NHS Research Ethics Committees (RECs) are convened to provide independent advice on the extent to which proposals for research studies to be carried out within the NHS comply with recognised ethical standards.

The primary purpose of a REC when considering the proposed study is to protect the rights, safety, dignity and well-being of all actual or potential participants. Ethics review is one of a series of safeguards intended to protect individuals. They are described in the Research Governance Framework for Health and Social Care. Research governance is intended to enable relevant research of good quality, as well as to forestall inappropriate research.

Ethical approval is therefore only one of the requirements for initiation of a research proposal. The Advisory Group was asked to report on the operation of NHS Research Ethics Committees and on the interface with other research approval processes. Its terms of reference are at Annex 1.

The report is set out in five sections and three Annexes:

1. Background information
2. The conduct of the Review
3. The perceived problems, with comments
4. Conclusions
5. Recommendations
Glossary

COREC  Central Office for NHS Research Ethics Committees
DH    Department of Health
GAfREC  Governance Arrangements for NHS Research Ethics Committees
LREC  Local Research Ethics Committee
MREC  Multi-centre Research Ethics Committee
NPSA  National Patient Safety Agency
PIAG  Patient Information Advisory Group
REC  Research Ethics Committee
RHA  Regional Health Authority
SHA  Strategic Health Authority
SSA  Site Specific Assessment
UKECA  United Kingdom Ethics Committee Authority
1. Background information

1.1 Local Research Ethics Committees

Local Research Ethics Committees were formally established in the NHS in England through publication of HSG (91)5, which required all Health Authorities to establish at least one. Many RECs were already in existence, especially those closely associated with the more active research sites in the NHS, and these committees were modified where necessary to fit the new requirements. This led to there being over 200 RECs.

They were not in any way co-ordinated, used differing application processes, had differing meeting schedules, and sometimes differing approaches to various research issues. The level of support from (and accountability to) their appointing authorities were equally variable.

A researcher who wished to carry out a study in more than one site might have had to apply to a large number of such LRECs. In one example brought to our attention over 240 applications had to be made.

Members of RECs were, and still are, volunteers, but receive reasonable expenses.

1.2 Multi-centre Research Ethics Committees

Multi-centre Research Ethics Committees (MRECs) were initially established in 1997, through publication of HSG (97)23. One was established in each of the (then) English NHS Regions. There are now 13 in total in the UK.

Since 1997, a researcher who wished to undertake a multi-site study for which five or more REC approvals would previously have been required, could seek one approval from any one MREC, the remit of each of which covered the whole of the UK. (For studies with one to four sites, the relevant LREC approvals were still required).

The establishment of the MRECs introduced the concept of reciprocity amongst RECs. Although not widely accepted initially, most of the REC community has gradually accepted the merits of just one committee giving an opinion on a multi-centre study.
Whilst this simplified matters to some extent, the LRECs were still required to
give their opinion on local matters - which gave rise to much delay, and often
disagreement.

1.3 COREC

In response to continuing problems with the processes around ethical review, and to
help ethics committees prepare for implementation of the European Directive on
Clinical Trials (2001/20/EC), the Central Office for NHS Research Ethics
Committees (COREC) was established in 2000.

Its remit was to work to improve the system of operation of the RECs, and to advise
DH on necessary policy requirements concerning the operation of RECs.

With the abolition of Regional Health Authorities, COREC took on the
administrative functions for MRECs. With the replacement of Health Authorities
by Strategic Health Authorities, it was charged with providing strong management
support for RECs, and became the budget manager. The Strategic Health
Authorities remained the appointing authorities for the LRECs.

COREC acted for the Department of Health in England and also provided a focus
for discussion and collaboration with the relevant bodies and individuals in Wales,
Scotland and Northern Ireland. It undertook most of the development work to
create a common UK system.

1.4 GAfREC

In 2001, the Department of Health issued the Research Governance Framework for
Health and Social Care. Building on work by COREC and representatives of ethics
committees, the Department then issued the related policy document, Governance
Arrangements for NHS Research Ethics Committees (GAfREC).

The aim was to create a comprehensive national system of NHS Research Ethics
Committees, moving on from Local Research Ethics Committees whose
establishment and subsequent development had in some cases tended to make them
rather parochial, strongly influenced by association with particular research
environments, and disparate in direction and quality.

The policy document took forward several quality developments, including more
rigorous appointment and accountability arrangements, and the rationalisation of
the geographical remit of individual committees.
1.5 Other Ethics Committees

NHS RECs had no formal remit to review studies taking place outside the NHS, although they were often asked for their advice on such research.

