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United Kingdom research governance strategy

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The new research governance strategy marks a radical overhaul of the arrangements for medical research in the NHS and academic institutions with far reaching implications for all those taking part in research. The days of registrars and consultants singlehandedly doing research projects are over

As part of the reforms to NHS research and development strategy announced in 2000, the Department of Health published a research governance strategy for England.[1] The basic framework governing research in England had remained unchanged since the 1960s. It is based on measures introduced after the second world war to protect research subjects, such as international convention law,[2] international codes of conduct for the medical profession,[3] and legal regulation of the pharmaceutical industry. However, the introduction of greater commercial interests into the NHS through research networks involving both public and private interests challenge these protective arrangements. We consider whether the new Research Governance Framework for Health and Social Care[1] and the new arrangements for research ethics committees will provide counterbalance to these interests.

Commercial potential

In our previous paper we discussed the many partnerships and networks springing up with the commercial sector, the lack of clear accountability arrangements, and the potential for conflicts of interest introduced by the reforms of NHS research and development.[4] The involvement of commercial interests was also promoted in the Health and Social Care Act 2001. This encourages NHS institutions to exploit the intellectual property derived from research on patient data and tissues for commercial gain. The head of research for GlaxoSmithKline described the NHS as one of the most underexploited resources of genetic data and tissue in the world,[5] which illustrates the large potential for conflicts of interest. The risks posed by maximising the economic potential of research on human subjects have been partly ameliorated by enhanced legal protection—for example, through the wide ranging Human Rights Act 1998 and the Data Protection Act 1998. Specific research areas are also becoming the subject of protective legislation—for example, the use of ionising radiation in research,[6] a new Human Tissue Bill, and regulation of clinical trials. Such legislation not only replaces professional codes of medical ethics with legal statute but places legal requirements on institutions, including NHS trusts.[7 8]

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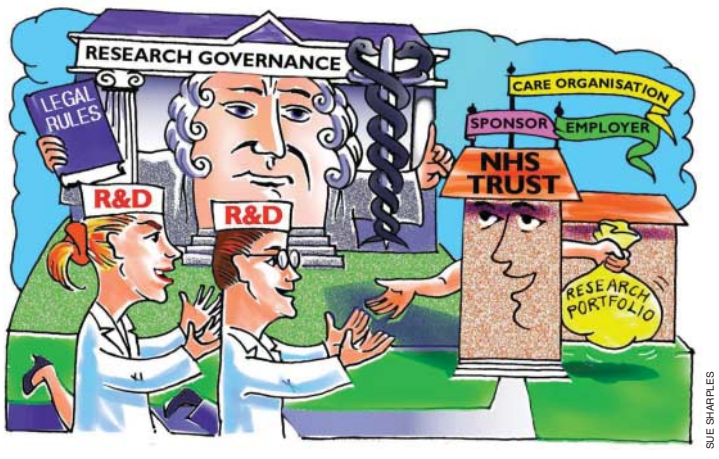

Main roles and responsibilities under research governance

Role	Responsibilities	Examples
Sponsor	Overall responsibility for ensuring adequacy of design and management including: Assessing quality of research Ensuring appropriate arrangements for conduct and monitoring the research	Main funding bodies (eg Medical Research Council), research charities, universities, NHS trusts
Funding organisation	Financial support for project	Department of Health, Medical Research Council, charities
Host or care organisation	Ensures that research conforms to framework	NHS trusts
	Infrastructure	
Employer (of investigators)	Ensuring research is properly managed and monitored	Universities, NHS trusts
Principal investigator	Design and conduct of study, reporting and dissemination of findings	Clinicians

Research governance framework

The research governance framework sets in place mechanisms for ensuring that research complies with all professional, ethical, legal, and scientific standards. The table gives the main roles and responsibilities for research governance. The framework sees the NHS as just one of many stakeholders in a healthcare economy. In line with this, the arrangements for overall oversight of compliance with standards are very flexible. The central role in the framework has been allocated to the research sponsor. The sponsor is responsible for ensuring that the design of the study meets appropriate standards and that systems and policies are in place to ensure appropriate conduct and reporting. The sponsor and all host organisations will need to agree with the funder how the new costs of sponsorship will be met. This will include the cost of implementing and maintaining the systems and controls required for research governance across all organisations conducting research.

