



# postnote

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## ETHICAL SCRUTINY OF RESEARCH

Recent legislation such as the Data Protection Act, Human Tissue Bill and Mental Capacity Act emphasize the importance of ethical scrutiny of research on human participants. Despite this, the process of ethical review is controversial. The UK system for ethical review is complex and varies between different types of research. A recent review of NHS research made a number of recommendations for changing the ethical review process. This note describes the various systems for ethical review of research involving humans and outlines key issues with the existing system.

### Background

#### Ethical issues in research

Participation in research can involve some risk or burden on the part of the research participant. Risks may be physical, psychological or emotional; burdens may be financial or temporal. Ethical review is intended to ensure that such risks are recognised and managed by researchers and to protect research participants from abuse or exploitation by researchers (see box 1). It usually involves assessing the risks to individuals, and may also include wider consideration of the impact of research on communities and social groups.

#### Types of research involving humans

Research involving humans can be divided into:-

- *Biomedical research*, a general term for work in fields like medicine, genetics, physiology or biochemistry, that may involve research on people (e.g. gene therapy). A subdivision of this is *clinical research*, often concerned with the development of a drug, medical device, or new surgical technique. *Clinical trials* are a specific type of clinical research in which new medicines or therapies undergo testing on humans to assess their efficacy, safety and quality;

#### Box 1: Ethical and Legal Foundations

The Nuremburg Code (1947) and the Helsinki Declaration (1964 and revisions) form the basis for many ethical principles used in current research governance frameworks. These principles are generally accepted to include:

- Informed consent and non-coercion of subjects;
- Confidentiality and data protection;
- Utility and quality of research;
- Research that does not harm the participants;
- Respect for human dignity of participants.

In addition to ethical appraisal by research ethics committees, a number of laws protect research subjects:

- Data Protection Act 1998 protects patient confidentiality and restricts the use of individuals' data;
- Human Tissue Act 2004 defines conditions for the removal, storage and use of human organs and tissue;
- Mental Capacity Act (2005) delimits an individual's right to consent to research or treatment, and the grounds on which a third party may consent to research upon an individual;
- EU Clinical Trials Directive 2001 is outlined in box 3.

- *Social science research* which is concerned with the study of human society and relationships. *Psychological research*, mostly concerned with the study of individuals, may overlap clinical and social science research in its approach. It extends from the society-orientated spectrum of social psychology to the individual-orientated focus of experimental psychology;
- In addition, social care and health services research may need special scrutiny because they can involve vulnerable research subjects such as children or the mentally ill.

#### Ethical scrutiny of research

The UK has no single, national ethics committee that undertakes research appraisal. Instead, there is a

centrally-administered system of regional ethics committees that assess any research on humans that uses NHS patients, resources, or that accesses participants via the NHS (referred to here as 'NHS research'). The scrutiny of non-NHS research remains the responsibility of the funding body or host institution. Researchers submit written proposals detailing their research to Research Ethics Committees (RECs). The REC then assesses each proposal individually to ensure it accords with accepted ethical practice (see box 1).

### Clinical/medical research

#### *Research in the NHS*

Ethical scrutiny of research involving humans in the NHS is undertaken by a system of RECs (box 2). The Central Office for Research Ethics Committees (COREC) was established by the DH in 1997 to provide operational support and advice to NHS RECs. In 2001, COREC issued the 'Governance Arrangements for NHS Research Ethics Committees' (GAfREC). These define the remit and accountability of RECs, and give guidance on membership and the process of ethical review.

#### **Box 2: NHS Research Ethics Committees**

NHS RECs are divided into local research ethics committees (LRECs) and multi-centre research ethics committees (MRECs). These committees were established to scrutinise research involving people that uses any type of NHS resource. LRECs review research proposals according to where the research is due to take place. MRECs were established in 1999 to streamline the review process by reviewing research taking place in five or more 'domains', rather than requiring review by each LREC. Research taking place in less than five domains still required review by a LREC in each domain. These arrangements have now been superseded by the 'single ethical opinion' introduced by the Clinical Trials Directive (see box 3).