Some private RECs have been established to review trials of new drugs in healthy volunteers (often called Phase 1 committees), to meet the regulatory requirements for drug trials. There are about 20 of these. The NHS has no direct responsibility for them.

Research on human subjects outside the NHS (and usually non-clinical) also takes place in the University sector; many Universities and Institutes of Higher Education have established their own RECs for this purpose. They do not have authority to review NHS studies. They were not considered further by this Review.

1.6 The EU Clinical Trials Directive

Directive 2001/20/EC was implemented in May 2004. The Regulations implementing the Directive in the UK set a statutory framework for the conduct of clinical trials of medicinal products, both within and outside the NHS. The Directive required EU Member States (including the UK) to arrange for the establishment and operation of Research Ethics Committees for the purpose of review of clinical trials of medicinal products.

The Regulations provide for a single UK-wide opinion for multi-centre studies. They also set a defined time period (60 days), and restrict the previous time-consuming iteration of correspondence between committee and applicant.

To avoid the confusion that would result from having parallel but different operating systems, the UK Health Departments agreed to apply this approach also to all other (non-medicinal) research.

1.7 UKECA

The United Kingdom Ethics Committee Authority was established by Statute through the Regulations that transposed the European Directive into UK law. It comprises the four UK countries. It is the authority through which the UK government discharges its responsibilities for providing an ethics review system under the Directive. Its remit extends beyond the NHS.

1.8 NPSA

As part of the Arms Length Body Review in the summer of 2004, it was decided the National Patient Safety Agency should “take over responsibility for COREC” from April 2005.
2. The conduct of the Review

2.1 The Ad Hoc Advisory group was set up by Lord Warner in November 2004 to report by April 2005. The terms of reference and membership are set out in Annex 1.

2.2 The group met on four occasions, one day of which was to hear oral evidence, and visited COREC. We are grateful to those who gave time to this process. Their contributions have helped us to reach our conclusions.

2.3 The Review noted comments in the medical press and during debates in the House of Lords concerning problems that researchers and others perceived in the overall process of initiating new research. We also received a substantial number of written submissions, primarily from the research community. We are grateful to all those who took the time to contribute and who are listed in Annex 2.

2.4 Many of the submissions we received focused on aspects of the operation of ethics committees, but many were more general in their scope. In particular, there was concern expressed frequently and very strongly about the difficulties encountered with obtaining permission to conduct research in NHS Trusts, as organised through their R&D departments.

2.5 Many of the criticisms reflect pent-up frustration with the operation of the REC system over a number of years, and do not always take account of improvements that COREC has introduced more recently. This is not unusual – for example, if a system is not user-friendly in its early versions, many would-be users will steer clear thereafter and thus be unaware of improvements. Nonetheless, it indicates the need for COREC to ‘market’ the new system.

2.6 Throughout our consideration of the issues we have agreed that the role of Research Ethics Committees is both to protect the interests of human participants in research and to promote research that is of real value. We do not accept the inference of a small number of submissions that research is good in itself and that research ethics appraisal is in some way a distraction from, or unjustified interference in, medical research. Just as the process of research ethics appraisal needs to be better focused and more efficiently carried out, so too researchers, and the research community more broadly, have a responsibility to work towards being better informed about ethical issues – including the importance of good quality medical research and the need to protect potential participants, and the relevant legal and governance responsibilities.
3. The perceived problems, with comments

3.1 The remit of RECs

The remit of NHS RECs focuses mainly on research in the NHS and in Social Care. However, legislative changes are creating a need also to provide for specific requirements for wider ethical review. The Human Tissue Act and the Mental Capacity Bill apply to human research outside as well as within the NHS. While this is outside the scope of this review, we believe COREC and the UK Ethics Committee Authority should propose governance arrangements to ensure consistent ethical review in this wider terrain.

The second aspect of the remit relates to what types of study should be submitted for ethics approval. It was felt, and we agree, that some studies, especially surveys and many studies on NHS staff, could normally be conducted safely without a requirement for REC review. However, researchers need clear guidance on what forms of study need ethical review, and should be able to check with an authoritative source (such as a named Scientific Officer within COREC) about uncertain areas.

3.2 Scientific and ethical review

The evidence submitted to us revealed a common perception that the NHS REC system is dominated by the review of clinical trials, and that the whole system is designed accordingly. Whilst it is true that the changes in the operating system were driven by the need to comply with the Clinical Trials Directive (in terms of single opinion, time frame and limited correspondence), the perception is not accurate - only some 15% of applications are for such trials and half of the committees do not review any trials at all.

