are randomly mixed together (Cohen et al., 1972) such that (1) solutions can precede problems, (2) solutions and problems may rely on serendipity for

decision options, or (3) everything can come together when the decision-making group convenes (Beach, 1997).

The participatory component of the structural and the garbage can models is taken further in the participation model of decision-making, which examines the advantages and disadvantages of member participation in addition to the conditions under which participation is justified (Beach, 1997). The participatory model of decision-making suggests that increased or broader participation by members leads to better decisions and greater satisfaction with the decision outcome. Participatory models conceptualize stakeholders as active players in the decision-making process on equal footing to one another or with equal opportunity to contribute or participate in the process.[1] Proponents of public participation argue that this process is a means to ensure that ordinary citizens have a direct voice in decisions regarding issues that affect them, such as research involving humans, either directly or indirectly. Thus, participatory processes provide private individuals an opportunity to influence public decisions and are a component of most democratic decision-making processes.

Interestingly, these theoretical arguments for participatory decision-making seem directly contradicted by some research on small group decision-making, which indicates that group discussion often focuses on what most members already know whereas that which is relevant but only known to certain members tends to go unmentioned or is ignored when it is brought up (Beach, 1997; see also Stasser and Titus, 1985; Sniezek et al., 1990). Gigone and Hastie (1997) and many others[2] refer to this as the "common knowledge effect" where the impact of information on the group judgment is greater if more members know about that particular decision-relevant information *before* the

[1] The literature is replete with examples of applications of participatory theory in such issues as workplace democracy, environmental disputes, risk, and public planning (see for example, Mason, 1982; Fiorino, 1990; Bachrach and Botwinick, 1992; Moote et al., 1997; Allen, 1998; Forester, 2001).

[2] A growing body of literature is emerging on the importance of information exchange in group settings (see for example, Brodbeck et al., 2002; Cruz et al., 1997; Cruz et al., 1999; Dennis, 1996; Gigone and Hastie, 1993, 1997; Gruenfeld et al., 1996; Hollingshead, 1996a, 1996b; Kameda et al., 1997; Larson et al., 1996; Larson et al., 1994, 1998a, 1998b; 1998; Lavery et al., 1999; Mennecke, 1997; Postmes et al., 2001; Propp, 1997; Savadori et al., 2001; Schittekatte, 1996; Schittekatte and Van Hiel, 1996; Shaw and Penrod, 1962; Stasser and Stewart, 1992;
Stasser et al., 1995, 1989, 2000; Stasser and Titus, 1985, 1987; Stewart, 1998; Stewart et al., 1998; Stewart and Stasser, 1995, 1998; Van Hiel and Schittekatte, 1998; Winquist and Larson, 1998; Wittenbaum, 1998, 2000; Wittenbaum et al., 1999; Wittenbaum and Stasser, 1998; Wittenbaum et al., 1996).

discussion. In a study of group judgment processes, Gigone and Hastie (1993) find that information pooled during discussion has almost no effect on the group judgments, as if members exchange opinions but still retain their original opinion. Moreover, shared information is usually more likely to be discussed, and discussed earlier in the process of decision-making (Winquist and Larson, 1998). The need to reach consensus in circumstances where most of the members already share similar preferences may decrease the amount of information exchange and result in early consensus (Kerr and Tindale, 2004).

The presence of the "common knowledge" phenomenon in an IRB decision-making setting has tremendous implications for the rationale behind the federal requirement to include certain types of members on an IRB. If the same phenomenon occurs in the IRB setting, the contribution of the nonaffiliated member or even the nonscientist members arguably could be nonexistent or irrelevant to the ultimate decision made by the board, particularly if the rest of the group does not openly share similar opinions or information about a research protocol. Thus, if the IRB membership is dominated by scientist members who tend only to wear their scientist "hat" or focus "primarily on scientific interests", public values—such as preferences for the outcomes of public-funded research—may never become a point of discussion in the IRB decision-making system. The degree to which members participate and share their opinions or concerns about a protocol also influences whether such opinions are ever voiced and, if they are brought up at all, to what extent. Members may believe that their individual opinion, if shared by most other members, is well informed even if they know they do not possess all of the relevant information about a protocol. Then, when new information is made available during the discussion they are likely to adjust their opinion insufficiently (Gigone and Hastie, 1997). But, relying on shared information at the expense of unshared information could lead to faulty decision-making (Henningsen and Henningsen, 2003). Because the composition of an IRB is somewhat diverse with respect to expertise that is relevant to a protocol, that relevant information which is held by most of the members might be assumed to be sufficient to recommend approval of a protocol, or even to recommend deferring or disapproving a protocol. The extent to whether this effect occurs in the IRB decision-making setting is uncertain and is not directly examined within the

scope of this dissertation. But, it does lead one to question whether the IRB decision-making process could result in decisions that have not considered the full range of possible outcomes, potential risks, and so forth, and whether such decisions are free of errors related to bias in judgment.

Most of the effort in organizational decision-making is not directed at reaching a specific decision, but at trying to understand a particular "problem" and conceive of options for dealing with it (Beach, 1997). Making a decision is not an end in itself; rather it is a means to achieving a broader goal (Orasanu and Connolly, 1993). This is certainly true of the IRB decision-making process where the broader goal is to protect human subjects and to some extent even the researcher and the university itself. The "problems" in an IRB setting might on one level be the process of approving a protocol, on another level dealing with adverse events of an existing approved protocol, and yet on another level handling noncompliance of research investigators. Depending on which problem the full board is addressing, several options are available. For the review process, the IRB has two sets of options that I will refer to as "bureaucratic options" and "protocol tweaks". The bureaucratic decision options are fairly straightforward. Basically, the IRB has four bureaucratic decision options: a protocol may be approved, approved with conditions (or required revisions), deferred (due to insufficient information to either approve or disapprove), or disapproved.

On the other hand, "protocol tweaks" are more difficult to assess albeit more interesting and possibly more telling about the IRB decision-making process. The option to "tweak" protocols is implicit primarily in the IRB decision to approve a protocol conditional on certain revisions. The decision to defer a protocol for more information also implies a "tweak" because the IRB is essentially telling the researcher that the protocol will not be considered until more information is provided. However, of the four bureaucratic options above, it is the IRB option to "approve with conditions" that perhaps is most affected by issues of expertise and other characteristics of the IRB. Consequently, the extent or type of "protocol tweaks" is also subject to features of group decision-making considered above.

Underlying the actual IRB decision-making process is the federal mandate, which is not simply to approve or disapprove research protocols but rather, to protect human

participants in research. Each of the problematic issues associated with the traditional models of decision-making is mirrored in the collective IRB decision-making process: ethical considerations, governance and democracy, judgment and values, and diversity of perspectives. Thus, the diversity among IRBs and their members presents an opportunity in which to examine the complex interplay of these issues with IRB decision-making processes and to consider the impact of IRB decisions on research with human participants. IRB members are presumed to consider decisions carefully because of concern about the consequences or outcomes, whose goodness or quality are measured against public values. So, if many members share certain information or even beliefs relevant to some feature of a protocol, the desire to modify a protocol based on such information may translate to a committee requirement in order to grant IRB approval (i.e., a protocol tweak). As noted previously, whether such "shared" information enters into the IRB decision-making process may depend not only upon the presence of group decision-making characteristics such as the "common knowledge effect" but also upon the participation of members and their willingness to contribute to the IRB decision-making process.

3.2.2 Participatory democratic theory

One solution to encourage a decision-making process that includes diversity in perspective is the application of participatory democratic principles. Participatory democratic theory assumes (1) that people are inherently capable of understanding their problems and expressing themselves about these problems and their solutions and, (2) that real solutions to problems require the fullest participation of the people in these solutions, ultimately without being dependent on authorities and experts (Oppenheimer, 1971). While participation in a decision-making process is seen as a value in and of itself, ordinary citizens generally are not privileged to participate in the science and technology policy process.

Cook and Morgan (1971) observe that participatory democracy implies two broad features in patterns of decision-making: (1) decentralization or dispersion of authoritative decision-making whereby authority to make certain decisions is displaced such that authority is brought closer to those affected by it, and (2) direct involvement of amateurs

in the making of decisions. They clarify that amateurs in this setting are individuals who do not carry credentials as formally trained experts; they are laymen and not professional participants (Cook and Morgan, 1971).

Participatory democratic theory assumes that cross-communication between groups increases mutual trust, respect, and understanding. It provides a basis for constructive cooperation among participants—such as scientists, nonscientists,[1] and lay members on an IRB. It is important to note that the requirement to include a nonaffiliated member on the IRB is not explicitly intended to ensure that the IRB decision-making process is participatory, but rather to expand the diversity in perspectives offered by members affiliated with the research organization and also to prevent potential bias in favor of the research organization. Though the federal requirement that at least one IRB member is non-affiliated with the research organization implies the inclusion of a person from the surrounding or potentially impacted community, such members may have credentials equal to the scientist members on the committee. From a functional perspective, the Common Rule suggests that the inclusion of the nonaffiliated member expands the diversity of perspectives on the committee and also helps to alleviate potential dominance and institute bias by the affiliated IRB members. Presumably if at least one IRB member is not concerned with what the research organization stands to gain or lose, the committee is less likely to unanimously approve poorly designed or unjustified research protocols on the basis of potential benefits to the university. On the other hand, unless nonaffiliated members are scientists in their own right, it is uncertain whether they will argue with scientist members about the scientific merits or research design of a human subjects

[1]The Common Rule membership requirements for an IRB were discussed in Chapter 2. While the FDA requirements are consistent with those laid out in 45 CFR 46.107, FDA provides the following elaboration on member characteristics. 21 CFR 56.107(c) requires at least one member of the IRB to have primary concerns in the scientific area and at least one to have primary concerns in the non-scientific area. Most IRBs include physicians and Ph.D. level physical or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 21 CFR 56.107(f). FDA believes the intent of the requirement for diversity of disciplines was to include members who had little or no scientific or medical training or experience. Therefore, nurses, pharmacists and other biomedical health professionals should not be regarded to have "primary concerns in the non-scientific area." In the past, lawyers, clergy and ethicists have been cited as examples of persons whose primary concerns would be in non-scientific areas. Some members have training in both scientific and non-scientific disciplines, such as a J.D., R.N. While such members are of great value to an IRB, other members who are unambiguously non-scientific should be appointed to satisfy the nonscientist requirement (FDA, 1998).

protocol. In reality, since the number of affiliated members typically far outweighs the number of nonaffiliated members on most (perhaps all) university IRBs in the U.S, one must wonder "how realistic is it to expect one nonaffiliated member to challenge a group of affiliated, mostly scientist members on the basis of a conflict between flawed research design (which they may not even recognize) and benefit to the organization?"

Returning to the concepts of public participation and participatory democratic theory, it is helpful here to examine their relationship to decision-making. Arnstein (1969) models public participation as a ladder with eight steps ranging from nonparticipation (manipulation and therapy) to a degree of tokenism (informing, consultation, and placation) to degree of citizen power (partnership, delegated power, and citizen control).[1] She further likens the idea of citizen participation to eating spinach: "no one is against it in principle because it is good for you" (Arnstein, 1969). Using Arnstein's model to describe the different degrees of public participation, at the most basic level participation may be actively receiving scientific or technical information about a specific issue. This form of "participation" was typical in the late 1940s through the early 1960s when most government agencies simply focused on getting information out to the public, an action deemed legitimate by the agencies as a "goodwill" gesture to let the public know about the good things the agency was doing (Creighton, 1999).

During the last few decades of the 20th century, interest in and debate over the role of the public in technological decision-making increased. Beginning in the 1960s, practically every piece of environmental legislation held requirements for public participation (Creighton, 1999), though most of these were nonspecific or, at best, akin to the public comment periods on various proposed rules and permit decisions (e.g., those issued by the U.S. EPA). By the 1980s federal agencies such as the EPA began moving

[1] More specifically each rung of Arnstein's ladder of participation are described as follows: **Manipulation** and **therapy** are non participative. The objective is to cure or educate the participants. The proposed plan is best and the job of participation is to achieve public support by public relations. **Informing** is an important first step to legitimate participation. But too frequently the emphasis is on a one way flow of information to the public. **Consultation** takes the form of attitude surveys and community meetings while **placation** allows citizens to advise but retains for power holders the right to judge the legitimacy or feasibility of the advice. **Partnership** entails a relationship in which power is distributed through negotiation between citizens and power holders and responsibilities such as planning and decision-making are shared. **Delegated** power gives citizens a clear majority of seats on committees with delegated powers to make decisions. At this level the public has the power to assure accountability of the program to them. Finally, at the highest level of participation, **citizen control**, citizens handle the entire job of planning, policy making and managing a program. (Arnstein, 1969)

beyond traditional rulemaking to more collaborative or consensus-building processes. The 1990s ushered in a heightened awareness that citizens could (or perhaps should) play a more active role in resolving environmental issues (and also matters of public health and transportation). Especially in the resolution of environmental problems, participation mechanisms such as citizen advisory boards and consensus conferences became more widely accepted forms of engaging the local public. By the end of the 20th century, practically every federal agency had at least some stance on public participation. For example, the U.S. Department of Energy is among the leaders in this area (Creighton, 1999) especially with regard to its handling of environmental issues.

Direct participation "is premised on the notion that democratic governance includes the full participation of individuals as individuals" (Laird, 1993). On Arnstein's ladder, this would include partnerships, delegated power, and citizen control. These would-be forms of "strong democracy" are introduced into the policy process in which citizens participate at least some of the time in decisions that affect them (see Barber, 1984). In direct participation, participation needs to be active and individual. Participatory democratic theory suggests that the only way individuals will learn about their own support of technology and about risks and benefits associated with technology is by actually participating in decision-making about such issues (Mitcham, 1999). Another underlying assumption of participatory democratic theory is that citizens are not isolated beings, and that social organizations play an important "educative" role in teaching them how to interact and work together and how to act socially as well as politically. Citizens are socialized to learn democratic norms by participation in social groups, workplaces, and other forums (Pateman, 1970; Mansbridge, 1980; Donovan et al., 2004).

Research suggests that broader participation may contribute to better decision-making because a more extensive range for values is likely to be considered in the decision-making process (Fiorino, 1990). Because citizens are both consumers of information and sources of it, participation *is* communication and, if effective in both directions, it is the basis for improving inputs to decisions (Wengert, 1976: Lawrence et al., 1997; Burroughs, 1999). Though not explicitly stated as such, the Common Rule implies this argument via the requirement that "the IRB shall be sufficiently qualified

through the experience and expertise of its members and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes" (45 CFR 46.107) and suggests a relationship between diversity of perspectives and comprehensive discussion of representative values related to human subjects research protection.

Sociologists of science have pointed out this "local knowledge" (i.e., knowledge held by the local community, typically about the local community), and contrasted it with theoretical knowledge brought to local contexts by scientific experts (see Collins and Evans, 2002). In many cases, local knowledge may be as relevant to appropriate decisions as systematic theoretical knowledge (Wynne 1991; Irwin and Wynne 1996). Fiorino (1990) argues that lay people have valid judgments that can supplement the understanding of experts. When experts and lay experts disagree, a venue for public deliberation opens in which scientific experts may be transformed (Wachbroit, 1999). Evidence from research studies on AIDS illustrates this very argument (see Epstein, 1996). Epstein notes that the establishment of randomized clinical trials as the gold standard in biomedicine led to the argument that their results were most informative if strict research guidelines were followed for selecting participants. Experts further argued that valid results could only be achieved if research participants were "clean" in the sense that they did not take any other medications while participating in the AIDS drug trials. But AIDS activists proceeded to challenge this assumption by demanding answers to questions such as why some groups of potential research subjects were excluded from the trials. These challenges—presented insistently, articulately, and publicly via the media, comments at professional meetings, and letters to journal editors—went on to reshape the design and methodology of clinical trials of AIDS drugs (Epstein, 1996). Eventually experts conceded and one went so far as to write an article[1] about the transformation (Wachbroit, 1999; see also Merigan, 1990). Consequently, activists (knowledgeable nonexperts or lay experts) have influenced both the biomedical world and the ethical and legal premises surrounding that world (Epstein, 1996).

[1] Merigan, T. (1990) "You *can* teach an old dog new tricks: how AIDs trials are pioneering new strategies," *New England Journal of Medicine*. 323(19): 134-1343 (November 8).

3.3 Participatory decision-making in research with human subjects

Earlier I noted that the fundamental dynamic of the IRB is the process of arriving at a decision about a research protocol—that is, whether it minimizes risk and maximizes benefit for participants and society, whether the research design is acceptable, and so forth—and alluded to the various decision choices available to the IRB. In the IRB setting, such decisions are made in two different capacities: individually before the convened IRB meeting, and then as a group at the convened IRB meeting (see Figure 1). Before the convened IRB meeting, each member is asked to independently conduct a review of the research protocols using the guidance put forth in the Common Rule (45 CFR 46). That is, each member individually must make a judgment about each of the four areas of concern previously discussed in Chapter 2: risk-benefit ratio, scientific merit, research design, and informed consent process.

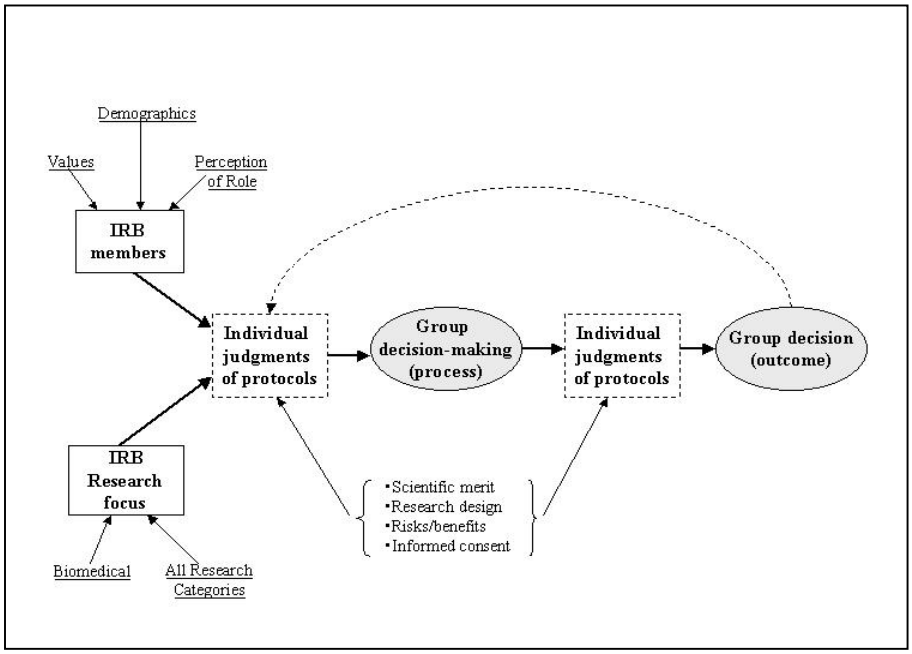

Figure 1. Conceptual model of the IRB decision-making process

The next phase of the review process takes place at the group level during the convened IRB meeting. At this stage, IRB members bring their individual concerns to the discussion for deliberation and clarification as a group until a decision is made about

whether each research protocol merits approval. In the following decision-making phase, members are asked once again to make an individual judgment of the protocol via a vote (sometimes formal or informal) to approve the protocol. The focus of this research study is on how individual member characteristics, participation, and expertise are related to the members' perceptions of the IRB decision-making process. While the data collected in this study do not allow for a comprehensive analysis of the overall group decision-making process, they do support analysis of member perceptions of that process, which subsequently begins to illuminate the group decision-making process and invites future research to further explain the complexities of the IRB process. To this end, it is helpful to understand the nature of small group decision processes in order to understand the process for formal participation (Benello, 1971).

If we define decision-making as a process in which choices are made or a preferred option is selected then a decision involves a point in time and space when values are allocated (Parsons, 1995). The decision-maker will make decisions consistent with his or her values—things that are important to him or her such as safety, fairness or equality. Not surprisingly a group of, say, nine IRB members will hold different sets of values individually shaped by their experiences as scientists, administrators, clergy, fathers, lawyers, or breast cancer survivors. The extent to which scientists fulfill their IRB role of having "primarily scientific interests", for example, is uncertain and arguably impacts the breadth of perspectives that substantively enter into the decision-making process.

The specific composition requirement for IRBs is an attempt to capture a variety of perspectives and values related to a research protocol. However, it is questionable whether the outcome could be truly representative unless members are selected to the IRB because they represent some potentially impacted faction of society or the research organization. One scientist from the biological sciences cannot possibly be considered representative of all scientists in all disciplines, for example. Moreover, the atmosphere of the meeting and the personalities involved can also influence whether and which values are promoted.

Increasingly, the "knowledge elite" expect that public decision-making should be left to the experts (Jasanoff, 1999) and, it is not unusual for lay people, and even experts,

to defer to presumed authorities or individuals with expertise in "adjacent areas" (for example, see Fuller, 1998; Woodfield, 2000; Sarangi and Clark, 2002; Selinger, 2003). Moreover, results from a pilot study of IRBs[1] suggest that, during IRB review of protocols, nonaffiliated and nonscientist members "tend to defer to the scientist members and tend to withhold because they don't want to hold up the process or maybe feel that their opinion won't be respected".

3.3.1 Decision-making and expertise

A central concern in achieving group purpose is the role of the expert within the group (Benello, 1971) and since the IRB process involves various kinds of social decisions, technical knowledge (i.e., expertise in some domain) is usually involved. Expertise is conceptualized in various ways. Generally, expertise is based on experience of some kind (Nowotny, 2003). Often experts are defined as individuals who possess a skill or knowledge in a particular area, such as science, medicine or psychology. The term "expert" often reflects more a person's pedigree rather than his or her possession of any particular body of knowledge (Wachbroit, 1999). For example, someone is not a scientist only by virtue of what s/he knows but also because s/he possesses certain credentials such as a degree in chemistry. Research on expertise has shown that experts also tend to possess certain characteristics when compared to novices in their field (Shanteau, 1992). Shanteau finds that experts have highly developed perceptual/content abilities; know what is irrelevant; are able to simplify complex problems; are able to communicate expertise to others; are self confident in their decision-making; possess a strong sense of responsibility; and are willing to stand behind their recommendations. In most studies of expertise, such characteristics distinguish experts in a field from novices or junior members in that domain.

Experts can also be classified according to different levels of contribution or understanding of a particular domain (Collins and Evans, 2002). They may possess sufficient knowledge about a domain to converse with other experts in that domain (interactional experts). They may possess adequate knowledge to contribute to the field itself (contributatory experts). Or, they may have enough knowledge to understand what

[1] Details of the pilot study are discussed in Chapter 4.

it means to contribute to a particular field (referred experts). Nowotny (2003) observes that "expertise has never before been so indispensable, while being simultaneously so hotly contested". Pressure to democratize science and technology decision-making further intensifies the debate over whose knowledge (or expertise) ought to be incorporated into decisions (Nowotny, 2003; Jasanoff, 2003). The IRB system is not immune to this dilemma, and IRB adversaries frequently accuse it of not having or using the appropriate expertise to determine whether research protocols merit approval. Yet, identifying the experts on an IRB is not as simple as labeling the scientists as experts and the nonscientists (or nonaffiliated members) as nonexperts. In fact, at any given time during the IRB process, an IRB member may or may not be an expert in the area of a particular research protocol. In that case, we are challenged to ask whether the concept of expertise on an IRB can or should be classified according to something other than disciplinary expertise, perhaps according to methodology or the research objectives of a particular area of research or perhaps some other classification, such as IRB processes.

The question of whether experts are better qualified to make the decisions that will benefit society, and whether citizens can even possess the necessary knowledge and skills to participate intelligently, is not new to the debate about democratic decision-making (Fischer, 2000). Moreover, one might argue that scientists are citizens like everyone else and therefore are capable of bringing public values into the decision-making process. In the U.S., decisions regarding science and technology (S&T) policy have traditionally been influenced by scientific experts or determined by political leaders advised by such experts. The general public often is assumed to be incapable of comprehending technical information and therefore, often is excluded from the domain of S&T decision-making. Though Fischer (2000, p. 35) tells us "there is good reason to believe that significant portions of the citizenry are more intelligent than usually credited", the majority of people are not motivated to question, and they see controversial scientific issues as outside their need and competence to judge; more often, they depend on a variety of authorities, which leads to an increasing trend of reliance on experts (Cross and Price, 1999). In studies where lay people have been shown to raise significant social issues about technologies that technical experts are likely to skim over, such

concerns have not been raised systematically or with sufficient depth to prevent unintended sociotechnological results (Sclove, 1995).

Proponents of participatory democratic theory would argue that experts (often assumed to be society's scientific and technical elites) play an increasingly influential role in decision-making (Fiorino, 1990). Expert perceptions of technical problems (such as the potential for risk associated with a human subjects research protocol) are judged to be more rational than the "subjective" perceptions of the less technically sophisticated public (Fiorino, 1990). While research on expertise in small group decision-making suggests that expertise is one of the most important resources available to the group (Baumann and Bonner, 2004), it is mitigated by the extent to which the group is able to identify who the experts in the group are. Some research suggests that groups can sometimes identify their best members (Baumann and Bonner, 2004; see also Littlepage et al., 1997; Littlepage and Mueller, 1997; Littlepage et al., 1995; and Trotman et al., 1983) but because expertise is often difficult to assess or even observe, individuals tend to rely on "proxy variables to develop expectations regarding the expertise of others" (Baumann and Bonner, 2004). These proxy variables may be age (see Kite and Johnson, 1988; and Lawrence, 1988), gender (see Cejka and Eagly, 1999; Hollinshead and Fraidin, 2003; and Wood and Karten, 1986), and ethnicity (see Biernat and Kobrynowicz, 1997; and Beirnat and Manis, 1994) among other things.

Expertise on the IRB also has implications for the credibility of the IRB. Credibility of the IRB is an important factor in its success, both within the institution and the surrounding community (Levine, 1981). If the IRB is viewed by the scientific community as a responsible organization, composed largely of knowledgeable peers (experts) and informed laymen, efficiently carrying out its mandate, and successfully interfacing with the investigators to assure "smooth sailing" of their proposals, cooperation of the investigators will generally be assured. If the IRB is viewed as an "enemy," a "police force", or an obstructionist group of bureaucrats and paper shufflers, such low level of cooperation will impede both scientific pursuits and proper functioning (Levine, 1981). To prevent the latter, Levine suggests the following four important considerations: (1) the membership of the IRB must be highly respected within the institution; (2) the IRB must focus its attention on important things and not allow its

efforts to be diluted by trivia; (3) the IRB must avoid a "double standard" wherein research funded by the National Institutes of Health (NIH) is accorded one type of review procedure and research funded by other sources is handled separately; and (4) the IRB must avoid developing an image as a police force, implying that the IRB mistrusts the scientific community.

3.3.2 Lay expertise in technical decision-making

Benello (1971) argues that because social questions involve value components as well as technical components, the values of the various group members must be integrated into the decision process. Accordingly, social decisions cannot be made for people by experts alone (whose role is to present the costs of various options clearly) while leaving the discussion of value consequences to the group (Benello, 1971). The desire for a community in which people can control the decisions that affect their lives is part of the very nature of society (Benello and Roussopoulos, 1971). In a participatory democracy, decision-making is the process whereby people propose, discuss, decide, plan, and implement those decisions that affect their lives. Benello and Roussopoulos (1971) argue that this requires the decision-making process to be continuous and significant, to be direct rather than representative, and to be organized around issues rather than personalities. In the participatory setting, there is limited role for self-appointed elites whose decisions have broad political impact on the society, but who are accountable only to themselves or to interlocked groups of their peers (Benello and Roussopoulos, 1971).

History has witnessed multiple debates on the issue of scientific autonomy versus public participation in technical decision-making. Most notable are two from the earlier part of the 20th century between Michael Polanyi and J.D. Bernal and between Vannevar Bush and Senator Harley Kilgore. In the 1930s, Polanyi (arguing from the position that outsiders cannot judge science) stressed the need for autonomy and self-governance of the scientific community, whereas Bernal believed autonomous science had numerous inefficiencies and benefits that could only be realized through a publicly debated plan involving government and representative components of society. The debate was again revived after World War II. This time, the sides were represented by Bush, arguing for

the university as the centerpiece of postwar science policy because of its independence and autonomy, and Kilgore,[1] who felt that a much closer linkage must exist between political institutions and the scientific community regarding the agenda for research.

Today similar debates continue about who should participate in the IRB decision-making process. In 2001 the National Bioethics Advisory Committee (NBAC) initially recommended an increase (to 50 percent) in the proportion of nonscientists and lay members on the IRB. In response, numerous academic professional associations made public statements against such recommendations on the grounds that lay members do not have the technical knowledge needed to make valid judgments about disciplinary research. In a 2001 public statement the Consortium of Social Sciences[2] (COSSA) opposed the NBAC recommendation that 50 percent of IRB members should be nonscientist, nonaffiliated members, stating that

> "such a ratio detracts from the peer review aspect of research. The more important issue is the competence of IRB members in the methods and topics of the research being reviewed. We support the notion of an increased number of public members. Nevertheless, to have 50 percent or more of the membership to come without expertise in research would prevent a meaningful judge of the ethical practices that are indeed part of the research."

In response, in NBAC's final publication in August 2001, the membership recommendation was reduced to 25 percent of the committee comprising participant perspectives, nonaffiliated members, and nonscientist members.

