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Research ethics by design: A collaborative research design proposal

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Abstract

Privacy by Design, a globally accepted framework for personal data management and privacy protection, advances the view that privacy cannot be assured solely by compliance with regulatory frameworks but must become an organisation's default mode of operation. We are proposing a similar template for the research ethics review process. The Research Ethics by Design framework involves research ethics committees engaging researchers during the design phase of the proposal so that ethical considerations may be directly embedded in the science as opposed to being viewed as addendums after the fact. This collaborative research design proposal results in the establishment of a culture of ethical research rather than research with ethical oversight. Both researchers and research ethics committees come to view the review process as one in which individual protection and collective benefit co-exist in a doubly-enabling positive-sum manner.

Keywords

biomedical model, collaborative research, humane medicine, privacy by design, research ethics by design

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Stephen Pinker, in a recent op-ed for the *Boston Globe* (Pinker, 2015), publically expressed his palpable frustration with research ethics committees (RECs). He indicted RECs as obstructionist, more intent on nit-picking minutiae than allowing research proposals to seamlessly maneuver the ethics process so that researchers can get on with the important work of improving the morbidity and mortality associated with medical illness. Any member of an REC recognizes in Pinker's position an attitude that, though extreme, exists in their own institution. Although he begrudgingly recognized the importance of such aspects as privacy in the review process, Pinker's message to ethicists in general remained "get out of the way."

One response to Pinker's diatribe would be to dismiss his attitude as excessively scientistic and oblivious to the subtleties that an ethical framework in medicine imposes. Ethicists may lament his attitude as reflective of the consequences of the biomedical model of the patient that has been promulgated by a technology-driven medical practice prompting them to simply dig in their heels to ensure that due deference is paid to those individuals who have unselfishly volunteered to participate in a research study. Another response is to recognize that there is a problem with how ethics and research are amalgamated in the present day research ethics review paradigm and that this paradigm is a primary cause of frustration on the part of researchers. Although it would be extreme to characterize the present-day association of research and ethics as adversarial, there is a sense in which this characterization rings true.

Researchers often perceive ethical considerations as an afterthought to be addressed after the real work of the research proposal has been completed. They are a necessary annoyance that must be addressed to appease a group of individuals whose focus is to impede scientific progress for the sake of paying lip service to whatever fiat of social convention is popular at the time. RECs, for their part, often operate with a rigidity that is insensitive to the practicalities that researchers encounter in conducting research programs. By focusing on documentation rather than empathetic review, procedure rather than thoughtful consideration, RECs create a burdensome environment that actually discourages researchers from using them as a resource or from developing and submitting new research proposals. Researchers are frustrated by the hurdles that the review process creates while RECs unsympathetically continue to perpetuate these hurdles in the name of patient welfare. The result is a dynamic tension whose resolution is the outcome of the review process but whose existence is based more on the accepted paradigm for the research ethics process than anything else.

Ethical oversight exists to ensure the establishment of a humane approach to the treatment of research participants in which psychological, ethical, and sociological issues are considered on par with their biomedical counterparts (Marcum, 2008). Although the present research ethics review process ensures compliance with regulatory frameworks, it cannot guarantee that the prescribed ethical guidelines will be followed to their fullest during the duration of the study. In fact, the

guarantee of a humane medicine approach to research rests just as much on the attitudes of the research team to the research participants as it does on the documentation of compliance with any regulatory framework at the time of the review process. By focusing on documentation and procedure, the research ethics review process ironically perpetuates a framework that was the cause for the need of the review process in the first place. If ethical considerations are simply hurdles to overcome in an adversarial review process rather than the basis of good research practice, RECs perpetuate the biomedical model of the research participant to the exclusion of the humane.

Accordingly, we are proposing a new paradigm for the research ethics process—a paradigm that may be best described as Research Ethics by Design (REbD). It follows the template of the Privacy by Design (PbD) framework that has been implemented globally, having been unanimously passed as an international framework for privacy in 2010 (Cavoukian, 2011). PbD advances the view that privacy cannot be assured solely by compliance with regulatory frameworks but must become an organisation's default mode of operation. This entails a proactive approach in which privacy concerns are addressed from the bottom-up, in the implementation phase, rather than as a reactive approach in which privacy considerations are identified only after the formal framework has been established.