Such perceptions seem to have been based on the experience of some applicants who felt that the committees did not understand their research or had preferences for certain clinical research methodologies. While the resulting criticism may be valid, it risks missing the point that RECs are not, and should not be, responsible for detailed scientific review.

Because it is unethical to conduct scientifically inadequate research, the RECs’ role is to be reassured that there has been adequate scientific review of the design. For most applications, this review will have taken place before the application reaches
the REC. We do not believe RECs should function as a secondary form of scientific review; indeed, to do so would have significant implications for REC membership. Where peer review has taken place, the RECs should accept this in all but exceptional cases; if it has not taken place, RECs should be able to refer the application, for scientific review purposes only, to a Scientific Officer based in COREC.

This clarification of the REC role implies that the training of REC members should focus on the core ability to identify and analyse ethical issues in research.

3.3 The operating system

A frequent complaint was about the “increased bureaucracy” involved in initiating research. Such comments were, in reality, as much directed at research governance processes as about RECs, and the interaction of the two needs to be addressed.

We do note, however, that changes such as the requirement for only a single application, the ability to book an agenda slot by telephone, the limiting to one set of supplementary questions, a common UK-wide application form, standard operating procedures for all committees, and standard letters, have all substantially reduced the bureaucracy which existed even two years ago within the MREC/LREC system.

There were favourable comments about the Central Allocation System, which has helped speed up access to RECs for multi-centre research. Better explanation of the overall process on the COREC website would be welcomed.

There is a requirement for the main Ethics Committee to “sign off” the suitability of the local researcher (the Principal Investigator) and the facilities, the so-called “site-specific assessment” (SSA). Currently, the information required is provided by LRECs. We consider that this is cumbersome, and it would appear to add little value to local approval by the host organisation.

3.4 The application form

A major focus of criticism amongst those submitting evidence to us relates to the application form itself. The comments we received need to be viewed against a denominator of some 8000 successfully completed applications since May 2004.
One aspect is the “electronic” nature of the form, which some applicants do not like. There is no doubt that early technical difficulties (especially with the downloadable version) also created considerable irritation.

Another complaint was the length of the form itself. The current form requires a lot of information from the applicant at the outset. Some applicants have found this very challenging.

It appears to us that the design of the form is well-intentioned, provided the applicant completes it on-line, when it is relatively easy to deal only with questions relevant to the study in question. We suggest a review of the accessibility and design of the on-line form would be helpful, focusing on ensuring it is as intuitive as possible.

However, the reality is that many researchers find it inconvenient to work entirely on-line. If they print the form off, they find it large and hard to follow and lose the benefits of dealing only with the sections relevant to their particular application. While we believe that the submission of applications should be on-line, the form design needs to reflect the reality that researchers frequently wish to fill in a draft off-line. A small number of questions at the beginning of the form that would enable ‘customisation’ to take place before printing for off-line use would be helpful.

### 3.5 Repeated requests for information

A wider issue came through strongly in the evidence we received. There is at present no single user-friendly, intuitive system covering both research governance and ethics approvals that asks researchers for information once, and then sends the relevant sections of information to those who need to see it.

Researchers find it onerous to present the same information in different formats for different purposes. We heard about plans to bring together the information requirements on a single web site. There are clearly opportunities for simplifying the information, without sacrificing rigour of review. This could reduce a material drain on the time available for research, as well as making related processes more predictable.

We commend the attempt to link the ethics and R&D application processes more closely, and recommend that progress on the new combined ethics/R&D system should be closely monitored. In particular, DH should monitor NHS Trusts’ and PCTs’ adoption of the new standard R&D application process, and find ways of addressing any deviations from it.
3.6 The issue of workload and capacity

The creation of a central support structure for NHS RECs, provided through COREC, made it possible to begin attending to the historic mismatch between capacity and need. Although there has already been a reduction in the number of committees with very small workloads, this imbalance still exists. There is strong evidence of over-capacity in some places.

We recognise that the present number and distribution of RECs evolved from a system established historically over decades. The nature and distribution of research have changed substantially in that time. Other factors have also changed the capacity and geographical pattern of applications, in particular the requirement for only a single review, and the recognition that assessment and review of the core ethical issues are not ultimately dependent on specific local knowledge.

We believe that a smaller number of RECs - perhaps one for each Strategic Health Authority, with a limited number of exceptions - would be more appropriate. Their operations would be more intense than at present, with a greater usage of electronic communications.

