



Governance arrangements for research ethics committees

A harmonised edition

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Governance arrangements for research ethics committees

A harmonised edition

Prepared by the UK Health Departments:

Department of Health Research and Development Directorate (England)

National Institute for Social Care and Health Research (NISCHR) (Wales)

Chief Scientist Office (Scotland)

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Contents

1	Introduction	6
2	Purpose and scope	8
3	Role and remit	15
4	Composition and membership	21
5	Requirements of research ethics committee review	28
6	Standard operating procedures	31
	Glossary	32
	References	34
	Annex A: Legal requirements for research ethics committee review	36
	Annex B: Enforcement authorities	39
	Annex C: Research Ethics Service head office functions	40
	Annex D: Functions of appointing authorities	41
	Annex E: National Research Ethics Service head office functions	43
	Annex F: Functions of the UK Ethics Committee Authority	44
	Annex G: Annual reports of research ethics committees	45

1 Introduction

1.1 What are research ethics committees and what do they do?

- 1.1.1 A research ethics committee is a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part.
- 1.1.2 The UK Health Departments provide for a Research Ethics Service so that research proposals relating to their areas of responsibility can be reviewed by a research ethics committee. The Research Ethics Service consists of research ethics committees, as well as head offices that co-ordinate the development and management of their operations.
- 1.1.3 Each of the research ethics committees within the Research Ethics Service is made up of members of the public, as well as people with specific knowledge that can help the committee understand particular aspects of research proposals. All the committee members are given training to understand research ethics.
- 1.1.4 When they review research proposals, these research ethics committees are independent of the researchers, the organisations funding the research and the organisations where the research will take place.

1.2 Why are research ethics committees needed?

- 1.2.1 Research is a core part of the NHS and other care services. Research enables these services to improve the current and future health and well-being of the people they serve. However, research sometimes involves a degree of risk because researchers cannot predict the outcome with certainty. It may also involve additional burdens or intrusions exceeding those involved in normal care.
- 1.2.2 Researchers must satisfy a research ethics committee that the research they propose will be ethical and worthwhile. The committee has to be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society.

- 1.2.3 In this way, research ethics committees aim to protect people who take part in research. This helps promote public confidence about the conduct of researchers and the dignity, rights, safety and well-being of research participants. As a result, more people will be encouraged to take part in research. This in turn leads to more, better and quicker improvements in health and social care.
- 1.2.4 The Research Ethics Service enables ethical research in partnership with researchers and their sponsors. Research ethics committee review complements researchers' own consideration of the ethical issues raised by their research and their involvement of service users, care professionals, methodologists and statisticians, academic supervisors, data protection officers etc, at the design stage.

1.3 What is the purpose of this document?

- 1.3.1 *Governance arrangements for research ethics committees* is a policy document of the UK Health Departments. It describes what is expected from the research ethics committees that review research proposals relating to areas of the UK Health Departments' responsibility. It also explains when review by these committees is required.
- 1.3.2 This policy covers the principles, requirements and standards for research ethics committees, including their remit, composition, functions, management and accountability. It also describes the Research Ethics Service in which the research ethics committees operate and the review they provide.
- 1.3.3 This document revises and replaces editions of the policy previously issued separately in England and Scotland in 2001. It also applies in Wales and Northern Ireland. This harmonised edition takes account of legal, policy and operational developments since 2001. It has effect throughout the UK from 1st September 2011.
- 1.3.4 Where a research study does not require review by a research ethics committee within the Research Ethics Service under this document, review may be undertaken by research ethics committees established by universities or other institutions. The Economic and Social Research Council's *Framework for Research Ethics* [1] sets out principles, requirements and standards for university committees that are compatible with those set out in this document.

2 Purpose and scope

2.1 Summary

- 2.1.1 The principles, requirements and standards set out in this document apply to research ethics committees (RECs) reviewing research that relates to areas of responsibility of the UK Health Departments. This includes research involving users of services for which the UK Health Departments are responsible. It also applies where the law requires review by a REC and the UK Health Departments provide for that review.