In more recent years, the debate on the issue of expertise (or lack thereof) in S&T decision-making has increased and publicized attention has been given to the topic. In particular, issues surrounding environmental concerns have practically demanded public

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[1] Kilgore argued that government support for science should be tied to explicit social and economic needs. His side of the debate can be viewed in the populist tradition and pushed to develop the state as a counterweight to the concentrated power of big business. The only major market failure that Bush identified in the governance of technological innovation was the support of university-based research – a market failure that private endeavors like those of Herbert Hoover in the 1920s had failed to close. (Zachary et al., 1994; available at www.cspo.org/products/conferences/bush/partone/roundtable1.html; visited on October 10, 2004)

[2] The Consortium of Social Sciences (COSSA) is an advocacy organization for the social and behavioral sciences, supported by more than 105 professional associations, scientific societies, universities, and research institutes. In response to NBAC's recommendations for IRBs, COSSA issued a statement on February 16, 2001 entitled: COSSA Responds to NBAC Report on "Ethical and Policy Issues in Research Involving Human Participants". The full statement is available at http://www.cossa.org/NBAC.html (visited on October 17, 2004).

involvement and in numerous cases, communities have taken it upon themselves to learn about highly technical issues and applicable technologies to either clean up their neighborhoods or prevent future contamination. The public has become more involved in decision-making about information technology and its associated risks.[1] The fight against AIDS, the war on cancer, and controversy over the appropriate disposal of hazardous materials further illustrate heightened public involvement in technical issues (for example, see Nelkin, 1975; Jasanoff, 1996; Epstein, 1996; Futrell, 2003). Yet, in general, the public does not play a very active role in S&T issues particularly at the decision-making level. Positivists[2] may argue that this is the way it ought to be; that only individuals with appropriate scientific training should have a voice in a decision surrounding S&T. Others argue (even on ethical grounds) that lay people should take part in such decisions if the public is in some way affected by a technology (see for example Cole, 1986). As noted previously, these considerations are implicit in the required composition of an IRB, where the nonaffiliated member intentionally is positioned to counterbalance potential institutional bias.

Supporters of the traditional positivistic perspective—that only experts (those formally trained in a scientific discipline) or those advised by scientific experts should determine technical issues—doubt whether the public is capable of understanding significant concepts such as "uncertainty" and nature of science as an incremental process (Brooks and Johnson, 1991). Apart from presumed ignorance, other factors—attitudes, beliefs, and motivations—may limit the extent to which the public can contribute to complex S&T policy decisions (see for example, Ravetz, 1986; McCallum and Santos, 1997; Rowe and Frewer, 2000). In contrast, other studies suggest that experts also have limitations in their technical knowledge (for example, Nelkin, 1986; Kraus et al., 1992; Jasanoff, 1997). Collins and Evans (2002) go so far as to argue that scientists have no

[1] For example, since 1998, the Internet Corporation for Assigned Names and Numbers (ICANN) has been responsible for the technical coordination of the domain name system of the Internet's. While some may argue that ICANN's efforts to incorporate broad scale public involvement in the corporation's decision process, ICANN has gone to great length to make public participation a cornerstone of its approach. Public participation is encouraged by open invitation and encouragement for the public from around the world to attend meetings in person or via the Internet (Lane, 2001).

[2] Positivism is the belief that science can be pursued only through what we can observe and measure objectively. The implication for technical decision-making is that we should accept what the scientists tell us because it is based on factual observation.

special contribution to make to technical decision-making in the public domain. Experts can, and in fact do, come in all shapes and sizes, not all of them credentialed. Such experts may be called "experienced-based experts" (Collins and Evans, 2002) and their specialized knowledge can contribute to technical decision-making.

Expertise in the IRB setting is similarly diverse. Most IRBs are a heterogeneous group composed primarily of scientists, other professionals (such as nurses, social workers, clergy, pharmacists, and administrators) and lay persons. The term "lay person" as applied to an IRB usually refers to a person selected from the community (sometimes, though not always, representing the community served by the research institute) who is generally not affiliated with the IRB institution in any other way. In some cases, the lay representative is typical of the research subjects who might participate in a study (45 CFR 46.107), and his or her ability to empathize with the potential subject is obviously a great strength that they bring to the IRB (Ghio, 1980). On many IRBs the focus of the lay person's review is (or is presumed to be) the consent form. If the consent form is unintelligible, confusing, or overwhelming to the lay reviewer, it will likely be similarly received by a potential subject. Thus, lay reviewers must be prepared to ask many questions when scientific matters or medical terminology require explanation.

However, the requirement to include at least one nonaffiliated member on the IRB does not ensure that this member is in fact a "lay person". As noted previously, on some IRBs, nonaffiliated members possess credentials similar to their affiliated counterparts, particularly in cases where the nonaffiliated member is a retired physician or faculty member from another university. On other IRBs, homemakers, clergymen, or local business leaders serve on IRBs but there is no guarantee there either that these members represent ordinary lay people from the surrounding community. While this is not necessarily detrimental to the IRB decision-making process, it likely does impact the ways in which decisions are made insofar as the extent to which certain values or issues are brought up for discussion and deliberated before deciding whether to approve a research protocol.

3.4 University research and the social contract

It is argued that science is most effective when scientists are free to choose their own research directions and agenda (McNeill, 1993). The phrase "social contract for science" refers to the relationship between science and society—an arrangement by which for the last few decades government has funded universities and other research institutions to conduct scientific research with minimal restrictions on how this money should be spent (see Bush, 1945). Under the "social contract for science", the federal government allocates research funds to universities with the understanding that the government will not interfere with scientific decision-making in exchange for science-driven, unspecified benefits to the public good (Fox and Braxton, 1999). However, with the implementation of IRBs the freedom of scientists *is* limited by the requirement to justify human subjects research on ethical grounds (McNeill, 1993).

Most basic research is done at universities (Guston and Kenniston, 1994) and while the choice of which research to support is driven largely by the universities themselves, the IRB essentially acts as a research gatekeeper each time it decides whether a research protocol should be approved. With the mandated creation of IRBs, universities essentially have been told to police themselves in the area of research ethics and scientific misconduct. Though many universities initially were slow to regulate the research system (Steneck, 1999a, 1999b), most research organizations now rely on a variety of mechanisms for promoting scientific integrity.[1] For example, with the recent surge in faculty research commercialization, many universities have created stand-alone policies that address faculty and institutional conflicts of interest. In fact, the Association of American Universities (AAU) recommends that any related financial interest in research involving humans typically should not be allowed (AAU, 2001).

Historically, public universities have been founded on three principles: teaching, research, and public service. Accountability to the public is embedded in the promise of public support via funds from state government to sustain the university. If the university is perceived as not fulfilling its public service mandate in ways satisfiable to the state, the

[1] The National Academy of Sciences (2002) provides a summary of some of the institutional mechanisms used at various universities for promoting scientific integrity. These include a regulatory-based approach, a performance-based approach, and an institutional self-assessment and peer review approach.

legislature for that state has the power to revoke state funds to the university.[1] Arguably public universities, whose mission statements often include an emphasis on research for the benefit of the public, may be held accountable to the public more so than a privately funded university, which is not as financially accountable to its surrounding community or state. Under these circumstances, the role of the nonaffiliated member on a public university IRB could potentially be more influential than on a private university IRB in that this member can go directly to the legislature over issues of how the university allocates funds for human subjects research (or any research).

Studies of university research foundations suggest that the relative importance of research and instructional interests in decision-making and the commitment of university resources to research are potentially important influences on the shape of a research foundation (Daniels et al., 1977). Another characteristic that shapes the research organization is whether the university is public or private (Daniels et al., 1977). Since the IRB is a well-defined component within the university organizational structure, such characteristics when combined with the university mandate could influence the decision-making process of IRB members.

Currently, the IRB has jurisdiction over determining whether and how a relevant financial interest should be disclosed to research participants.[2] Most university IRB guidelines stipulate that a researcher who has a financial interest in the results of a research protocol cannot serve as principal investigator on that project. Furthermore, IRB members with *any* conflicts of interest generally are required to recuse themselves from the voting process, and even from the discussion, for such research protocols. Since the primary responsibility for handling complaints of misconduct in science rests with the research organization (National Academy of Sciences, 1992), such constraints become relevant in understanding and explaining IRB decision-making processes at different universities. Moreover, the autonomy of the IRB or the degree to which it is embedded within the institution becomes relevant in that each IRB must apply its own discretion

[1] For example, the University of Okalahoma's Research Institute was dissolved by the Oklahoma state legislature due to conflicts with the Oklahoma state legislature over management control, specifically the issue of controlling the expenditure of what legislature considered as state revenues rather than university revenues. (see Cross, G. (1986*) The University of Oklahoma Research Institute: 1941-1973.* Norman, OK: The University of Oklahoma Office of Research Administration.)

[2] The Institute of Medicine (2003) recommends that a separate committee should review financials conflict of interest associated with human subjects research protocols.

about what constitutes an acceptable research protocol. Federal human subjects research policies are written such that an IRB decision to reject a protocol or to require modifications cannot be overturned by anyone at the institution, including the president of the institute. Effectively the buck stops at the IRB.

3.5 IRBs as the "subject" of research

Previously in this chapter, I discussed the role of experts and lay expertise in technical decision-making. This relationship is central to characterizing the deliberation of human subjects research. What should the role of experts be in such deliberations? And what should the role of the public be in oversight of human subjects research? The research oversight system offers a rich and complex setting in which to examine decision-making and participation in highly specialized and technical areas. Examining IRB decision-making allows us to tease apart the expert-nonexpert distinction in an area where science and society are destined to merge. Creighton (1999) argues that participation should be focused such that the public has the opportunity to participate in the decisions that are of greatest interest to it, in ways that provide genuine opportunities to influence the decision. In some technical areas experts simply cannot escape public influence (Dickson, 1988; Jasanoff, 1990; Mitcham, 1999). This includes much, perhaps all, human subjects research as most of it is carried out for the purpose of somehow benefiting humanity (e.g., cancer research, mental health research, research on commercial sports drinks, and research on relationships).

The behavior of IRBs is a particularly interesting research topic because these committees are composed of an uncommon combination of reviewers: not all are from the same discipline (or even neighboring disciplines) of the research investigator, and IRBs are required to include at least one nonaffiliated member from the community. Thus, an IRB is a unique body within the science policy process where the normal social forces and authorities of science might be expected to be less likely to apply (Barke, 2002). The regulatory requirements on board composition described earlier are minimal (even vague) and do not stipulate how an institution ought to select members to satisfy the regulation. A member at one university may be classified as a scientist, while a different university may classify the same person as a nonscientist member. When asked,

members might even categorize themselves differently than they are categorized by those that select them to the committee (e.g., by the IRB administrator). Additionally it is not clear if IRB members (or member types) are representing anyone other than themselves, or whether the three member categories should be considered representative at all.

Normally the "outcome" of a decision-making process refers to its substantive decisions, conclusions, or recommendations which can be evaluated using a variety of criteria including stakeholder satisfaction with the results, cost effectiveness, or risk minimization (Beierle, 1999). And in fact, a pragmatic argument for public participation in S&T decision-making is simply that public participation will lead to better outcomes (Van Eijndhoven, 1997; Schot and Rip, 1997; Sarewitz, 1996; Mitcham, 1999). Participation affects satisfaction with the process and the outcome (March 1994). Participation has an integrative effect and aids the acceptance of collective decisions (Pateman, 1970). Individuals are more likely to participate in decision-making when their own interests are affected than when they are not, more likely to participate when they think they can affect the decision outcomes than when they think they cannot, and more likely to participate when they think they have no alternative ways of acting appropriately or accomplishing what they want than when they think there are other ways (March, 1994). But Beierle (1999) cautions that narrowly interpreting "outcome" to mean only substantive decisions misses some of the key features of a participatory process—those which justify inviting the public into the decision process in the first place. Moreover, broader interpretation of outcomes includes the degree to which participatory processes achieve a set of "social goals" (Beierle, 1999).

For democracy to really work, we must have maximum participation and the development of individual potential to contribute (Oppenheimer, 1971) to the choice of "social goals". In the same way that people with reputations are listened to differently than people who are unknown (Oppenheimer, 1971), scientists on the IRB may be listened to differently than nonscientists or lay members. In situations where the group has not had sufficient time to develop, a dissenting member may be reluctant to speak up or voice opposition to the rest of the group. This seems especially likely if that member is the lay member on an IRB and finds himself in disagreement with the scientist members.

As the following section will illustrate, prior research on IRBs has not adequately examined the IRB decision-making process with these characteristics in mind.

3.5.1 Prior research on IRBs

Much of the prior research about IRBs focuses on functional issues such as workload, frequency of meetings, percentage of protocols approved (e.g., see Bell et al., 1998) and not on the decision-making process itself or related decision outcomes. Those key studies that attempt to characterize IRBs are briefly summarized here.

The earliest known study of IRBs, conducted in 1969, surveyed 300 biomedical IRBs about their approval decisions (see Barber et al., 1973). In two separate but related studies, Barber et al. set out to examine conformity and deviance in researchers' expressed standards and actual behavior with respect to informed consent and the appropriate risk-benefit ratio of their research. The first study entailed a national survey of the primary IRB contacts at 293 biomedical research institutions, in which respondents were assessed on their expressed standards on ethical issues involving hypothetical biomedical human subjects research protocols. The second, more intensive study consisted of personal interviews with human subjects researchers from two biomedical research institutions (Barber et al., 1973). The results of both studies were used to examine patterns of strictness and permissiveness in reviewing human subjects research protocols. Barber et al. found that the majority of biomedical human subjects researchers are aware of the importance of voluntary informed consent, that a majority are not willing to allow undue risk based on the hypothetical research scenarios, and that most biomedical researchers do not conduct studies in which the risk-benefit ratio is unfavorable for the patient-subjects (Barber et al., 1973). However, Barber et al. also found that a "significant minority" exists that is "more permissive" and is either unaware of or unconcerned with consent issues, is willing to take undue risk, and is actually conducting studies that include unfavorable risk-benefit ratios for participants. Barber et al.'s study provides a glimpse into the early structures of the IRB process and gives some insight into the types of members who served on those committees. At the time of the study (1969), less than 25 percent of the participating universities (all biomedical) included any kind of "outsider" on their committees, and in most cases those outsiders

had expertise in clinical research at some other university. It is important to note a major drawback to Barber et al.'s study: the survey on ethical standards and review processes was administered to only one member on each participating IRB. While Barber et al. argue that their data are "representative of medical schools, of their affiliated teaching hospitals..." it is questionable whether the perspectives offered by the sole respondents (in some cases the IRB administrator, in others the IRB chair or an IRB member) are truly representative of the group decision-making process of each institution's IRB as a whole or the perceptions of that process as held by other IRB members.

Gray et al. (1978) conducted one of the more comprehensive national evaluations of the IRB system to date in which they assessed IRB performance in an empirical study of 61 (again mostly biomedical) committees. The study focused on action taken by IRBs on whether to approve a protocol, and on the perceptions of principal investigators toward the human subjects review system. Interview surveys were conducted with more than 2000 research investigators whose protocols had been reviewed by their IRB, over 800 IRB members, and almost 1000 human research subjects. The survey data collected by Gray et al. illuminate early IRB procedures including the mechanism for voting on protocols, meeting attendance, extent to which IRBs modify protocols, and the perception that the committee makes judgments that it is not qualified to make.

Some of Grey et al.'s key findings are summarized here. IRB members who were *not* biomedical or behavioral scientists reported themselves as less active (participatory) and influential compared with their scientist counterparts. About two-thirds of the participating IRBs had a procedure to screen out protocols that did not need full board review; about half used a primary reviewer system; about half took formal votes on all protocols and almost all took a formal vote on at least some protocols. Their data also suggest that IRBs that review relatively risky research are more careful in their reviews, using a more comprehensive set of issues during the review of protocols, and tend to require more modifications prior to IRB approval. Gray et al. described the composition of the IRBs in their sample (50 percent were biomedical scientists, 21 percent were behavioral scientists, and the remainder included administrators, lawyers, nurses, clergy, etc.), but they did not specifically relate this composition to the IRB procedures and processes described above. Additionally, the study examined the differences in the extent

to which each IRB is comprehensive in its discussion of the protocols; yet, specific information about how the related scores were constructed or their interpretation are not provided by Gray et al. In short, Gray et al. describe the demographics and to some extent the perceptions that members, researchers, and participants have about the IRB process but they fall short of explaining how these perceptions relate to the actual IRB decision-making process, how decisions are shaped by that process, and what members' perceptions are of their roles in that process.

Other studies have examined inconsistency across IRBs (Goldman and Katz, 1982) and perceptions of the IRB process by research investigators (Cleary, 1987; Ferraro et al., 1999). Goldman and Katz (1982) assessed the inconsistency across IRBs by submitting identical research protocols—each with unethical components, flawed research design, and incomplete consent forms—in oncology and anesthesiology to 32 IRBs at major universities with medical schools. Among the 22 participating IRBs, the results showed consistency in the nonapproval of only three protocols, substantial inconsistency in the reasons offered in support of similar decisions about each protocol, and substantial inconsistency in the application of standards of ethics, methodology, and informed consent (Goldman and Katz, 1982). Based on these results, Goldman and Katz conclude that these inconsistencies would result in the approval of flawed research studies. In a study of the impact of IRBs specifically on political science research, Cleary (1987) also found variation among universities with respect to what constitutes human subjects research, what research qualifies as exempt or expedited, and requirements for written versus verbal consent. Ferraro et al. (1999) surveyed human subjects researchers at the University of North Dakota to determine attitudes toward, perceptions of, and experiences with the University of North Dakota's IRB. Ferraro et al. found that only a small percentage (15 percent) of participants surveyed felt that the IRB had impeded their research efforts. The majority of respondents believed that the IRB process improved their research protocols. However, the majority (75 percent) also felt that the IRB should refrain from requiring revisions of research design unless such revisions benefited the protection of human participants.

Three more recent studies have conducted evaluations of the IRB system (see GAO, 1996; Bell et al., 1998, and OIG, 1998). A 1996 study by the Government

Accounting Office examined policy and oversight roles of the National Institutes of Health, the Office for Protection from Research Risks (the predecessor to OHRP), and the Food and Drug Administration. The federal role in protecting human subjects was evaluated based interviews with NIH, OPRR and FDA officials, in addition to a review of regulations, policies and procedures (GAO, 1996). Additional interviews were conducted with research institute officials, IRB members, and researchers, as well as experts in bioethics, medicine, law and social science. At least two conclusions from the GAO evaluation are relevant to this dissertation. First, some IRBs find it difficult to adequately review human subjects issues because their members are not familiar with technical components of a study. Secondly, IRB autonomy is compromised when members have financial ties to studies and when members are reluctant to criticize studies directed by leading scientists.

In a subsequent study, the Office of the Inspector General (1998) conducted interviews with federal officials and representatives of about 75 IRBs. Particularly relevant to this dissertation is the OIG finding that IRBs review too much, too quickly and with too little expertise, particularly at larger institutions. IRBs are also expected to support institute interests that provide revenue and prestige to the institute and because there is only minimal nonaffiliated member representation, IRBs have only minimal ability to counterbalance institutional interests. OIG found that it was not unusual for IRBs with 15-20 members to include only one or two nonaffiliated members. The IRB system provides minimal training and education for members, which is a disadvantage particularly for nonscientist and nonaffiliated members.

Finally, Bell et al. (1998), under contract with the NIH, examined IRB procedures at 491 institutions to identify the number of hours IRB members contribute to the process, how long meetings last, general opinions about adequacy of IRB review, concerns about review outcomes, and other procedural topics. The study included 435 IRB members, 632 research investigators, 245 IRB administrators, and 394 IRB chairs. Bell et al. found that most (78 percent) of the changes that participating IRBs required for approval dealt with issues of informed consent form, while only 6 percent of the protocols required modification to the research design before approval was granted. The Bell et al. study concluded that, while IRBs are performing consistently with the

regulatory requirements for human subjects review, IRB structures and procedures could be perfected and training and education of members could be expanded.

While these studies elucidate IRB procedures to some extent, minimal empirical data have been gathered on IRB decision-making—that is, the internal mechanisms and characteristics of these committees—particularly with respect to the characteristics of board members, and whether or how such characteristics influence IRB decision processes, mechanisms of group discussion, quality of decision, or institutional context and perception about scientific misconduct.

3.6 Rationale for the research questions

That the responsibility to protect human subjects is explicitly value-directed adds a layer of complexity to the decision-making process. Members have the freedom to exercise their collective independent judgment to interpret the regulations and establish policies for ethical research standards at their institutions (Beach and Wright, 2000). March (1994) notes that participation rules in decision-making processes generally reflect three concerns: personal consequences, social benefit, and the creation of community. More specifically, democratic theory implies that a proper decision system will provide greater access to those who are affected by its decisions. In the human subjects oversight system, IRB decisions typically affect four distinct groups, either directly or indirectly: (1) human research participants, (2) the general public, (3) research investigators, and (4) the university. Secondly, March notes that because some people are seen as making a great contribution to society, they are often given greater access to the decision-making process based on their competences or expertise in a particular area. Scientists (and science in general) are often seen as making a great contribution to humankind and perhaps this notion is (intentionally or otherwise) reflected in the disproportionate number of scientists that typically serve on IRBs. Finally, March observes that rights and obligations to participate are linked to acceptance as colleagues or members of a particular community. This characteristic is implied via the nomination or selection process of certain IRB members to the committee. Interestingly, however, these three democratic concerns appear at odds in the IRB setting, where likely research participants are only minimally represented, high profile researchers are not necessarily the scientists

serving on the IRB, and the policies for identifying IRB members do not seem to be based on any sort of system-wide acceptance criteria.

In the human subjects protection system, judgments and values are inherently interconnected with the issue of risk. But risk research has shown that experts and lay citizens approach the characterization of risk in different ways. Experts tend to characterize risk in an objective and rational way, while the public is portrayed as seeing risk in a manner that seems subjective, emotional, or irrational (Slovic, 2000).[1] Risk perception can also depend on age, gender, and race. Studies suggest that women and younger scientists tend to be more risk averse than their peers (see for example, Barke and Jenkins-Smith, 1993; Slovic, 2000; Wester-Herber and Warg, 2002). In characterizing risk, two judgments are made: (1) that a particular process or outcome merits serious attention and (2) what constitutes an unacceptable level on the outcome dimension (Slovic, 2000; Stern and Fineberg, 1996). Since IRBs are composed of a unique group of experts and nonexperts (or lay persons) who must make judgments about the level of risk in the research protocol in order to decide whether to approve it, these observations suggest that further research is needed to understand:

> *How do different IRB members make decisions about whether to approve a human subjects research protocol—that is, about risk-benefit ratio, scientific merit, research design, and adequacy of informed consent? (RQ1)*

Theoretically, the diversity of IRB membership should enable it to assess the ethical acceptability of a research proposal with respect to its scientific merit, sensitivity to community attitudes, and safeguarding of participant rights and welfare. If IRBs are composed as directed in 45 CFR 46.107, scientist members will be drawn from varying disciplinary backgrounds, ideally representative of those campus departments that conduct human subjects research. While IRBs may or may not select scientist members specifically for their methodological expertise, that form of expertise is broadly represented by the very nature of the diversity of disciplinary backgrounds often represented on the IRB.

[1] However, Slovic notes that the characterization of the public in this manner is a disservice to democracy and decision-making.

The IRB Guidebook (Penslar and Porter, 1993) specifically comments on the role of the nonaffiliated member:

> "The nonaffiliated member of the IRB should be drawn from the local community-at-large. Ministers, teachers, attorneys, business persons, or homemakers are possible candidates. The person selected should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to the type of community from which the institution will draw its research subjects. If the community is rural and agricultural, perhaps a farmer would be appropriate, in addition to a minister and/or attorney. If the community is predominately African-American, Hispanic, or other minority, then it would be advisable to have a member of that particular minority (or those minorities, if there is more than one significant minority population) on the IRB. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB."

Some studies (such as NBAC) suggest that the mix of IRB member types should be more proportionate such that the number of nonscientists and nonaffiliated members is increased beyond the current requirement to include at least one of each type of member (National Bioethics Advisory Committee, 2001). Yet, it was pointed out earlier that professional associations express concern that an already burdened system will become slower due to increased questioning of proposed protocols by presumably non-technically trained IRB members or non-experts in the field.[1] The scientist members are the implied "experts", whereas the nonscientists and particularly the nonaffiliated members usually are assumed to be the "nonexperts" in this process. Research has also shown that experts tend to promote their own self-interests, often at the expense of the public (Dahl, 1985). And indeed, per the Common Rule, a stated role of the nonaffiliated member on an IRB is to keep the board from making decisions that are institutionally biased.

Much of the normative literature on decision-making tells us that if decision-makers follow a particular preferred process, good outcomes will be achieved (March, 1994; Beach, 1997). Since people tend to be concerned about how the outcome or consequence of a decision is going to make them feel about the decision itself (Larrick, 1993), individual characteristics and experiences may lead to variation in how IRB

[1] See for example the responses to the NBAC (2000) recommendations from the Federation of American Societies for Experimental Biology (www.faseb.org/opar/ppp/nbac_resps.html), Consortium of Social Science Associations (www.cossa.org/NBAC.html) (both sites visited on October 17, 2004).

members approach human subjects research decisions. Because women tend to think science is not as useful as men think it is (Fox & Firebaugh, 1992), gender characteristics may lead IRB members to judge the benefits associated with a particular research protocol in very different ways. Similarly, a member, who experiences frequent criticism of the IRB process by departmental colleagues about the impact IRB review has on their grants, may be more sensitive to unintended consequences of an IRB decision on the research process. Or for example, a member may have had, or know someone who had, a personal experience (whether negative or positive) as a research participant. Consequently, the composition of IRB members can dictate variation in the range of attitudes toward science and the risks and benefits of scientific research. These considerations suggest additional research is needed to investigate the effects of membership characteristics on the IRB process. Such observations lead to the question:

> *What is the relationship between members' roles on the IRB and their level of expertise as these characteristics relate to their experiences and perceptions of the IRB process? (RQ2)*

The narrow focus of previous studies on IRBs is understandable. After the federal requirement to establish university IRBs, little was known about how many existed and much less about the workload, numbers of members, or structures of the committees. IRBs have now existed for nearly 40 years and there is a clear need for deeper understanding of these decision-making entities beyond bureaucratic characterization. The purview of the IRB over reviewing scientific design and merit is being questioned by both the research community and even some IRBs. Furthermore, many social scientists argue that the federal guidelines for IRB review subject social science research to unrealistic requirements that were initially developed for biomedical research models. To begin to understand these allegations and to find answers to these questions, more substantive knowledge is needed about what actually occurs during the IRB decision-making process. Previous IRB research contributed to the characterization of what goes into and comes out of the "black box" of IRB decision-making. By answering the two research questions articulated above this research attempts to look beyond IRB inputs and outputs and to begin to explain the dynamics inside the "black box" of IRB decision-making. While a comprehensive explanation of the IRB group decision-making process is

beyond the scope of this dissertation. This study takes the first steps toward such an explanation by conducting an initial examination of the IRB process as perceived by those who participate directly in it.

3.7 Why will a participatory democratic process work better for human subjects research than a non-democratic process?

The concept of governance can be reduced to one fundamental question: who gets to decide? In the context of human subjects decision-making, this simple question has tremendous and far reaching implications for research policy and for the governance of science. It has been pointed out earlier that through their decision-making process, IRBs act as gatekeepers of research conducted at their organizations. It has been further noted that IRBs are composed of a unique combination of scientists and nonscientists and lay members, and of experts and nonexperts. The mechanism by which these two IRB characteristics are related and consequently impact science and society is the dynamic of participation. Up to this point, I have discussed the normative arguments for public participation in decision-making about technical issues, with the assumption that a participatory democratic process is better for human subjects research oversight. Thus, the focus of this section, which ultimately justifies the theoretical underpinnings of this study, is why democratic participation is better than non-democratic participation.

Increased public involvement in science and technology and increased efforts to involve the public in decision-making when feasible (Rosener, 1978; Rowe and Frewer, 2000) could alter the dynamics of decision-making bodies like the IRB if recommendations for more nonscientist and lay person participation (like those suggested by NBAC and Kennedy's and DeGette's proposed pieces of legislation for human subjects review policy)[1] are adopted.

[1] During the 107th Congress, Representatives Diana DeGette and Jim Greenwood and Senator Edward Kennedy introduced two separate pieces of legislation in an attempt to overhaul the Federal human subjects protection system. Each legislation incorporated recommendations made by the Government Accounting Office, DHHS Inspector General, and NBAC. Neither legislation passed; however, discussions emerged about (1) the effectiveness of the current IRB system, (2) ways to address conflicts of interest, and (3) the appropriate scope of coverage for the Federal requirements. On November 21, 2003, Representative DeGette introduced H.R. 3594, the Protection for Participants in Research Act of 2003. The bill, a modification of the earlier bill introduced during the 107th Congress, extends protections to all research, regardless of funding source; imposes financial conflict of interest requirements for investigators; modifies

There are many justifications for including citizen representatives from society in the decision-making process about research benefits and risks to human subjects and to society, but putting those rationales into practice is neither simple nor certain to produce the desired effects that participatory theorists promise. There is no certainty that IRB members not affiliated with the institute will (or can) bring a broader humanistic perspective to the scientific decision-making encountered in IRB process. The participation of lay persons in IRB decision-making may slow this process or make it "messier," but such benefits of "discursive democracy" (Dryzek, 1990) include disagreement, critique, and reasons that are not tied strictly to facts. Conversely, it may be argued that scientists are capable of bringing public values into the IRB decision-making process on the grounds that they are also members of society—"specialized citizens" as it were (Fischer, 2000)—often with children and families of their own, and dealing with health issues and other concerns similar to nonscientists.

Cook and Morgan (1971) offer a two-part argument in support of direct involvement of "amateurs" in authoritative decision-making (such as human subjects oversight). Both are applicable to the IRB setting. First, the actual process of direct participation in some way makes participants "better" citizens. Participation is a learning experience that changes the psychology of the participants. Many theorists argue that the experience of direct participation can shape a new person since it socializes people into new beliefs, attitudes and values (Cook and Morgan, 1971). Average citizens are often reticent to participate in technical decision-making, even when invited to do so, because they do not feel capable in communicating about such technical issues. However, the past 20 years have seen numerous community participation cases where participating citizens are empowered by such experiences (e.g., community participation in environmental remediation issues, not-in-my-back-yard/NIMBY issues, and so forth) and actually develop a localized form of technical knowledge and a deeper understanding for science in general.

IRB membership to include more lay members and members unaffiliated with the institution; and expands OHRP's enforcement mechanisms to address violations of the Common Rule. (Detailed information about the provisions of this legislation is available at http://olpa.od.nih.gov/legislation/108/pendinglegislation/humansub.asp; visited on October 10, 2004).