3.7 The constitution of RECs and membership issues

Changes in appointment procedures for members have led to a more open system over the last few years. This has served to refresh the membership of RECs and to decrease the previous close links with individual research sites, thereby reducing the potential for conflict of interest. It is crucial that RECs are independent of applicant researchers, and their hosts and sponsors.

The current membership of RECs is drawn in general from a relatively narrow spectrum of society, members tending to be professional in background and from an older age group. We do not have evidence of ethnic mix but doubt that RECs overall reflect the mix of the communities that make up our society. In ethical terms this is relevant if, for instance, different religious and other perspectives are to be taken into account. In interpreting ethical principles in practice RECs should be broadly representative of the community.

Although recruitment has been more efficiently handled recently, and the total membership of committees (varying from around 12 to 18 members) is often full, problems still remain. We understand that there is not infrequently a risk of meetings becoming inquorate, because of absence or because staff are called away for other duties. There are also pressures because of the time commitment of
preparation and attendance at meetings – often held out of hours – and the necessary training.

There is a strong tradition of voluntary service on NHS RECs. We were asked to recommend how to maintain the viability of a voluntary system, taking account of these various pressures.

If a voluntary approach is to be sustained there needs to be better recognition (especially by NHS employers) of the commitment of NHS staff, including formal recognition in job plans. Similarly, we suggest that the Royal Colleges and other bodies should be invited to consider whether membership of a REC should be recognised for continuing professional development.

Nonetheless, we do question whether the purely voluntary nature of appointments is sustainable for the future needs of ethical review, especially in those cases where it is (or might become) a statutory requirement. We believe that a move towards fewer Research Ethics Committees whose members are paid, either directly or through their employer, should be seriously considered.

### 3.8 Inconsistency of decisions by RECs

Committees are required to be independent in their decisions. Whilst they all have regard to the same international statements of principles, such principles require interpretation; therefore, there is bound to be a subjective element in ethical opinions. This makes some variation inevitable, but the extent of inconsistency is clearly an irritation.

The Group felt that committees could be assisted in their decision-making by building on the newly introduced system of quality assurance, more systematic collection and dissemination of “good practice” case studies, guidance on examples of difficult issues and arranging regular exchange of members. Such measures could contribute to a reduction in inconsistency without undermining the professionalism and discretion of individual committees.

### 3.9 Challenges for members and administrators

It has to be recognised that whilst the recently introduced changes in constitution and operational systems were essential, they have been far from comfortable for RECs themselves, whose members are volunteers. The administrators in particular have had an arduous task. We recognise and applaud the commitment and professionalism of all those involved in adapting to the changes.
The changes required were very considerable indeed, and it is to the credit of COREC that they have been achieved without even more disruption to the committees and their users. We noted from some user groups that the UK is well in advance of the European Community in adapting its previous operating systems to meet the requirements of European legislation.

The support amongst members and administrators for the newly introduced system of quality assurance is to be warmly welcomed and its implementation and roll-out should be closely monitored.

### 3.10 The UK dimension

Whilst the remit of the Ad Hoc Group was to consider the REC system in England, it was impossible not to reflect that increasingly there is a need for close working across the UK. (Indeed, in the case of review of clinical trials, this is a statutory duty).

Neither scientific research nor the impact of its results stop at national borders. There seems an overwhelming argument for more effort in consolidating and further developing UK-wide systems.

We recommend that DH should increase its dialogue with the relevant departments of the other countries to seek ways of further underpinning a common UK system.
4. Conclusions

1. It should remain the role of research ethical review to safeguard the rights, dignity, safety and welfare of potential human research participants by providing an independent opinion on the ethical implications of a research proposal. Vigilance must be applied at all stages to preserve the independence of the RECs’ decisions from political, research or management interests.

2. Research of relevance and good quality is essential to underpin further developments in health and social care. This gives Research Ethics Committees a secondary role – to facilitate ethical research.

3. In addition to research in the NHS and Social Care, there is now a need also to provide for the requirements for ethical review set out by the new statutory and regulatory environments, such as for human tissue and mental capacity.

4. There has been a major improvement in the efficiency of the process of ethical review in the very recent past that has not yet been fully appreciated. COREC and the RECs are to be warmly congratulated, but some problems still remain.

5. RECs should deal with ethical rather than scientific review.

6. Much research, such as surveys, service evaluation and research on NHS staff, does not require ethical review.

7. The REC operating system is perceived to be bureaucratic and should be better described and presented. The procedure for site-specific assessment (SSA) is cumbersome.