2.2 Purpose

- 2.2.1 The UK Health Departments are committed to enhancing the contribution research can make to their areas of responsibility. Research is essential for protecting and improving health and well-being, as well as for achieving modern, effective care services. At the same time, research can sometimes involve an element of risk, because research can involve trying something new. It is important that any risks are minimised and do not compromise the dignity, rights, safety and well-being of the people who take part. Proper governance arrangements are essential to ensure that service users and the public can have confidence in, and benefit from, high-quality, ethical research.
- 2.2.2 The public has a right to expect the highest scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements. The UK Health Departments' *Research Governance Framework* [2–5] sets out the responsibilities for the various elements of research governance. *Governance arrangements for research ethics committees* sets out principles, requirements and standards for RECs that review research proposals relating to responsibilities of the UK Health Departments.

2.3 Scope

Policy requirements for research ethics committee review

- 2.3.1 This document applies, and REC review is required, where research relates to the following areas of the UK Health Departments' responsibility:

Nation	Health Department	Services
England	Department of Health	NHS and adult Social Care
Wales	Department for Health and Social Services	NHS and Social Care
Scotland	Scottish Government Health Directorates	NHS
Northern Ireland	Department of Health, Social Services and Public Safety	Health and Social Care

2.3.2 REC review as described in this document is required if a specific research project involves:

- (a) potential research participants¹ identified from, or because of, their past or present use of the services listed above (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls;
- (b) potential research participants identified because of their status as relatives or carers of past or present users of these services¹;
- (c) collection of tissue (i.e. any material consisting of or including human cells) or information from users of these services¹; or
- (d) use of previously collected tissue or information from which individual past or present users of these services¹ could be identified, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, the possession of someone to whom the tissue or information is made available,

unless any of the exceptions or other exclusions described in paragraph 2.3.9–2.3.14 apply.

2.3.3 REC review under this document is also required for:

- (a) xenotransplantation (i.e. putting living cells, tissue or organs from animals into people), which, as a matter of Government policy² [6], is recommended to take place in a controlled research context, carried out with a research protocol approved by a REC within the UK Health Departments' Research Ethics Service;
- (b) health-related research involving prisoners, for which the National Offender Management Service, Scottish Prison Service and Northern Ireland Prison

¹ Including those who have died within the last 100 years.

² New interventional procedures are overseen and scrutinised by the National Institute for Health and Clinical Excellence (NICE). In addition to xenotransplantation, RECs may need to consider studies of other new procedures as advised by NICE.

Service require review by a REC as well as compliance with their own approval procedures; and

- (c) social care research projects funded by the Department of Health, which must always be reviewed by a REC within the Research Ethics Service for England.

Legal requirements for research ethics committee review

2.3.4 Irrespective of whether the research involves the health and social care services for which the UK Health Departments are responsible, this document applies where the law requires review by a REC and the UK Health Departments provide for that review. The relevant legislation is listed in Annex A.

- 2.3.5 Broadly speaking, this legislation requires REC review of research proposals involving:
- (a) people who lack (or lose) the capacity to give informed consent to take part (or to keep taking part) in the research;
 - (b) processing of confidential patient information³ without consent where this would otherwise breach confidentiality;
 - (c) material consisting of or including human cells, which has been taken from the living or the deceased (where paragraph 2.3.6 applies);
 - (d) patients who are cared for in private and voluntary sector nursing homes (in England, Wales and Northern Ireland) and/or residents of residential care homes (in Northern Ireland only);
 - (e) exposure to ionising radiation;
 - (f) medical devices that are not CE-marked (i.e. not compliant with European Directives) or CE-marked medical devices that have been modified or are being used for a new purpose;
 - (g) investigational medicinal products;
 - (h) practising midwives conducting a clinical trial; or
 - (i) protected information from the Human Fertilisation and Embryology Authority register.

2.3.6 REC review is required by law for research involving material consisting of or including human cells where:

³ 'Patient information' means information, or any derivation thereof, however recorded, which relates to the physical or mental health or condition of an individual, to the diagnosis of his or her condition or to his or her care or treatment. 'Confidential patient information' is patient information where the identity of the individual is ascertainable from the information (or from it and other information in, or likely to come into, the possession of the person processing it) and the information was obtained or generated by someone who, in the circumstances, owed an obligation of confidence to the individual.

- (a) it involves storage or use of material from the living collected on or after 1 September 2006 and the research is not within the terms of consent for research from the donors (England, Wales and Northern Ireland only)⁴; or
- (b) it involves material from the living or the deceased which is not held on premises with a licence from the Human Tissue Authority for research (England, Wales and Northern Ireland only); or
- (c) it involves organs retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal (Scotland only); or
- (d) it involves organs, tissue blocks or slides retained from a hospital post-mortem examination, or tissue blocks or slides retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal, unless lawful authorisation has been given for use in research (Scotland only); or
- (e) it involves analysis of DNA in material from the living and the research is not within the terms of consent for research from the person whose body manufactured the DNA (UK-wide)⁵.