The second argument for involving amateurs is even more applicable to IRBs and human subjects research oversight. That is, decisions shaped by direct participation mean "better" consequences (Cook and Morgan, 1971). Cook and Morgan admit that one could debate the definition of "better" but in general, they define it as more effective problem solving. On the IRB, the so-called amateur may really be an "expert" in certain matters either because of the learning experience of the participatory process or because of knowledge s/he acquired in normal daily activity. This idea hails back to Aristotle who stated in *The Politics*:

> "There is this to be said for the many. Each of them by himself may not be of a good quality; but when they all come together it is possible that they may surpass collectively and as a body, although not individually, the quality of the few best. Feasts to which many contribute may excel those provided at one man's expense. In the same way when all meet together, the people may thus become something in the nature of a single person, who as he has many feet, many hands, and many senses, may also have many qualities of character and intelligence."

It was not until 1859 that Mill building on Tocqueville's observations of democratic practice specifically articulated that the process of participating in democratic decision-making made participants better citizens (Mansbridge, 1999). Mansbridge notes that central to Mill's claim was the notion that taking responsibility for others in the course of collective decision-making enlarges the participants' conceptions of their interests. This awareness is particularly applicable to the IRB decision-making process where the primary purpose is to protect human participants in research. Mansbridge also reminds us that the father of the term "participatory democracy"—Arnold Kaufman—argued that "democracy of participation may have many beneficial consequences, but it's main justifying function is and always has been, not the extent to which is protects or stabilizes a community, but the contribution it can make to the development of human powers of thought, feeling and action".

Yet Bozeman (2002) observes that contemporary discourse is often dominated not by public values, but by market intervention, technical efficiency, and the private value of public things. The IRB decision-making process is not immune to the discussion of such issues, particularly when the increasingly more common issue of investigator or institutional conflict of interest must be considered as a factor in balancing risks and

benefits to potential research participants. Moreover, diversity in membership, expertise, experience, personality, values and beliefs of IRB members combine with organizational politics, culture, and a variety of multi-level decision outcomes to produce a complex arena in which decisions attempt to advance knowledge yet protect research participants.

Models of decision-making are not substitutes for, nor do they fully capture, such complex decision procedures but they do provide a useful starting point for understanding and for identifying areas of potential improvement of the systems such as the IRB. They also aid in assessing the interaction of actors regarding a judgment procedure and they promote the discovery and resolution of problems that might occur during the decision-making process. In the case of the human subjects protection system, a simplistic model can be a particularly insightful way to begin to understand, explain, and improve the IRB decision-making process. To this end, in Chapter 3, such a conceptual model was presented to illustrate the IRB decision-making process. That model is based on the IRB literature and on informal observation of the Georgia Institute of Technology IRB,[1] which I observed and assisted for almost two years while thinking about the research conducted in this dissertation.

While no one theory or model is sufficient to adequately explain all the dynamics occurring among actors and institutions during the policy process (Olsen, 2001), the process of analyzing the decision task in and of itself in order to identify a model is beneficial nonetheless for a more complete understanding of the associated policy process. Given the unique composition of members on an IRB, a number of characteristics must be considered in order to explain the decision-making process of these committees: the ways in which experts (the scientists?) approach problem solving and decision making compared with nonexperts (the nonscientists?), differences in how experts versus lay people perceive risk, what defines an "expert" (disciplinary perspective, methodological expertise, experiential knowledge), decision making in the face of uncertainty, gender differences in understanding of and confidence in science, and public values decision making among others.

[1] The Georgia Institute of Technology IRB did not participate in this study because of the potential to increase validity problems brought about by members' knowledge of the details of the methods and questions used in the study. However, anecdotal information was obtained from my informal observation of these meetings and helped to shape some of my thinking about this subject.

A major function of participation in the theory of participatory democracy, noted earlier, is an educative one including both the psychological aspect and the gaining of practice in democratic skills and procedures (Pateman, 1970). Pateman subsequently argues that in participatory theory, participation refers to equal participation in the making of decisions and political equality refers to equality of power in determining the outcome of decisions. Fiorino (1990) summarizes four participatory theory-based criteria for evaluating whether an institutional mechanism is democratic. First, the mechanism should allow for direct participation of amateurs (nonexperts) in the decision-making process. Perhaps in the IRB process, the nonscientists or nonaffiliated members may represent nonexperts or amateurs, both of whom are given an equal voice in the IRB decision-making process, at least in theory. Arguably in many cases, the scientists themselves could also be classified as nonexperts when the research area of a protocol is outside their disciplinary domain. Second, mechanisms can be assessed to the extent that they enable the public to share in a collective decision-making process. IRBs are designed to provide the nonexperts, and in particular the nonaffiliated members, with the opportunity to contribute to the collective decision-making process. Regardless of expertise or background, any member on an IRB can voice his or her opposition to particular aspects of a scientific study or question the risks or benefits or even the scientific merit of the research.

A third criterion is the extent to which a process provides a structure for face-to-face discussion over a period of time as a means to discuss, deliberate, search for shared values and transform conflict into resolution (Fiorino, 1990). There is no federally mandated schedule for when or how often IRBs must meet, other than the stipulation that full board review must take place at a convened meeting of a majority of members that includes at least one nonscientist. These face-to-face meetings provide an arena for extracting public values issues and for ensuring that adequate consideration is given to the Belmont principles in human subjects research protocols. Fiorino's fourth criterion for assessing whether a mechanism is participatory is the extent to which citizen participants are provided the opportunity to participate on equal footing with technical experts. The IRB process allows any member, expert or not, to question other members about proposed research, issues of risks and benefits, and scientific merit. Through a

discursive process of mutual education about such issues, both experts and nonexperts are enabled to participate more effectively and equally in the IRB decision-making process. Whether lay members or affiliated nonscientist members choose to exercise equal participation in the meeting is, however, questionable.

While this study is not a formal evaluation of IRBs based on these criteria, such measures offer useful insight into how we might examine the IRB decision-making system in the context of a democratic decision-making process via the principles of participatory democratic theory. Thus, the data collected in this research will be analyzed with these principles in mind and will employ participatory democratic theory principles as a means to probe the bigger picture questions about expertise and decision-making at the boundary of science and society.

3.8 Summary

This chapter identified and reviewed conceptual dimensions of the some of the decision theory literature (particularly as it relates to small group decision-making) and participatory democratic theory literature. The case for studying IRBs was argued specifically via the literature from decision-making in science and technology and in particular, in the case of university research. A summary of previous empirical studies on IRBs was provided. Limitations and gaps in the theoretical literature and the empirical research were identified and used to justify the research questions that guide this study.

4.0 METHODOLOGY

4.1 Introduction

Chapter 3 provided the theoretical framework for conducting this research and identified several research questions. In this chapter, I describe and justify the methodology used to provide data to investigate the research questions and to study the decision-making process at seven university IRBs. A brief introduction to the methodology was provided in Section 1.4 of Chapter 1; this chapter aims to build on that introduction. Chapter 4 is organized around four major topics: the sample domain, the sampling procedures, qualitative research techniques, and data processing.

4.2 Justification for design and methodology

A case study design was selected to develop an explanation for IRB decision-making. Several explanatory case study approaches were considered; however, due to the low level of understanding about the IRB decision-making process, a clinical case study approach (de Vaus, 2001) was ultimately chosen. Unlike theory-testing case studies or theory-building case studies, clinical case studies are case centered and use theory to understand a case (de Vaus, 2001). Qualitative information about individual experiences, perceptions and values was gathered individually from 37 research university IRB members. A case study approach is appropriate for the investigation of cases when it is necessary to understand parts of the case within the context of the whole (de Vaus, 2001).

A qualitative research design is particularly useful here because there are aspects of the functioning of an IRB that cannot easily be quantified, e.g., the experience of board members and the quality of the IRB decision yet are essential to our understanding of how IRB decision-making works. A semi-structured interview protocol was designed to elicit information about how members define their role on the IRB (what does IRB review entail), how they perceive the role of other members (what is the purpose of each type of member required to serve on the IRB), and how they perceive their impact on the decision-making process and outcomes of the committee (what is the purpose of the IRB). Other areas of inquiry included the efficacy of current IRB procedures and the estimated impact of potential changes to IRB regulations. General topics were explored

with the respondents to help uncover their perspectives while preserving the way in which each respondent framed and structured their responses (Marshall and Rossman, 1995). Such semi-structured protocols do not constrain the interviewees to answer a list of specific questions. Instead, these procedures attempt to guide respondents with several general topics and probes, such that the elicited ideas evolve from their perspective and are not unduly responsive to a priori expectations.

The conceptual model presented in Chapter 3 informed the theoretical basis of the interviews. It portrays the IRB decision-making process (that takes place within the convened IRB meeting) as I have come to understand it based on the empirical literature on IRBs and on my tenure working with the Georgia Institute of Technology IRB, and suggests that IRB members bring to the process their own set of values, perceptions, and judgments, which are further shaped by the research focus of the IRB (e.g., biomedical versus social and behavioral science research). Because my focus is on member perceptions of the group decision-making process that occurs at the *convened* IRB meeting, the model does not illustrate final decisions about protocols that are made prior to the convened full board meeting, such as whether a protocol qualifies for expedited review. Generally, the IRB administrator or staff (sometimes in conjunction with the IRB chair) decides whether a research protocol may be "exempt" from or "expedited" through full board IRB review. In either case, such protocols are not typically reviewed by the fully convened IRB membership and the related decision-making process about them is not the focus of this study.

Thus, it was my expectation that the individual judgments and related experiences or expertise of members are initially used to decide whether a protocol satisfactorily addresses federally-mandated review areas such as scientific merit, research design, risks and benefits to research participants, and informed consent. In other words, members receive a protocol (or some portion thereof) to review prior to the full board meeting. They conduct that review independently and, in the context of the four review areas laid out in the Common Rule, form a judgment about whether the research protocol merits approval. The members then convene as a group to discuss all human research protocols submitted for review, with each person contributing his or her own comments and concerns based on their independent review.

Subsequently, through the process of group discussion, I posit that individual judgments are sometimes reshaped and the protocol components sometimes rejudged until the group is satisfied that the regulatory criteria are met. At that point a decision to approve, approve conditional on revisions, defer (or table for more information), or disapprove is made. At this second, group level of decision-making IRB members from diverse backgrounds make the case for what risks they perceive as acceptable, whether the methodological design will minimize risk, whether human participants (or even the researcher and the university) are adequately protected, and so forth. It is at this level that expertise, participation, and small group dynamics are particularly relevant and likely to impact the decision outcome.

4.3 Sampling and sample size

The participants in this research study are experiential experts in the IRB process and for that reason, the sampling methodology employed is mostly purposeful. The decision to focus on universities rather than hospitals, government agencies, or other types of research organizations primarily was based on time and budget constraints, which did not permit sampling across IRB types for this study. It was also based on difficulty I experienced with gaining access to hospital IRBs during an earlier pilot study. However, I believe that universities are an appropriate subpopulation for this research given the breadth of research issues and disciplines, and potential for variability in their IRB structure and member selection procedures.

The sampling strategy employed both comparable case selection (i.e., only research universities) and reputational case selection (i.e., where possible, universities that received a compliance determination letter[1]). The starting point for identifying

[1] OHRP reviews institutional compliance with the federal regulations governing the protection of human subjects in HHS-sponsored research 45 CFR 46. The agency evaluates all written substantive allegations or indications of noncompliance with the HHS regulations, which are either made known to OHRP by a variety of source, including the institution itself (because institutions are required by law to report any serious or continuing noncompliance issues to OHRP). If complaints or concerns arise regarding an institution's human subject protection practices, OHRP opens a formal evaluation and, if necessary, requires corrective action by the institution. During this evaluation, findings of noncompliance are issued in the form of determination letters, which before being made public are edited to remove those portions that relate to issues still under discussion with the institution. Compliance determination letters are intended to correct noncompliance issues and to prevent them from reoccurring. OHRP reports that most corrective actions are resolved at the OHRP level and do not have to be handled at a higher level. In serious cases,

comparable cases was the annual list of research universities that rank in the top tiers of *U.S. News and World Report*. Selection of participant sites was not purely random because an effort was made to include universities (i.e., reputational cases) that received at least one compliance determination letter in response to purported human subjects violations. It was expected that because of a compliance issue members at such universities could more broadly discuss issues that might inform our understanding of the relationship between IRB decision-making process and outcomes. Thus, a purposeful set of 25 universities from the *U.S. News and World Report* 2003 list of "top tier" universities was sent an email invitation to participate in the study. The text of the invitation email can be found in Appendix B. The sample boundaries, other than the university characteristics described above, included the requirement that participating universities allow me to interview the administrator, the IRB chair, a scientist member, a nonscientist member, and a nonaffiliated member on at least one IRB at the university. The choice of which members who would participate was determined by the IRB administrator. In most cases the administrator simply forwarded the invitation to participate on to the IRB members, allowing them to decide whether or not they wanted to be interviewed. In at least one case the administrator appears to have selected specific members.

The resulting sample contained seven universities and 37 participating IRB members, including 21 scientist members, 13 nonscientist members, and six nonaffiliated members. Note that the total number of each type of member interviewed is different than the total number of IRB members (37) interviewed because it includes chairs and administrators in their membership role (i.e., scientist or nonscientist) as well as their administrative role. For example, the 13 nonscientist members also include the six nonaffiliated members because they too are nonscientists. Seven administrators (three of whom are not voting members on their IRBs) and seven IRB chairs were also interviewed. With one exception all of the chairs consider themselves, and are considered

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OHRP may revoke its approval of an institutions Federalwide assurance or even suspend research activities at the institution. In most cases, OHRP requests verification that the institution has implemented the changes necessary to overcome the noncompliance problems. Often this will be revising policies, improving researcher training, and so forth. (available from: www.hhs.gov/ohrp/compliance; visited on October 12, 2004).

by their IRB members and administrators, to be scientists. At University D, the IRB administrator actually classified the chair as a nonscientist because of the chairs disciplinary background (business); however all other IRB members at University D (including the chair) classified this chair as a scientist member.

In general, choices of informants were driven by the conceptual questions, and not by a concern for "representativeness" (Miles and Huberman, 1994). The primary concern in this study is with identifying and explaining the conditions and processes by which IRB decision-making takes place at university IRBs, not necessarily with the generalization of the findings to other research settings such as hospitals and private research centers.

4.4 Data collection and procedures

Building on the theoretical framework presented in Chapter 3 and on preliminary results from a pilot study conducted in 2002 (described below in section 4.4.4) I designed data collection instruments to capture the elements of the decision-making process as perceived by IRB members and to determine how those members participate in the process. The interview protocol was further refined by posing the questions to three IRB members who serve on the IRB at my university.[1] The following methodological discussion applies particularly to university IRBs.

4.4.1 Instrumentation

Data were collected via personal interviews with IRB members at the seven research universities. Interviews were designed to obtain rich contextual information on specific IRB functions and processes from the perspective of the members who perform them. A semi-structured interview technique was selected to facilitate a deeper understanding of IRB functioning, from institutional and individual board member perspectives. The interview questions (see Appendix C) were designed to draw out the participants and to get them to reflect on their experience as an IRB member and their

[1] This round of pre-testing the protocol was conducted not to gather data, as in the pilot test, but rather to assess how the potential participants would interpret each questions and whether questions were clear and made sense as asked. During this phase, I conducted a mock interview with each of the three Georgia Tech IRB members while simultaneously discussing their perceptions and interpretations of the questions.

perception of their role and the role of other types of members on the IRB. The interviews, ranging from 45 minutes to two hours, were carried out on site at each university. All interviews were tape recorded to ensure accuracy of the participant responses. A set of supplementary interview questions (see Appendix D), also tape recorded, was posed to the administrators at each university to obtain factual information to assist the characterization of each university IRB. To improve the accuracy of results, both sets of interviews were fully transcribed prior to data analysis. Ethical considerations for these procedures are discussed in more detail in Section. 4.8.

4.4.2 Observational data

The interview questions were designed to examine how individual IRB members participate in the decision-making process. However, because there is no guarantee that members truly participate how they say they do, observing them in an actual IRB meeting provides an extra degree of reliability to their responses. Each university permitted me to attend and observe an IRB meeting in session at the university. Observational notes were recorded at the meetings, but tape recording was not permitted. I also recorded my personal notes and impressions during and immediately after each site visit. By attending an IRB meeting at each university, it was possible to see how members actually participate and to observe the decision-making environment in general, both of which provide additional information about the IRB decision-making culture. The observation notes for each university—coded and analyzed in a similar manner to the interview transcripts—are particularly useful for beginning to characterize the decision-making process at the group level and for improving the reliability of the results.

4.4.3 Archival data

Two additional data sources—university policies and compliance determination letters—were used to further characterize the culture of the IRB decision-making process at each university. All of the universities in this study make available, via the Internet, their university policies on research with human subjects. Additional resources such as review checklists were obtained from the administrator during the on site interviews.

The second source of archival data came from compliance determination letters between July 2000 and February 2004[1], which are made public via the Office of Human Research Protections website.[2] Prior to conducting the personal interviews, I collected data on whether compliance determination letters were issued against the universities in my sample at any time up through the interviews. Where relevant, the nature of such complaints and the board's role in the events that led to such complaints were incorporated into the interview protocols to identify any relationships between these outcomes, member participation, decision processes, or general IRB structure.

4.4.4 Preliminary studies

Personal interviews were conducted during a pilot study in April 2002 with IRB members from two research organizations in Georgia to explore anticipated differences in member perceptions and to develop a useful interview protocol. The resulting transcripts suggested that member behavior is influenced by position or role on the committee. Furthermore, those respondents indicated that IRB members may perceive their role, and the role of other members, in different ways. For example, members not affiliated with the organization may feel that their purpose on the board mainly is to ensure that the consent document is adequate, whereas scientist members may tend to emphasize issues regarding the research design. Furthermore, nonscientists on one IRB may be considered to be scientists on the IRB of another organization.

Another perception that emerged in the preliminary interviews with nonaffiliated members was the belief that they were less active or participatory than scientist members, an observation also supported in the extant literature on IRBs (Gray et al., 1978). The following quotes from IRB members interviewed during the pilot study reaffirm the need for in-depth examination of roles of different types of IRB members and how these roles impact IRB decision-making processes and outcomes:

> "The consent form is a priority for community members. Community members are not primarily responsible for judging [research] design." *(Nonaffiliated member, social and behavioral science IRB, April 2002)*

[1] If compliance letters were issued after the last site interview/observation, they were not included in this analysis.
[2] The OHRP website provides compliance determination letters at http://www.hhs.gov/ohrp/compliance/letters/ (visited on September 25, 2004).

> "Scientists always talk more because they can break down quantitative aspects, etc. especially the statistician. But, [participation] depends on the issues and protocols." *(Nonscientist member, social and behavioral science IRB, April 2002)*

> "Nonaffiliated and nonscientist members participate less. They do not have as many comments and they don't review [as primary reviewer] as many protocols. They tend to defer to scientist members and tend to withhold because they don't want to hold up the process or maybe feel that their opinion won't be respected." *(Scientist member, biomedical IRB, April 2002)*

> "Everyone looks at the consent form. Scientist members typically focus on the rationale for a proposed study and on its design. Nonscientist and nonaffiliated members tend to look at whether there is consistency between the lay synopsis and informed consent." *(Scientist member, biomedical IRB, April 2002)*

The preliminary interviews suggest disparate views among members and types of IRBs (i.e., social and behavioral IRBs versus biomedical IRBs) that call for systematic study to examine the relationship between composition and behavior.

4.5 Case study analysis

Case study analysis revolves around assessing the "fit" between an individual case and the theory or theories being tested (de Vaus, 2001). De Vaus emphasizes that because case studies are fundamentally theoretical, their analysis is also fundamentally theoretical and must be built around the theoretical propositions being developed. Thus, in order to really understand the IRB process and its related outcomes, it is helpful to understand the characteristics of the individuals who participate in that process—the member characteristic proposition—and the corresponding culture—the IRB culture proposition. Case study analysis is ideally suited to achieve this understanding and developing preliminary hypotheses about the relationship between member characteristics and IRB decision-making.

The theoretical propositions that shape and guide this research center on the characteristics and roles (and perceived roles) of the different types of members who participate in the IRB process. In earlier chapters, I proposed that the IRB process—ultimately the decision-making process and the decision outcome—might be affected by such individual member characteristics as gender, expertise, and level of participation in

the process. Furthermore, characteristics of the IRB and its affiliated university may affect the IRB process. That is, features such as whether the IRB is affiliated with a public funded or privately endowed university; or, whether it reviews social and behavior or biomedical or all types of research for the university. It is, therefore, a primarily goal of analysis to "test" these theoretical propositions.

Yin (1989) suggests that cross-case analysis can only be done after each individual case is understood as a whole. I achieve this objective by first examining each university case individually, organizing each one around the theoretical concepts and research questions that guide the research. By analyzing each case around a common framework it becomes possible to compare the cases to arrive at higher-level generalizations (de Vaus, 2001).

4.6 Data analysis software

N6 software[1] was used to manage and conduct qualitative content analysis of the interview and observation data in this study. N6 permits reliable tracking of pieces of data and reflection on the emerging concepts, which enhances the interpretive accuracy of analysis. N6 allows the researcher to store and organize text databases, code words and phrases within the text, search and retrieve the text for occurrences of a particular theme, and generate theory by displaying the categories or themes and their interconnections (Richards, 2002).

N6 operates using a node structure, which employs an index tree that can be altered as data analysis evolves. In N6 terminology, a category (i.e., a theme) that stands by itself is called a "free node". While reading through transcripts, "nodeworthy" ideas can be placed into the free node section of N6's index tree structure, which functions as an electronic container for holding ideas. During early coding, this allows the researcher to simply create holding areas for both theoretical codes and codes that emerge during the initial pass through the transcripts without worrying about exactly where each idea belongs. As coding and analysis progress the researcher is able to move these free nodes into more organized groupings. N6 refers to this as a node hierarchy, in which the first

[1] N6 is the sixth version of the NUD*IST (Non-numerical Unstructured Data Indexing Searching and Theorizing) software package developed by QSR International specifically for analyzing qualitative data (see www.qsrinternational.com; visited on October 20, 2004).

level node is called the parent node and those under it are called child nodes. For example, in this study "gender" is a parent node, whereas male and female are considered the child nodes of the parent. Similarly, scientist, nonscientist, and nonaffiliated member are all child nodes of the parent node "IRB member type". A hierarchical node name includes all the parent nodes. In the case of the above examples, the hierarchical code name is "base data" because it represents the basic demographic data of all the participants in this study (see Figure 2). The numbers in parentheses in Figure 2 represent the "address" of each node, which is used by the software to locate each code during analyses.

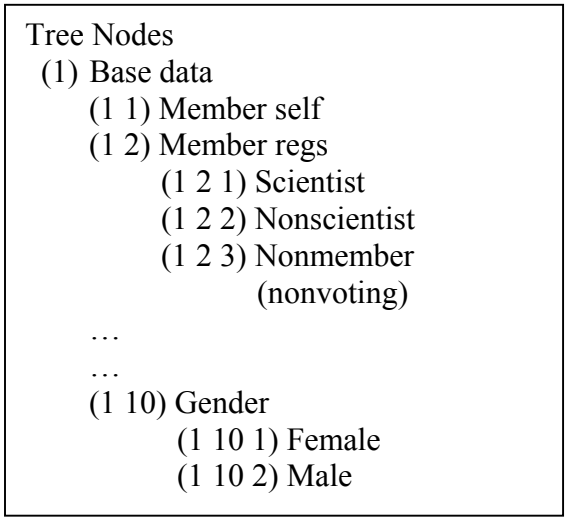

Figure 2. Example of node index tree and hierarchical structure.

Once nodes and the tree structure are created, they can be explored in their original occurrences in the interview and observation transcripts. N6 permits the researcher to "spread the text" in order to view a larger portion of the transcript around a particular code and situate the context appropriately. In other words, the text stored at any node can be retrieved and reviewed at any time to verify its context. Moreover, using N6 it is also possible to generate reports about all of the text that is coded at a particular node. This means that instead of manually going through each transcript in search of text and corresponding codes, N6 will group together all of the text associated with the code "deference", for example. Now just the portions of each transcript that contain the code "deference" can be more easily compared, which subsequently allows the researcher to

interrogate the data in ways that would ordinarily be very tedious. The next section discusses the coding approach more specifically.

4.7 Coding scheme

Coding proceeded in multiple phases consistent with the qualitative research approach. A "provisional start list" of codes (Miles and Huberman, 1994) was developed from the research questions, conceptual framework, and observations made during a two-year research assistantship with the IRB at my home institution (see Table 1). In true qualitative fashion, interview data were coded throughout the data collection process using a multi-tiered approach.

4.7.1 Phase I: open and flexible coding

First, the raw data were sorted into manageable conceptual categories (e.g., member characteristics, expertise, participation, IRB purpose) using an open coding approach (Strauss, 1987). Open coding is so named because the categories or concepts are flexible and open to modification as analysis progresses. I began coding data from interview transcripts and field notes using the predetermined list of coding categories suggested by my conceptual framework, research questions, and the literature (see Table 1). As anticipated additional categories (for example, "*not* research design" and "*not* scientific merit") emerged as the analysis progressed. The final coding thesauruses are provided in Appendices E and F.

Using an open and flexible coding approach as I reviewed the interview material, I assigned descriptive codes to pieces of text that represent either important concepts (e.g., expertise, risk-benefit ratio, "not our job"), emerging common patterns between respondents (e.g., willingness to defer to scientists, reluctance to speak out on certain issues), or distinct responses by different subgroups (e.g., scientists versus nonscientists). Text associated with each code was isolated and then re-grouped into broader conceptual categories to allow for meaningful comparison and interpretation in the subsequent phases of coding described below. For example, during my initial phase of coding I liberally noted references to different dimensions of participation, regardless of whether the action took place prior to or during the convened IRB meeting. At this stage in

coding, I allowed every code equal status with every other code before placing codes into a meaningful hierarchy for interpretation.

Table 1. Preliminary codes derived from conceptual framework and IRB literature

Code	Description
Member characteristics	Scientist, nonscientist, or nonaffiliated (lay) member; chair; administrator; gender; IRB experience
Expertise	Disciplinary expertise; methodological expertise; lay expertise; lack of expertise; development of expertise over time
Participation	Presence (or lack thereof) of mechanisms that encourage members to participate; email; group training and workshop opportunities; assignment of reviews to members; direct participation; influence over decision outcome; number of nonaffiliated or lay members; resources for participation (compensation)
Decision-making culture	Formality of meetings; discussion process; consensus; deference to authority or experts
IRB purpose	Purview of IRB; whether or not to review scientific merit or research design; protect human subjects; minimize risks

As noted earlier N6 is used to create a node system to serve as an uncoordinated collection of "free" categories that serve as a "parking space" or as an electronic container for ideas (Richards, 2002) about the interview transcripts and emergent codes until logical relationships can be identified between categories (such as member type, public or private university, and gender). Thus, I used N6 to search the text of each transcript for words from the preliminary list of codes such as "expertise", "experience", "participation" and variations on these words to be sure I did not overlook occurrences such as "expert" or "participate" with similar meanings.

For each of these text searches N6 permits the creation of a new document that includes only the occurrences of the specified text, which can then be expanded to show the context of a key phrase or word in its original transcript. Using this newly created document, only the relevant portions of text can be re-read in order to determine whether a word or phrase actually referenced the concept on which the text search was performed. For example, using N6 I searched all the texts for the word "expertise". By expanding the paragraphs where expertise was mentioned, it is possible to determine whether the

respondent was talking about lacking expertise to judge research design, deferring to disciplinary experts to decide the merit of a protocol, possessing expertise to determine the level of risk, and so forth. Clearly there exist important differences in the meaning of expertise in each of these contexts that cannot be fully appreciated without referring to the original context of the interview response.

4.7.2 Phase 2: pattern coding

During open coding, certain "patterns" or repeated relationships between properties and dimensions of categories begin to appear (Strauss and Corbin, 1990). Thus in the second phase of coding, I re-read across all the interview transcripts to specifically identify such similarities and differences using a pattern coding approach (Miles and Huberman, 1994). At this level, I focused on the actual interview responses in the context of the interview questions asked and assigned code labels for thematic categories one category at a time (Strauss, 1987). This pattern coding stage is useful for identifying patterns or ways in which key concepts cluster together or relate to one another (Neuman, 2000). Data are put back together in new ways by making connections between categories (Strauss and Corbin, 1990).

An example is useful. Using the earlier example of "participation", after initially coding all the transcripts and placing each potential dimension of participation into "free nodes" in N6, I recombined each code into two broader categories of participation: group participation and individual participation. Group participation thus encompasses any participatory actions taken by members *during* the convened IRB meeting and the associated group decision-making process. On the other hand, individual participation refers to member involvement in the review process that occurs outside of the convened IRB meeting (e.g., clarifying questions with investigators during pre-meeting review of the protocol, conducting expedited reviews, review of assigned protocols).

This level of coding is particularly useful for making comparisons between different types of IRB members and their decision-making processes or attitudes towards concepts such as "expertise" or" purview of IRB". This stage also permits the identification of overlapping codes that could be combined or single codes that may need to be further refined. Using the N6 software, this is achieved by placing free nodes into a

"tree structure" where, for example, a node for "member role" (a parent node) has subcategories for scientist, nonscientist, and nonaffiliated member (child nodes of the parent node).

4.7.3 Phase 3: thematic coding

During the final review of the data, identified themes were used to aid in the analysis and interpretation of the IRB member interview responses and to identify structural relationships between the thematic categories. In the third pass through the data, I compared and contrasted themes across the cases using the N6 software capabilities to "interrogate" the date. I used the tree node and free node indexing system to "ask questions" about the themes and concepts identified during the first two coding passes and in the context of my research questions. Using Boolean style search techniques, I was able to examine where, for example, certain codes intersect with or occur near other codes. Using such collation operators allowed me to examine text coded at categories within specified relationships, such as how different types of members view the purview of the IRB, or whether there are differences between members' views depending on whether they serve on a public university IRB or a private university IRB.