8. The IT system that underpins the operating system is generally successful, and the recently introduced combined approach with R&D is to be welcomed. Further opportunities for linkage of information supply amongst ethics committees, R&D departments and other regulatory bodies should be kept under constant review.

9. The application form attracts frequent criticism. Much of it is related to earlier electronic versions or because of the use of paper versions of what is designed as an on-line form. Nevertheless, the form could be more intuitive and a more easily usable paper version developed.
10. The current operating system, requiring as it does comprehensive information to be supplied “up front” for the RECs, has exposed a very variable level of understanding of ethical issues within the research community. We feel this is at the heart of some of the criticisms of the form itself. It reveals a need for researchers and health professionals to have access to information, support and training. This may aid the ability of researchers to identify and consider the ethical issues arising out of their proposed research. Consequently, they might be better able to describe, in their submissions to RECs, the ethical arguments in favour of their proposed research project (whilst acknowledging potential harms and how they propose to minimise the risks involved).

11. There is over-capacity in current NHS RECs. It is timely to rationalise further the number of RECs, with more intense operation for the smaller number resulting.

12. We believe that the totally voluntary system of RECs may not be sustainable and, indeed, may no longer be appropriate. It is likely that it inhibits application for membership by sections of society that should be better represented.

13. There appears to be some inconsistency amongst committees that cannot be explained by the necessary judgemental aspect of ethical review.

14. The scale of the changes in operation that have recently been required of RECs should be acknowledged. The Chairs, members and support staff have responded magnificently.

15. DH officials and colleagues in the other UK countries should look imaginatively at pursuing more harmonisation of governance arrangements, given that there are moves for harmonisation across Europe.
5. Recommendations

The achievements of the ethical review system attained so far, whilst impressive, have been largely incremental. The time has now come for a step change in the system of RECs, to address perceived weaknesses in the system, and provide better support for Chairs, members and administrative staff. Building on these achievements, the aim of these proposals is to raise the status and profile of RECs, and lay the firm foundation for a REC system that can be more responsive to changing requirements in the future in a UK-wide context. The Ad Hoc Group's recommendations are as follows.

1. The remit of NHS RECs should not include surveys or other non-research activity if they present no material ethical issues for human participants. COREC should develop guidelines to aid researchers and committees in deciding what is appropriate or inappropriate for submission to RECs.

2. RECs should not reach decisions based on scientific review. In the unusual situation of a REC having reservations about the quality of the science proposed, they should be able to refer to COREC for scientific guidance.

3. The recently introduced managed operating system has been well received. Its use of IT points the way to further efficiency and quality improvements. We believe that responsibility for site-specific assessment should be transferred to NHS hosts as soon as acceptable mechanisms for quality assurance are in place.

4. The application form and application process call for improvement. The form should take more explicit account of differences between types of research and should also give more space and attention to ethical issues.

5. We strongly encourage NHS research hosts to adopt common national systems. Substantial improvement to local R&D procedures and their interaction with ethical review - including the ability to make multiple use of information supplied once - is required in order to reduce bureaucracy and timescales. This is the most pressing of all our recommendations.

6. We believe that a smaller number of RECs - perhaps one for each Strategic Health Authority, with a limited number of exceptions - would be more appropriate. Their operations would be more intense than at present, with a greater use of electronic
communications. The time commitment required of members and support staff for training should be more formally recognised, as should the time taken in committee hearings and preparation. This implies paying REC members appropriately, either directly or through compensating their employers.

7. Research Ethics Committees must represent the public interest as well as patient perspectives on research. This means that membership needs to be drawn from a wider mix of society and that all members need to be supported by appropriate training. We believe that our recommendation that we move towards a system of fewer, paid RECs will support this objective.

8. The issue of excessive inconsistency amongst committees should be addressed by concentrating on the provision of appropriate training, and on capturing and sharing good practice where issues and arguments have been already explored. The newly introduced system of quality assurance by peer review amongst committees and their members should assist this process and should be further developed.

9. We propose the creation of “Scientific Officers” in COREC to support the work of committees. They might undertake much of the preliminary assessment required, and review reports. Chairs, for whom it is a major burden, currently undertake this work.
Annex 1

Terms of reference

The Ad Hoc Advisory Group on NHS Research Ethics Committees will:

1. provide independent advice to DH Ministers on the operation of NHS Research Ethics Committee (REC) review of R&D involving individuals, their organs, tissue or data in the NHS in England;

2. take stock of developments and trends affecting the remit, administration, operation and workload of NHS RECs in England;

3. review the relationship between NHS RECs and other research approval requirements, and consider regulatory blocks impeding research;

4. recommend how to
   • reduce the time required of researchers starting high quality research;
   • provide for a single point of entry, consistent process, and single decision appropriate for all the types of research requiring a NHS REC’s opinion;
   • strengthen the systems, structures and processes supporting NHS RECs to make their business process as efficient as possible and improve users’ and committee members’ experience of it;
   • maintain the viability of the present voluntary system, taking account of the pressures on it.