Clinical Trials are regulated by the EU Clinical Trials Directive (see box 3). This requires a single ethical opinion to be given on a clinical trial in any Member State. In May 2004, the UK Ethics Committee Authority (UKECA), composed of UK health ministers, was created as the body responsible for establishing, recognising and monitoring RECs to review clinical trials of medicines under the Directive. UKECA has recognised a number of (mostly NHS) RECs to review clinical trials proposals; COREC acts for UKECA in providing advice/assistance to these committees. Over 80% of applications to NHS RECs relate to research other than clinical trials. In March 2004, COREC introduced Standard Operating Procedures (SOPs) for NHS RECs. The SOPs implement the requirements of the Directive. Only one REC application is now required for any clinical trial, and this is made on a standard application form. COREC decided that the SOPs should also apply to all other NHS research reviewed by NHS RECs.

#### *Non-NHS research*

Clinical trials in private facilities are required by law to receive approval from a recognised REC. Other private sector research on people may be reviewed by NHS RECs, although there is no statutory obligation for this. Many proposals will still pass through institutional ethics

#### **Box 3: The EU Clinical Trials Directive**

In 2001, the European Union announced new requirements for the conduct of clinical trials among its member states, in the form of the Clinical Trials Directive. The Directive covers "the conduct within the EU of clinical trials on medicinal products involving human subjects." It required Member States to establish ethics committees on a legal basis, and encompasses every clinical trial on medicinal products, regardless of the sponsor or funding body. This means that even clinical trials that fall outside the NHS REC system in the UK are required to receive approval by an ethics committee; the Directive does not distinguish between commercial and non-commercial trials. The Directive was translated into UK statutes in the form of the Medicines for Human Use (Clinical Trials) Regulations 2004, which came into force on 1<sup>st</sup> May 2004.

committees which may vary widely in their remit, membership and process. Currently there is no equivalent oversight body to COREC for non-NHS RECs. Many universities now have their own ethics review committees that scrutinise research proposals: a recent study found that four fifths of UK universities have their own REC<sup>1</sup>. Major funders of research, such as the Medical Research Council (MRC) and Cancer Research UK, require that proposals for research involving people, data, or tissue receive a favourable opinion from a research ethics committee before funding is provided.

### Social research

Social research that involves NHS resources, facilities, staff or data must be subject to ethical review by the NHS REC system. Non-NHS projects may have to be approved by university or institutional ethics committees, although there is no statutory requirement for this. Social and psychological researchers have emphasised the need for ethical review of their research in order to retain public confidence, and participation, in projects. Recent years have also seen an increase in the use of social research data in policy, which has led to an increased awareness of the need for good ethical and professional research practice.

Until recently, there were few attempts to formulate a single ethical code for social research. However, this has changed with recent developments including:

- Publication of the DH's Social Care Implementation Plan and of the Department of Work and Pensions' mission statement outlining its approach to ethical issues in research.
- Pending publication of the Government Social Research Unit's framework for ethical assurance of Government-commissioned social research, intended to ensure consistency of standards in social research across Government departments. The Scottish Executive is currently conducting a similar review.
- Publication of the Economic and Social Research Council's Research Ethics Framework for social science research<sup>2</sup>.

## Issues

### Key Principles

COREC's Standard Operating Procedures (SOPs) are publicly available and provide procedural guidance to

NHS RECs on matters such as membership requirements, but do not offer ethical guidelines. As a result, there can be wide variation between committees in what is considered 'ethical' research practice. A similar situation exists among institutional non-NHS RECs. Researchers applying to more than one REC find such variation frustrating and time-consuming.

#### *Guidance on ethical conduct*

Professional associations such as the British Psychological Society, the Royal College of Physicians, or the Social Research Association, provide ethical guidelines for their members. The MRC also publishes an extensive series of ethics guidance that is widely used. Although many of these are based on the principles of the Nuremberg Code and Helsinki Declaration, there remains confusion amongst researchers, particularly those who span more than one discipline, around which ethical standards to follow. Where standards conflict or contradict, it is hard for researchers to decide which are the 'right' ones to follow.

