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Topics

# Effective streamlining of ethics and governance processes: fact or fiction?

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*Regulatory processes governing healthcare research have been very controversial within the academic and health sectors. We assume that it is generally accepted that there need to be institutional structures and systems to ensure researchers pursue ethical research in healthcare and that the chosen site can feasibly support the project in question. Having said that the efficiency and proportionality of ethics and research governance processes have frequently been called into question. This paper will examine some of the attempts made by the National Institute for Health Research (NIHR) to streamline ethics approval as well as research and development processes. It will consider the extent to which the changes made by the NIHR have been successful, and then briefly consider the future direction of governance within healthcare research.*

***Keywords:*** *streamlining, proportionality*

## Introduction

Regulatory processes governing healthcare research have been very controversial within the academic and health sectors. We assume that there needs to be institutional structures and systems to ensure the ethical nature of healthcare research projects [1]. This is clear from the Declaration of Helsinki, Article 5, which states: 'In medical research on human subjects, considerations related to the wellbeing of the human subject should take precedence over the interests of Science and Society' [1]. Having said that, the efficiency and justification of all the various ethics and research governance processes have frequently been called into question [2-3], and not only by researchers themselves [4].

The evolution of research ethics committees is presented in the Department of Health Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees [5]. Initially, Local Research Ethics Committees (LRECs) were in existence at each site, operating largely as independent entities, with autonomous application processes and working practices. This led to difficulties, particularly when attempting to carry out a multi centre study [5]. Multi Centre Research Ethics Committees (MRECs) were established in 1997 in an attempt to streamline the process. MRECs were intended to replace LRECs for studies involving five or more sites. However as local issues may have ethical implications, opinions on local issues were still required from LRECs, leading to dissatisfaction

within the research community and to a perception that MRECs had increased bureaucracy and not decreased it at all.

In 2000 the Central Office for Research Ethics Committees (COREC) was established, in a further effort to streamline processes across all UK Ethics committees. One of the achievements in this regard was the establishment of a generic application form to be accepted by all ethics committees within the National Health Service (NHS). The EU Clinical Trials Directive was implemented into UK law by the Medicines for Human Use Regulations 2004. The aim was to standardize conduct of clinical trials across all European Union (EU) member states. With regard to ethical approval, the Directive required a standardized process across the UK for ethical approval of clinical trials, with an ethical opinion to be received within 60 calendar days from submission. This single ethical opinion was to apply to every UK site. In 2007 COREC was replaced by the National Research Ethics Service (NRES), part of the National Patient Safety Agency (NPSA). As well as continuing the work of standardizing practice, NRES was charged with improving the efficiency with which projects were handled. This included the establishment of the Central Allocations Service – a single contact point for registering a project at any UK ethics committee, as well as the appointment of Research Ethics Advisors to screen applications at an early stage and the introduction of a fast track procedure for studies deemed to have no material ethical issues [6].

Despite these efforts there were still criticisms of the ethics and governance processes within the UK, which were neatly summarized by the Academy of Medical Sciences [8]:

- Excessive approval times
- Duplication of work
- Lack of consistency in regulatory requirements across different sites
- Inappropriate constraints on access to patient data
- Lack of proportionality
- A healthcare culture that fails to fully appreciate the value of research.

Note that the first three relate purely to efficiency of what systems are in place to oversee research while the others question the values which undergird those institutional structures. In response to criticisms of efficiency, various attempts have been made by the National Institute of Health Research (NIHR) to streamline ethics and governance processes. In this article we lay out these attempts and consider whether they have been successful. We will finally examine the future planned changes to the management of clinical research in the UK.

## Research infrastructure

In 2006 the Department of Health outlined its vision for making the UK a leading force in healthcare research. The white paper 'Best Research for Best Health' [7] introduces the notion of 'bureaucracy busting,' – 'streamlining administrative processes to create a vibrant and efficient research environment.' A radical overhaul of the UK Research and Development (R&D) infrastructure within the National Health Service (NHS) was supposedly implemented to this end. Six topic specific research networks were introduced to promote and streamline research in areas of research priority for the NHS. These six topic specific networks comprized of Cancer, Dementia and Neurodegenerative Diseases, Mental Health, Diabetes, Stroke, Medicines for Children and Primary Care. Comprehensive Research Networks were designed to facilitate other high quality research studies falling outside of the topic-specific networks and to improve governance and research management functions in defined geographical areas across England.

## The administrative changes

This overhaul of the research infrastructure has been accompanied by changes to administrative systems, which were intended to ensure that ethics systems and governance processes were

transparent for researchers and more consistent across ethics committees which review proposed research protocols, and NHS Trusts which host the research and which might also sponsor them. Crucially, these administrative changes were designed primarily with efficiency in mind. The Integrated Research Application System (IRAS), for example, was introduced as the interface between researchers, ethics committees and research governance offices. IRAS aims to introduce standard ethics and research governance forms, ensuring that the transition between researcher, ethics committee and local R&D office is smooth. To avoid duplication any information entered in one form will automatically be updated on any other forms within IRAS where this information is required.

As part of this system, the Co-ordinated System for Permissions (CSP) was introduced to ensure that NIHR portfolio studies are processed in a clear and consistent manner by R&D offices, and in line with clear operating guidelines. To avoid unnecessary duplication, CSP divides governance checks into global and local checks. Global checks (eg ensuring that the study has ethical approval, that funding arrangements are sound and that a sponsor is in place) are carried out once, by the lead site.