5. confirm the operational boundaries within which NHS RECs work;

6. consider options for investment and measures to contain recurrent costs.

The Group will take account of:

1. the legal basis for NHS RECs, including legislation affecting their remit;

2. the Doyal Report on student research, The Human Tissue Bill and The Mental Capacity Bill;

3. the focus of health and social care research governance on protecting the dignity, rights, safety and well-being of individuals (including their organs, tissue or confidential data) when the NHS owes them a duty of care;

4. the financial and human resources available to the NHS REC system.
Membership of the Ad-hoc Advisory Group

**Chair**  Michael O’Higgins, Director, PA Consulting

**Members**  Professor Alex Markham, Cancer Research UK  
Professor Janet Darbyshire, Director of MRC Clinical Trials Unit  
Professor Michael Parker, The Ethox Centre, Department of Public Health, University of Oxford  
Harry Cayton, Director for Patients and the Public

**Secretariat**  Jim Connelly, Research Governance Manager, RDD

**Observers**  C. Marc Taylor, Department of Health  
Michael Stevens, Chief Scientist Office, Scotland  
Louise Haines/Giulia Vidal, Wales Office of R&D  
Stephanie Harcourt, Department of Health, Social Services and Public Safety, Northern Ireland  
Sue Williams/Sue Osborn, Joint Chief Executives, NPSA
Annex 2

Written submissions received from:

(1) Patient Information Advisory Group (PIAG)
(2) Royal College of General Practitioners
(3) The Royal Surrey County Hospital NHS Trust
(4) Oxford Radcliffe Hospitals NHS Trust
(5) Royal College of Psychiatrists’ Research Unit
(6) Maureen Fitzgerald, PhD, NSW, Australia (project info on her website)
(7) Dr Nora Donaldson (Head, Clinical Research Statistics, R&D, King’s College Hospital)
(8) Philip Smith, PhD (R&D Co-ordinator, Mid Essex Hospital Services NHS Trust)
(9) Dr Vicky Wood (R&D Support Manager, University of Bath)
(10) Medeval Ltd
(11) The NHS Confederation
(12) Geoff Hall
(13) BioIndustry Association (BIA)
(14) Independent Research Ethics Committee
(15) South West Surrey LREC
(16) Professor John Saunders (Chairman, MREC for Wales)
(17) The Academy of Medical Sciences
(18) MRC Advisory Group on Public Involvement (AGPI)
(19) MRC and Wellcome Trust
(20) Dr Richard Nicholson (editor), Bulletin of Medical Ethics
(21) South West Devon REC
(22) NHS R&D Forum
(23) Hammersmith Medicines Research (HMR)
(24) Professor Anthea Tinker (Chairman, King’s College London REC)
(25) Association of British Healthcare Industries (ABHI)
(26) Centre for Socio-Legal Studies
(27) Peninsula Medical School
(28) Amrat L Mistry (lay member of LREC)
(29) Professor Peter Furness (Chair, Leicestershire Clinical Ethics Committee)
(30) Wakefield District REC
(31) Professor Tom Meade (Chair, London School of Hygiene & Tropical Medicine (LSHTM))
(32) Eleanor Grey (lay member of the Metropolitan Multi-Centre REC)
(33) Susan Kerrison (Assistant Director of R&D, UCLH NHS Foundation Trust)

(34) Association of the British Pharmaceutical Industry (ABPI)
(35) Scottish NHS R&D Managers
(36) The Association of Research Ethics Committees (AREC)
(37) Professor William Yule (Co-chair, Institute of Psychiatry and South London & Maudsley REC)
(38) Dr Sandra Evans (Chairman, Eastern MREC)
(39) Professor David Caplin (lay member of a Primary Care Trust LREC and an MREC)
(40) Dr Alex Scott-Samuel (Director, IMPACT, University of Liverpool)
(41) GlaxoSmithKline
(42) The Royal College of Anaesthetists (RCoA)
(43) Mrs Patricia Moberly (Chairman, Guy’s & St Thomas’ NHS Foundation Trust)
(44) Gill Habicht (REC Manager, Huntingdon & Peterborough/Fenland RECs)
(45) Dr Richard Lewis (Special Advisor, National Patients Safety Agency (NPSA))
(46) Professor Peter Huxley (Professor of Social Care, Institute of Psychiatry, King’s College London)
(47) Dr Richard Coppin
(48) Dr Tony Peatfield (MRC)
(49) Dr Rose Woodhill, Sheffield Hallam University
(50) Dr Gordon Taylor, R&D Support Unit, University of Bath
(51) Lord Turnberg