From April 2004, all research conducted in care organisations must have a research sponsor. Large funders, such as the Medical Research Council, are expected to take on the sponsorship role, but other organisations or small charities are unlikely to do so. Sponsorship may be delegated to universities or the NHS or contracted out to another organisation at a cost to the funder.

The primary role of NHS trusts in the framework is as care organisations. Care organisations must ensure that all research on NHS patients, their tissue, and their data, as well as research on NHS staff and research carried out in NHS premises, is conducted according to the framework.[9] This means that research must have an appropriate sponsor. In addition, adequate arrangements must be in place to ensure that the conduct of the study complies with all the relevant standards required for a favourable independent scientific review. In practice, this means that all research has to be approved by the chief executive of the relevant NHS trust. When the trust is also the sponsor, it must have in place its own systems for independent scientific review and monitoring. If the trust also employs the principal investigator, it will have additional responsibility for providing training and education for researchers and ensuring that principal investigators properly manage the research through audit and monitoring. Clearly, a conflict of interest could arise between a trust's duty to monitor and control research in the patients' interests and its requirements to generate income from research to balance finances.

New roles for ethics committees and public

The framework also modernises regulation of research by insisting on public participation in all aspects of the process. Recently, major advances have occurred in public involvement in research with charities. The Alzheimer's Society paved the way by allowing its members to prioritise research projects and to monitor their conduct.[10] Yet the new arrangements for research ethics committees seem to run counter to these developments because they largely ignore the need for public accountability and involvement. To ensure they comply with the new European Union clinical trials directive, research ethics committees are being drawn into a new centralised structure overseen by a new organisation, the Central Office for Research Ethics Committees. From May 2004 they will become the responsibility of the new United Kingdom Ethics Committee Authority.[4]

Traditionally, research ethics committees have been responsible for scientific quality, safety, and ensuring that the risks of the research have been adequately communicated to research subjects.[11] As safety and scientific quality will be the responsibility of the research sponsor or care organisation, the new committees will have responsibilities only for conveying the risks to research subjects and for other ill defined ethics. Although such committees will be independent of NHS trusts, the arrangements for ensuring the expertise of members, finance, and accountability are unclear. Without resources, independence is not guaranteed. In addition, despite a background of public distrust in scientific research[12 13] and the current vogue for public involvement, ethics committees will meet in private and no requirements have been placed on the new ethics authority to be responsive to research subjects. Research ethics committees were part of the self governing arrangements for the medical profession, but now that they are free of any institutional base and professional control and in the absence of adequate safeguards they risk capture by industry or governmental interests.

Dilemma for NHS trusts

The Department of Health is pressing ahead with requirements for NHS trusts to implement all aspects of the framework by 2004. However, as the following case study shows, this is far from straightforward. Implementation is not entirely within the NHS's control and is complex for trusts with large research portfolios.

Case study

Our trust has an annual income of over £350m, of which £37m is support funding for research and development. It has the second largest research portfolio in the United Kingdom and at any one time has over 1100 ongoing projects, with over 370 new projects approved each year. Since 1997, the trust has undertaken projects in partnership with over 350 organisations, including one special partner, University College London. The current projects have over 750 principal investigators, most of whom have a substantive employment contract with University College London, not the trust. In addition, only 5% of our research portfolio is currently regulated—that is, only 5% involves commercial clinical trials. The remaining 95% of the portfolio has no identified sponsor.

In relation to the research governance framework, the trust has multiple roles as an employer, care organisation, and potentially as sponsor. Even if sponsorship arrangements are agreed with other institutions, the trust will be in a position to support research only if funders ensure the costs of sponsorship and supporting clinical services are reimbursed adequately.

If research projects are conducted with other institutions, potential exists for overlap and fragmentation. To clarify such arrangements, the Department of Health requires that NHS trusts negotiate a framework agreement between all their research partners setting out the division of responsibilities. However, with over 350 potential research partners, this is no small task, and accountability and funding responsibilities will be difficult to establish. The Department of Health requires that the trust put in place systems for monitoring the conduct of research—complaints systems, tracking of adverse events, and audits. But it is unclear how the monitoring of over 1000 projects will be resourced. New resources will be required to ensure that the arrangements for monitoring the conduct of the research are transparent and adequate to protect patients, safeguard the trust's reputation, and avert litigation.