#### *Who Benefits?*

Written standards do not always make it clear whose interests ethical scrutiny protects – participant, researcher or industry. The group Consumers for Ethics in Research (CERES) notes that SOPs state that individual participant's interests and well-being are of primary importance. CERES believes that many RECs favour the researchers' interests over the subjects', and few have systems for patient/user feedback or involvement.

#### *Do no harm?*

A number of groups, including the Royal College of Psychiatrists and the Genetics Interest Group suggest that the central tenet of ethical review – that research should not harm the participant – is itself problematic, and may jeopardise research that benefits a community more broadly. For example, much social and psychological research is intrusive and may involve difficult or emotionally disturbing situations, such as asking a participant to recount experiences of abuse. With the participants' consent, however, such research can be extremely valuable. The Royal College of Psychiatrists and the Social Research Association suggest that there should be greater emphasis on the provision of care to research participants both during and after the research process, rather than on avoiding difficult or disturbing situations altogether.

#### *Applied Ethics*

Practical application of ethical principles can sometimes restrict the conduct of research. For example, the Alzheimer's Society has suggested that REC principles are too restrictive for dementia research. They note that research proposals for work on subjects with dementia is frequently rejected by ethics committees as the status of the subjects may not allow the research protocol to meet ethical standards for informed consent. However, the Society points out that despite this, many patients with dementia or their carers are keen to participate in research on the grounds of its long term benefit.

Similarly, patient confidentiality is cited as a key ethical principle that must be adhered to. The Genetic Interest Group has noted that maintaining patient confidentiality in studies of rare genetic diseases which affect tiny numbers of the population is nearly impossible. Research proposals for such work will often be rejected by RECs for failing to ensure patient privacy, despite the consent of the patients.

#### *Student projects*

The conduct of student projects within health and social care also presents ethical problems. Student projects are intended to increase the student's understanding of scientific methods rather than to generate new knowledge.<sup>3</sup> Because the main benefit of the research is to train the student, many student projects will contravene a key ethical criterion, that research should prioritise the well-being of the research subject. Yet student research forms a necessary and useful part of training for future researchers and carers. A recent DH review of NHS RECs recommended that surveys and other non-research activities (such as student projects) should not fall within the remit of NHS RECs<sup>4</sup>.

#### **Diversity of research reviewed**

The requirement that all research involving NHS resources should be approved by an NHS REC has been questioned. Although the principles underlying ethical review of research should be the same in both health and social care, the academic disciplines differ. Social research protocols differ from clinical and medical research protocols in scope, content and intent. Social research proposals may be rejected or delayed by NHS RECs because the predominantly clinically-trained membership is not familiar with these differences.

For example, proposals for research into social care involving NHS patients, staff or resources must receive approval from the NHS REC system. However, this system has proven to be unsuitable for many social science research proposals as different social research methodologies create misunderstandings when reviewed by NHS REC members. Establishing MRECs with specific research competencies of members, such as a focus on social research, may be one way of avoiding this. The DH is currently conducting a review of ethical scrutiny of social care research with the intention of providing a coherent national system of social care ethical review.

#### **Membership, funding and training**

REC members participate on a voluntary or expenses-only basis. DH recommends that NHS RECs meet at least once a month. However, the growing focus on, and subsequent burgeoning of, ethical scrutiny means that RECs are increasingly busy. The DH review of NHS RECs has recommended a switch to a system of fewer, more active RECs whose members are paid, either directly or through compensating their employers.

Training provision varies widely between RECs. COREC funds area-based training and organises some training centrally. New members are expected to attend an introductory course in research ethics and to attend a

minimum of two days' training a year, but this is difficult to enforce. Training for members of institutional RECs is at the discretion of the committee. The DH review of NHS RECs noted that "all members need to be supported by appropriate training"<sup>4</sup>. However, training providers feel under-supported by COREC, which has not accredited courses or listed them on its website. Training providers are not guaranteed that LREC members will be funded to attend courses from year to year, which makes investment in long-term training strategies difficult.