Similarly, it is possible to ask questions such as whether IRB members talk about deference to other members or staying silent when they also talk about the concept of expertise. Or, how IRB members talk about making a decision to approve a research protocol and where close by they also talk about lack of expertise to do so. I also examined participation of members such as how nonscientist members participate when research design of a protocol is the subject of discussion. These contextual searches were performed using N6, by asking questions about how interview text is coded by one node in the context of coding by another node and they provide potential answers to the research questions that guide this study.

Throughout this process, I attempted to link emerging themes and patterns particularly with the literatures on participatory democratic theory and small group decision-making to my preliminary propositions about the influences of IRB member characteristics on the decision-making processes and outcomes. For example, I looked for

evidence that members of the group might be influenced by the group process (as suggested by decision research on conformity).

4.8 Limitations of selected methodology: reliability and validity

Validity in qualitative research is defined as the extent to which the data is plausible, credible and trustworthy. Maxwell (1992) identifies three types of validity that are relevant to qualitative research in general. Descriptive validity is the accuracy of what is reported by the researcher (for example, events, objects, behaviors, and environment). Interpretive validity is the accuracy in interpreting what is going in the minds of the participant and the degree to which the participant's views, thoughts, feelings, intentions and experiences are accurately understood by the researcher. Theoretical validity is the extent to which the theoretical explanation developed fits the data and therefore is credible and defensible.

Case study designs are devised to yield sensible, plausible accounts of events and in this way internal validity is achieved (de Vaus, 2001). De Vaus further claims that case study designs achieve explanations by constructing "a full picture of the sequence of events, the context in which they occur, and the meaning of actions and events as interpreted by participants and their meaning as given by a context." The external validity of case studies is enhanced by the strategic selection of cases rather than by the statistical selection of cases (Yin, 1989). To allow for more meaningful comparison, this study was intentionally restricted to university IRBs and particularly to those that are classified in the "top tiers" of all research universities. Furthermore, the validity of data interpretation is improved throughout the dissertation by continually linking observations and interpretations back to the literature, which frames this study. In this manner, it can be seen that such interpretations are, in fact, the product of conscious analysis. Interpretations and findings are further substantiated with the actual words of the research participants where possible.

A major assumption about reliability when conducting qualitative research is the acceptance that different researchers or researchers using alternative measures will get distinctive results because each researcher sees data collection as an interactive process (Neuman, 2000). Triangulation—or the use of multiple methods, data sources, and

theories—to substantiate data sources increases the reliability of qualitative research. Increased agreement between sources of data permits the more reliable the interpretation of the data. In this study, three data sources are used—personal interviews with IRB participants, archival data sources, and nonparticipant observation of IRB meetings—and examined via qualitative data analysis and case study methods. Moreover, results are interpreted vis-à-vis two theoretical perspectives: small group decision-making and participatory democratic theory. Additional conventions were followed to enhance reliability. For example, throughout the study, extensive use was made of fields notes recorded during and immediately after each site visit.

4.8.1 Intercoder reliability

Miles and Huberman (1994) assert that definitions become sharper when two researchers code the same date set and discuss their difficulties in coding. Disagreements indicate that a definition ought to be expanded or clarified (Miles and Huberman, 1994). To check reliability of coding beyond that which is offered by using the N6 software program, I asked two independent coders to code three (approximately 10 percent) randomly selected transcripts. Coders were instructed to do line-by-line coding of the text, using the coding thesauruses in Appendices E and F, to search for specific key ideas or phrases listed in the column entitled "synonyms/related themes". Each time a key idea or phrase was identified, the coder was instructed to label that text according to the code listed in the first column. The fact that two coders independently assign the same code is assumed to be a sufficient indication that the researcher himself or herself, coding the same response in accordance with his or her instructions, would similarly have chosen that same code (Hak and Bernts, 1996). Reliability calculations were performed for three scenarios: between the two independent coders, between Coder 1 and the researcher, and between Coder 2 and the researcher. The results are summarized in Table 2. Reliability was calculated according to Miles and Huberman's (1994) formula:

Reliability = Number of Agreements/(Total Number of Agreements + Disagreements)

Agreement between coders should be in the 90 percent range, depending on the size and range of the coding scheme (Miles and Huberman, 1994).

Table 2. Intercoder reliability calculations for key themes

Randomly selected transcript	Reliability between independent coders	Reliability between Coder #1 and researcher	Reliability between Coder #2 and researcher
24	89%	87%	90%
27	95%	95%	93%
34	84%	88%	86%

4.9 Ethical considerations

This research study was found by the Georgia Institute of Technology IRB to be of minimal risk to the research participants in this study, and as a consequence underwent expedited IRB review. Prior to submitting the research to the Georgia Tech IRB, considerable thought was given to the possible ways in which participants might perceive risk associated with their involvement in the study. While university IRBs conduct their proceedings behind closed doors, many openly list the names of IRB members on the Internet. Yet, usually the review process is conducted akin to the peer review process in which the research investigator does not know who reviews his or her proposal. Given the tension that is currently present within the research oversight system, it is understandable why many universities choose to maintain such a "blind review" system.

I deliberated several approaches for how to identify IRB members that participated in this study. The most comprehensive way to represent IRB members and their institutions was to name both the participant and their university affiliation. Given the possibility that some universities might not want particularly negative aspects of their process identified publicly, I anticipated that this option would lower my initial response rate. A second method of identification considered was to identify participants only by their university affiliation. But, at some universities, it might be easier to further identify IRB members because the university may only have one nonaffiliated member or one scientist member with a particular disciplinary background that is evident from the person's responses especially when combined with a member list on the Internet. Furthermore, this second method of identification would also make it very easy to identify the chair and administrator at each university. The third method of identification considered was to provide complete confidentiality to participants, identifying them by

member type only and in the context of the type of IRB on which they served and the type of university (public or private) in which the IRB operates.

In the end, and in order to maximize the response rate and to provide an environment in which potential participants would be comfortable providing maximum disclosure of their IRB experience, I opted to provide full confidentiality. This decision was reaffirmed by repeated expression from the participating IRB members that I not identify them or their university. During my initial contacts, several university IRB administrators asked me to verify confidentiality. One IRB went so far as to require me to sign a statement of confidentiality for attending the IRB meeting and to submit the resulting observation transcript for final approval. IRB approval and consent forms are located in Appendix A.

4.10 Summary

This chapter described the research methodology and sampling procedures used to examine the IRB decision-making process at seven research universities. In exploring the dynamics of these boards, my primary research objectives were two-fold. First, I set out to characterize these IRBs, including their member composition, the type(s) of research they review, the ways in which members participate in decision-making, and the processes by which members determine whether the proposed research merits IRB approval. The second research objective was to investigate whether a relationship exists between these characteristics and IRB decision making processes at the group level and whether it can be explained, at least in part, by the variables such as selection criteria and composition of IRB members, roles of members, and group dynamics. To determine these attributes, data were collected using in depth personal interviews with IRB members, and using archived documents from the universities (IRB policies and guidelines) and from the Office of Human Research Protections (compliance determination letters). To improve reliability of the data, observations were recorded of an in-session IRB meeting at each participating university. Reliability and validity issues were also discussed.

In the remaining chapters, I present patterns of results and analyze them for their relevance to the research questions. In Chapter 5, I briefly introduce the IRB members

who participated in this study. In Chapter 6, each university IRB is profiled on an individual case level based on the data obtained from the personal interviews, available archived documents at each university, and available compliance letters. Chapter 7 presents a cross-case analysis, comparing the decision-making process across all seven IRBs. In Chapter 8, I will discuss my findings from Chapters 5, 6 and 7 within the context of the literature presented in Chapter 3 and draw conclusions and implications for policy and practice.

5.0 IRB MEMBER CHARACTERISTICS

5.1 Introduction

This chapter presents a brief introduction to the individuals who participated in this study. Demographic information is provided about the group as a whole and also according to the regulatory-defined subgroups (scientists, nonscientists, and nonaffiliated members).

5.2 Research participant demographics

The subject group in this research consisted of 37 IRB members from seven U.S. research universities. The overall demographics are summarized in Tables 3 and 4. The classification of participants as presented in this section is based on information provided by the administrators at each university. This is important to point out because the IRB administrator's definition of a scientist or nonscientist may be different than the individual IRB members' definitions of themselves, as was noted previously. This variation in definition or classification of member types is important for explaining the relationship between member types and their perceived role on the IRB and their perceptions of the IRB process because it must be taken into consideration when interpreting related interview responses.

For example, at University D three members (specifically, researchers in education, business, and economics), including the IRB chair, classified themselves as "scientist members". One of those respondents (a researcher in economics) was not sure whether he was correctly classifying himself but he was also relatively new to the process (having served only one semester on the IRB). However, during my interview with the IRB administrator at University D, she specifically referred to the members from these disciplines as "nonscientists". In contrast, one member (a nurse) at University C classified herself as a nonscientist while the IRB administrator at that university clearly identified this member as a "scientist". The only other conflict in member classification occurred at University A, where one member who is pursuing a social science PhD classified herself as "probably a scientist". However, the IRB administrator classified this member as a "nonscientist until she completes her degree". Since the administrator's

definition is the one that is used to satisfy the regulatory requirements for committee composition, I use this classification throughout the data analysis to provide an initial profile of the sample group in this study. However, where relevant to those members' responses I will point out this difference in classification and how it might affect the interpretation of responses.

Table 3. Demographics of members according to Administrator classification

	Total	Scientist	Nonscientist	Nonaffiliated	Male	Female
Chairs	7	6	1	0	3	4
Administrators	7	1	6	0	0	7
Scientists	21	-	-	0	11	10
Nonscientists	13 (16)[1]	-	-	6	5	8 (11)[1]
Nonaffiliated	6	0	6	-	4	2

Table 4. Demographics of members according to Self classification

	Total	Scientist	Nonscientist	Nonaffiliated	Male	Female
Chairs	7	7	0	0	3	4
Administrators	7	1	6	0	0	7
Scientists	24	-	1[2]	0	12	12
Nonscientists	10 (13)[1]	-	-	6	5	5 (8)[1]
Nonaffiliated	6	0	6	-	4	2

Of the 37 participants, 21 are classified as scientist members, 10 as nonscientist members, and six as nonaffiliated members.[3] All of the nonaffiliated members are also classified as nonscientists. Seven IRB chairs and seven IRB administrators were also interviewed. While all of the chairs classified themselves as scientist members, only six were classified as such by their IRB administrators (as noted above). One IRB administrator is classified as a scientist member, while three are classified as nonscientist

[1] Three of the IRB administrators are nonscientists; however, they are not voting members on their IRBs. The numbers in parentheses represent the number of participants if these three individuals are included in the total counts.
[2] One member (with an engineering background) classifies herself as both a scientist and nonscientist. The IRB administrator classifies this member as a scientist.
[3] Recall that three of the original 37 participants are not voting members on their IRBs. These three participants are IRB administrators, and also nonscientists. However, their responses to interview questions are not included in analyses of perceptions shared by the nonscientists who are voting members.

members. The remaining three IRB administrators are non-voting members on their IRBs.

The members interviewed represent notable breadth in disciplinary expertise and years of service on their IRBs (see Table 5). The cells in Table 5 are sorted according to university ID, affiliation, and role on the IRB as designated by the IRB administrator, respectively. Twenty-one participants are female; 16 are male. All of the IRB administrators are female. Four females are chairs of their IRB. Four of the nonaffiliated members are male. Of the 21 scientist members,[1] about half (10) are female. Nine of the scientist members received their highest degree in a medical field. The remaining scientists (12) have doctoral degrees in social science disciplines. The educational backgrounds of the 13 nonscientist members include health administration, public health, social work, law, art history, engineering, theology, and research administration. The backgrounds of the nonaffiliated members are also diverse: two are employed in social work areas (primarily with the elderly community), one works for a local art museum and has a background in art history, one is a retired engineer, one is a clergyman, and one is a homemaker with a law degree.

[1] As they are classified by the IRB administrator on each IRB. If the self classification is used, the total number of scientist members is 24.

Table 5. Demographic information for study participants.

Univ ID	Affiliated	Member Regs	Member Self	Expertise	Position	University Type	IRB type	IRB years	Gender	Doc ID
A	no	nonscientist	nonscientist	engineering	member	private	social behavioral	4	M	25
A	yes	nonvoting member	nonscientist	research admin.	admin	private	social behavioral	4	F	22
A	yes	scientist	scientist	sociology professor	chair	private	social behavioral	5	F	23
A	yes	scientist	scientist	psychology professor	member	private	social behavioral	4	M	24
B	no	nonscientist	nonscientist	humanities	member	private	biomedical	16	F	16
B	yes	nonscientist	nonscientist	policy	admin	private	biomedical	8	F	11
B	yes	scientist	scientist	physician	chair	private	biomedical	8	M	10
B	yes	scientist	scientist	health research	member	private	biomedical	3.5	F	12
B	yes	scientist	scientist	physician	member	private	biomedical	2.5	M	13
C	no	nonscientist	nonscientist	lawyer	member	private	biomedical	6	F	21
C	yes	nonvoting member	nonscientist	research admin.	admin	private	biomedical	5	F	17
C	yes	scientist	nonscientist	nurse	member	private	biomedical	2	F	18
C	yes	scientist	scientist	physician	member	private	biomedical	7	M	19
C	yes	scientist	scientist	physician	chair	private	biomedical	6	M	20
D	yes	nonscientist	scientist	education professor	member	public	comprehensive	2	F	32
D	yes	nonscientist	scientist	economics	member	public	comprehensive	0.5	M	35
D	yes	nonscientist	scientist	research admin.	admin	public	comprehensive	5	F	36
D	yes	nonscientist	scientist	business professor	chair	public	comprehensive	8	F	37
D	yes	scientist	both	engineering	member	public	comprehensive	2.5	F	33
D	yes	scientist	scientist	social science professor	member	public	comprehensive	9	M	34

Table 5 continued. Demographic information for study participants.

Univ ID	Affiliated	Member Regs	Member Self	Expertise	Position	University Type	IRB type	IRB years	Gender	Doc ID
E	yes	nonscientist	scientist	social work	member	public	social behavioral	2	F	2
E	yes	scientist	scientist	nursing professor	member	public	social behavioral	1	F	1
E	yes	scientist	scientist	clinical psychology	member	public	social behavioral	2	M	3
E	yes	scientist	scientist	psychology	admin	public	social behavioral	2.5	F	4
E	yes	scientist	scientist	physician	member	private	biomedical	2.5	M	14
E	yes	scientist	scientist	psychology professor	chair	public	social behavioral	5	F	15
F	no	nonscientist	nonscientist	clergy	member	public	comprehensive	2.5	M	27
F	yes	nonscientist	nonscientist	research admin.	admin	public	comprehensive	3	F	29
F	yes	nonscientist	nonscientist	research admin.	member	public	comprehensive	6	F	31
F	yes	scientist	scientist	physician	member	public	comprehensive	1.5	M	26
F	yes	scientist	scientist	physician	chair	public	comprehensive	8	M	28
F	yes	scientist	scientist	physician	member	public	comprehensive	1	F	30
G	no	nonscientist	nonscientist	business	member	private	social behavioral	1	M	6
G	no	nonscientist	nonscientist	business	member	private	social behavioral	2	M	7
G	yes	nonvoting member	nonscientist	university admin.	admin	private	social behavioral	1	F	5
G	yes	scientist	scientist	sociology professor	chair	private	social behavioral	4	F	8
G	yes	scientist	scientist	sociology professor	member	private	social behavioral	6	M	9

5.2.1 Scientist members

Twenty-one scientist members participated in this study. With one exception (a nurse), all possess either PhDs or MDs in science or medicine. Nine received their highest degree in a medical field. Eleven hold PhDs in a social or behavioral science discipline and one is a nurse. Almost half (10) of the scientist members are female. Of the female scientist members, one is a physician, one is a nurse and the rest have social science backgrounds. Of the 11 scientist members who are male, seven are physicians and four have social or behavioral science backgrounds. In this study, the average number of years of IRB service for scientist members is 4.3. The range of IRB service is one to nine years (mode = 2.5 years). All of the chairs consider themselves to be scientist members, and with one exception their committee members agree. The exception is University D, where the chair has a business education background and is classified as a nonscientist according to the IRB administration. While there is no stipulation that the IRB chair must be a scientist, the IRB administrator classification is what is reported to the Office for Human Research Protection (OHRP) as part of the university IRB registration. The average range in years of IRB tenure for chairs is four to eight (average = 6.3 years).

5.2.2 Nonscientist members

Nonscientist members in this study include both affiliated IRB members and members not affiliated with the universities. The affiliated nonscientist members have backgrounds in university administration, business, the humanities, and theology. IRB tenure for nonscientist members ranges from one-half to 16 years (average = 4.6 years). The average is 3.5 years when calculated without the member who holds 16 years of experience.

5.2.3 Nonaffiliated members

As mentioned above, all of the nonaffiliated members are also nonscientist members. They have an average of 5.3 years of IRB experience, with one member having served 16 years on her IRB. When this member's experience is excluded from the

average, nonaffiliated members have served an average of 3.1 years on the IRB. Four of the nonaffiliated members are male.

6.0 Individual Case Analysis – University IRB Profiles

6.1 Introduction

In 2003, more than half (55 percent) of basic research conducted in the U.S. was performed at universities (Shackelford, 2004) with the U.S. research university serving as the benchmark for the rest of the world (Commission of the European Communities, 2004). These characteristics make the research university an ideal laboratory in which to examine aspects of the IRB decision-making process. Though human subjects review is required at any institution or organization that receives federal funding for human subjects research, the university represents a unique opportunity to get inside the "black box" of the IRB decision-making process and examine its complexity from the inside out for several reasons explained below.

Generally it is more difficult to gain access to the IRB meetings or to related documents at private organizations such as hospitals or medical research centers. Such institutions typically do not make their human subjects research policies or their IRB membership publicly available. In contrast most universities publicly post their human subjects research policies and in many cases make their committee membership lists available on the Internet. While the IRB meetings at universities are private to the extent that they are not "open door" meetings, guests and visitors are generally permitted to attend a meeting if arranged in advance with the IRB staff or chair. Thus, the research university is an ideal venue for this research not only because it allows for a study of decision-making at the cutting edge of research, but also because—perhaps by the very nature of its purpose—it provides entrée into a system that elsewhere tends to be closed to outsiders. For these reasons, universities with the Carnegie Classification of Doctoral/Research Universities were invited to participate in this study, using the sampling methodology discussed in Chapter 4.

Universities that agreed to participate are profiled here in a manner that provides the context in which their IRBs are situated, but without revealing the actual identity of the university. Because the universities and IRB members in this study explicitly requested confidentiality associated with their participation, I do not disclose the identity of any of the IRB members or their university affiliation. Thus, I have chosen to profile

each university according to several academic characteristics and IRB traits in a descriptive but nonidentifying manner. While this choice may take away from the credibility of the results, it was a critical decision to maximize participation and depth of interview responses, particularly given the current regulatory climate for human subjects research. For more information about ethical considerations refer to section 4.9.

The Carnegie Classification of Doctoral/Research University describes such universities as those that "offer a wide range of baccalaureate programs and…are committed to graduate education throughout the doctorate." About seven percent (i.e., 248, or 162 public and 86 private) of U.S. universities are classified as Doctoral/Research Universities.[1] These same universities tend to be classified among the "top tiers" by *U.S. News and World Report* in its yearly rankings of U.S. colleges and universities. The universities in this study are further profiled according to publicly available statistics including approximate number of graduate students enrolled, breadth of disciplinary programs offered and range of total expenditures for research and development. Within the sample group, four universities are privately endowed and three are publicly funded. All participating universities have an affiliated medical school or center; however, this was not a stipulation for participation. The universities are located across the U.S. and are not concentrated in any particular geographic area. A summary of overall university profiles is provided in Table 6.

[1] The Carnegie Classification of Institutes of Higher Education, 2000 Edition.

Table 6. Summary of university statistics[1]

Univ ID	Type/Carnegie Classification	Approx. range # Graduate Students	Approx. range # Faculty (male/female)	Approx. range Research $ (FY2001; in millions)
A	Private; Doctoral/Research University-Extensive	5000-10,000	1500-2000 (80/20)	300-400
B	Private; Doctoral/Research University-Extensive	<5000	2500-3000 (50/50)	200-300
C	Private; Doctoral/Research University-Extensive	5000-10,000	2000-2500 (not disclosed)	100-200
D	Public; Doctoral/Research University-Intensive	<5000	<1000 (60/40)	<100
E	Public; Doctoral/Research University-Extensive	>10,000	>3000 (50/50)	>400
F	Public; Doctoral/Research University-Extensive	5000-10,000	1500-2000 (60/40)	100-200
G	Private; Doctoral/Research University-Extensive	<5000	2500-3000 (70/30)	>400

An important distinction in oversight committees is the extent to which they apply or carry out their human subjects protection jurisdiction. The method, intensity, and frequency of research oversight activities depend upon university resources (e.g., staff and budget) allocated to the IRB. Information about these demographics of the IRBs was obtained directly from the IRB administrator at each of the participating university. Figure 3 illustrates a breakdown of the number of IRB members in the study according to university type and the research focus of the IRB. The bar patterns in Figure 3 represent the percentage of study participants serving according to the type of IRB on which they serve and the type of university in which the IRB is located. The legend provides the numerical distribution of members broken down similarly. For example, 17 participants serve on IRBs at public universities. Of that group, five participants serve on an IRB that reviews social and behavioral research. The remaining 12 public university IRB members serve on IRBs that review all types of human subjects research at their respective

[1] With the exception of the Carnegie Classifications, the data for this table were obtained from available reports from the participating universities. To protect the identity of the universities, ranges are provided to decrease the likelihood that comparing this table with publicly available information could reveal their identities.

universities. Neither biomedical IRBs at public universities nor comprehensive IRBs at private universities are represented in this study. This was an unintended result related to the response of universities invited to participate in the study.

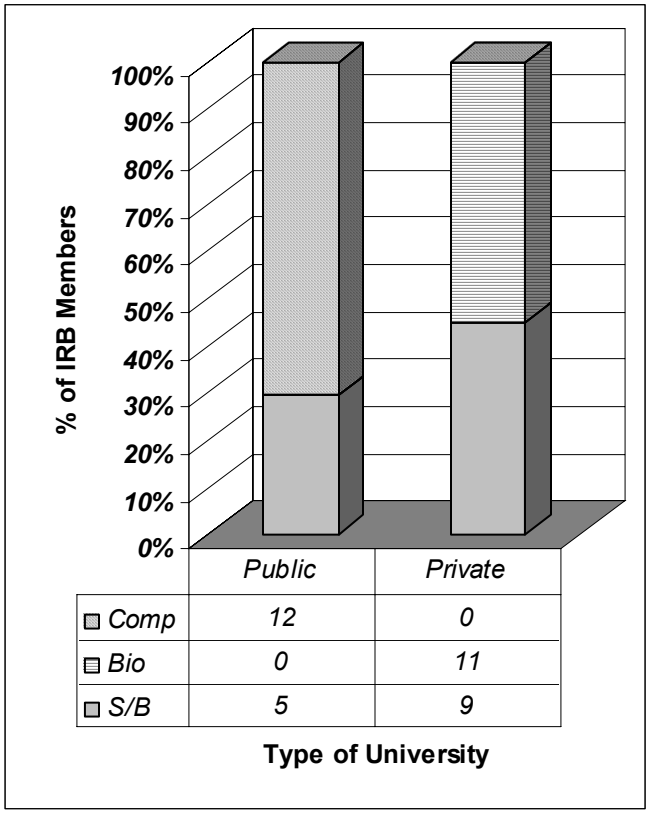

Figure 3. Breakdown of participating IRB members by type of university and IRB

Additional detail with respect to university-level demographics is provided in Table 7, which indicates the approximate total number of protocols each university reviews per year, the total number and type of members on the committee that participated in this study, and how frequently each IRB convenes as a full committee.

Table 7. IRB demographics (university level).

Univ ID	Research Focus of IRB	Total # Protocols/Year (Full/Expedited/Exempt)	# Members & Composition (Sci/Nonsci/Nonaff)	Meeting Frequency
A	Social/behavioral	**100** (15/35/50)	**9** (7/2/1)	Every 2 weeks
B	Biomedical	**1000** (360/500/140)	**17** (13/4/1)	Once per month
C	Biomedical	**2100** (1320/?/?)[1]	**13** (11/2/1)	Once per month
D	All types (comprehensive)	**150** (75/?/?)	**7** (3/4/0)[2]	Once per month
E	Social/behavioral	**144** (?/0/0)	**9** (7/1/2)	Every 2 weeks
F	All types (comprehensive)	**772** (394/?/?)	**13** (7/5/1)	Once per month
G	Social/behavioral	**700** (72/?/?)	**15** 13/2/2)	Once per month

6.2 University A

University A is a Doctoral/Research University-Extensive,[3] privately endowed university with a separate but affiliated medical school. The approximate number of graduate students attending University A ranges between 5000 and 10000. The university offers degrees in a wide range of disciplines including engineering, business, law, medicine, arts, humanities, theology, and social and physical sciences. The university employs between 1500-2000 faculty (roughly 80 percent male and 20 percent female). Research & Development (R&D) expenditures for FY 2001 totaled between $350-400 million.

University A operates separate IRBs for the review of social and behavioral research and biomedical research. The IRB that participated in this research was the social and behavioral committee. The official university IRB was originally established in

[1] Information that was not provided or obtainable at the time of interviews is represented by a question mark (?).
[2] Shortly before University D agreed to participate in the study, the nonaffiliated member resigned from this committee. At the time of the interviews, the IRB at this university was still searching for a replacement from the community.
[3] Doctoral/Research University-Extensive means that, during the Carnegie Foundation study period, a university awarded 50 or more doctoral degrees per year across at least 15 disciplines.

the early 1980s, although an earlier committee was established in response to the PHS regulations issued in the mid 1960s. University A has always maintained two separate and distinct IRBs for the review of biomedical and social/behavioral research. The operation funds for the social/behavioral IRB are allocated from the Provost, via the university office that handles the pre-award funding process. The committee reports to the university Vice Provost for Research. University A's social and behavioral IRB meets twice per month and meetings typically last about 90 minutes. Meetings are held during lunch and food and beverages are provided. Approximately 100 protocols are reviewed per year, with about 15 percent undergoing review by the full board. About 35 percent of the protocols are reviewed via the expedited review process; the remaining 50 percent fall under the exempt category (per 45 CFR 46) and are not reviewed by the convened IRB.

University A does not have a written policy on how members are selected to the IRB. Usually members are identified via word of mouth. Networking off campus is used to identify nonaffiliated members. With the exception of the nonaffiliated member, all members must be approved by a university-wide committee and are subsequently officially appointed by the Provost. The IRB chair is selected by the Provost but is also determined simply by whichever member is willing to take on the responsibilities of the IRB chair. Members are not compensated for their service; however, the chair receives release time from two classes for service on the IRB.

While the social and behavioral IRB has not received any compliance directives from OHRP, the biomedical IRBs at University A have received two compliance determination letters, citing issues about the use of appropriate consent procedures in research. According to OHRP, the biomedical IRBs satisfactorily responded to these charges.

Member characteristics

Nine members serve on the social/behavioral IRB.[1] Five are female and four are male. All of University A's members are Caucasian. Two scientist members participated

[1] The biomedical IRBs at University A did not participate in this research. However, publicly available information was obtained about these IRBs. The biomedical IRBs at University A are comprised of five

in this study; Both hold doctorates in social science fields (sociology and psychology). Two nonscientists serve on the committee, one of whom is the nonaffiliated member who participated in this study. The other nonscientist is a lawyer who works for the university. University A also has three alternate members who are former IRB members that no longer serve actively on the board.

Observation of IRB meeting

University A's IRB employs a primary reviewer system whereby members are individually assigned to fully review specific protocols and lead the related discussion at the convened meeting. All members, regardless of position or member role on the IRB, can serve as primary reviewers. The meeting I attended began at lunchtime and lasted one and a half hours, during which time three full board research protocols were presented and considered for IRB approval. The meeting atmosphere was informal and casual; the group discussion was tape recorded. Two nonaffiliated members were present at this meeting, including one who was introduced as a new member who will serve as an alternate nonaffiliated member. The group was given information about the background of the new non-affiliated member; however, backgrounds of the other members were not disclosed to the new member. Both nonaffiliated members are retired professionals (formerly, one an engineer and the other a "natural" scientist). The official start of the meeting began with group approval of the previous meeting minutes.

With the first protocol, the issue of conflict of interest between IRB members and research protocol arose. The member with the conflict expressed concern about leaving the room but was told to stay and "put your head down during the vote" because the room was cramped[1] and it would prove difficult to get in and out quickly. All the members, except one, have social science backgrounds; however, from the discussion of each protocol it was not obvious which member came from which disciplinary background.

The role of member expertise manifested itself in the discussion such that members with relevant expertise appeared to speak on behalf of research investigators in

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committees: four meet monthly and one meets as needed. Each committee has a separate chair (all are male scientist members). Committees are comprised of 16-25 members (on each committee one member is nonaffiliated, 4-6 are nonscientists, and the remainder are scientists).

[1] At this particular meeting, the group had to meet in a room that was not their typical meeting space.

order to facilitate approval of a protocol. For example, in one case an IRB member attempted to make the case for why a protocol should receive a "waiver of consent". In spite of the member's justification, however, the chair remained firm that a waiver should not be granted in this case and would be required for approval of the protocol.

The role of the IRB chair at University A was one of a facilitator. Her personality was strong and her opinions about the IRB approval process were evident. By comparison with other members, her knowledge of both investigators and research being conducted at the university was vast and comprehensive. In spite of the strong presence of the chair, the group tended to defer more to the administrator (who is not a voting member) particularly when it was not clear what the impact of the IRB decision will be on a research study. The administrator, who appeared very confident in her knowledge of the human subjects regulations, was quick to step into group discussion to assist members in understanding the impact of their decisions within the regulatory context and prior IRB history. The administrator also served the function of keeping the group abreast of current regulatory issues that could potentially impact the scope of the review process. For example, the issue of whether oral histories are subject to IRB review was brought up at this meeting and the administrator provided extensive discussion about the current OHRP opinion.