Oral evidence taken from:

(1) Dr M F Bone, Director, the Association of Research Ethics Committees
(2) Sarah Buckland, Director, Involve
(3) Chris Counsell, Member, R&D Forum
(4) Professor Janet Darbyshire
(5) Nick Deaney, Medical Director, ABPI
(6) Wendy Fisher, Chair, R&D Forum
(7) Gill Habicht, Administrator, Papworth LREC
(8) Louise Haines
(9) Stephanie Harcourt
(10) Professor Joan Higgins, Centre for Public Policy and Management, University of Manchester
(11) Professor Alan Horwich, R&D Director, Royal Marsden Hospital
(12) Dr J Lamberty, Chairman, the Association of Research Ethics Committees
(13) Professor Alex Markham
(14) Dr Janet Messer, Manager, R&D Forum
(15) Michael O’Higgins, PA Consulting
(16) Dr Liam O’Toole, Director, UKCRC
(17) Professor Michael Parker
(18) Emma Pendleton, R&D Manager, Great Ormond Street Hospital
(19) Professor Alan Roberts, Pro-Vice Chancellor, Leeds University, Chair of Bradford LREC
(20) Harold Schmidt, Assistant Director, Nuffield Council of Bioethics
(21) Professor Peter Smith, Council Member, Nuffield Council of Bioethics
(22) Dr Richard Tiner
(23) Michael Stevens
(24) Sue Williams
The organisation of NHS Research Ethics Committees

1. We propose that RECs should be re-organised into a nationally networked system with fewer committees meeting more frequently. The number of committees required would depend on:
   - an assessment of total workload (estimates for which are now available from the NHS Research Ethics database, and from professional organisations for non-NHS work);
   - a decision on how many applications it is reasonable for a REC to review at one sitting;
   - a decision on the frequency of meetings;
   - the agreed remit of committees;
   - the number of sub-committees operating under a committee.

2. It is proposed that committees should meet during normal working hours. Meetings of a particular committee would be on a given weekday, but over the whole network, there would be meetings on every weekday. Discussion is needed as to whether a whole day (two sessions) should be set aside, with the meeting itself taking one session, the other being used for training and preparatory work.

3. It is proposed that lay members should be compensated for their work.

4. It is proposed that expert members who are NHS staff should have their work on a REC recognised by their employers in their job-plans, and should therefore receive no additional remuneration. Whether their employers should receive compensation is for consideration. Locum fees should be available to independent practitioners if they would otherwise be out of pocket. Royal Colleges should consider recognising service on RECs as an acceptable part of continuing professional development.

5. Some members come from non-NHS organisations such as Universities and Higher Education Institutes. These bodies obtain ethical review free of charge, and their employees’ service should be seen as part of the “knock for knock” agreement between the Universities and the NHS.

[Some expert members (especially for Phase 1) may come from other organisations or be self-employed ‘consultants’ (or retired). This could be an additional cost.]
6. REC should be supported by administrative staff of good calibre whose grading should adequately reflect the responsibility they carry.

7. The administrative support for REC should include a network of scientific officers responsible for technical, ethical, regulatory and expert scientific support to the Chair and the committee. These officers could also offer advice to researchers at the early stages of project development and support the R&D function.

8. Site-specific assessment of the local investigator and research environment should be delegated to the host institute, which should report its assessment to the REC concerned, closing the gap between research governance and ethical review.

9. The concept of prior accreditation of researchers ("Research Passport") and specific research units (signed off by Research Ethics Committees) could be further explored.

10. Committee members should undergo induction and continuing training individually, as whole committees and as part of a network. Training should be seen as a core activity of the committee and the time commitment required should be formally recognised and recompensed where appropriate.

11. Whilst committees should be capable of undertaking core generic ethical review of most research proposals, some could have (or could develop) specific expertise in particular areas, which might reflect their particular expert membership and their training. Examples would be in review of clinical trials, of research in children, of research in adults with incapacity, of research in mental health, of qualitative research, of research in prisoners.

12. One group of committees would take particular responsibility for “Phase 1” trials in healthy volunteers and early phase trials in patients. It is possible that a dedicated group of committees should be created primarily to review Social Care research or to combine Social Care research with other research under the broad umbrella of “Social Sciences”.