Other provisions for research ethics committee review

- 2.3.7 RECs may agree to consider applications in respect of activities preparatory to research (e.g. the establishment of research databases or tissue banks, or pre-trial advertising and screening for healthy volunteers) and research proposals which fall outside the normal scope described above, capacity permitting. When they do this, the principles, requirements and standards set out in this document will apply.
- 2.3.8 REC review is always available to applicants in respect of research funded by any of the UK Health Departments.

Exceptions

- 2.3.8A This document does not apply in England and Wales if research proposals are reviewed by a committee operating in accordance with the Economic and Social Research Council's *Framework for Research Ethics* [1], unless:
- (a) the research involves withdrawing standard care; or
 - (b) the research involves NHS patients or service users as research participants (see paragraph 2.3.2); or
 - (c) the research is a social care research project funded by the Department of Health

⁴ In addition to REC approval, the researcher must not be in possession of, or likely to come into possession of, information from which the donor can be identified.

⁵ In addition to REC approval, the researcher must not be in possession of, or likely to come into possession of, information from which the person whose body manufactured the DNA can be identified.

(see paragraph 2.3.3); or

- (d) there is a legal requirement for review by a REC (see paragraphs 2.3.4 and 2.3.5).

With these conditions, the *Framework for Research Ethics* sets out principles, requirements and standards for review by university committees that are compatible with those set out in this document.

- 2.3.9 This document does not apply to research reviewed by the Ministry of Defence Research Ethics Committee (MoDREC). Where research approved by MoDREC continues within the services for which the UK Health Departments are responsible following transfer of participants into their care, it does not then require separate REC review under this document. MoDREC operates to standards set out separately by the Ministry of Defence which are compatible with those in this document.
- 2.3.10 REC review under this document is not required for research anywhere in the UK involving previously collected material consisting of or including human cells except where it is required by law under paragraph 2.3.6(a)–(d) above, or where the research also involves use of identifiable information about patients or service users under paragraph 2.3.2(d), or where consent for research has not been given by the donors or the research is outside the terms of consent for research. Using anonymous material with due consent presents no outstanding issues of research ethics.
- 2.3.11 REC review under this document is not required for research involving human biological material not consisting of or including cells⁶, except where it is required by law under paragraph 2.3.6(e) above, or where the research also involves use of identifiable information about patients or service users under paragraph 2.3.2(d).

Other exclusions

- 2.3.12 Care providers owe a duty of care to users of their services. They are responsible for ensuring that ethical issues and risks in the course of the care they provide are considered. RECs are not expected to consider applications in respect of activities that are not research, for example clinical audit, service evaluation and public health surveillance. Guidance on differentiating such activities from research is available from research governance offices and from www.nres.npsa.nhs.uk [7]. REC members who give advice on the ethics of such activities should make it clear that they are not doing so in their capacity as a REC member.
- 2.3.13 Employers owe a duty of care to their employees. It is different from the duty of care that care providers owe to users of their services. RECs are not expected to assume

⁶ Guidance on identifying 'relevant material' for the purposes of the Human Tissue Act 2004, i.e. material consisting of or including human cells, is published by the Human Tissue Authority at www.hta.gov.uk.

employers' responsibilities or liabilities, or to act as a substitute for employers' proper management of health and safety in the workplace. It is for employers to ensure that they are fulfilling their duties as employers when their employees take part in research. Research involving staff of the services listed in paragraph 2.3.1, who are recruited by virtue of their professional role, does not therefore require REC review except where it would otherwise require REC review under this document (for example, because there is a legal requirement for REC review, or because the research also involves patients or service users as research participants).