As an observer, I was unable to determine which members fulfilled which regulatory role (i.e., scientist, nonscientist, nonaffiliated member) based on the nature of the discussion. With few exceptions every member contributed opinions to each protocol that was reviewed at this meeting. The member who spoke the least is a lawyer, which I came to know during the meeting discussion.

Two themes emerge from this meeting and seem to characterize the personality of the IRB as a whole. First, the IRB is concerned about its role as a "facilitator of research". Rather than critiquing the research design of protocols, members of the group note that "friendly suggestions" might be made in the investigator's IRB letter. Research investigators are told that these "friendly suggestions" are not a requirement for IRB approval, but recommendations that are based on the research experience of the IRB members and possibly worth the investigator's consideration for improving the research design of the study. The second feature that characterizes this group is the level of

equality in member role. Any member, including the nonaffiliated member, may serve as a primary reviewer. But perhaps more interestingly, the reviewers also serve in a liaison role between the IRB and the research investigators at the university. In other words, members are encouraged to communicate openly (i.e., not anonymously) with the researchers prior to and after the IRB meeting. For this particular meeting, the nonaffiliated member had in fact contacted the research investigator for more information via email during the reviewer's pre-meeting review of the protocol. There seemed to be genuine concern among all members at University A that the research investigators are adequately engaged in the IRB process. Frequently, the chair or other members suggested calling the investigators directly to obtain additional information that may facilitate the approval process.

6.3 University B

University B is a Doctoral/Research University-Extensive, privately endowed university with an affiliated medical school. The university offers degrees in disciplines from the social and physical sciences, medicine, law, theology, arts, humanities, and business. University B enrolls less than 5000 graduate students. The university employs between 2500-3000 faculty (roughly 50 percent male and 50 percent female). R&D expenditures for FY 2001 totaled between $200-300 million.

University B operates five separate but equal IRB committees, four of which are dedicated to the review of biomedical research. The original IRB, which served the entire campus, was established around 1975. The biomedical review committees report to the Dean through the School of Medicine. IRB operating resources come from the university through the School of Medicine. Each committee meets once per month, such that during any given week one of the biomedical committees convenes. The typical workload includes about 10-15 applications for renewal of currently approved protocols and 7-10 applications for new research protocols. In contrast, the social and behavioral IRB meets once per month and reviews 2-3 full protocols per month on average. Between January and October 2003, about 1000 protocols underwent IRB review: 50 percent by the full board, 36 percent via the expedited review process, and 14 percent via the exempt review process.

The current IRB chair at University B is the chair for each of the biomedical committees, which allows for some consistency in decision-making across the four committees. He has a medical background and had IRB experience at another university prior to joining University B. The chair receives a portion of his salary from the IRB budget to compensate him for his service on the IRB. Each biomedical committee also has a vice chair, who receives a salary supplement of $5000 per year. Nonaffiliated members receive $150 per meeting, whereas affiliated members are not compensated monetarily. Meetings are held in the afternoon and typically last about two hours with food and beverages are served at each meeting.

During the mid 1990s, University A underwent an audit by the Food and Drug Administration (FDA), which resulted in findings that led to a reorganization of the overall university IRB structure. A recent FDA audit resulted in no findings. University B has received one compliance determination letter, which addressed concerns that one of the university IRBs approved a consent form that did not provide adequate description of research procedures. To OHRPs satisfaction, the university responded to this charge by developing training and education programs that provide members with information about the elements of informed consent.

Member characteristics

Each biomedical IRB has 15-17 members, while the committee that reviews social and behavioral research protocols is comprised of nine members. Across all the committees, 37 members are female and 36 members are male. The demographic characteristics for the biomedical committee which I interviewed and whose meeting I attended were somewhat more diverse compared with the other universities in the sample. This committee consists of 17 members, 12 men and 5 women. Of these individuals, eight hold MD degrees, eight hold a Masters degree, six hold PhD degrees. The committee includes two nonaffiliated members drawn from the surrounding community. Two of the affiliated members also represent the university-affiliated Veteran's Affairs medical center.

Two members are Latino (one scientist and one nonaffiliated member), three are Asian (all scientists), one is African-American (a nonaffiliated nonscientist member), and

the rest are Caucasian (representing a mix of member types). There is no written policy on how members are selected, though in general the staff work directly through the various departments on campus to identify willing representatives from each discipline.

Six IRB members were interviewed at University B; four of them are classified as scientists. Of those four, three are physicians and one is a social scientist. One of the two participating nonscientist members also fulfills the role of nonaffiliated member and has remained in that role for 16 years, the longest IRB tenure of any member interviewed in this study.

Observation of IRB meeting

University B's IRB initially exhibited an informal atmosphere, in which members interacted very casually and joke around while waiting for the meeting to start. Dinner is provided as an incentive to encourage members to attend the meetings. Because there were several new members joining this IRB at the time of my observation, the chair asked all members to introduce themselves and say something about their research. Through this process, both I and the IRB members became at least somewhat aware of the domains of expertise of fellow members.

This IRB also tapes the meeting discussion. A primary reviewer system is used, which includes secondary reviewers to back up the primary reviewer. Ideally the secondary reviewers submit their review to the primary reviewer who then pools all the information and presents it to the entire committee. Otherwise reviews appeared to progress in a random fashion, with the chair asking "who wants to present next". Discussion continued until group consensus was achieved and all members were satisfied that their concerns had been stated and addressed. No formal votes were taken; however, for protocols approved with conditions, the chair summarized the conditions and asked for any objections before moving on to the next protocol.

My knowledge of the members' expertise or disciplinary background is based on what was said during the discussion. For example, several times during different reviews the chair specifically requested different members to contribute because they had more experience in a particular area of the protocol research. It appeared that most of the members are physicians; however, from pre-meeting discussion at least one member is a

social scientist who has served on the board for 18 years. Most of the members, regardless of disciplinary background, focus on issues of risk and the consent form.

The chair assumed the role of facilitator and frequently reminded members about their IRB duty and what various IRB definitions mean (e.g., expedited, high risk, key concerns to look for in renewal applications). He was consistent about making sure that all members contribute if they have something to say. In one case, a scientist member was interrupted by other members and the chair made a point to come back to this member so his concerns could be stated. The chair also regularly contributed the discussion to clarify items that other members did not seem to know. This chair seemed to have broad knowledge about the protocols and an extensive awareness of human subjects research being conducted on the campus. He fully reviews every protocol that comes through the IRB. The chair also exhibited willingness to admit ignorance about some topics and routinely throughout the meeting, he solicited expertise from other members when clarification about research methods or standard procedures were needed to facilitate discussion. When members struggled with whether a issue they brought up is significant or not, the chair often stepped in to clarify and occasionally reverted to his own formal review of that particular protocol. Though he was not dominating, members did appear to defer to him particularly when he interjected to clarify certain issues about which the group otherwise was uncertain.

Unfortunately, the nonaffiliated member that I interviewed from University B did not attend the IRB meeting I observed at University B. While the membership list indicated another nonaffiliated member was in attendance, it was not apparent to me who this person was based on participation or protocol concerns demonstrated by members.

Interestingly the structure of this meeting seems to go back and forth between informal and formal. Most of the members addressed the chair as “Dr”, while the chair addressed members mostly by their first name. At other times during the discussion, however, the chair referred to some of those same members as “Dr”. In one instance, when the chair referred to a member as “Dr”, she quickly corrected him to use “Ms” (because she did not hold a PhD) and then proceeded with her review.

6.4 University C

University C is a Doctoral/Research University-Extensive, privately endowed university with an affiliated medical school. The university offers undergraduate and graduate degree programs including disciplines spanning the arts, humanities, medicine, physical and social sciences, law, theology, education, business, and policy. Less than 10,000 graduate students attend University C. The university employs between 2000-2500 faculty (male/female ratio is not published). Total R&D expenditures for FY 2001 ranged between $100-200 million.

The official university IRB was established in the late 1980s, although an earlier committee was established in response to the PHS regulations issued in the mid 1960s. Currently University C operates five IRBs, three of which serves the biomedical research community at the university—two that review new submissions and amendments to existing protocol and one that only reviews renewal applications for currently approved protocols. The other two IRBs at University C review social and behavioral research protocols. The biomedical committees report to the Dean of the School of Medicine. The IRB staff operates within the university office that manages funding-related activities at the university. The operating budget comes from the Dean of the medical school.

Each committee meets once per month and meetings typically last 4-5 hours, with lunch and beverages provided. On average committees reviewing new submissions and amendments review about 30 new protocols each meeting, whereas the committee responsible for renewal applications typically reviews about 60 protocols per meting. Review of expedited protocols is usually done by the chair or vice chair of each committee.

University C has received two compliance determination letters from OHRP. The issues identified in these letters addressed concerns about inadequate committee review of research design, inadequate disclosure of risks in consent forms, consent forms written at too high a reading level, inadequate written IRB policies, lack of written meeting minutes, and insufficient data and safety monitoring procedures. The university responded satisfactorily to these charges by modifying its policies to address each area of concern, by providing retraining of its IRB members, and by developing a reviewer checklist for IRB members.

Member characteristics

The committee that I interviewed is comprised of 13 members (four female and nine male). Three of the female members are nonscientists, one of whom is the nonaffiliated member, and one is a scientist. All of the male members are scientists. University C does not have a written policy on how members are selected to the IRB. In general the Dean of the medical school appoints members such that all the departments are represented on the committee. Department chairs may also recommend members. Nonaffiliated members are recruited through referrals from local community organizations. The chair serves as chair for all three of the biomedical committees and is appointed by the Dean. Members are not compensated; however each year they are presented with a small token of appreciation from the university.

Observation of IRB meeting

As with most of the other university IRBs, this IRB offers food as an incentive to encourage members to attend the meeting. The initial atmosphere was very informal and casual but as soon as a quorum was met, the chair assuaged all conversation and called the meeting to order immediately. The structure thus became very formal. For the most part, members referred to one another on a first name basis though some members referred to each other as "Dr". Overall the tone of the meeting was light yet serious and extremely focused; however, when some members spoke directly to the nonaffiliated member the tone was noticeably informal and casual.

With regard to meeting structure, University C's IRB offers an added incentive to members to get them to the meeting on time. Members present their reviews in order of their arrival; that is, whoever arrives at the meeting first presents *all* of their reviews first. The exception to this "rule" is for members who have another obligation and need to leave the meeting early.

Awareness of expertise was immediately apparent at this meeting. In addition to what I would call symbolic evidence of expertise—several members wore white physician coats—members explicitly solicited certain expertise from other members during the protocol reviews. For example, during the first review the primary reviewer (a

physician) immediately looked around the room for the statistician to confirm whether the power of a particular protocol was sufficient.

Early discussion during the meeting occurred mainly between the primary reviewer and the IRB chair. Throughout the meeting the chair was quick to point out limitations of his knowledge but it was obvious that he has extensive and substantive knowledge in many areas of research germane to this particular university. The chair consistently served in a facilitator capacity, moving discussion along. Frequently he contributed to the substantive issues of the discussion adding information to help clarify issues that reviewers brought up as concerns. In this manner, his role almost seemed that of a liaison between the research community at the university and the IRB.

The IRB meeting at University C was somewhat different that the other meetings in that the discussion style seemed very intense. It was immediately apparent that no time is wasted during the discussion; however, this style seems mostly due the chair's personality because later in the meeting when the chair recused himself due to a conflict of interest with a protocol, the discussion became much more relaxed and slower-paced. As soon as the chair re-entered the discussion the discussion speeded up again.

This was a very large group (16-20) of IRB members and, other than the white coat symbolism discussed above, it was not always apparent to me who was from what discipline. Deference to a particular member or type of member was not apparent at this meeting. In one case the group deferred to the opinion of the nonaffiliated member and granted approval of a protocol subject to her final review of the modifications. In another instance, disagreement between the chair and the primary reviewer (another physician member) over the issue of compensation in a protocol resulted in the chair deferring to the reviewer.

6.5 University D

University D is a public university with a separate but affiliated medical campus. University D is classified as a Doctoral/Research University-Intensive[1] and is the only university with that classification participating in this research study. The university

[1] This classification indicates that, during the most recent Carnegie Foundation study period, this university awarded at least ten doctoral degrees per year across three or more disciplines, or at least 20 doctoral degrees per year overall.

grants degrees in a variety of disciplines including architecture, liberal arts, business, humanities, engineering, education, public affairs, public health, social and physical sciences and medicine. Less than 5000 graduate students are enrolled at University D. The university employs less than 1000 faculty. Roughly 60 percent of University D's faculty members are male and 40 percent are female. R&D expenditures for FY totaled less than $100 million.

No data were available to determine when University D established its original IRB; however, the university currently operates multiple IRBs. The IRB that participated in this study is responsible for reviewing all research for the main campus, which is primarily social and behavioral but also includes public health protocols and any biomedical protocols that have a social science component. For this reason University D's IRB is classified as a "comprehensive" IRB. Two biomedical IRBs also separately serve the affiliated medical campus. The "comprehensive" IRB reports to the Dean's office. Resources for operating the IRB come from general university funds and indirect costs. The "comprehensive" IRB meets monthly for two to four hours. The IRB office reviews approximately 10 protocols per month, with three to five of these undergoing full board review. The IRB administrator and the Chair generally perform expedited reviews.

University D does not have a formal written policy for how members are selected to the IRB. Generally the IRB accepts whoever is willing to serve or is nominated by the Dean; however, an attempt is made to ensure representation from the major schools on campus. Nonaffiliated members are identified by word of mouth or personal contacts. The chair is provided release time, but no extra salary compensation. Community members receive $25 per meeting. University D has received no compliance directives from OHRP.

Member characteristics

Eight members (five females and three males) currently serve on the "comprehensive" IRB at University D. Just prior to when these interviews were conducted, the nonaffiliated member on this IRB resigned from the committee for reasons that were not disclosed to me. The committee is presently struggling with identifying a nonaffiliated member from the surrounding community. The exclusion of

this member category will be discussed further in the remaining chapters. Of the existing affiliated members, all but one member are Caucasian. The classification of member roles on this committee is interesting because three of the members who classified themselves as scientist members are actually classified as nonscientist members for regulatory purposes, per the IRB administrator. This difference in perception of roles is relevant when attempting to explain differences in how scientists versus nonscientists approach the IRB decision-making process and will be discussed further in Chapter 7.

Observation of IRB meeting

Compared to the other IRBs in this study, the IRB at University D had a very different atmosphere that was apparently immediately. The group was very small (with only six of the eight IRB members present) and there was no nonaffiliated member. Several months prior to my site visit, the nonaffiliated member resigned from the IRB for reasons that were not disclosed to me. The meeting structure was very informal and casual; no incentives are offered to members for their participation. This meeting had the feel of a coffee shop gathering where a few faculty members may have gathered together to discuss several controversial issues at the university.

All of the current members come from social science backgrounds and seem to share equal roles on the committee. Interestingly, this was the only IRB in the study where at least half the members interviewed categorized themselves differently than the IRB administrator classified them. Throughout this meeting, the female members spoke twice as much (sometimes more often that that) as compared with the two male members on the committee. It does not appear that the participation level of these two quieter (less participatory) members is obviously related to their experience on the IRB. However, they represent the extremes at either end of the length of IRB service on this particular committee. One has less than a year on the IRB, while the other member has served on the committee for almost ten years (longer than anyone else on this particular committee).

Every member on this IRB is expected to fully review every protocol. There is no primary reviewer system and no particular order to presenting. Members literally launch right into listing their concerns about the first protocol listed on the meeting agenda. Interestingly, formal votes are taken only for some protocols and with no apparent

pattern. In at least one case, and unlike other IRBs in this study, the motion to vote was made and taken by the administrator not the chair. The administrator and the chair share a strong role on the committee. As with other IRBs in this study, the chair possesses a vast knowledge of the research conducted on campus. She also serves as a facilitator and seems keenly aware when all of the members are not participating equally in the discussion. To compensate for their lack of participation, the chair occasionally called on these members by name and asked them if they had stated everything they wanted to say about a protocol.

Like University A, members on this IRB seem to serve in a liaison role with the research investigators. However, it appeared that members do so with reluctance that may in part be due to a negative perception of the IRB or the IRB process by the university community. Nonetheless, the chair explicitly asked one member to speak with a student researcher's faculty advisor about IRB concerns about a particular protocol.

Disagreement over issues of concern was discussed at length in order to capture all members' viewpoints. However, full group consensus did not necessarily seem to be the goal of this IRB in all cases. In at least one case, one member continued to voice concern about the methods of a protocol. To satisfy the member's concerns the chair asked "would it help if…" and suggested that the member, the IRB chair and the researchers meet to discuss the member's concerns. This approach seems connected to the liaison role discussed above and very possibly may be why IRB members at this university seem to embrace the liaison role less than those at University A. I observed no evidence of deference by or to any particular member at this meeting.

6.6 University E

University E is a Doctoral/Research University-Extensive, public research university with an affiliated medical school. The university grants degrees in disciplines such as the arts, humanities, social and physical sciences, architecture, business, medicine, education, engineering, law, nursing, public affairs, and social work. More than 10,000 graduate students are enrolled at University E. The university employs more than 3,000 faculty (roughly 50 percent male and 50 percent female). R&D expenditures for FY 2001 totaled greater than $400 million.

The original IRB at University E was established during the early 1970s. The university now operates five separate committees, all of which report to the Provost. Resources for operating the IRB come through the grants and contracts division of the university. The IRB that participated in this study meets every two weeks for two to three hours, with food and beverages provided. Approximately six new protocols undergo full board review per meeting. Another six to eight renewal protocols undergo re-review at each meeting. A separate subcommittee to all IRBs at University E generally performs expedited reviews.

University E does not have a formal written policy for identifying or selecting members to serve on the IRB. The committee has "certain requirements and looks for certain attributes in order to make sure that we have people who will…be able to fulfill certain roles. Because we do social science research, everyone is pretty much oriented towards social science. We do however have someone from the nursing department who we hope can provide us some kind of maybe basic medical information just to warn us if we hit biomedical stuff and don't recognize it." To identify nonaffiliated members, the IRB administrator at University E directly contacts local social service organizations and issues public announcements for potential volunteers. In lieu of compensation members are provided with complimentary parking for the meeting and expenses paid for IRB training workshops. University E has received no compliance directives from OHRP.

Member characteristics

Nine members (six females and three males) currently serve on this IRB. Six members are classified as scientists; three are nonscientists including one nonaffiliated member. One of the IRB members was also a doctoral student at the time of these interviews and is categorized as a nonscientist until the PhD is awarded. As was the case with University D above, this classification was determined by the IRB administrator and differs from the IRB member's self classification of "scientist". One administrator-classified nonaffiliated member on this IRB (who did not participate in the study) is technically not "nonaffiliated" because she received her master's degree from the university. However, she worked closely with the surrounding community at the time of the interviews and consequently brought the community perspective into the IRB

discussion. The other nonaffiliated member apparently is a prisoner's advocate but did not participate in the meeting I observed.

Observation of IRB meeting

University E's IRB appeared to follow the same general pattern of most other IRBs in this study—informal, casual atmosphere with food offered as an incentive. Everyone was first introduced to me, which also served the purposed (albeit unintentionally) of informing or perhaps reminding other members of the types of expertise on the committee.

This IRB employs a primary reviewer system in which both affiliated and nonaffiliated members may serve as primary reviewers. While other members contribute to the discussion based on their review of some of the protocol package, only the primary reviewer receives the full IRB application that includes both the protocol and the research proposal and other supporting research materials. The primary reviewer presents a summary of the entire protocol, which suggests that all portions are examined fully during the initial review. Throughout the presentation by the primary reviewer, other members interjected with their own questions. Different members interjected with questions to each other, asking what would make dissenting members feel more comfortable so the protocols could be approved. This type of group deliberation seemed to be the standard mechanism of achieving consensus on this IRB. Formal votes were taken after each review was presented and fully discussed.

The general view of members on this IRB is that it is not within their purview to review the research design. In such instances where research design issues are brought up, members explicitly stated that it was outside the IRB purview but still presented their concerns about the design. The belief that research design issues "outside our purview" was mentioned several times throughout the meeting.

Extensive deference to certain members was not apparent on this IRB. In one case where members did differ in opinion about a protocol issue, the chair suggested deferral to the primary reviewer. In at least one case, the primary reviewer (coincidentally a graduate student) appeared to look to the administrator for verification on which position to take. Though the administrator had only a few years of experience in her IRB

administrator role, she also holds a PhD, which could explain why the IRB member appeared to seek the administrator's approval on this particular protocol. Interestingly with this particular protocol, the administrator's recommendation was to defer it; however, the primary reviewer seemed clearly bothered by this and asked whether there was some "middle ground option" because she was concerned about the impact that the deferral would have on the research study. As with other IRBs, this IRB used the option of inviting PIs to the subsequent IRB meeting to clarify questions that were not adequately addressed in the protocol but were required for final approval.

Based on issues of concern or participation style, it was not evident who possessed what background or expertise. The chair seemed to play the role of a discussion facilitator to keep the meeting discussion moving along. Yet, his personality was not strong or domineering. However, it should be pointed out that his official role on the committee is actually Vice Chair but at this meeting, he was filling in for the IRB chair who was not in attendance.

6.7 University F

University F is a Doctoral/Research University-Extensive, public university with an affiliated medical center and enrolls between 5000-10,000 graduate students. The university offers degrees in a variety of academic disciplines including medicine, engineering, liberal arts, social and physical sciences, business, policy, social welfare, nursing and fine arts. The university employs between 1500-2000 faculty (roughly 60 percent male and 40 percent female). R&D expenditures for FY 2001 totaled between $100-200 million.

The IRB at University F was established in the late 1970s. In 2001, a single committee was divided into two separate committees that review all research—both social/behavioral and biomedical—for the university campus. The assignment of research protocols to each committee primarily depends on when the protocols are submitted during a given month, and to some extent whether the protocol is a new protocol or one that is undergoing the renewal process. Both IRBs report directly to the Provost for Research and together operate autonomously within the university structure. Operating resources come through the office of the Vice Provost for Research.

Each committee meets once per month; meetings usually last about three to four hours. Meetings are held at the end of the day and dinner is served to the members. On average, both IRBs review about 800 protocols per year. Approximately half of these undergo full board review. Twenty-five percent of the full-board protocols are new submittals and 25 percent are renewal applications. IRB members also review expedited protocols. University F identifies potential IRB members via recommendations from current members. The administrator interviews and selects potential members. Nonaffiliated members are also identified via current IRB members and also undergo a similar interview process prior to appointment to the IRB. The Institutional Official selects the Chair, but to some extent this depends on who is willing to serve in this capacity. None of the members receive compensation for their service on the IRB.

University F has received two compliance determination letters from OHRP. Issues identified by OHRP included deficiencies in informed consent (appropriate procedures and accurate representation of risks and benefits), review of protocols without sufficient information, lack of appropriate expertise on the IRB to adequately review some research, written IRB policies, safeguards for a vulnerable population, and continuing review policies. OHRP reports that University F responded satisfactorily to these charges by developing improved written IRB policies, providing more detail to research investigators about what is required for IRB approval, and assuring that the appropriate expertise is available in order to adequately review certain protocols.

Member characteristics

Each IRB at University F is comprised of 14 members. On the committee I interviewed, five members are female (one is an African-American, scientist member). One of the male members is Asian and a scientist member. The nonaffiliated member is a male, nonscientist member. The majority of members serving on this IRB are physicians serving in the scientist role. The nonscientist members come from research administration and social work-related backgrounds. These members voluntarily reported that they do not participate as actively in the group discussion. The IRB experience on this committee is wide ranging regardless of the role of the member.

Observation of IRB meetings

University F's IRB meeting was informal and casual. Dinner was served to members as an incentive to participate. Meeting minutes are approved once a quorum is achieved. The IRB employs a primary reviewer system in which the primary reviewer presents their synopsis of the research study and their concerns with the protocol. However, it appeared that all members receive all information associated with a protocol and independently conduct their own full review, which is submitted to the administrator at the end of each protocol review. Members who were not primary reviewers interjected throughout the presentation with questions of their own. The expertise of primary reviewers appeared to be matched with the protocol research area where possible (e.g., pediatrician reviews protocol that involves children). However, in comparison with the other university IRBs, it appeared that many of the physicians on University F's IRB possessed knowledge about the recent literature beyond that of their immediate medical specialization based on the substance of the group discussion.

The chair fulfills a facilitator role on this IRB, permitting discussion to continue sometimes even off track, but then bringing everyone back to the issue at hand for a vote. He occasionally sought out members who were not contributing verbally to the discussion and asked for their opinions. Although the chair did not have a dominant personality, it was evident that he is knowledgeable about the breadth of research conducted at the university.

Based on what members said and how they addressed each other (first name basis), it was not apparent to me who was serving the IRB in what role. Because my interviews were held prior to the meeting I knew who the nonaffiliated member was and who at least one of the nonscientist members was. Both of these members hardly contributed to the discussion unless they were specifically asked about their opinion by the chair or another member. In most of these cases, they replied that they had nothing to contribute. On one protocol, however, the nonaffiliated member initiated discussion about concerns that he had about the welfare of children participating in the study. His concerns seemed to parallel his experience working with families in his profession (clergy), which suggests that he voices concerns about issues with which he feels most knowledgeable.

The IRB administrator and staff appear to play a major role in educating the group about regulatory issues. Throughout the discussion, these members were asked to clarify regulatory items that impact the protocols.

Deference to certain members did not seem pervasive. However, in at least one case where the primary reviewer was a physician and the secondary reviewer was a nonscientist, the nonscientist deferred to the primary reviewer (a scientist/physician) and offered no substantive input on the review. Domains of expertise were not obvious. While there are several social scientists serving on this IRB, I could not tell who they were based on the discussion. Disagreement over protocol issues seemed to be handled in a two phase process. The chair allowed discussion to continue among members and then asked them to "get back to where we were". After the group considered all suggested possibilities for how to facilitate the research while satisfying the regulations, if consensus was not achieved through the discussion, a formal vote was taken.

6.8 University G

University G is a Doctoral/Research University-Extensive, privately endowed university with a separate but affiliated medical school. Less than 5000 graduate students attend this university. The university offers degrees in disciplines such as engineering, life sciences, physical sciences, arts and humanities, law, management, medicine, and architecture. The university employs between 2500-3000 faculty (roughly 70 percent male and 30 percent female). R&D expenditures for FY 2001 totaled greater than $400 million.

The IRB at University G was established in the mid-to-late 1960s. A separate IRB serves the medical campus. The social and behavioral IRB serves the main campus and reports to the Vice Provost for Research. Operating resources for the IRB are allocated by the Vice Provost for Research. The social and behavioral IRB meets monthly for one to two hours over lunch. Expedited reviews are conducted by the chair or if the chair has a conflict of interest there tend to be three long standing members who are called upon to do the expedited reviews. The IRB reviews about six full board protocols per month.

The chair consults with the Vice Provost to select affiliated members to the committee. Members are not compensated for their time; however the chair receives a

faculty stipend that can be used for research related activities. No OHRP compliance directives have been issued to University G.

Member characteristics

Currently this IRB is comprised of 15 members. All of the affiliated members are considered to be scientist members, whereas two nonaffiliated members satisfy the minimum requirement for the nonscientist position. Ten members are male; five are female. Both nonaffiliated members are male and come from business backgrounds. All members are Caucasian.

Observations of IRB meeting

As with the previous IRBs, the atmosphere at University G was very informal. Lunch was provided to members as an incentive to participate. The meeting begins with informal group discussion about general campus matters that relate to human subjects issues. Votes were taken by show of hands.

University G's IRB employs a primary reviewer system. Although two reviewers are assigned to each protocol, they share equal roles in that one is not primary and the other secondary. Rather they are "co-reviewers". They are invited by the chair to decide between them who would like to present first. Nonaffiliated members serve in the primary reviewer role in the same manner as affiliated members.

The IRB chair clearly serves a facilitator role at University G. Members also seem to defer to her and look to her for confirmation of their concerns about protocols. She has a strong personality; however, she is not domineering and did not attempt to control the discussion at the meeting I observed. The chair has obvious extensive breadth of knowledge about human subjects research on the campus. Her role as a campus liaison with the IRB was also apparent in that she frequently conducts educational seminars about the IRB with researchers and students.

As with some of the other universities in this study, University G's IRB seems conflicted with its purview over research design and scientific merit. On the one hand, reviewers state "although we are not really supposed to review scientific merit" yet then continue on to discuss and judge scientific merit.

Interestingly, the IRB chair frequently exhibited concern about the potential impacts of the IRB decisions on research at the university. Other members also express these concerns at different points in the discussion. Overall, the committee seemed intent on finding ways in which they can make the process more informative for investigators so that the IRB review process goes smoothly. It is also telling that during the discussion there were many references to a "university X culture" or the "university X research investigator stereotype" as if the members were acknowledging that the researchers at this university did not like to be told what to do. In spite of this perception, there was no implication that this perception changed *how* members review protocols or *what* issues they focus on. Rather, it seemed to more greatly impact the way members sought to overcome such issues, so as not to hinder the research process.

6.9 Summary

In this chapter, I presented justification for studying IRB decision-making in the university setting. Each of the universities that participated in this research was profiled according to their Carnegie Classification, R & D expenditures, and IRB demographics. In Chapter 7, I will compare and contrast members' perceptions of the decision-making processes across IRBs, and in the context of the research questions that motivate this study.

7.0 CROSS-CASE ANALYSIS – COMPARING AND CONTRASTING UNIVERSITY IRBS

7.1 Introduction

A primary objective of this chapter is to identify and explain member-related differences in perceptions of decision-making among university IRBs. To this end, the interview and observation data were analyzed using qualitative content analysis to identify trends in the data. Moreover, the use of a case study approach permits the development of an "inside view" (Young and Mills, 1980) of IRB member behavior. Cross-case analysis enhances generalizability and deepens understanding and explanation (Miles and Huberman, 1994) about the human subject review system within these public and private research universities, and the use of multiple case studies or cross-case study designs also increases external validity (Yin, 1984). In these ways, qualitative analysis is used to assess data at the IRB member level and at the overall university level, specifically according to whether the research focus is primarily biomedical, social/behavioral, or "comprehensive"[1] in nature. A summary of the detailed coding strategy described in Chapter 4 is provided here.