13. We acknowledge the contribution to the review in the study undertaken by Professor Doyal into ethics and student research. It seems to us that we must try to reduce the number of student projects presented to REC. Where a proposal clearly raises ethics issues we recommend in the interests of patient safety that the proposal must be evaluated by a full ethics committee. It could be one created for this purpose.
Discussion

1. Fewer committees meeting more frequently would:
   - provide a structural basis for more consistent review;
   - facilitate a rapid and responsive service to applicants;
   - allow more focused and consistent training;
   - allow some rationalisation of administrative and other support;
   - provide good value for money.

2. The geographical distribution of committees should reflect that of the active research community.

3. The frequency of meetings must be realistic.
   - “Full-time” committees would be so few in number that geographical distribution would be problematic. Recruitment could be a serious problem in the expert category, as professionals would have to take “career breaks” in order to serve. This could also be very problematic in terms of career planning (eg maintenance of clinical skills), and financial recompense to their employer would be inevitable. There is also considerable benefit in having “expert” members who are still actively engaged in their own disciplines.
   - Weekly meetings might be possible, but the workload would still be very high in terms of the “homework” necessary. Again, the low numbers required might militate against reasonable geographical distribution.
   - Meeting twice a month seems a realistic solution. The meetings would need to be on a monthly calendar basis to fit in with normal NHS clinical session planning; this would result in some 24 meetings per year.

4. A dedicated membership, with a clear sessional commitment, would considerably lessen the danger of committees becoming inquorate. Indeed, fewer members would be required per committee than are currently appointed. A system of a pool of “retained locums” with previous experience is also an interesting possibility. “Swaps” of members between committees for limited periods would serve to broaden experience and increase consistency of review.

5. The level of administrative support depends ultimately on the number and type of applications to be handled, but establishing a number of “nodal” offices supporting several RECs could lead to economies of scale and more robust support. Cross-cover
for sickness, leave etc would be an added advantage. [It should be remembered that some redundancies would be inevitable, and this would require sensitive handling. The formation and inclusion of a set of committees or sub-committees for review of Social Care research into the overall system could decrease the need for redundancies.]

6. The innovative provision of a networked “scientific support service” could be a major development in terms of quality and consistency. We found that, currently, Chairs undertake a lot of work which could be easily (and perhaps more consistently) handled by a cadre of professional staff with training and expertise.

This could include:

- a preliminary scan of the applications for obvious defects (and, perhaps, discussion with the applicant so that they can be corrected in advance);
- the initial assessment of the adequacy of prior peer review;
- the assessment for the requirement for (and then obtaining) any individual expert reports;
- the assessment of adverse event reports and annual reports.

The final decisions remain with the committees and the Chairs. This service could be particularly valuable for “Phase 1” committees. We would also see such individuals as being a very valuable focus of communication and training for Trust R&D departments, research sponsors and with researchers themselves.

**Governance of NHS RECs**

Key features must be:

- a clarity and transparency;
- independence from
  - researchers, research organisations and sponsors;
  - “political” interference in appointments or opinions;
- a system for the UK.
A worked example

Assumptions (on a UK-wide basis):

1. 10,000 applications per year for current NHS research;
   1,000 applications per year for “Phase 1”;
   1,200 additional applications per year for Social Care research.

2. Phase 1 committees would need to review fewer proposals (they are very complex
   and require a higher scrutiny of the methodology). If four protocols were reviewed
   per meeting, there would therefore need to be 250 meetings per year.
   
   With 24 meetings per committee, 10 committees would be required - or 12 to cope
   with fluctuations in application rate.

3. Other REC’s could look at six to eight applications per committee per meeting (say
   seven). With approximately 1600 meetings needed and allowing 24 meetings per
   committee, 70 committees would be required.

Conclusion

If meetings were held twice-monthly, the costs per committee of 12 Phase 1
committees and 70 other committees would be approximately £126,000:

i. current cost of an MREC (to include office costs, IT, expenses, training and
   admin salaries) is about £70,000
ii. add lay members’ fees - £150 per day, 24 days, five lay members: £18,000
iii. Scientific Officer (0.5 WTE): £25,000
iv. additional fee for “Chair”: £3,000
v. fees for other (non-NHS) experts: £10,000

The total for 82 committees’ costs would be around £10.8 million.

Other costs: “COREC” (or similar) central support costs: around £4 million.

These figures include costs for Social Care research which is currently not in the
COREC budget.

This is a UK-wide estimate.