- 2.3.14 Healthcare market research⁷ may be undertaken by professional market researchers on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBI), it does not require REC review except where otherwise required by law, e.g. if it requires approval under the Mental Capacity Act. The BHBI guidelines require that informed consent is obtained from patients for provision of any personal data or to undertake additional procedures such as questionnaires or interviews.
- 2.3.15 At the request of the sponsor, chief investigator or host organisation, RECs may exceptionally review research excluded from the normal scope of review under paragraphs 2.3.12–2.3.14 where the Research Ethics Service agrees that the proposal raises material ethical issues. The parties responsible for managing those issues remain liable for the assessment which informs that management.
- 2.3.16 Research projects involving human subjects or their tissue or information may be undertaken on the premises of NHS/HSC or social care organisations by third party organisations, for example contract research organisations or research units owned by universities or voluntary organisations. Where the project falls within the scope of paragraphs 2.3.2–2.3.3 above, for example because it involves participants recruited through NHS/HSC or social care organisations, REC review is required. Where the project only involves care organisations insofar as it involves use of or access to the organisation's premises or facilities, REC review is not required. Responsibility for considering and managing any risks relating to access to or use of the premises or

⁷ Under the BHBI guidelines, market research 'attempts to generate an understanding of and knowledge about a market place and "consumer" behaviour within it by gaining information (data) from specific samples of "consumers" and extrapolating results to a wider population. It is scientifically conducted research where the identity of the individuals providing the information collected, and all personal data they give to the researchers, are kept fully confidential by the latter and cannot be disclosed, or used, for any non-research purpose. ... A research purpose is where information is systematically collected to assess the opinions, attitudes and behaviours of the population under study. It does not include data collection intended directly to create sales or to influence the opinions of participants. Nor does it include data collection as a means of information gathering for use on future sales or marketing activities (direct) for example, to generate potential sales leads/contact details (and related details on consumer usage and consumption patterns). Direct action should not be taken in relation to named individuals or organisations, as a result of "research" as defined.'

facilities by visitors lies not with the Research Ethics Service but with the organisation concerned.

3 Role and remit

3.1 Summary

- 3.1.1 Research ethics committees (RECs) act as part of an efficient, accountable and independent Research Ethics Service to protect the dignity, rights, safety and well-being of people who take part in research.

3.2 Role of research ethics committees

Protection of research participants

- 3.2.1 Whatever the research context, the interests of participants come first. Their dignity, rights, safety and well-being must be the primary consideration in any research proposal, as well as in REC review. RECs must be assured that there are proportionate safeguards to protect people taking part in research.

Science and society

- 3.2.2 RECs act primarily in the interests of research participants. The interests of researchers and research are always secondary to the dignity, rights, safety and well-being of people taking part in research. RECs also take into account the interests and safety of the researchers, as well as the public interest in reliable evidence affecting health and social care, and enables ethical and worthwhile research of benefit to participants or to science and society.
- 3.2.3 The benefits and risks of taking part in research, and the benefits of research evidence for improved health and social care, should be distributed fairly among all social groups and classes. Selection criteria in research protocols should not unjustifiably exclude potential participants, for instance on the basis of economic status, culture, age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. RECs should take these considerations into account in reviewing the ethics of research proposals, particularly those involving under-researched groups.

Proportionate scrutiny

- 3.2.4 REC review is proportionate to the scale and complexity of the research proposed. Research proposals that present no material issues of research ethics do not warrant consideration at a full meeting of a REC. They should be identified on receipt in accordance with standard operating procedures so that the ethical review may be undertaken by an executive sub-committee of a REC. The REC's opinion on such proposals may be given by the executive sub-committee. See paragraphs 5.5.1 and 5.5.2.
- 3.2.5 Each research proposal is subject to review by no more than one REC within the UK Health Departments' Research Ethics Service, unless required by law or by a managed appeals process.

Independence and impartiality

- 3.2.6 RECs are independent and impartial. A REC's opinion must be free, and must be seen to be free, from conflicts of interest. This includes freedom from pressures of:
- (a) political influence;
 - (b) institutional affiliation;
 - (c) trades union or profession-related interests;
 - (d) direct or indirect financial inducement or any impression thereof;
 - (e) coercion;
 - (f) strategic concerns;
 - (g) market forces; and
 - (h) agency-, discipline- or topic-related bias.
- 3.2.7 Although RECs may be appointed by bodies that have functions relating to care provision, their decisions are independent of care providers' own managers, including their research managers. Care providers, regulators, RECs' appointing authorities and the UK Health Departments may not interfere in the deliberations or opinions of RECs. See paragraphs 3.2.8 and 5.4.2. RECs play no part in management decisions about the provision of care services or support for a research project.
- 3.2.8 The protection of research participants and the enabling of ethical research are best served by co-operation and communication between all those who share responsibility for the research. Except when it would compromise their independence, RECs should collaborate with regulators, actual and potential research participants, researchers, funders, sponsors, employers, organisations providing care and care professionals. See

paragraph 5.4.2. RECs should also collaborate with one another, for example to share relevant information from previous applications or expertise in reviewing particular types of research.