7.2 Patterns of data for each research question

In Chapter 4, I described my analytical approach for coding the interview texts. The results of those analyses are presented here in the context of the research questions and propositions that motivated this study. To be able to explain differences among IRB decision-making processes we need a better, more complete understanding of the actual process that takes place within an IRB meeting. The decision-making literature suggests that group members assess and use expertise in different ways that subsequently impact the group choice and potentially the quality of the decision outcome. The literature on participatory democratic theory further suggests that the notion of expertise is related to participation in decision-making. Both of these concepts—participation and expertise—were investigated in this study and can be used here to begin to dissect the process by which an IRB arrives at a decision to approve a human subjects research study. However, it is important to restate that this analysis is limited by the fact that these data represent

[1] In this study, I use the term "comprehensive IRB" to denote IRBs that review all research for their university, as compared with IRBs that review only biomedical or social and behavioral research.

individual members' retrospective perceptions of the group decision-making process at their university.

7.2.1 Research Question 1: How do IRB members decide whether to approve a human subjects research protocol—that is, about risk-benefit ratio, scientific merit, research design, and adequacy of informed consent?

Implicit in the IRB decision-making process is the assignment of scientific and ethical values articulated by a diverse set of individuals, some with scientific training and interests, and some with expertise in areas completely nonscientific. Regardless of their individual expertise or experience, IRB members as a group decide whether to approve a human subjects research protocol by assessing the four criteria required by 45 CFR 46: scientific merit, research design, risk-benefit ratio, and adequacy of informed consent. Specifically how they go about "assessing" is one of the objectives of this research. While the IRB Guidebook[1] offers some suggestions on how members can proceed with this assessment, in reality, members do not appear to follow a specific process. Each required criterion is discussed below with evidence via the eyes of individual IRB members to inform our understanding of how they perceive the decision-making process to unfold during the IRB meeting. Across these criteria, I looked for differences that emerged between IRBs at public and private universities, between male and female IRB members, among social and behavioral, biomedical, and comprehensive IRBs, and among the different types of IRB members (scientist, nonscientist, and nonaffiliated).

Risk-Benefit

Assessing the risk-benefit ratio is one of the primary goals of the IRB. The IRB Guidebook suggests that this process includes a series of steps: (1) identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research; (2) determine that the risks will be minimized to the extent possible (3) identify the probable benefits to be derived from the research; (4) determine that any risks are reasonable in relation to the benefits to subjects, and the importance of the knowledge to be gained; (5) assure that potential subjects will

[1] The IRB Guidebook was prepared by OHRP to assist IRBs in fulfilling their mandate. It can be found at the OHRP website (http://www.hhs.gov/ohrp/irb/irb_guidebook.htm; visited on September 25, 2004)

be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits; and (6) determine intervals of periodic review, and, where appropriate, determine that adequate provisions are in place for monitoring the data collected.

Most likely the approach that, say, a sociologist, medical doctor, or clergy member will take towards performing these steps is influenced not only by educational training but also by personal and professional experiences. The risk literature is replete with evidence that experts perceive risk differently compared with how lay citizens perceive the same risk (for example, U.S. Environmental Protection Agency, 1987; Slovic, 1997; Sjöberg, 1999). If so, how then do these differences in perception factor into the risk-benefit assessment of a human research protocol?

Fischer (2004) suggests that public perception of risk can be understood through a form of rationality that is shaped by the circumstances under which the risk is identified and publicized, the standing or place of the individual in his or her community, and the social values of the community as a whole. Ordinary citizens, without advanced technical knowledge, tend to rely on past experiences to understand risk (Fischer, 2004; see also Hill, 1992). When IRB members in this study were specifically asked how they assess the risk of a proposed research study, none stated that they use a formal method of risk-benefit analysis. Instead IRB members assess the risk-benefit based mostly qualitatively and on personal experience ("probably subjective on our part"). In the words of one committee chair:

> Common sense and medical expertise. I also consider the regulations (such as Helsinki and Nuremberg) and the history of human subjects research in this country. *(Scientist member, comprehensive IRB, public university)*

Additionally, IRB members also try to imagine how they would feel if their parent or child or friend were participating in the research, or if they themselves were participants as described by this social scientist IRB member:

> Each of us may have different points or thresholds at which we become uncomfortable. As a result we tend to talk about things that start out as just simply "would that make me feel bad. Is that like embarrassment? Would that make me reconsider?" So the "what if" kinds of things that may not have been addressed. Those are very subtle nuanced ways of responding that poses a certain level of risk that, as long as you sensitize the subject to potential embarrassment or

> feelings of discomfort, that is sufficient to address it. *(Scientist member, comprehensive IRB, public university)*

Nonaffiliated members also rely on common sense or what "feels right"; however, the issue of deference to the scientist members also factors into their informal risk assessment. Because citizens tend to trust physicians more than other types of experts (Bostrom, 1997), deference to the physicians on an IRB could impact whether the potential risks of a study are given full consideration or even brought up in the first place:

> I ask the physicians what they think and to clear it up for me. I have a few resources where I can go for help sometimes. *(Nonaffiliated member, comprehensive IRB, public university)*

The chair at a comprehensive IRB, also at a public university, provides a detailed example to illustrate the challenges that members experience during their evaluation of potential research risks:

> A lot of them [risks] you hope are already stated by the investigator. The reviewer, one of whom should be semi familiar with the kinds of stuff that would go on on that project, would hopefully be aware of some of those risks and maybe add a few more. The nonscientist reviewers will often be the one who talks about nonphysical risks more, so breaches of confidentiality for instance, losing your insurance because somebody finds out you've got disease X. Or that somebody finds out you're participating in an HIV study your reputation is damaged. Those are sometimes risks that aren't thought about by the investigators actually. It a balance of what the PI tells you and what you glean from the protocol and what you and the other committee members bring to that whole process maybe not as an expert in that particular thing but your own experience as a scientist and frequently as a physician, as well as somebody who after a while has had some experience reviewing research protocols. You get a feel after a while that this kind of study often has risk X as a primary problem. Probably one of the hardest things is the issue of not just identifying the risk but quantifying it and then balancing that in some way if you can against the benefits. For that, if we don't know on the committee we will sometimes talk to the PIs to get their opinions or some other expert in that field. So for instance if there was a drug study that sounded like it may be a bit risky or if we didn't know how risky, we might ask the PI for more detail or we might ask somebody else in that same field and try to come up with a nonbiased view on the whole thing. I think quantifying these things is the hardest part. *(Scientist member, comprehensive IRB, public university)*

It was pointed out earlier that the characterization of risk involves two judgments: (1) that a particular process or outcome merits serious attention and (2) what constitutes

an unacceptable level on the outcome dimension (Slovic, 2000; Stern and Fineberg, 1996). Consider, for example, a common IRB scenario in which members must assess whether using a classroom setting for some types[1] of research that subject students to potential coercion by virtue of the fact that the students are a captive audience. The decision whether to include research venue as an issue of concern or potential risk reflects a value judgment about the primary purpose of the classroom. Some IRB members may not be concerned that a researcher intends to request participation from his students during normal class time. Yet, other IRB members may feel strongly that students are paying tuition to use classroom time for learning and not for participating in their professor's research study. One study participant expressed this specific concern, which also emerged during interviews with other members on his committee:

> The venue also matters, like in the classroom setting. It's a lot different if you advertise for volunteers and advertise that this is the nature of the questions and they could be upsetting. I'm pretty okay with that even if you want to ask a few sensitive questions. It's just that when you're going to walk into a classroom and say "this is what I want you to do but if you really don't want to do it, that's okay. You can just sit quietly in your seat but you can't leave." That's pretty coercive for me and I can just imagine someone coming to class to get a lecture in psychology and then having to take this questionnaire that's upsetting or offensive. *(Scientist member, comprehensive IRB, public university)*

To further complicate this, IRB members are asked to make judgments about potential risks to potential participants who probably have different values and consequently may make a different judgment about the same issue when invited to participate in the research. What constitutes an acceptable risk for one member may be, and often is, completely different for another member or the potential participants. The same IRB member from the prior example tells how he attempts to bring public values into the IRB decision-making process:

> For example, just the classroom setting issues. We think about what are the values that our students share; we need to be sensitive to those values. *(Scientist member, comprehensive IRB, public university)*

In contrast, one nonaffiliated IRB member shares a perspective on the challenges for scientist IRB members to fully comprehend local community values:

[1] Certain types of research in the classroom may subject students to some level of risk, e.g., surveys on sensitive topics such as sexual abuse.

> …most of them [scientists] are homeowners. They're families. They're parents, have children in school and so forth. They certainly do bring a lot of that but I also see that their children go to the same schools as all of the other professors. All of their social activity deals in the academic environment. And a lot of them have never been out in [local areas] where people live in trailers; a lot of seasonal employment, a lot of people are on food stamps and so forth. They've never been there. They don't understand it. They will make their contribution to this fund and that fund but they've never been hungry in their life. They've never had to want for a car that will get them to work on time. And so they lack that perspective. But they do bring that perspective of having children and putting up with teenagers and all that stuff. So it depends on where they're coming from, where they've been and where they are now. *(Nonaffiliated member, social/behavioral IRB, private university)*

As is often the case with other technical issues, the decision outcome thus reflects the value judgments and priorities of those making a decision that can be neither objective nor purely scientific (U.S. Department of Agriculture, 2003). As evidenced by these and other direct quotes, IRB members do not appear to follow any prescribed or standardized methods of assessing the risks or benefits of research protocols aside from occasionally using "in house" developed check-lists, which simply list topics to look out for (e.g., are vulnerable subjects involved, are risks listed in the protocol).

Scientific merit and research design

IRB purview to review the topics of scientific merit and research design continues to generate much debate within the broader research community. Yet, the value of research depends upon the integrity of study results (Penslar and Porter, 1993). Because these topics are inherently intertwined, I will discuss them together for purposes of analysis and interpretation. While the federal regulations clearly stipulate that the IRB is responsible for reviewing scientific merit and research design, this is perhaps the one area where IRB adversaries accuse committees of not using the full flexibility provided in the regulations. In reality the review of scientific merit and research design provides a challenge for most IRBs. As discussed in previous chapters, the IRB is composed of a diverse set of individuals with backgrounds in medicine, social science, nursing, law, theology, and administration juxtaposed with diverse personal life experiences.

Methodological choices for research design are often discipline specific. What constitutes the "norm" in one field may be frowned upon in another. These differences are brought into the decision-making process of the IRB and can present stumbling blocks for approving a protocol. To determine whether (and which) IRB members assess scientific merit and research design, I asked members to tell me in their own words "what elements of a research protocol the IRB is responsible for reviewing" (Question 21), and then more specifically "what elements does the member tend to focus on" (Question 27).

Using N6 software to organize participant responses, I find several interesting differences (see Figures 4 and 5) that I will discuss in the context of each preliminary proposition: member characteristics and IRB culture. With regard to the first proposition—member characteristics—this research suggests that more scientists than nonscientists consider "research design" and "scientific merit" as *standard* elements of IRB review. In response to the first question (Q21), 71 percent (15) of the scientists compared with 31 percent (4) of the nonscientists (including nonaffiliated members) stated that the IRB is responsible for reviewing the "research design" of a protocol. In other words, 15 interview transcripts from scientists were coded for "research design" compared with only 4 interview transcripts from nonscientists. Yet, in the case of "scientific merit", both types of members list it as a required review element almost equally: 57 percent (12) of the scientists compared with 54 percent (7) of the nonscientists. These numbers reflect only whether or not a member explicitly listed the terms "research design" or "scientific merit" in their response to these two questions.

Using N6, I was able to further limit the responses to just this question and examine the context of member responses in more detail to determine if there was any difference in the amount of discussion about these review elements. In fact, re-reading the full context of the text units coded for these two review elements indicates that scientists do talk about "research design" more often than nonscientists. Similarly, although scientists and nonscientists equally mention "scientific merit" as a required IRB review element, scientist members also talked about this review element more often than nonscientists did during the interviews.

The second dimension of member characteristics involves analyzing the data according to the gender of the member. Using similar techniques describe above, I used

N6 to group together elements of review (Q21) according to whether the respondent was male or female. Differences are apparent in three of the four key categories of risk-benefit ratio, research design, scientific merit and informed consent form. Both male and female members list "informed consent" and "risk-benefit assessment" as the most important IRB review criteria. However, more female members than male members also consider "research design" and "scientific merit" when deciding whether to approve a human subjects research protocol. Interestingly, although more female than male members list "research design" as an important review element, more female members also state that IRBs should *not* review research design. Closer examination of the transcripts coded at each of these key nodes (i.e., words/phrases or categories) suggests additional gender differences in IRB review. Although both male and female members list "informed consent" and "risk-benefit assessment" as key review areas, the male members that list it actually talk about it more often in their interviews.

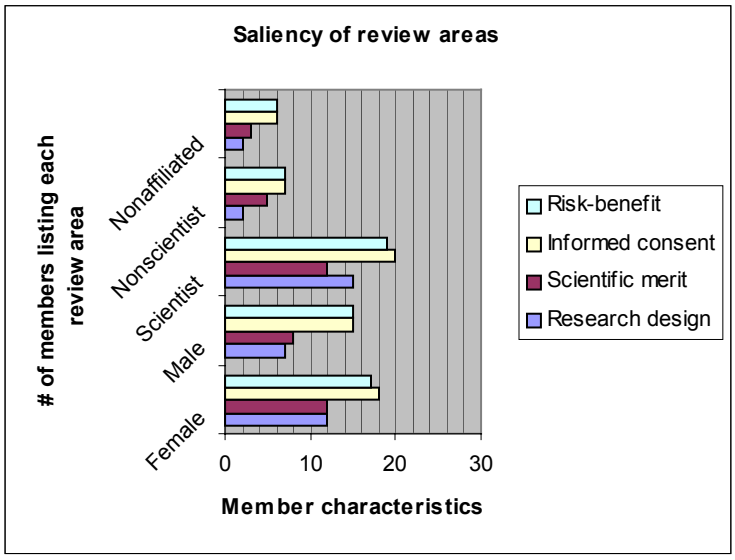

Figure 4. Total number of transcripts coded for each IRB review criterion, organized according to "member characteristics".

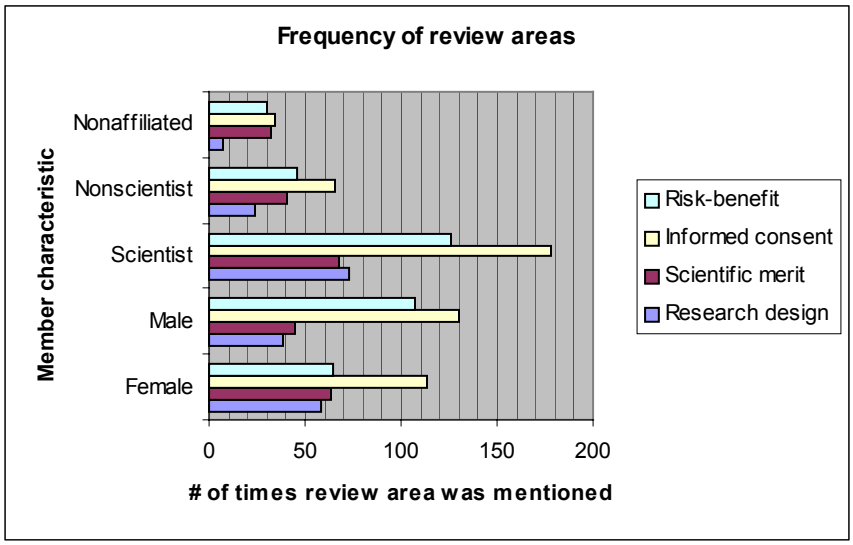

Figure 5. Total number of times a specific IRB review criterion was listed during all interviews, according to "member characteristics".

To better understand these differences, I also examined participant responses according to the "IRB culture" proposition—that is, according to type of university and type of IRB (see Figures 6 and 7). In response to Question 21, roughly the same number of members at both private (10) and public (9) universities lists both "research design" and "scientific merit" as within the IRB purview. Closer examination of what these IRB members actually say about "research design" and "scientific merit" in the full context of their responses shows that public university IRB members mentioned these terms more often as part of their IRB decision-making process. Given that public universities are, to a great extent, driven by a public service mandate perhaps IRB members at public universities are more concerned with ensuring that research funds and resources are spent on well-designed and meaningful research studies. Moreover, as long as the federal human subjects guidelines are satisfied, private universities are not usually held accountable to the public for how the universities spend their research dollars.

I also coded the transcripts for instances where IRB members specifically mentioned that their job was *not* to review scientific merit or research design. The same number of members (5) at both private and public universities specifically used the terms "*not* research design" and "*not* scientific merit". However, members at public universities talked more about *not* reviewing research design; that is, the phrase was brought up more

often during the course of the interview. For example, in the case of "*not* research design", four IRB members at public universities specifically listed this compared with only two IRB members at the private universities in this study.

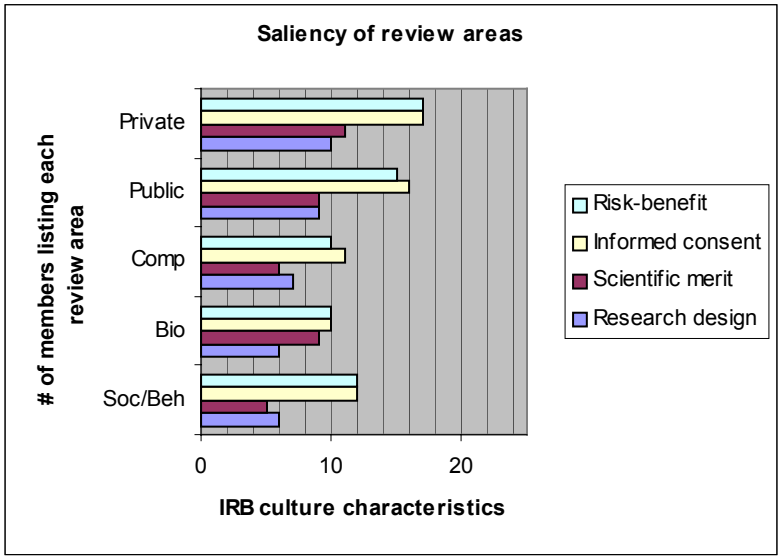

Figure 6. Total number of transcripts coded for each IRB review item, organized according to "IRB culture characteristics".

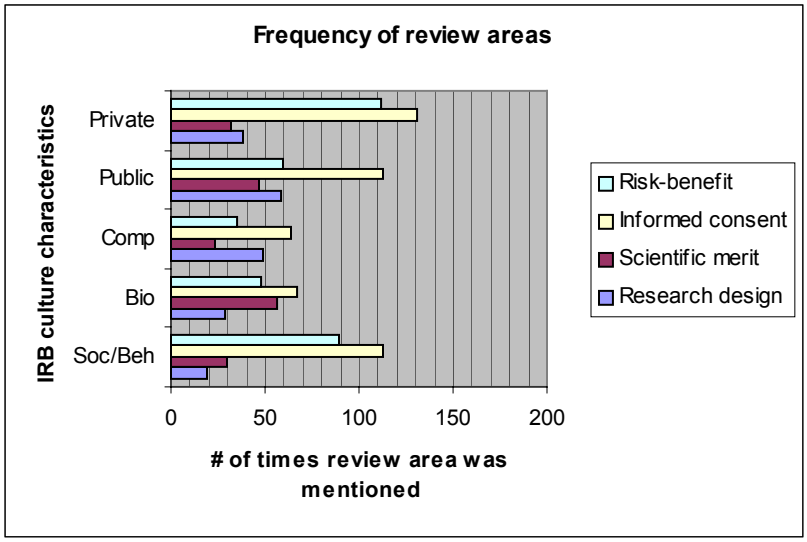

Figure 7. Total number of times a particular IRB review item was listed during all interviews organized according to "IRB culture characteristics".

Next, the data were analyzed according to the type of IRB—biomedical, social and behavioral, or comprehensive. A few differences are notable and possibly reflect the types of research primarily reviewed by each IRB. Compared with biomedical and comprehensive IRBs, social and behavioral IRBs more often list "consent process" and "debriefing" as key IRB review elements. Social and behavioral science IRBs also list "*not* scientific merit" and "*not* research design" more frequently than their biomedical and comprehensive IRB counterparts. Often the risks in social and behavioral research—because they are not usually physical risks—are more difficult to identify. Typically, social and behavioral research studies encompass subtler forms of risk such as economic or social risk that initially seems less "risky" compared with physical risk. For example, family member of research participants can be stigmatized by a participant's involvement in a particular study (NRC, 2003). Additionally, because there is no solid base of evidence regarding nonphysical risks, it may be difficult to estimate such risk (NRC, 2003).

Members of the social and behavioral science IRBs in this study noted that they review many psychology studies, which often involve deception and these studies usually must also include participant debriefing. Differences between these committees' review of the overall "consent process" as distinct from the actual "informed consent form" suggest that the potential risks in social and behavioral research are often subtle and ought to be covered adequately via the consent process and not simply listed on the informed consent form. An interesting difference emerges with respect to members *not* reviewing scientific merit or research design. Although more social and behavioral IRB members specifically say they do *not* review scientific merit or research design, they spoke about IRBs *not* reviewing research design more often than *not* reviewing scientific merit. The chair of a social and behavioral IRB offers an illustrative explanation:

> According to the medical IRBs if you do poor science, anytime you request a subject [to participate] is disrespectful of their human rights. You should not ask their time unless this is going to be excellent science. One minute of poor science is excessive respondent burden is essentially what they say. My understanding is you'll get a bunch of people arguing whether it's poor science or not. From a psychologist's point of view, it's good science. From a pathologist's point of view, who never talks to a human being and only looks at slides it may look

> stupid as hell. I think that's ridiculous. I think if your disciplinary peers think its worthwhile science then we have to take their word for it. I don't think I can judge. A lot of the anthropology stuff looks interesting to me but it doesn't look like science and it's not my job to judge. So they will say over there [on the medical IRB] that the only risk is that the science is poor and we're not going to let you do it. We don't do that. In addition, a lot of our protocols are from graduate and even undergraduate students. Every undergraduate protocol I've ever seen is technically bad science. They can have a beautiful instrument, whatever. They do not have the dollars to go out and interview a representative sample of anything. For their honors thesis they're going to interview 30 people about this but it's not representative. We believe that it is not a waste of participants' time if it contributes indirectly to generalizable knowledge by helping to train [the student]. I don't see it as so much different than a pilot study that big wigs do in order to be able to put it in their grant application that 'we tried it on 30 people and this is what it looked like.' I think it is cutting hairs. We could never get away with imposing that because we would bring I'd say 70 percent of graduate research and 100 percent of undergrad research to a screaming halt and that's not what universities are about. *(Scientist member, social and behavioral IRB, private university)*

To further answer my first research question—how do IRB members decide whether to approve a human subjects research protocol—I asked members a series of questions to examine determine their perceptions of the roles of different types of members on the IRB, and specifically how each type of member reviews research methodology: What aspects of protocols do (scientist members, nonscientist members, nonaffiliated members) typically focus on?" (Q53, Q55, Q58, respectively) And, more specifically "how do nonscientist (and nonaffiliated) members generally participate when research methodology is being discussed?" (Q57, Q60, respectively)

The responses to these questions suggest that scientist members, regardless of their disciplinary background, tend to dominate the discussion about research design, whereas nonscientists (whether affiliated or not) tend to defer to the scientists during such discussions or to phrase their concerns as a question to the group (as opposed to a declarative statement about a protocol deficiency). A scientist member describes how nonaffiliated members on his committee typically participate in discussions about research methodology:

> Well…either they'll stay silent or if they bring something up or if there's a question it might be asking for more information or bringing up something that a scientist member needs to say and explanation of why you wouldn't do it scientifically some other way. *(Scientist member, social and behavioral IRB, public university)*

Similarly, other scientist members note that:

> …two of them [community members] participate almost not all. One participates here and there when she's asked and clearly can serve quite well. And the fourth one who I'm thinking of specifically if she doesn't understand something methodologically she'll ask "Why? Why do they want to do that?" or "What's the reason for that intervention?" or "Why would someone want to put themselves through such a thing?" *(Scientist member, biomedical IRB, private university)*

> They tend to leave this to the other members unless they are asking for clarification on something. Our previous members [a retired professor] did participate though and often posed questions such as "what do you think about this approach?" *(Scientist member, comprehensive IRB, public university)*

Nonaffiliated members seem to agree:

> We sit there and listen and ask questions if we have any. *(Nonaffiliated member, biomedical IRB, private university)*

> Ask questions like "is this really important" or "is this worthwhile?" *(Nonaffiliated member, social and behavioral IRB, private university)*

> There are often discussions of course on research potential, benefits, the consent process. And of course they [scientist members] gravitate towards their expertise and in these cases, uh, I'm trying to think of how I can provide an example. Um, in a behavioral study involving children, we often will have someone that has experience in child psychology jump in and say "well I don't understand why this is happening this way" and it's, you know, accommodates discussion so it's a, you know, it's an intriguing process which I again observe, as much as I participate. *(Nonaffiliated member, social and behavioral IRB, private university)*

> Very little. I don't know the working of the drug. If they're talking about the mechanism of drug delivery, I don't know it. Now if they're talking about, say, a stint, the chair will turn and say "for our nonscientist members, a stent is whatever…" It's very helpful. Or he'll explain a device. He often will say "for our nonscientist members, this is a drug that does such and such" and that's helpful but we don't get into those discussions. As soon as they start talking specifics, I start flipping through other things…it's not a perfect system. *(Nonaffiliated member, biomedical IRB, private university)*

Other responses to these same questions about nonscientist member participation in the discussion about research methodology offer additional insight into the differences between how scientists and nonscientists approach the federal requirement to assess the research methodology criterion.

> We usually just sit back and let the physicians discuss that. *(Nonscientist, comprehensive IRB, public university)*

> I guess in my case I know a little bit about research but not really the kind of research they do. I guess it's more a question of is this really important or worthwhile. I don't know that...we've said we only deal with research [design] if it's not good and because of that it's a waste of somebody's time. I don't think that we've actually rejected any on that basis. Maybe we have. I think we would if it was necessary. *(Nonaffiliated member, social and behavioral IRB, private university)*

> They generally don't say much when methodology is being discussed. Sometimes the scientist members become nonscientists depending on the research area or methodology being discussed. *(Scientist, social and behavioral IRB, private university)*

> Our two nonscientists do have fair familiarity with some aspects of study design. So they're a little more sophisticated in that than the community member who generally has none so the nonscientists might well make some comments speaking specifically to study design, from their point of view. I mean they won't quibble about "is this dose of this drug better than this dose of that drug?" But they'll talk about general aspects of design. The community people are more apt to say "well I don't know about the science but I wouldn't do this on a bet, it just sounds horrendous." *(Scientist, comprehensive IRB, public university)*

These responses suggest the typical roles different members tend to assume when research methodology is a discussion point. The other side of this discussion relates to the overall "scientific merit" of a human subjects research protocol. As previously noted, some IRBs explicitly state that they usually do not purposely review for scientific merit. But most participants in this study agree that this review element is ever present in the discussion process if not overtly so:

> …we have to always look at the risk/benefit ratio so, there's an implicit question 'is the risk to the subject worth the scientific benefit of the study?' And I think there have been one or two instances during the past year where we really questioned that. So it's an implicit question but not one that we typically address and discuss explicitly. Beyond that though, looking at the rigor of the study, the assumption is that the department provides oversight training and will sign off on

> the merit of the study. If there's a granting agency, whenever there's a grant then there's a place for the chair to sign off on all proposals. So there's an assumption then that within all departments there's an oversight. And in the instances where there has been poor scientific rigor, letters have gone back to the chair as well as to the PI. Or in the instance of junior faculty, not necessarily just to the chair or the department, but also to their mentor with the assumption that it's their responsibility to kind of keep tabs rather than us as the IRB. *(Scientist member, social and behavioral IRB, public university)*
>
> In general, they try not to look at the basic science of it but every once in a while you come upon a protocol where the science is so bad that to let anyone enroll in it when you know that there can be no result worth publishing or worth thinking about, that would not make sense. So we say 'well it's not going to hurt anybody, let it go ahead' but every once and a while you do come across a protocol where you actually look at the science of it and say 'this is bogus and to waste anybody's even five minutes at this is ridiculous' much less to put drugs in people, or it is underpowered and there is no way you can learn anything from doing this horrible thing to three people, so why inflict it on three people. *(Nonaffiliated member, biomedical IRB, private university)*

Informed consent

A fourth component of IRB review is the informed consent process, which includes the actual consent form. Informed consent is one of the primary ethical requirements that underpin research with human subjects; it reflects the basic principle of *respect for persons* (Patton and Porter, 1993). Yet, many researchers forget that informed consent is an ongoing process and not just a piece of paper that research participants must sign to participate in a study. Truly informed consent assures that prospective research participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate (Patton and Porter, 1993). Issues of coercion, deception, debriefing, compensation, and of course the risks and benefits to participants are key elements an IRB should consider during a review of the informed consent process. This is the only component of IRB review that is addressed in great detail by the federal guidelines, which specifically state that via the consent form, each participant must be provided with:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. (45 CFR 46.116)

Thus it is not surprising that this element of the IRB review process shows the least variation among IRB members with respect to whether they agree or disagree on issues in this area of review.

In the previous section I offered some explanations for differences that exist between male and female members, among social and behavioral, biomedical, and comprehensive IRBs, and between IRBs at public and private universities. To summarize here, the nature of the research protocol, or the associated level of risk, appears related to the amount of discussion over the consent process and elements of informed consent such as compensation, debriefing, and data confidentiality. For example, the issue of data confidentiality is often the greatest risk in social and behavioral science research. This is consistent with the finding that social and behavioral IRBs mention "data confidentiality" as a key element in the IRB review process more often than their peers who serve on biomedical IRBs where the risks are often physical or drug-related.

7.2.2 Research Question 2: What is the relationship between members' roles on the IRB and their level of expertise as they relate to their experiences and perceptions of the IRB process?