There are seven foundational principles for PbD:

1. Proactive not reactive; preventable not remedial. PbD does not wait for privacy risks to materialize or privacy infractions to occur—it aims to prevent them.
2. Privacy as the default setting. Personal data are automatically protected in any given data management system or business practice by default.
3. Privacy embedded into design. Privacy is an essential component of the core functionality of the system by being embedded in the architecture rather than being added on post-facto.
4. Full functionality: positive-sum, not zero-sum. By being embedded in the architecture of a system, privacy does not have to restrict data access; both privacy and security can be accommodated.
5. End-to-end security: full life-cycle protection. By embedding privacy into the system before the first element of information is collected, all data are protected until they are destroyed at the end of the process.
6. Visibility and transparency. Stakeholders are assured that their data are protected according to stated promises and objectives; the component parts and operation of a system are visible and transparent.
7. Respect for user privacy. By requiring that the design of systems keeps the interests of the individual uppermost, it empowers user-friendly options and remains user-centric.

We believe that it is possible to re-interpret each of these foundational principles to make them fully applicable to the research ethics review process. Doing so, however, will require a major change in the mission statement and operation of RECs. By encouraging the consideration of ethical issues in a bottom-up fashion during the design phase of research studies, the onus will be on RECs to engage researchers at that early stage to provide the direction needed to accommodate ethical concerns pre-emptively; revisions will be unnecessary and the appropriate ethical treatment of participants maximally ensured even after the review process is finished. RECs will therefore become ethical research facilitators rather than just post-facto reviewers. The goal will be the development of a culture of ethical research rather than one of research with ethical oversight. Researchers will come to embed ethical considerations into the framework of their science, and RECs will participate in the development of ethical research proposals. Both researchers and RECs will come to view the review process as one in which individual protection and collective benefit may co-exist in a positive-sum manner.

Because formal submission and review by committee still exists in REbD, nothing is lost vis-à-vis the present review process. What is gained by the early engagement of researchers with ethical considerations is the creation of a culture in which the research participant's subjective aspirations are automatically treated on par with their physical disabilities. The framework that supports the biomedical model of the participant is seductive, and its ability to overwhelm us to the exclusion of other frameworks is the main obstacle in the adoption of a humane medicine. Because it is so seductive, any modification of this framework for researchers must occur internally within the culture of science and cannot be imposed or abstractly argued outside of it (Borrett, 2013). RECs must confront researchers on their own terms to allow the principles of ethical research to be incorporated voluntarily in their mindset. The result for researchers will hopefully be that ethical considerations are seen as embedded within the framework of science, and not viewed as addendums. Ethical research rather than research with ethics oversight will become the norm.

At our institution, there has been a marriage of ethical instruction and research proposal development for many years. Our Office of Research that helps researchers procure research funding and develop and modify research proposals is overseen by a research ethicist. She interacts with researchers on their own terms, presenting ethical considerations not as items that need to be addressed in order to pass the review process, but as issues that define good research practices. We have seen a gradual change in the attitude of researchers over the years in which ethical considerations are entertained in the earliest phases of research development. As a result, a culture of collaborative ethical research has developed. Mandating ethical training for researchers through the completion of formal ethics modules outside of the practice of medicine does little to change a mindset. The dialogue with

researchers, although ethically framed, must always be within the idiom of science and focus on research proposals as scientific entities. It has only been with the continued interaction with researchers in the design of scientific protocols that this gradual change has been observed, in which ethical considerations are seen as constitutive of good research practice rather than as hurdles to overcome in the review process.

For their part, RECs are also partially to be blamed for the "mission creep" that is occurring within their culture (Gunsalus et al., 2006). Just as the researchers extract participants from their lived experience and reduce them to the parameters of the biomedical model, RECs extract subjects from the perspective of individuals in whom interaction with the research team will persist for the duration of the study, and reduce them to an alternative set of parameters that facilitate compliance with ethical frameworks. That is not to say that RECs fail to embrace a humane perspective in the review process. The need to comply with ethical frameworks necessitates such a parametric reduction in the review process. The difficulty is that this approach can acquire a momentum of its own and overshadow thoughtful, empathetic review. Assurance of a humane perspective by the research team is as sure a guarantee of ethical treatment of research subjects as is compliance with ethical frameworks. By engaging researchers at the onset of every study, RECs can initiate the paradigm shift needed for the establishment of a default humane medicine. In addition, by adopting the viewpoint of the researcher through early interaction, the REC's perspective can expand to include the societal benefit of research. This may also mitigate any obsession with inflexible adherence to regulation and policy.