Competence and efficiency

- 3.2.9 REC review must be competent, timely and authoritative. The membership, ongoing training and performance management of RECs, as well as the operational and administrative support they receive, are arranged to maximise the quality, rigour and promptness of REC review and the efficiency of their decision-making processes. A REC should give its opinion within sixty calendar days of receipt of a valid application⁸. The sixty-day period excludes the time an applicant may take to supply additional information requested by the REC. RECs may make a request for additional information once only, which must be in writing.
- 3.2.10 RECs must operate according to the law in the conduct of their business, for example by following due process and complying with their own standard operating procedures. They must also have regard to statutory provisions for ethical review of particular types of research, e.g. the requirements for a favourable opinion of a clinical trial under the Medicines for Human Use (Clinical Trials) Regulations or for approving research involving adults lacking capacity under the Mental Capacity Act or the Adults with Incapacity (Scotland) Act. Guidance on the application of this legislation to ethical review and REC operating procedures is provided by the Research Ethics Service head offices.
- 3.2.11 It is not the role of the REC to offer a legal opinion on research proposals, but it may advise the researcher, sponsor or host organisation whenever it considers that legal advice might be helpful to them. Researchers, sponsors and organisations where the research is carried out remain responsible for making sure the research is conducted in accordance with the requirements of law, relevant regulators and guidance, e.g. the Data Protection Act, the Codes of Practice issued under the Mental Capacity Act and Human Tissue Act, or recognised standards of Good Clinical Practice.

Compliance and enforcement

- 3.2.12 If REC review is required (see Section 2), organisations providing care must ensure that the research they host has a favourable REC opinion. The research may not begin until a favourable REC opinion has been given.

⁸ Except where (a) the application relates to a clinical trial of an investigational medicinal product (CTIMP) for gene therapy or somatic cell therapy or the product contains a genetically modified organism, in which case the REC must give an opinion within 90 days, or 180 days if a specialist group or committee is consulted; or (b) the application relates to a CTIMP for xenogenic cell therapy, in which case no time limit applies.

- 3.2.13 If REC review is required, sponsors may not allow any research they are sponsoring to begin without a favourable REC opinion.
- 3.2.14 The chief investigator is the researcher who takes primary responsibility for the design, conduct and reporting of the research. The chief investigator is responsible for the content of the REC application and for the scientific and ethical conduct of the research.
- 3.2.15 Although RECs must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research, they are not responsible for enforcement if the research turns out to be unsafe or is not carried out as agreed. This responsibility rests with the relevant regulators or comparable bodies, as well as with the researchers' employer and sponsor and with the care organisations where the research takes place (or through which the researchers have access to participants, or their tissue or information) or where the researchers have contracts. Statutory enforcement authorities are listed in Annex B.
- 3.2.16 The Research Ethics Service should agree channels of communication with the relevant bodies in order to exchange advice. RECs should use these channels to alert the bodies responsible for enforcement if they have grounds to suspect that enforcement action is warranted.
- 3.2.17 RECs receive annual reports about the progress of the research they have reviewed. These reports explain any developments affecting participants' dignity, rights, safety or well-being. A REC should reconsider its favourable opinion in light of pertinent information⁹ that comes to its attention. If the REC, given that information during its initial review, would not have reached a favourable opinion, it should notify the relevant statutory enforcement authority. Where the law does not specify the responsibility for enforcement, the REC should notify the chief investigator and the sponsor that its opinion is no longer favourable.

3.3 Remit

- 3.3.1 RECs established and operating in accordance with the principles, requirements and standards set out in this document are recognised by the Secretary of State for Health, the Welsh Ministers, the Scottish Ministers and the Department of Health, Social Services and Public Safety for Northern Ireland.
- 3.3.2 Together, these RECs – as well as head offices that co-ordinate the development and management of their operations – form the UK Health Departments' Research Ethics Service.

⁹ RECs are not expected to duplicate the ongoing checks for which others are responsible (see paragraph 5.4.2). For instance, safety reports in respect of research that is subject to Clinical Trials Regulations or Medical Devices Regulations are received and reviewed by the Medicines and Healthcare products Regulatory Agency.