Two themes—suggested by both the theoretical literature and the participant transcripts—are relevant to this research question: expertise and participation. Expertise

on the IRB is important because these interview responses suggest that nonscientist members (whether affiliated or not) tend to defer to scientist members (whom they perceive as "experts") particularly on issues involving research design and scientific merit, and even potential risk. IRB members observe "there tends to be deferral to whoever is perceived to have expertise on the issue" *(scientist member, biomedical IRB, private university)*.

Expertise, as a concept, was defined in Chapter 3 as having a variety of characteristics. Often experts are defined as having specialized knowledge of some kind (Nowotny, 2003), a particular set of credentials or pedigree (Wachbroit, 1999), or the possession of certain characteristics that are distinctive from novices in the same field (Shanteau, 1992). Though IRB members loosely use the terms "expert" or "expertise" when talking about how research protocols are reviewed, expertise on the IRB cannot be conveniently compartmentalized into any of the definitions drawn from the literature. The challenge with defining expertise on the IRB is in some ways a strength for the IRB process and in other ways a source of contention for IRB adversaries. It is a strength because members from varying disciplinary backgrounds are required by law to meet and assess the risks and benefits of a research protocol. Arguably, such variation in expertise encourages the value of diversity of perspective. And, this diversity of perspectives and expertise is, in theory, more likely to result in a more comprehensive assessment of potential risks and benefits than if all IRB members come from the same disciplines or experience base. The drawback is that frequently in spite of the diversity of expertise, all of it is never entirely applicable to every protocol that comes through an IRB for review. In fact, critics of IRBs argue that not enough of it is relevant or useful for performing appropriate review. Even among IRB members, perceptions are mixed with regard to how expertise impacts the decision-making process:

> One of the dilemmas is that you don't have your own area of expertise. Your own area of specialization doesn't mean diddly squat in terms of the majority of the protocols that come through. That's one of the things that I've found alarming in the past when things do go wrong and [people say] "well why didn't the IRB do these literature reviews and why didn't the IRB do this type of thing?" I'm sorry but knowledge is so specialized. *(Scientist, biomedical IRB, private university)*

> I personally am usually very cautious about going beyond that level if it's a topic that I don't know anything about [beyond the basic level of looking at the consent]. What

> I will do is ask questions like "is this something that should concern it?" that either concern me or that are outside of my area of expertise. But there are amazingly a lot of things that are inside your area of expertise. Frame of reference is important for doing much more. *(Scientist member, biomedical IRB, private university)*

Expertise also becomes highly relevant in the context of participation and group consensus. We have seen previously that nonscientist members, and nonaffiliated members in particular, tend *not* to participate in discussions of topics about which they feel unqualified or are lacking in expertise. But participation, or lack thereof, is affected by more than verbal contribution to the IRB discussion. Even if members actively participate—that is, they provide verbal input—in a technical *discussion* about risks and benefits or research design, ultimately even scientist members are likely to defer to whoever has the most relevant expertise on a particular issue especially if that issue spawns a debate at the IRB meeting:

> The challenge then is whether or not you're going to defer to someone who presumably has more expertise or you're not going to defer to them because you think their conflict of interest is too great. I don't know how that gets worked out. I think it gets worked out through a process of trusting your best judgment and also then saying 'you know we've got 20 more protocols to review' and that may prompt someone then to either be overly conservative and say "well can we at least ask the investigator for more information before we give them any kind of approval". Or it may prompt people to say "well you know let's just trust this reviewers judgment this other person's judgment on the committee and move on." *(Scientist member, biomedical IRB, private university)*

> Most of the time the group agrees. We can get the majority opinion to shift to one particular point of view. There tends to be deferral to whoever is perceived to have expertise on the issue. I think that's one of the big weaknesses of the IRB, if it's not composed well. For example, on the subject of risks and benefits in my area, people tend to defer to me. If I don't know it I'll say I don't know, we need to send this back to the investigator. But you wonder if always the expertise is of the highest quality because most of the time there is this deferral to whoever is perceived as having the expertise and maybe that perception is not always accurate. *(Scientist member, biomedical IRB, private university)*

7.3 Summary

This chapter presented qualitative content analysis results for interviews with 37 IRB members, compared across all of the IRBs. N6 qualitative analysis software was used to organize the data in a manageable way so that questions could be asked of the

data in order to inform the research questions driving this study. Using direct quotes I attempted to answer my research questions using the actual words of the participants themselves. In the next chapter, I will tie these findings together to draw conclusions about the relationship between member composition (specifically characteristics of expertise and participation) and the IRB decision-making process. I will then discuss my conclusions and recommendations in the context of possible contributions to theory and practice, as well as potential areas for future research.

8.0 CONCLUSIONS AND IMPLICATIONS

8.1 Introduction

The point of departure for this research was the observation that institutional review boards are increasingly being placed directly into the crossfire of researchers' fight for academic freedom on the one hand and a push to expand public governance of science on the other. To increase our understanding of how IRB members make decisions about whether or not to approve human subjects research, I argued that systematic research was needed at the local level to inform our understanding of the actual decision-making process and specifically how that process is affected by the characteristics of the IRB members. In this chapter I present my conclusions about the data analyzed in the previous chapters. Using these results, I also offer explanations for each research question and consider the implications of my findings for participatory democratic theory, small group decision-making, and human subjects research policy and practice.

While the research described in this dissertation has application and direct usefulness to IRBs at universities and other research organizations, perhaps more importantly the findings also contribute to our understanding of decision-making at the intersection of science and society. The timing of this contribution is particularly important because, as discussed in Chapters 1 through 3, there has been very limited research on the "black box" of the IRB decision-making process and how it is affected by committee member characteristics. Given the current global push for democratizing science and technology and the 2001 NBAC recommendations for increasing the percentage of lay persons serving on IRBs, the results of this research are both timely and useful.

8.2 Conclusions about each research question

The value of the face-to-face group lies in its ability to nurture and integrate individual needs rather than reshaping the individual to meet the needs of the institution (Benello, 1971). This observation is particularly applicable to the IRB decision-making process, in which the needs of the institution are supposed to be secondary to the needs of individuals, specifically the potential research participants. In previous chapters, I

explored two dimensions of the IRB decision-making process, specifically (1) at the individual, pre-IRB meeting level and (2) at the convened group level of the actual IRB meeting. Now I will attempt to tie these two levels of participation together in a meaningful way that will inform our understanding of the IRB decision-making process.

8.2.1 Research Question 1: How do IRB members decide whether to approve a human subjects research protocol—that is, about risk-benefit ratio, scientific merit, research design, and adequacy of informed consent?

The details surrounding the decision to approve a research protocol depend on whether the member is a scientist, nonscientist, or nonaffiliated member. While each of these members, for the most part, agrees on the list of protocol elements[1] that IRBs should review, disparity exists with regard to the extent that different IRBs (social and behavioral, biomedical, and comprehensive), male and female members, and IRBs at public and private universities focus on each element. The difference that emerges most clearly is whether or not, or to what extent, IRBs should and do review research design and scientific merit. Regardless of gender, type of university (public or private), or type of IRB (biomedical, social and behavioral, or comprehensive), nonscientists and nonaffiliated members in this study tend to defer to the scientists on the committee on matters of scientific merit, and especially on matters of research design. Scientists, on the other hand, are more likely to review the research methodology but they, too, are willing to defer to other scientists whom they perceive as having more expertise in a particular area.

The research focus—social and behavioral, biomedical, or comprehensive—also impacts the ways in which IRB members determine whether to approve a protocol. Specifically, members on social and behavioral IRBs focus on particular aspects of "informed consent" (such as adequacy of informed consent and issues of data confidentiality) compared with their counterparts on biomedical and comprehensive IRBs, who tend to emphasize elements of risk and research design.

[1] That is, risk-benefit ratio, scientific merit, research design, and adequacy of informed consent (45 CFR 46).

8.2.2 Research Question 2: What is the relationship between members' roles on the IRB and their level of expertise as these characteristics relate to their experiences and perceptions of the IRB process?

IRB members in this study perceive the IRB process as informal and casual. Yet, there were repeated references to the concept or importance of expertise by *all* members, regardless of their role on the committee. Several types of expertise are apparent in the IRB decision-making process. IRB chairs perform in a knowledge liaison type of role, filling in gaps in knowledge among IRB members and often connecting issues about research protocols that allow IRB members to move forward with a final decision. IRB administrators provide regulatory expertise and context for IRB decisions. This function is especially useful when information from a prior IRB decision bears relevance to a decision in process. Administrators offer institutional memory as it were. The scientist members affiliated with the university usually bring disciplinary expertise and methodological expertise to the IRB. However, unless there is intentional representation from each academic discipline (and even then, the breadth of expertise is questionable) adequate expertise for reviewing some protocols is lacking. Finally, IRB members perceive that lay expertise is brought into the process via the nonaffiliated member. However, this study suggests that nonaffiliated members are unsure about what their purpose is on the IRB other than to ensure that the consent form is understandable. Thus, there is no obvious mechanism by which lay expertise is certain to be considered. Furthermore, if small group decision-making characteristics such as the "common knowledge effect" exist in the IRB setting, lay expertise would need to be shared by the affiliated members in order to be fully considered during the IRB process.

Although IRB members do not need to be experts in scientific methodology or statistics, they should understand the basic features of experimental design, and they should not hesitate to consult experts when aspects of research design seem to pose a significant problem (Penslar and Porter, 1993). In fact, both scientist and nonscientist IRB members in this study acknowledge that they consult with experts in other areas if they feel their own knowledge is lacking. It is probably impossible to have a nonaffiliated member who both represents the local community and is highly knowledgeable about research design, unless the local community is highly educated as a whole in similar

areas to the research in which they are likely to participate (and such research would probably violate the ethical principle of equitable subject selection). This dilemma poses a challenge to achieving full member participation during IRB discussion about methodological issues.

Results from this research suggest that both nonscientist and nonaffiliated members do not participate in the same way as scientist members in the discussion about the "more technical" issues of human subjects research. That alone is not necessarily problematic. However, what is disturbing is the tendency that nonscientist members defer to the scientist members (whom they often perceive as "experts") either because they feel unqualified to even ask questions about research design, or because they believe that their role is only to review the consent portions of the protocols. Members perceive this deference to expertise or perceived expertise not only during discussions about research design and scientific merit, but occasionally about potential risk. As one member explains: "There tends to be deferral to whoever is perceived to have expertise on the issue" (scientist member, biomedical IRB, private university).

8.3 Conclusions about the research problem

Where then does this leave us with our understanding of how to resolve the policy problem that emerges from the regulation of human subjects research—that is, to ensure that human research participants are granted the three basic ethical rights of justice, beneficence, and respect for persons—while continuing to advance scientific knowledge? I began this research with one primary objective: to attempt to dissect the human subjects oversight system to enable a better understanding of the "black box" of IRB decision-making. To achieve this objective I examined IRB members' perceptions of the IRB process at seven research universities according to the principles of participatory democratic theory and research on small group decision-making. I argued that a participatory model was useful because of the expectation that better decisions will result if the IRB decision-making process incorporates a representative yet diverse set of perspectives from scientists and nonscientists (including the public).

8.3.1 Implications for theory

To adequately compare the participatory features of IRB decision-making against principles of participatory democratic theory requires a much more elaborate and extensive research design than feasible for dissertation research. Thus, I have chosen to make some necessary concessions regarding participatory democratic theory by comparing the IRB decision-making process (as perceived by individual IRB members) with Fiorino's (1990) criteria for assessing whether an institutional mechanism is democratic. Specifically, these criteria are: (1) is direct participation of amateurs in the decision-making process allowed, (2) how extensively does it enable the public to share in a collective decision-making process, (3) does the process provide a structure for face-to-face discussion as a means to discuss, deliberate, search for shared values, and transform conflict into resolution, and (4) are citizen participants provided the opportunity to participate on equal footing with technical experts. How then does the IRB fare against these criteria? The process clearly allows for direct participation of amateurs in the decision-making process. However, the selection of those "amateurs" (nonscientists) is ambiguous at best. IRBs, at least in this study, do not adhere to written policies or consistent criteria for identifying the nonscientist members. In fact at the time of this study, they did not have a written policy for the selection of members. Furthermore, once on the committee, there is no mechanism to guarantee that the nonscientists or nonaffiliated members will participate in all (and in some cases, any) of the decision-making process. In that case, it is arguable whether they bring anything unique to the decision-making process in terms of incorporating public values into human subjects research.

With regard to the second criterion for a democratic process, IRBs also fair poorly. Most IRBs do not go to great length to exceed the minimum requirement to include one nonscientist and one nonaffiliated member on their committees. Generally, their argument is that it is "difficult to find good members". Affiliated IRB members in this study were quick to point out that nonaffiliated members ought to possess similar values for research and knowledge creation as the university-affiliated members do. That is, they should support the conduct of research and advancement of scientific knowledge,

two values not necessarily shared by all members of the general public. Furthermore, any attempt to mandate an increase in the number of nonscientists and particularly lay members is likely to generate opposition from the research community. Recommendations for such a requirement have already met with opposition as previously discussed.

Perhaps the IRB scores best on Fiorino's third and fourth criteria of a democratic institutional mechanism: does the process provide a structure for face-to-face discussion as a means to discuss, deliberate, search for shared values, and transform conflict into resolution; and, are citizen participants provided the opportunity to participate on equal footing with technical experts. Because of the federal regulations, IRBs *must* convene a face-to-face meeting to discuss and deliberate human research protocols. During my observations of each IRB meeting in progress, it was evident that some values are articulated and deliberated, and conflicting opinions about such values are discussed until the committees arrive at consensus. In cases where members oppose the final recommendation or vote, those differences are reflected in the letters sent to the research investigators. Although the IRBs participating in this study include only the minimal requirement for citizen representation on their committees, those nonaffiliated members appear to have equal opportunity to participate in the decision-making process. Interviews with these members reveal that they feel welcome to share their views during that process. Whether they choose to do so is a different matter, as noted in Chapter 6.

With regard to participation and whether the IRB process follows the principles of participatory democratic theory, these data suggest that (according to Fiorino's criteria) the IRB process is not a truly democratic process in the sense that those on the committee who "represent" the public are really not so representative, and probably cannot be representative particularly in such a limited participatory capacity when the requirement for including nonaffiliated members is so minimal. One might argue that this comparison is unfair because the IRB was not designed to be a truly democratic process; rather it was merely designed to allow for diversity in perspectives to be achieved through specific composition of the committee. In Chapter 3, I articulated why a participatory democratic process is best for IRB decision-making, specifically noting Kaufman's argument that participatory democracy not only allows for protecting society at large, but it also

contributes to the development of human powers of thought, feeling, and action. Consequently, by assessing the IRB process against Fiorino's set of normative democratic characteristics, opportunity exists to vastly improve the current human subjects oversight system, and perhaps even decision-making at the boundary of science and society, such that via the IRB goal to protect human research subjects, the playing field at the science-society intersection is leveled. Scientists should rest assured that realizing this objective does not freely grant nonscientists access to the realm and rigor of scientific research. Rather, it encourages breadth and depth of discussion about how scientific research involving humans ought to be conducted such that both protection of human participants and contribution of scientific research are maximized.

8.3.2 Implications for policy and practice

Fischer (2000, p. 45) presents us with a new question to ask about professional knowledge and citizen participation: rather than questioning the public's ability to participate in technical decision-making, we must ask, *"how can we interconnect and coordinate the different but inherently interdependent discourses of citizens and experts?"* The results of this study suggest that the IRB is a useful and insightful arena for beginning to answer this question, particularly if recent recommendations to increase lay participation on IRBs are implemented. But even presently, due to the diversity of disciplines represented on an IRB, at one time or another during the decision-making process any IRB member is no more an expert than the nonaffiliated or lay member who sits next to him or her at the IRB meeting.

The composition of the IRB has the potential to greatly impact the types of issues—that is, a range of values—that are discussed during IRB review of research design, scientific merit, risk-benefit and informed consent. But member roles are not well defined. A scientist member on one university IRB may characterize as a nonscientist on another university IRB, which could alter the ways in which that member's contributions to the IRB process are perceived. Members even define themselves differently in some cases which could further impact the decision-making process, how members respond to each other, and the extent to which members participate or believe they ought to participate. Because different types of members approach the review process in various

ways, characteristics such as deference to expertise and the common knowledge effect can further impact the degree to which certain IRB issues are considered and ultimately factor into the decision. A good example is the conundrum that some IRBs experience with regard to whether or not to review scientific merit or research design. The extent to which a protocol is "tweaked" before it finally merits IRB approval hinges upon each of these dimensions and challenges of the IRB process.

As earlier risk research has shown, experts and the public (usually assumed to be the nonexperts) do perceive risk differently. Take, for example, the decision to vaccinate a child or even to invite a child to participate in a vaccine research study. Ball et al. (1998) find that "although physicians may focus on the statistics regarding general vaccine effectiveness and known risks of vaccine-preventable diseases, parents making vaccination decisions may perceive risks in a broader religious, cultural, and personal context." Arguably, IRBs composed of primarily physicians or members from a single race, religion or culture potentially could overlook such issues in the IRB decision-making process unless someone who is sensitized to these differences points them out. Although most participants (whether scientist, nonscientist, or nonaffiliated members) in this research study believe that scientists are capable of bringing public values into the IRB decision-making process, many of them also provided caveats that support the requirement for member diversity on IRBs:

> The problem is that we all have our own blinders…that's why the requirement for different members makes sense *(Scientist member, social/behavioral IRB, public university)*.

> …when so involved in a review and bringing that professionalism and that academic perspective to a review, sometimes that perspective is not fully considered, which is why as a community member I can bring some of that to the committee. *(Nonaffiliated member, social/behavioral IRB, private university)*

A more difficult question is how to determine *how much* diversity is sufficient to impose as a minimum membership requirement for IRBs. I have already stated that the current regulations are very vague and leave IRB member selection up to the universities, as long as the minimum number of members is satisfied. Several of the IRBs in this study admitted that their IRBs are neither racially nor culturally diverse and that this was a potential problem. Yet, they followed up this acknowledgement with the complaint that it

is difficult to find community members with the adequate "educational background so that they won't be intimidated by the group that they're working with" or members that are "not opposed to the research process". To further complicate this issue, the federal guidelines explicitly state that, although IRBs should make every effort to maximize diversity among members, they should not select members on the basis gender.

Based on the results of data analyses and discussion in the previous chapters, I conclude with the following recommendations to begin improving university IRB decision-making:

Recommendation 1: IRBs should develop and implement clear and written guidelines for member selection and member role on the IRB.

None of the universities participating in this study had written policies for member selection at the time the research was conducted. Interview responses confirm that these universities tend to rely on word of mouth, contacts through existing IRB members, or volunteers to identify and recruit potential new members. This is the case for recruiting both scientist and nonscientist members, as well as for recruiting nonaffiliated members. While many of the IRB administrators and chairs interviewed pointed out that efforts are made to include a diversity of disciplinary backgrounds, in many cases identifying IRB members comes down to finding "warm bodies" willing to serve on "yet another university committee". Additionally, IRBs must consider the expertise they possess at any given time and be consistent about how such expertise is connected to appropriate roles on the committee. Some members in this study are perceived to serve in different roles depending on who classifies their role on the IRB. For example, at University D several members classify themselves as scientist members on their IRB; yet, their IRB administrator considers them to be nonscientists based on their academic disciplines. The way in which someone perceives their role can affect the ways in which they carry out that role or how they believe they are expected to perform within that role. Research discussed in Chapter 3 suggests that people respond to expertise in different ways, often deferring to those with perceived expertise. Phenomena such as the "common knowledge effect" can lead to certain information either factoring into or being omitted from a decision. Arguably, combining these two decision-making characteristics with

ambiguous roles on the IRB has great potential to influence the IRB process and ultimate outcomes.

A rationally thought-out member selection policy would further serve to enhance IRB credibility among the research community. Currently, some research investigators allege that IRBs lack credibility and expertise to judge protocols that are often outside their domain, causing delays in and unnecessary burden upon the research process. Contrary to what research investigators allege, IRBs (at least in this study) are also concerned with facilitating research and not just protecting human subjects.

Understandably, it can be challenging to identify the "right" person to serve in the nonaffiliated capacity. IRB members complain that it is particularly difficult to identify nonaffiliated members who not only support the goals and objectives of scientific research, but also reflect local community values as much as possible *and* are willing to actively participate in a decision-making process that offers little to no compensation for their time or contribution. But, results from this study suggest that universities are not trying hard enough to find these potential members. In fact, it appears that some universities are willing to overlook the fact that their nonaffiliated member may not be so "nonaffiliated" or is hardly representative of the surrounding community. For example, at University E, the nonaffiliated member is actually a graduate of one of the university's academic programs. And, at University D, the IRB administrator suggested that she will try to recruit an outgoing affiliated member into the "community member" role. Such interpretation of the federal regulations on IRB composition does little to add to diversity in perspectives among IRB members. Universities must discuss, develop and implement policies for selecting IRB members, particularly with regard to the nonaffiliated members and members who have prior or current experience as actual research participants. Greater attention to the member selection process could only improve upon the current "policy" which seems to rely mostly on serendipity or "who you know".

Recommendation 1.1: Mandatory service on the IRB should be encouraged for researchers conducting human subjects research.

Recommendation 1.2: Mock IRBs should be implemented at the student level, with the requirement that graduate students (at a minimum) and even undergraduate students participate.

These two recommendations are related to Recommendation 1 in that they address the structure and composition of the IRB. IRB members interviewed in this study articulated that they had a different appreciation for, or at least an understanding of, the IRB process. At least one participant noted that the reason she got involved with her IRB was because as a research investigator she was so frustrated with the process. Recommendation 1.1 should also be extended to student researchers. In this study, only University E included a student member on the IRB. However, that member's nomination to the committee was because of circumstance rather than student status. The objective of Recommendation 1.1 is not necessarily to "convert" researchers into IRB cheerleaders. Rather, the diversity in perspectives and expertise potentially represented on the IRB sensitizes members to and deepens their appreciation of methodological and philosophical differences among different disciplines. For example, the inclusion of students as official IRB members invites a perspective that is particularly beneficial for research involving students as research participants.

Similarly, students (i.e., would-be or will-be researchers) can benefit from early exposure to the peer review and ethical review components of the IRB process, either by direct participant as an IRB member or via a mock IRB process. Generally they are not as yet disenchanted with the IRB process or skeptical of its purpose, which may encourage greater freedom of discussion at IRB meetings regardless of areas of expertise or experience—two factors that seem to inhibit more seasoned scientists and nonscientists alike. Additionally, because student research tends to be "weaker" in terms of its research design, the process of openly discussing the relationship between research design and the other IRB review elements is likely to lead to more careful consideration of and improvements in the research design.

Recommendation 2: IRBs must resolve and be prepared to defend their position on reviewing research design and scientific merit.

One of the criticisms many scientists level at IRBs is that they have no business critiquing scientific research for which they allegedly possess no qualifications. This is a serious challenge for IRBs, particularly in light of the federal requirement that IRBs *should* review research design and scientific merit. As with member selection, the IRBs in this study do not appear to have written policies that specifically address IRB review of research design or scientific merit, other than by reference to the 45 CFR 46 IRB review elements in their institute IRB guidelines. Two participating universities in this study seem to have found an approach that blends the regulations with the realities of reviewing research outside the domain of the IRB expertise. IRBs at both private University A and public University E have taken the approach of offering "friendly suggestions" or "friendly gestures" to researchers in instances where members feel that the proposed research design is lacking or may not achieve the research objectives. This process—"free" but not required research design advice—might be most invaluable for junior researchers, and certainly for student researchers. But, it must be pointed out that the IRBs interviewed at both of these universities review social and behavioral research protocols in which the choice of research methodologies and contribution to knowledge often is not as "cut and dry" as those of biomedical research protocols. Certainly the implications of such "friendly" advice may be drastically different for human subjects research in which potential physical risk is higher.

Recommendation 3: The federal policy on human subjects research must be revised to specifically and adequately address the differences among domains of human subjects research.

This recommendation echoes that which many social science researchers have already demanded. One of the most notable differences to emerge from this research study is the difference between the elements of IRB review emphasized by members on social and behavioral committees compared with their counterparts on biomedical and comprehensive IRBs. Undoubtedly differences do exist with regard to both risk and benefit. This is implicit in the very nature and purpose of social and behavioral research compared with biomedical research. And in fact, efforts have been made and continue to

examine these differences in greater detail than possible here (see National Research Council, 2003).

Similarly, the issue of student research warrants greater discussion in the context of appropriate IRB review. Unless departments are subjecting student research projects to stringent review at the departmental level, most student research probably will benefit from IRB review of elements of scientific merit and research design, as well as assessment of the risk-benefit ratio and informed consent process. While some IRBs are already reviewing student research, many others do not and rely solely on students' advisors who often are not as intimately aware of the details of the student's methodology as one might expect.

These study results also suggest that IRBs often decrease the importance of reviewing research design or scientific merit for student research. That decision is justified via the argument that such review would prevent the research from ever happening in the first place, and thus impinge upon the inherent benefit to the student of conducting research at all. This argument is a disservice to research and to students. While the burden on the IRB may increase by reviewing all student research, if student researchers are not subject to the same criteria as more experienced researchers, they only are they denied a valuable learning experience but they also enter the research world inappropriately prepared to conduct "real research". Arguably, the IRB review process can (and often does) add value to a research protocol particularly in the case of student research where the research design has much room for improvement. In the same way that experiential learning outside of the classroom complements scholastic learning, skills needed to develop scientifically sound research proposals can be learned from the IRB review process.

8.4 Limitations

Every study has limitations; some imposed upon it (as discussed in Section 1.7) and some that result from inherent weaknesses within the methodology of choice. In this study, open-ended questioning techniques were used as the primary method for investigating the complex issues that exist in decision-making at the boundary of science and society. Compared with quantitative techniques such as survey methods, qualitative

methodologies are used more appropriately with smaller numbers of participants to elicit deeper and more complex understandings. This study focused on an in-depth examination of the perceptions IRB members have about their IRB experience and their perception of the IRB process. For this reason it was limited to small groups of IRB members at seven strategically selected IRBs.

This is a qualitative study of the voices of IRB members in which I examined members' understanding of their IRB experiences, the meanings they attached to these experiences, and the implications these experiences have on the oversight of human subjects research and governance of science. A qualitative approach was chosen because it permits deeper understanding of the phenomena explored in this study, knowledge not gained by previous quantitative studies of IRBs. The extent to which the results of a study can be generalized to another setting or group of people is an important consideration, and even a primary objective, in quantitative research (Benz and Newman, 1998). But such generalization is not easily determined for qualitative studies. Benz and Newman go so far as to argue that if the purpose of a research study is to generalize, then one should employ quantitative methodology. As with most case study designs, the purpose of this study was *not* necessarily to generalize but rather to investigate various aspects of the IRB decision-making process through the eyes of those who actually participate in this process. To this end, IRB member experiences are quoted in context to substantiate the research findings about the relationship between IRB member composition and members' perceptions about the IRB decision-making process.

Rather than assessing the generalizability to other research settings or decision-making processes it makes more sense to consider the results in the context of the following questions: Can this research be applied to other samples? Do the findings of the research hold up in other settings or situations? What is the likelihood that a given outcome or event will happen again if given the same circumstances? (Benz and Newman, 1998) Because similarities exist between the different types of members at each of the participating IRBs, the "thick description" (Geertz, 1973; Denzin, 1989) of these characteristics enables generalization to some extent, particularly to other research universities that conduct human subjects research. With regard to the second concept of generalizability, it is possible to show that the behavior observed in this study, with

regard to participation, perhaps is not dependent upon context. Previous studies of lay participation in technical decision-making also demonstrate deference to experts in such settings.

Patton (1990) argues "the validity, meaningfulness, and insights generated from qualitative inquiry have more to do with the information-richness of the cases selected and the observational/analytical capabilities of the researcher than with sample size." If the number of subjects is too small, it is not possible to make statistical generalizations or to test hypotheses of differences among groups but if the purpose of a study (such as this one) is to understand the world as experienced by one specific person, this one subject is sufficient (Kvale, 1996). Every reasonable effort was made to include a diverse set of IRB participants to capture the experiences of each member type. Because the proportion of nonaffiliated members serving on IRBs tends to be small compared with affiliated and particularly scientist members, fewer nonaffiliated members are represented in this sample. However, three to five interview transcripts often provides the situational diversity necessary for identifying thematic patterns (Pollio et al., 1997), which was achieved for each type of IRB member in this research study.

8.5 Further research

One of the reasons for my interest in IRB decision-making is because there are so many unanswered questions about this process and yet so many criticisms of it. Analysis of the data obtained for this study only emphasizes how much research remains to be done in order to more fully characterize the IRB decision-making process and its implications for governance of science. The most obvious area in which this research can and should be extended is to other human subjects research settings such as universities with smaller research budgets, hospitals, private research organizations, and even private IRBs. Before it is possible to implement any of the policy recommendations presented above, additional research is needed in these areas to determine whether the differences observed here are endemic only to research universities. Additional qualitative research studies would help to further characterize the ways in which members assess risk in a human research protocol. Armed with that knowledge, larger scale, quantitative studies should be done to enhance generalizability of anticipated findings. Thus, the next phase

of research is to conduct more extensive studies on the actual *IRB group-decision making process* to investigate whether member perceptions of the IRB process corroborate with the actual decision-making process. Such research should include more extensive and longer-term observations of group deliberations at convened IRB meetings.

Another area that merits additional examination is comparative research to identify and understand differences between the U.S. human subjects research system and similar systems in other countries. U.S. researchers argue that our policies are too strict or are not appropriately applied to social science research. If the larger scale studies suggested above find these allegations to be true, it is possible that we might learn from other countries where researchers may share different opinions about human subjects research oversight. Coincidentally, some countries require a greater proportion of research ethics committee members to be from the local community. In contrast with the U.S., scientists do not dominate those committees. The U.S. might also consider whether certain distinctions about research might improve our human subjects oversight system. For example, in France, biomedical research is divided into two areas: research of direct benefit to the individual, and research of no direct benefit to the individual such that specific rules apply depending on whether or not a direct benefit is anticipated for the person consenting to the research (McDonald, 2000). Similar distinctions might also be considered for social and behavioral science research, in which the potential risks to participants are often minimal or nonexistent compared with those of biomedical research.