Identifying RECs as research facilitators involved in the design phase of research studies may suggest a conflict of interest that detracts from their ability to function as protectors of patient participant rights. The existence of an arm's-length independent review process is at present an accepted principle in the ethical treatment of humans in research studies. This principle must seem compromised if an REC member interacts with a researcher in the development phase of a research protocol and then comes to review the same protocol during the formal review process. The argument is specious because it assumes a zero-sum game whereby participant welfare has to occur at the expense of the ease by which research is reviewed and realised. It is a consequence of the adoption of an adversarial framework to arbitration in which any benefit to one party must occur at the expense of the other. Mediation represents an alternative framework to arbitration in which a negotiated settlement can result in benefits to both parties. REbD follows this mediational framework; both the researchers and the RECs see the review process as one in which individual protection and collective benefit can co-exist in a positive-sum manner. Individual protection is maintained because compliance with ethical frameworks still must occur during the review process. In addition, a paradigm

shift in which a humane medicine is the default position of an institution promotes ongoing recognition of the participants' psychological and social needs even in the absence of REC oversight. Collective benefit is maintained because the research can proceed without the hurdles that amendments and re-submissions entail. In addition, the more an REC participates in research design and appreciates the societal implications of good medical research, the less likely it is to obsess about inconsequential parameters and documentation.

Some independence of RECs from the researchers is still required for REbD to succeed. The REC can participate in the research design to facilitate ease of the review process but can receive no credit. If no personal benefit can accrue, it is shielded from concerns of bias in the review process. Similarly, the REC can have no monetary relationship to the researchers or their sponsors. If this degree of independence is agreed to, even commercial research can be accommodated by a REbD framework.

It is instructive to review the seven principles that will serve as the foundation of a REbD and highlight the practical implications of each. We have chosen to include the original seven headings of PbD in order that privacy aspects, which clearly form part of all research ethics reviews, maintain their original template:

1. Proactive, not reactive. Rather than wait for ethical concerns to be identified in the review process or ethical infractions to occur during the study period, REbD aims to prevent them from occurring.
2. Ethical research as the default position. The goal is to establish ethical research rather than research with ethical oversight. The latter subscribes to the biomedical model of the patient, whereas the former is more consistent with the humane position. Once a culture of ethical research has been established in an institution, ethical concerns are entertained at all times and are considered on par with scientific issues. Because researchers have knowledge of the principles of ethical research, the conduct of the study after the review process is completed will also be consistent with the ethical guidelines.
3. Ethics embedded in the design of the research proposal. The SPIRIT statement (Chan et al., 2013) that is accepted globally as the template for research design indicates the need to accommodate research ethics review in its checklist. It does not provide any direction, however, in how to incorporate ethical considerations into the design. The seven principles of ethical conduct concerning research in human participants developed by Emanuel et al. (2000) provides a framework that the researcher can be exposed to and guided through in the development of a research proposal.
4. Full functionality: positive sum, not zero sum. By embedding ethics in the design phase, ethical considerations are seen as part of the science, with no

negative impact on the study execution. By including the REC in the design of the research proposal, review criticism and the need for revision will be diminished without any negative impact on participant well-being.

5. End-to-end ethical incorporation. Oversights in the review of research projects do occur and can escape the attention of the REC. In addition, once the study passes the review process, ethical considerations may arise during the conduct of the study that the researcher alone will need to address. Through the culture of ethical research established by REbD, the negative impact of these factors will be minimized and a more complete end-to-end incorporation of ethical principles in the conduct of the study by the researchers will result.
6. Visibility and transparency. In PbD this principle refers to the knowledge that stakeholders will have that their data are protected according to stated promises and objectives. Although this is applicable to REbD, there is an additional benefit relating to visibility and transparency of the research ethics review process across and within RECs. A major source of frustration from a researcher perspective is the variability between RECs and, at times, the idiosyncratic nature of recommendations within an REC. A standardized template for researchers to use in the design phase that is the same as the one that RECs use in the review phase will make the entire process more visible and transparent. The REbD paradigm encourages the development of such a mutual template.
7. Respect for human research participants at all times. This is the default position in a culture of ethical research and the basis of a humane medicine.

Researchers will no doubt continue to subscribe to the biomedical model of the patient, and RECs will continue to obsess about procedure and documentation. The attraction of the adversarial paradigm in research ethics reviews will persist. REbD seeks to minimize these tendencies by embedding ethics directly into research design and allowing RECs to play a role in the design process. When both researchers and RECs see the review process as one in which individual protection and collective benefit co-exist in a positive-sum manner, not only will Pinker's concern about obstructionism be addressed, but the groundwork for a more humane medicine will be established.

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