In an attempt to ensure that the research governance arrangements do not become fragmented, our trust has established a joint research and development governance committee with membership from University College London and the trust and reporting to the trust's board. It is also working to establish a common pool of resources to take forward the work. The remit of the committee is to jointly develop the framework agreement and related policies, as well as to put in place the mechanisms to prioritise funding even where sponsorship arrangements are agreed. A large part of research governance activity will focus on training and education to ensure researchers understand the rules and are competent to undertake studies. Pilot audits of informed consent forms, scientific quality, and data protection policy have also been undertaken. The committee is also considering how to use performance appraisal and employment contracts to enforce the requirements for research governance if training and education fails.

The trust has worked with the four ethics committees to harmonise policies for researchers. This is becoming increasingly necessary as new legislation means that responsibilities can no longer be neatly divided between the research ethics committees and NHS trusts. For example, under the Data Protection Act 1998 the trust is required to ensure that the patient information sheets comply with the act. Such negotiation will be more difficult as ethics committees are drawn into a central structure.

Summary points

- Research governance means a change of emphasis from professional codes of conduct to legal rules
- Research ethics committees have a more limited role and are drawn away from the profession into a new centralised structure
- NHS trusts with large research portfolios have multiple roles—sponsor, care organisation, and employer
- Negotiations and written framework agreements are needed to establish responsibilities for governance and its funding between many different research partners
- Researchers have more obstacles to getting started but should get better training

Conclusion

The reforms of NHS research and development mark a new era in clinical research. The research governance framework has the potential to strengthen the protection of research subjects by sharing responsibility between the medical profession, academic and healthcare institutions, and the law and by increased public participation. However, the problem still remains that without clear lines of accountability the new structures for research and current proposals for foundation trusts could fragment research governance arrangements and weaken accountability to parliament. Research governance imposes new duties of care in the education and training of researchers and monitoring of research that have considerable financial implications for all organisations hosting research. Principal investigators, particularly new researchers, will face more obstacles to getting started as they will have to obtain formal approval for their study not only from a research ethics committee and the care organisation but also from a sponsor. They will also have to demonstrate to the NHS trust that they have secured the necessary resources to ensure the financial viability of all research relating to patients under its care. But to offset this there should be greater opportunities for training and education in all aspects of research.

However, regulators throughout Europe have already voiced concerns that the drive to make medical research an engine of economic development will compromise safety.[14] The new climate presents a considerable challenge to the protection offered by the new research governance framework. Faced with increased commercial imperatives universities, NHS

trusts and researchers could risk distorting the prioritisation and conduct of research.[15] As in the United States,[16 17] such institutions will tread a fine line between maximising economic rewards and protecting the research needs and rights of their patients.

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Corrections and clarifications

Patients' voices are needed in debates on euthanasia
A couple of errors slipped into this Education and Debate article by Yvonne Y W Mak and colleagues (26 July, pp 213-5). Omission of two words changed the focus of a reported study: Lavery and colleagues studied the origins of desire for medically assisted death in HIV, not the origins of such deaths (see the second paragraph in the section "Research data on euthanasia"). In the figure, the labelling for the bottom curve was rather confusing: it should say "assumed wholeness before cancer"(not "assumed before cancer wholeness").

US agrees to cheap drug imports—as Florida officials break fake drugs ring
We failed to check the status of the politician Rosa DeLauro, who was mentioned in this news article by Fred Charatan (2 August, p 246). She is indeed a Democrat representative but she's from California (not Connecticut, as we stated).

Cultural safety and the health of adolescents
In this Personal View, we mistakenly published the names of only two of the three authors, and we also put these two names in the wrong order (23 August, p 457). The complete list of authors, in the correct order, is: Nicola J Gray, Frances A Hughes, Jonathan D Klein. The error has been corrected online. We apologise to the authors for this mistake, which arose from an electronic glitch when the article was being typeset and which was not picked up by the editorial team.