## A more efficient system?

It was hoped that these changes would reduce unnecessary duplication, thereby reducing approval times and maybe even increasing participant recruitment. However, as the Academy of Medical Sciences Report [8] makes clear, there remains dissatisfaction within the research and R&D community about the ways in which these processes have been implemented while their overall aim was sincerely welcomed. In part, the process struggles to keep up with the constantly evolving legislative environment [9]. A standardized process is constantly in flux where regulatory requirements are changing, and standards of practice are expected by a number of different regulatory bodies. The purely administrative burden on researchers may not thus have been significantly reduced for some types of study, subject to such a changing regulatory environment. However, the burden may not have been as great as it might have been given the old system.

The measure of how effective these interventions have been in reducing bureaucracy is controversial, since criteria for measurement are not always clear or agreed. For example, at what point should metrics be taken to measure approval times? How does one measure the length of time each step in the process has taken? Who is responsible for each step in the process? This uncertainty means that performance metrics need to be treated with a degree of caution.

Nonetheless encouraging data has emerged from the NorthWest Exemplar Programme which is a restructured method of approval for commercially sponsored studies through NHS Trust R&D [10]. This programme is the result of a collaborative effort by the NIHR, NHS and pharmaceutical industry in the North-West of England. It ensures that studies are fully prepared and receive local R&D approval according to a clear model, based on standardized processes, templates and strict timeframes for the completion of an agreed set of core approval steps. The most recent report of the programme shows a reduction of approval times for those studies entering the programme which is truly an encouraging reflection of streamlined processes [11].

But could it be that these achievements in the North West of England might reflect a reduced workload in this area, compared with the rest of the UK? Indeed, it is now well-documented that industry has been relocating their studies to other countries, stating that the UK approval systems are bureaucratic, cumbersome and expensive [12]. The recent closure of Pfizer at Sandwich, Kent in the UK may be further evidence of this trend.

However, the number of patients recruited into UK clinical trials more than doubled between 2007-08 and 2009-10 [13]. Also, according to the most recent published data, the

number of patients recruited into industry studies on the NIHR portfolio has increased by 2486% since last year [10]. These are encouraging signs, suggesting that the streamlining efforts have actually resulted in the UK becoming a more attractive prospect for the pharmaceutical industry overall.

Alternatively, one could argue that the efficiency of the R&D process is not in itself the major draw for commercially sponsored research. Industry sponsors may pick particular well known and respected researchers to undertake the work and so be prepared to wait a while longer to work with their host institution

## Further planned changes

Despite these positive achievements, the general feeling within the research community is that there remains much work to be done [2,3]. The Academy of Medical Sciences was commissioned by the government to conduct a review of the current ethics and governance systems and to make recommendations for continued improvement [8]. One of these recommendations is to establish a 'Health Research Agency' which would serve as a central point for ethical applications, would coordinate all regulatory checks only the once, and whose approval which would apply over the entire NHS.

In addition the number of checks needed for a single project, the level of stringency of the ethics and governance oversight would, it is hoped, be proportional to the risks posed by the study. Around the same time as the Academy of Medical Sciences published their recommendations, the Research Support Service (RSS) Framework was introduced by the NIHR [14]. The framework was published in September 2010 to provide a national set of standards for approval and governance of all studies in the NHS. It is claimed that these will 'harmonise and streamline complex local research management and governance processes' and provide proportionate risk management processes which will assuage the fears of risk averse local Trusts. The Framework is currently merely guidance but the standards could eventually be linked to the Care Quality Commission's Standards for Trusts and become compulsory [14], [Kerrison 2011, personal communication]. The Framework has three elements:

- An operational capacity statement: This is essentially a contract between the NHS Trust and the R&D Department. It will outline the services that R&D is contracted to provide and the money that the Trust is contracted to pay to receive this. In this way the feasibility of studies at site should be clearer from the outset.
- An R&D Study Readiness Assessment and Planning Tool: The readiness assessment and planning tool are designed to form a feasibility assessment of whether or not the Trust can support a particular study. Again, in this way the feasibility of studies at site should be clearer from the outset.
- A suite of SOPs (Standard Operating Procedures) for the set up and control of studies is recommended, to standardize local practice. A key focus of the SOPs will be that of proportionality.

The Academy of Medical Sciences recommendations and the RSS Framework are very new and it remains to be seen how they will be applied in practice. Also, some aspects seem to be mutually exclusive. For example it is not clear how the Health Research Agency's role of centralized processing will relate to the RSS SOPs.

Once approved, these changes would have the added advantage of allowing local NHS sites to concentrate on monitoring of studies once recruitment has begun which they have had to neglect in the past.

## Conclusion

It appears that the streamlining efforts by the NIHR have resulted in some positive outcomes. However the Academy of Medical Sciences Report [8] makes it clear that many still feel that the process is overly bureaucratic and

burdensome. Further changes to the regulatory infrastructure seem likely in the near future. These are likely to lead to a greater consistency between the risks posed by a study and the stringency of its ethical and governance review.

## Competing interests

Stuart Braverman and Rajinder Sidhu are both employed by the UCL / UCLH / Royal Free Joint Biomedical Research Unit and are responsible for Research Governance.

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