Finally, research should be conducted to determine whether IRB review adds value to the research process. In other words, does the IRB process make research better not only insofar as human subjects are protected but also with regard to the potential contributions such research can make to society and scientific knowledge in general? I have suggested in my conclusions that IRB review can be a value-added process, particularly for student research but perhaps even in research conducted by junior faculty. This suggestion is likely to invite strong criticism from the research community (particularly by social and behavioral scientists), which is precisely why research on the value-added component of IRB review is warranted.

APPENDIX A: ORIGINAL IRB APPROVAL AND CONSENT DOCUMENTS

RESEARCH CONSENT FORM

Georgia Institute of Technology
Project Title: Decision-Making in the Human Subjects Review System
Investigator: Eliesh O'Neil Lane

You are being asked to be a volunteer in a research study on decision-making in the human subjects review system. The principal investigator, Eliesh Lane, is a PhD candidate at the Georgia Institute of Technology in Atlanta, GA. This research is funded in part by a dissertation improvement grant from the National Science Foundation (NSF).

Purpose: The purpose of this research is to better understand IRB procedures for deciding whether to approval a research protocol that involves human participants. Approximately 30 IRB members from six different research universities in the U.S. are being interviewed for this study.

Procedures: If you decide to be in this study, your part will involve one personal interview, which will last approximately one hour. The interview will be conducted on-site at your university. During the interview, you will be asked questions about your experience as an IRB member and about the decision-making process for research protocols reviewed by your IRB.

Risks/Discomforts: There are no known risks associated with your participation in this study.

Benefits: You are not likely to benefit directly in any way from your participation in this study. However, it is hoped that the results of this study will lead to a better understanding of system that reviews research involving human research participants.

Compensation to You: There is no compensation for your participation in this study.

Confidentiality: The following procedures will be followed to keep your personal information confidential in this study. The data that are collected about you will be kept private to the extent allowed by law. To protect your privacy, your records will be kept under a code number rather by name. Your records will be kept in locked files and only the Principal Investigator and her dissertation advisor will be permitted to look at them. Your name or university affiliation will not appear when results of this study are presented or published.

To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB will review study records. The Office of Human Research Protections may also look at study records. The National Science Foundation, which has partially funded this research, has the right to review study records as well. Again, your privacy will be protected to the extent allowed by the law.

The interview will be tape recorded to ensure accuracy of the interview text. I am the only person who will have access to these tapes and they will be used only to ensure accuracy of your responses. Tape recordings will be erased immediately upon their conversion to text. Although your identity will be kept confidential, as described above, you may review verbatim quotes if you choose to do so. If you are interested, you may also request a synopsis of the completed study.

Costs to You: Other than your time to participate in the interview, there are no costs to you for participating in this study.

Consent Form Approved by Georgia Tech IRB: October 17, 2003 - October 16, 2004

Participant Rights:

- Your participation in this study is completely voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will also be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

Questions about the Study or Your Rights as a Research Participant:
If you have any questions about the study, you may contact the Principal Investigator, Eliesh Lane at 404-385-2083 or eliesh.lane@pubpolicy.gatech.edu. The dissertation advisor for this research is Dr. Richard Barke. He may be contacted at 404-894-8282 or richard.barke@iac.gatech.edu.

If you have any questions or concerns about your rights as a research participant and would like to talk to someone other than the researcher, you may contact Alice Basler, IRB Administrator at the Georgia Institute of Technology, at 404-894-6942 or alice.basler@osp.gatech.edu.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to volunteer in this study.

_____
Participant Name

_____
Participant Signature Date

Eliesh Lane
Name of Person Obtaining Consent

Eliesh Lane
Signature of Person Obtaining Consent Date

APPROVED *Consent Form Approved by Georgia Tech IRB: October 17, 2003 - October 16, 2004*

APPENDIX B: INVITATION TO PARTICIPATE IN RESEARCH STUDY

Dear <insert IRB administrator's name>,

I am a PhD candidate in Science & Technology Policy at the Georgia Institute of Technology. My dissertation research examines the decision-making processes in the human subjects review system. Recently, I received dissertation research funding from the National Science Foundation (Award No. SES-0240394) to collect data for this research. The project summary is included below to provide more information about the study, which has received IRB approval from Georgia Tech.

Today, I am writing to invite the participation of one of <insert university name> IRBs. Your participation would consist of short interviews with about 5-6 committee members (including one scientist, one nonscientist, one nonaffiliated member, the chair, and the IRB administrator). My NSF grant provides travel funds such that I would conduct the interviews at <insert university name.

Upon completion of my research, I would be happy to share the results with <insert university name>. I look forward to hearing from you and sincerely hope that I will have the opportunity to meet some of the members of your IRBs. If it is helpful to speak with my advisor about the study, you can reach him at 404-894-8282. His name is Dr. Richard Barke (Professor in Public Policy and Associate Dean of the Ivan Allen College of Liberal Arts at Georgia Tech). My number is 770-491-0063 if you would like to talk with me.

Best regards, Eliesh Lane
****
Dissertation Research

Decision-making in the Human Subjects Review System

Eliesh O'Neil Lane, PhD Candidate
Georgia Institute of Technology

Research Summary

Human subjects issues rest at the intersection of research in areas of engineering, science, technology and society. With this research come questions about risks and benefits to research participants and society. A group of individuals, chosen at the local institutional level, known as the institutional review board (IRB) decide whether to approve research protocols with human subjects. Current IRB regulations provide general guidance on board member composition. By law, IRBs include one scientist, one nonscientist, and one nonaffiliated member.

Recent research studies have examined such IRB issues as workloads and efficiency, primarily focusing at the administrative level (e.g., on the chair and/or the institutional review board administrator) or on quantifying the number of different types of members

(see Bell et al., 1998). However, as the human subjects protection system comes under intense legislative and media scrutiny and confronts significant revision, much is still unknown about their operation. Systematic theory-driven empirical research is lacking on the effects of varying compositions of IRB membership and on how IRB behavior varies from institute to institute.

In this study, I will conduct personal interviews with IRB members from a sample of research universities to explore the relationship of IRB composition with decision processes about ethical and value issues of human subjects research. This research will contribute to larger questions in the scholarly body of knowledge regarding processes and social contexts of scientific research.

****

Eliesh O'Neil Lane, MS
PhD Candidate, Science & Technology Policy
Georgia Institute of Technology
Atlanta, GA 30332-0345
www.spp.gatech.edu

APPENDIX C: IRB MEMBER INTERVIEW PROTOCOL

*Q1 How did you come to be a member of the Institutional Review Board?

*Q2 What is your current position at the university?

*Q3 How long have you worked here?

*Q4 Have you ever served (or do you serve) on an IRB at another organization? In what role?

*Q5 Do you currently serve (or have you ever served) on any other type of research ethics committee (e.g., IACUC, Biosafety)?

*Q6 How were you selected to serve on this IRB?

*Q7 Why do you think you were chosen to serve on the board?

*Q8 Tell me about your experience as an IRB member.

*Q9 What is your position/role on the IRB? (Administrator, Chair, scientist,

*Q10 Did you have any training in preparation for your role on the IRB?

*Q11 Describe the training you receive(d) in preparation for your role on the IRB.

*Q12 What type of research does your IRB typically review (e.g., biomedical, social/behavioral, etc.)?

*Q13 Has this always been the case?

* Q14 Who assigns protocols to you for review? (N/A for administrators)

*Q15 Do you know how they are assigned? (Probe: On what basis - randomly, based on your area of expertise, etc.)

*Q16 How is your typical IRB meeting organized?

*Q17 How formal are the meetings?

*Q18 How are the meetings structured?

*Q19 What is the role of the Chair?

*Q20 What do you feel about the atmosphere for members to express their opinions?

*Q21 Tell me about the elements of a research protocol that the IRB is responsible for reviewing.

*Q22 About how many hours do you spend preparing for a typical IRB meeting?

*Q23 Describe what you do to prepare for the meeting?

*Q24 Do you talk with other members about the protocols up for review prior to the meeting?

*Q25 Does your IRB use a web-based system to review and manage protocols? Do you use this system? How?

*Q26 Do you prepare/submit reviews ahead of time?

*Q27 Before the actual meeting, what aspects of the proposals do you usually focus on during your review?

*Q28 During the actual IRB meeting, how do you usually bring up issues or problems with a protocol?

*Q29 (N/A for "biomedical only" or "social/behavioral only" boards) Which elements of a protocol do you usually focus on for a biomedical study?

*Q30 N/A for "biomedical only" or "social/behavioral only" boards) Which elements of a protocol do you usually focus on for a social or behavioral science study?

*Q31 (N/A for "biomedical only" or "social/behavioral only" boards) Do you review biomedical protocols and social/behavior science protocols differently?

*Q32 Now I'd like you to think about the different types of members who serve on an IRB. How do you define each of the member types on your IRB? In other words, what education or experiential background do "scientist" members on your IRB possess?

*Q33 Are there qualities or characteristics "scientist" members share?

*Q34 What educational or experiential background should an IRB member possess to be classified as a "scientist" on the board?

*Q35 What qualities or characteristics should scientist members possess?

*Q36 What about the "nonscientist" members? Education or experiential background?

*Q37 Shared qualities or characteristics?

*Q38 What educational or experiential background should an IRB member possess to be classified as a "nonscientist" on the board?

*Q39 What qualities or characteristics should nonscientist members possess?

*Q40 And the "nonaffiliated" members? Education or experiential background?

*Q41 Shared qualities or characteristics?

*Q42 What educational or experiential background should an IRB member possess to be classified as a "nonaffiliated member" on the board?

*Q43 What qualities or characteristics should nonaffiliated members possess?

*Q44 (If applicable) What role does your IRB's student member serve? Who does s/he represent?

*Q45 Now think about the Chair of your IRB, tell me about his or her (your, if Chair is answering) role on the IRB.

*Q46 Would you characterize the Chair as a scientist, nonscientist, or nonaffiliated member?

*Q47 What is their role in leading the discussion?

*Q48 Do others sometimes tend to take the lead?

*Q49 Which members typically take the lead in bringing up or discussing issues?

*Q50 What issues do they typically focus on?

*Q51 How do other members typically respond to this person?

*Q52 Thinking about the scientists on your IRB, how do they usually address questions or issues about a proposed research protocol? How do they bring up problems with a protocol? (Probes: via email or a web-based system prior to the meeting, during discussion at the meeting, or in another way)

*Q53 What aspects of the proposals do they typically focus on? (Probes: scientific rigor, research potential, risk potential, etc.)

*Q54 (N/A for "biomedical only" or "social/behavioral only" boards) Do you think there is a difference between how scientist members review biomedical protocols and social/behavior science protocols?

*Q55 Now let me ask you about the nonscientists on the Board: do they typically bring up questions or issues about a proposed research protocol? How? What aspects of the protocol do they usually focus on?

*Q56 (N/A for "biomedical only" or "social/behavioral only" boards) Is there a difference between how nonscientist members review biomedical protocols and social/behavior science protocols?

*Q57 Tell me about the role of nonscientist members when research methodology is being discussed.

*Q58 What about the nonaffiliated members? Compared to other members, how do they approach the discussion about a protocol?

*Q59 (N/A for "biomedical only" or "social/behavioral only" boards) Is there a difference between how nonaffiliated members review biomedical protocols and social/behavior science protocols?

*Q60 How do nonaffiliated members generally participate when research methodology is being discussed?

*Q61 What happens when members disagree on certain aspects of a proposal? (e.g., the research objectives, the potential for risk, whether/how much compensation is coercive, etc.) In other words, how are disagreements are handled for (each of the major types of issues)?

*Q62 Are there cases in which conflicts of interest (with respect to a protocol focus) emerge among the IRB members in the decision-making process? How are these usually handled?

*Q63 Do you ever (or have you ever) feel like you need to convince the IRB that a protocol should be approved? Or disapproved? For what reasons? (e.g., a colleague's proposal, your department head's proposal, the proposal of a student you supervise)

*Q64 When protocols are approved pending modifications, tabled/deferred, or disapproved, how do PIs generally receive IRB feedback?

*Q65 Does the IRB administrator send an email or a letter?

*Q66 How much detail about the IRBs concerns or suggestions is typically given?

*Q67 How does the IRB work with PIs to incorporate this feedback?

*Q68 Has your IRB ever received complaints regarding its decisions?

*Q69 For what reasons (generally)?

*Q70 From whom (e.g., PIs, other research administrators, OHRP)?

*Q71 Are such complaints formal (e.g., letters, emails) or "informal" (e.g., phone call, hallway discussions)?

*Q72 What is the process by which PIs can appeal the IRBs decision? How do they view this process?

*Q73 How does your IRB generally respond to such complaints or appeals?

*Q74 Has your IRB ever reversed a decision to disapprove a protocol based on a PIs appeal?

*Q75 Under what circumstances (generally)?

*Q76 Now I'd like you to reflect on the meaning of your role on the IRB. Given what you said about how you came to be an IRB member and what it's like for you to fulfill this position, what does it mean to you to be a (scientist, nonscientist...) member on the IRB?

*Q77 What do you believe is the purpose of your university's IRB?

*Q78 Given that, what do you feel is the most important function of the IRB?

*Q79 Do you think all of the IRB members here perceive the purpose of the IRB the same way?

*Q80 What about the researchers whose proposals you review? Would they agree with your perception of the role of the IRB?

*Q81 What weight do you feel your opinion carries on your IRB?

*Q82 Do you feel that your IRB training adequately prepared you for this job?

*Q83 (If applicable) How would you compare your experience on this IRB with other IRBs (or research ethics committees) on which you have served or currently serve?

*Q84 Reflecting on the different types of IRB members: What do you feel is the rationale for requiring IRBs to include at least one scientist, one nonscientist, and one nonaffiliated member?

*Q85 What purpose do you think scientists on the IRB should serve?

*Q86 What about nonscientists?

*Q87 What about nonaffiliated members?

*Q88 Who or what do you think scientist members represent on the IRB?
What do they represent? Or who?

*Q89 What about nonscientists?

*Q90 What about nonaffiliated members?

*Q91 Do you think scientists are capable of bringing public values into the IRB decision-making process?

*Q92 If you could, would you change the composition of IRB member types on your IRB?

*Q93 Do you think the breakdown of scientists and nonscientists is appropriate? If not, what would you change?

*Q94 What, in your opinion, would necessitate a change in the number of scientist or nonscientist members on the board?

*Q95 Do you think the number of nonaffiliated members is appropriate? If not, what would you change?

*Q96 What, in your opinion, would necessitate a change in the number of nonaffiliated members on the board?

*Q97 (Only for "biomedical only" or "social/behavioral only" boards) Given the research focus of your IRB, do you think the board makes decisions differently than if the research focus included social/behavioral science protocols (or biomedical protocols)?

*Q98 If you could, is there anything you would change about how decisions are made on your IRB?

*Q99 If you could, is there anything you would change about how your IRB responds to appeals or complaints by researchers?

*Q100 The Institute of Medicine recently recommended that IRBs should only be responsible for reviewing the ethics of human subjects research and that scientific and financial conflict-of-interest issues be left to other oversight committees for review. What are your thoughts on this recommendation?

*Q101 Do you think the IRB process does its job adequately?

*Q102 Is there another way to uphold the Belmont Principles (i.e., respect for persons, beneficence, justice)?

*Q103 I have reached the end of my questions. Is there anything you would like to add about your experience as an IRB member or what it means to you to be an IRB member?

APPENDIX D: SUPPLEMENTAL INTERVIEW PROTOCOL FOR IRB ADMINISTRATORS

*QS1 When was "your university's" IRB created?

*QS2 How many IRBs are there and what are their research focus areas?

*QS3 How many members serve on this/these IRB(s)?

*QS4 What is the organizational structure in which the IRB is situated? Is your IRB within the Office of Sponsored Programs, directly under an academic officer, or in another department? To whom does the IRB report?

*QS5 Where do the resources (e.g., budget) for the IRB come from?

*QS6 How frequently does your IRB meet?

*QS7 How long do the meetings usually last?

*QS8 Approximately how many protocols does your IRB review each month or year?

*QS9 About how many of these are reviewed by the full board?

*QS10 Do you assign expedited protocols to the board? How?

*QS11 Does your IRB use an electronic communications system (e.g., IRBWISE)? Do members utilize its capabilities for reviewing and posting their comments on protocols?

*QS12 Please describe the demographic characteristics of your IRB. How many women and men? What is the ethnic breakdown?

*QS13 What role (e.g., Latino nonscientist, male nonaffiliated member, etc.) does each fulfill?

*QS14 Does your IRB have a policy on how members are selected to the board?

*QS15 How do you identify or recruit nonaffiliated members?

*QS16 How is the IRB chair selected?

*QS17 Are there any student members on your IRB? How many? What role do student members serve?

*QS18 Do any of your members receive compensation for their service on the IRB?

*QS19 Has your IRB ever received any compliance directives (e.g., letters from OHRP)?

APPENDIX E: FINAL CODEBOOK FOR INTERVIEW PROTOCOLS

Code	Definition/explanation	Synonyms/related themes
Elements of Individual Decision-making		
Participation	Presence (or lack thereof) of mechanisms that encourage members to participate in the decision-making process both independently before the convened IRB meeting and as a group during the convened IRB meeting	Communicate with other members via email or phone Group training and workshop opportunities Assignment of reviews to members Opportunity to directly participate Influence over decision outcome (weight opinion carries during group discussion) Number of nonaffiliated or lay members on the committee Presence of nonaffiliated or lay members during vote Resources for participation (incentives, compensation)
Decision-making culture	Refers to the group discussion process, specifically characteristics of the convened IRB meeting such as how formal or structured the meetings are, how disagreement over specific issues are resolved (e.g., level of risk, research design, compensation)	Formality or structure of meetings Consensus versus majority vote Work out differences of opinion through discussion Give and take on certain issues Incorporate differences of opinion in condition letter to research investigator Deference to authority or experts Presence of dominant personalities
Elements of IRB review		
IRB purpose	The purview of the IRB; what	Protect human subjects Minimize risks Protect the researchers

	members believe is the purpose or goal of the IRB	Protect the university Facilitate research
Scientific merit	Benefit of the research to society and/or knowledge in general	Scientific value Value of the research Potential outcomes Contribution to knowledge generation Contribution to science (or medicine) Research is worth doing
Research design	IRB must consider potential risks that are posed by design features employed to assure valid results as well as by the particular interventions that may be performed in the course of the research. Subjects participating in a study whose research design involves **random assignment** to treatment groups face the chance that they may not receive the treatment that turns out to be more efficacious. Subjects participating in a **double-masked** study take the risk that the information necessary for individual treatment might not be available to the proper persons when needed. In behavioral, social, and some biomedical research, the methods for gathering information may pose the added risk of invasion of **privacy** and possible violations of **confidentiality**. Many risks of research are the risks inherent in the methodologies of gathering and analyzing data, although the more obvious risks may be those posed by particular interventions and procedures performed during the course of research.	Research methods or methodology Recruitment of participants Subject selection, sampling issues – who research is limited to, generalizability of the results to other populations Random assignment to study groups Does the research design adequately answer or have the potential to answer the research questions? Internal consistency between the research protocol/IRB application and the research design; consistency with the informed consent document
		Coercion - Potential coercion to participate (e.g., excessive compensation, classroom settings) Deception - Consider when the

Informed consent process	Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of **respect for persons**. Informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. This assurance protects all parties: both the subject, whose **autonomy** is respected, and the investigator, who otherwise faces legal hazards. The terms and phrases listed in the next column indicate the various elements of informed consent that emerge during human subjects research.	research design involves incomplete disclosure or deception, and if so, is debriefing included in the research process Debriefing (if deception was used) Full disclosure of risks, benefits, and required elements of participation (i.e., what must the participant do to participate in the study) Anonymity versus confidentiality Data confidentiality - Confidentiality is discussed; how will confidentiality be assured (specific steps that will be taken) Consent as a process throughout the study and not just a form for participants to sign at the beginning of the study. Who will consent the potential participants (research investigator, graduate assistants, etc.)? Do they have human subjects training? If vulnerable populations are involved, do the people consenting them have extra training to work with these populations? Reading level of consent form (8^{th} grade level) Conflict of interest - Disclosure of conflict of interest that research investigator or university may have with any potential outcomes of the study (e.g., financial benefit) Research venue – where will research be performed? Vulnerable populations – are additional provisions in place to protect participants such as mentally disabled, children, prisoners, etc.
	A valued or desired outcome; an	Anticipated benefit

Benefit	advantage. The benefits of research fall into two major categories: benefits to subjects and benefits to society. Direct payments or other forms of compensation offered to potential subjects as an incentive or reward for participation should <u>not</u> be considered a "benefit" to be gained from research.	Advantages or gains to participants Contribution to general knowledge in a particular domain Opportunity for further understanding, prevention, or alleviation of a serious problem affecting the health or welfare of study population Research experience of investigator (esp. if s/he is a student researcher) Expected research outcomes
Minimal Risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	No risk Low level of risk No more risk that one might experience in everyday life
Risk	The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." In the process of determining what constitutes a risk, only those risks that may result from the research, as distinguished from those associated with therapies subjects would undergo even if not participating in research, should be considered.	Physical Harms (injury or illness) Psychological Harm (stress, embarrassment, emotional) Social and Economic Harms (loss of a job as a result participating in the study) Legal Harms (lawsuits resulting from participating in a study) Negative outcomes for participants Negative press for university Would I want my parent, child, friend, etc. to participate? Would I be comfortable participating in this study? Is experience of research investigator adequate to conduct the study safely?
	The IRB's assessment of risks	

Assessment of risk-benefit ratio	and anticipated benefits involves a series of steps. The IRB must: (1) identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research; (2) determine that the risks will be minimized to the extent possible; (3) identify the probable benefits to be derived from the research; (4) determine that the risks are reasonable in relation to be benefits to subjects, if any, and the importance of the knowledge to be gained; (5) assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits Evaluation of the risk/benefit ratio is the major ethical judgment that IRBs must make in reviewing research proposals. The risk/benefit assessment is not a technical one valid under all circumstances; rather, it is a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit.	Level or degree of potential or likely risk Potential benefit Potential value to participant, to society, to knowledge Compare potential risks to likely benefits
NOT research design	Some IRBs feel that they are not or should not be responsible for assessing the quality of a protocol's research design. Member must explicitly state that their IRB is not responsible for or should not be reviewing the research design of a research protocol	NOT research methodology NOT methodology NOT our job to review research design NOT peer review (of design or methods) Leave research design to the peer review process
	Some IRBs feel that they are not or should not be responsible for assessing the scientific merit of a study. Some members also believe that certain research (e.g., most student research) should not be subject to this criterion because there is inherent value to	NOT scientific review NOT scientific value NOT our job to review scientific merit or value

NOT scientific merit	society by virtue of the student's experience conducting the research study. Member must explicitly state that their IRB is not responsible for or should not be reviewing the scientific merit of a research protocol	NOT peer review (of merit or value) Value is not always obvious
Member characteristics	Characteristics or qualities inherent to each member or that each member brings to the decision-making process	Scientist Nonscientist Nonaffiliated (or lay) member Chair Administrator Gender Years of IRB experience Service on another IRB Role on committee (e.g., devil's advocate, institutional memory)
Expertise	Domain of expertise	Disciplinary expertise Methodological expertise Lay expertise Lack of expertise Development of expertise over time (group expertise)

APPENDIX F: FINAL CODEBOOK FOR IRB MEETING OBSERVATION TRANSCRIPTS

Code	Definition/explanation	Synonyms/related themes
Elements of Group Decision-making		
Participation	Presence (or lack thereof) of mechanisms that encourage members to participate in the decision-making process both independently before the convened IRB meeting and as a group during the convened IRB meeting	Assignment of reviews to members Opportunity to directly participate Influence over decision outcome (weight opinion carries during group discussion) Number of nonaffiliated or lay members present at meeting Presence of nonaffiliated or lay members during vote Resources for participation (incentives such as food)
Decision-making culture	Refers to the group discussion process, specifically characteristics of the convened IRB meeting such as how formal or structured the meetings are, how disagreement over specific issues are resolved (e.g., level of risk, research design, compensation) Also includes leadership roles of various members, history of group, cohesiveness of group, composition of group	Formality or structure of meetings Consensus versus majority vote Work out differences of opinion through discussion Give and take on certain issues Incorporate differences of opinion in condition letter to research investigator Deference to authority or experts Presence of dominant personalities Leadership style of IRB chair (autocratic versus democratic) Role of IRB administrator (group history, regulatory knowledge) Agreement on purpose of IRB Favorable opinion of IRB chair Homogeneity of group

		Respect for different opinions and perspectives
Elements of IRB review (discussed in group setting)		
IRB purpose	The purview of the IRB; what members believe is the purpose or goal of the IRB	Protect human subjects Minimize risks Protect the researchers Protect the university Facilitate research
Scientific merit	Benefit of the research to society and/or knowledge in general	Scientific value Value of the research Potential outcomes Contribution to knowledge generation Contribution to science (or medicine) Research is worth doing
Research design	IRB must consider potential risks that are posed by design features employed to assure valid results as well as by the particular interventions that may be performed in the course of the research. Subjects participating in a study whose research design involves **random assignment** to treatment groups face the chance that they may not receive the treatment that turns out to be more efficacious. Subjects participating in a **double-masked** study take the risk that the information necessary for individual treatment might not be available to the proper persons when needed. In behavioral, social, and some biomedical research, the methods for gathering information may pose the added risk of invasion of **privacy** and possible violations of **confidentiality**. Many risks of research are the risks inherent in the methodologies of gathering and analyzing data, although the more obvious risks may be those	Research methods or methodology Recruitment of participants Subject selection, sampling issues – who research is limited to, generalizability of the results to other populations Random assignment to study groups Does the research design adequately answer or have the potential to answer the research questions? Internal consistency between the research protocol/IRB application and the research design; consistency with the informed consent document

	posed by particular interventions and procedures performed during the course of research.	
Informed consent process	Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of **respect for persons**. Informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. This assurance protects all parties: both the subject, whose **autonomy** is respected, and the investigator, who otherwise faces legal hazards. The terms and phrases listed in the next column indicate the various elements of informed consent that emerge during human subjects research.	Coercion - Potential coercion to participate (e.g., excessive compensation, classroom settings) Deception - Consider when the research design involves incomplete disclosure or deception, and if so, is debriefing included in the research process Debriefing (if deception was used) Full disclosure of risks, benefits, and required elements of participation (i.e., what must the participant do to participate in the study) Anonymity versus confidentiality Data confidentiality - Confidentiality is discussed; how will confidentiality be assured (specific steps that will be taken) Consent as a process throughout the study and not just a form for participants to sign at the beginning of the study. Who will consent the potential participants (research investigator, graduate assistants, etc.)? Do they have human subjects training? If vulnerable populations are involved, do the people consenting them have extra training to work with these populations? Reading level of consent form (8^{th} grade level) Conflict of interest - Disclosure of conflict of interest that research investigator or university may have with any potential outcomes of the study (e.g., financial benefit) Research venue – where will

		research be performed? Vulnerable populations – are additional provisions in place to protect participants such as mentally disabled, children, prisoners, etc.
Benefit	A valued or desired outcome; an advantage. The benefits of research fall into two major categories: benefits to subjects and benefits to society. Direct payments or other forms of compensation offered to potential subjects as an incentive or reward for participation should <u>not</u> be considered a "benefit" to be gained from research.	Anticipated benefit Advantages or gains to participants Contribution to general knowledge in a particular domain Opportunity for further understanding, prevention, or alleviation of a serious problem affecting the health or welfare of study population Research experience of investigator (esp. if s/he is a student researcher) Expected research outcomes
Minimal Risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	No risk Low level of risk No more risk that one might experience in everyday life
Risk	The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." In the process of determining what constitutes a risk, only those risks that may result from the research, as distinguished from those associated with therapies subjects would undergo even if not participating in research, should be considered.	Physical Harms (injury or illness) Psychological Harm (stress, embarrassment, emotional) Social and Economic Harms (loss of a job as a result participating in the study) Legal Harms (lawsuits resulting from participating in a study) Negative outcomes for participants Negative press for university Would I want my parent, child, friend, etc. to participate?

		Would I be comfortable participating in this study? Is experience of research investigator adequate to conduct the study safely?
Assessment of risk-benefit ratio	The IRB's assessment of risks and anticipated benefits involves a series of steps. The IRB must: (1) identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research; (2) determine that the risks will be minimized to the extent possible; (3) identify the probable benefits to be derived from the research; (4) determine that the risks are reasonable in relation to be benefits to subjects, if any, and the importance of the knowledge to be gained; (5) assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits Evaluation of the risk/benefit ratio is the major ethical judgment that IRBs must make in reviewing research proposals. The risk/benefit assessment is not a technical one valid under all circumstances; rather, it is a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit.	Level or degree of potential or likely risk Potential benefit Potential value to participant, to society, to knowledge Compare potential risks to likely benefits
NOT research design	Some IRBs feel that they are not or should not be responsible for assessing the quality of a protocol's research design. Member must explicitly state that their IRB is not responsible for or should not be reviewing the research design of a research protocol	NOT research methodology NOT methodology NOT our job to review research design NOT peer review (of design or methods) Leave research design to the peer review process

NOT scientific merit	Some IRBs feel that they are not or should not be responsible for assessing the scientific merit of a study. Some members also believe that certain research (e.g., most student research) should not be subject to this criterion because there is inherent value to society by virtue of the student's experience conducting the research study. Member must explicitly state that their IRB is not responsible for or should not be reviewing the scientific merit of a research protocol	NOT scientific review NOT scientific value NOT our job to review scientific merit or value NOT peer review (of merit or value) Value is not always obvious
Member characteristics	Characteristics or qualities inherent to each member or that each member brings to the decision-making process	Scientist Nonscientist Nonaffiliated (or lay) member Chair Administrator Gender Years of IRB experience Service on another IRB Role on committee (e.g., devil's advocate, institutional memory)
Expertise	Domain of expertise	Disciplinary expertise Methodological expertise Lay expertise Lack of expertise Development of expertise over time

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