### Accountability and transparency

Most RECs meet in private and there is no requirement for any RECs, including NHS RECs, to make minutes of meetings publicly available. As a result, rather than providing a public forum for the accountability of researchers,<sup>5</sup> RECs are open to accusations of coercion by researchers. While the DH review of NHS RECS recommended drawing REC membership from "a wider mix of society", some suggest that the actual role of lay members is too vague. In practice they may not be recognised by expert members of RECs as credible judges of research<sup>6</sup>.

It is widely acknowledged that RECs need to maintain independence from political, institutional, professional or market influences. However REC members are often drawn from groups with particular interests in health and social care issues. Although members are appointed as individuals and do not represent those groups while on the committee, the potential for a conflict of interest exists (see box 4). It has also been suggested that maintaining REC independence from capture by industry and governmental interests is difficult under the new centralised COREC system<sup>7</sup>.

#### Box 4 Composition of NHS RECs

COREC guidelines state that an NHS REC should consist of a maximum of 18 members, of which at least a third should be 'lay' members who are independent of the NHS; at least three members must be independent of any organisation where research under review is likely to take place. At least half of the lay members must be people who are not, and have never been, health or social care professionals. Expert members should be selected to ensure a range of expertise within the REC that includes: relevant methodological and ethical expertise in clinical, non-clinical, and qualitative research methods; clinical practice; statistics and; pharmacy. In addition, the REC should have a balanced age and gender distribution, with members from black and ethnic minority backgrounds and those with disabilities.

### Complexity and inconsistency of ethical review

The Government Social Research Unit's framework for ethical assurance of all social research conducted by or for the Government is an attempt to produce an umbrella ethical framework for all social research conducted by government departments. There are few other attempts to unify the various systems of ethical review currently in place, resulting in a disparate and confusing system for both researchers and potential research participants.

A key criticism of ethical review within the NHS has been the time and effort it takes from researchers to pass the

process and the inconsistencies between different RECs, particularly at a LREC level. The recent DH review of the operation of NHS RECs recommended that the "issue of excessive inconsistency...should be addressed by concentrating on the provision of appropriate training, and on capturing and sharing good practice". It further noted that the newly introduced system of quality assurance by peer review among committees and their members should be further developed<sup>4</sup>.

The Clinical Trials Regulations have imposed a limit of 60 days for a REC to reach a decision on a proposal. COREC has introduced a standard application form for all research proposals to harmonise the application process. However, the DH review of NHS RECs noted that the form should take more explicit account of differences between types of research and should also give more space and attention to ethical issues<sup>4</sup>.

Researchers often comment on the unnecessary complexity of the ethical review process. Members of the Academy of Medical Sciences, for example, have criticised the complexity and bureaucracy of the ethical framework in the UK. There is a lack of coordination between key bodies and disparate pieces of legislation attempting to regulate research ethics, and duplication of review can occur. Other commentators point to the examples of Canada and Australia, both of which have introduced regulatory systems that apply to all research involving people and that are co-ordinated across all research disciplines.

### Overview

- The system for ethical review of research involving humans is complex and varies considerably between medical, social and psychological research, NHS and non-NHS research. There is a clear need to reduce the complexity and to improve coordination of the system.
- Concerns have been raised about inconsistent ethical standards, inappropriate ethical review, lack of transparency and co-ordination and efficiency of the various ethical review systems.
- New frameworks in development should ensure that duplication of ethical scrutiny is avoided.

### Endnotes

- 1 Tinker A & Coomber V *University Research Ethics Committees* (Nuffield Foundation 2004)
- 2 ESRC *Research Ethics Framework* (May 2005) [www.york.ac.uk/res/ref](http://www.york.ac.uk/res/ref)
- 3 Working Group on Ethical Review of Student Research in the NHS *The Ethical Governance & Regulation of Student Projects: A Proposal* (2004)
- 4 [www.dh.gov.uk/assetRoot/04/11/24/66/04112466.pdf](http://www.dh.gov.uk/assetRoot/04/11/24/66/04112466.pdf)
- 5 Ashcroft R & Pfeffer N, *BMJ* 2001;322:1294-1296
- 6 Dyer S *Health & Place* 2004; 10: 339 - 348
- 7 Kerrison S, McNally N, & Pollock AM *BMJ* 2003; 327: 553 – 556

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