3.3.3 In general, any REC anywhere in the Research Ethics Service may carry out the review required by Section 2. Specific RECs within the Research Ethics Service may be recognised, or otherwise designated, for review of certain types of research proposal, according to legal, policy or operational requirements. A list of these RECs is available from www.nres.npsa.nhs.uk.

3.3.4 Each head office within the Research Ethics Service is accountable to the relevant Health Department:

Head office	Remit	Accountability
National Research Ethics Service (NRES)	RECs in England ¹⁰	Department of Health
Office for Research Ethics Committees for Wales	RECs in Wales	Department for Health and Social Services
Chief Scientist Office	RECs in Scotland	Scottish Government Health Directorates
Office for Research Ethics Committees Northern Ireland	RECs in Northern Ireland	Department of Health, Social Services and Public Safety

3.3.5 The head offices work with each other to maintain a consistent approach, on behalf of appointing authorities, to the operations of all RECs within the UK Health Departments' Research Ethics Service. The responsibilities and functions of the head offices are listed in Annex C.

3.3.6 Appointing authorities are the bodies that establish RECs, appoint and indemnify their members, seek their recognition if the law requires it and monitor their performance through annual reports¹¹. Each appointing authority identifies a named officer, who is not otherwise involved in the management of Research Ethics Service staff, who has responsibility for governance of the RECs on behalf of the chief executive (unless the named officer is the chief executive). The chief executive has overall accountability. The responsibilities and functions of appointing authorities are listed in Annex D.

3.3.7 The head office of the Research Ethics Service for England, the National Research Ethics Service (NRES), performs some functions on behalf of the other head offices. It

¹⁰ The NRES head office performs some functions outside England. See paragraph 3.3.7, 3.3.8, Glossary and Annex E.

¹¹ The relevant head office is responsible for day-to-day and ad hoc management of the operation and performance of RECs. Annual reports to appointing authorities should demonstrate the REC's compliance with the principles, requirements and standards set out in this document. A list of the required elements of an annual report is at Annex G. The annual report should be submitted to the appointing authority for approval by the board, and should be published.

also acts in respect of some UK-wide functions for the UK Health Departments and for the UK Ethics Committee Authority (UKECA), which is the statutory body that recognises RECs for the review of clinical trials of investigational medicinal products. Functions performed by the NRES head office are listed in Annex E. In this respect, the NRES head office is accountable to the UK Health Departments and UKECA. Functions performed by UKECA are listed in Annex F.

- 3.3.8 The NRES shall establish a National Research Ethics Advisers' Panel, appropriately constituted to help optimise research ethics committee review and so improve the research environment in the UK. This panel will offer strategic leadership on matters including service development, policy, training, quality assurance, ethical arguments and debates and stakeholder engagement. Hosted within the NRES, the panel will be a resource available to the UK Health Departments' Research Ethics Service and to the appointing authorities of the RECs within that service.

4 Composition and membership

4.1 Summary

- 4.1.1 Research ethics committees (RECs) harmonise public and professional opinion in reaching decisions about proposed research. Their members reflect the diversity of society and do not represent vested interests.

4.2 Composition of research ethics committees

Nature of membership

- 4.2.1 The membership of a REC should allow for a sufficiently broad range of experience and expertise so that the rationale, aims, objectives and design of the research proposals that it reviews can be effectively reconciled with the dignity, rights, safety and well-being of the people who are likely to take part.
- 4.2.2 RECs are expected to reflect current ethical norms in society as well as their own ethical judgement. REC members may come from groups associated with particular interests but they are not representatives of those groups. REC members are appointed in their own right to participate in the work of a REC as equal individuals of sound judgement, relevant experience and adequate training in research ethics and REC review.
- 4.2.3 A REC should contain a mixture of people who reflect the currency of public opinion ('lay' members), as well as people who have relevant formal qualifications or professional experience that can help the REC understand particular aspects of research proposals ('expert' members).¹²
- 4.2.4 The Research Ethics Service as a whole should reflect the diversity of the adult population of society, taking account of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. This applies to both the lay and expert membership. Appointing authorities should take steps, with support from the relevant head office, to publicise the work of

¹² The term 'professional member' can imply someone whose job is to be a REC member (rather than an unpaid volunteer drawn from the care professions etc), so 'expert member' is used instead. For this reason, 'experts by experience' are counted as lay members.

RECs and encourage applications for membership from groups who are under-represented.

Appointment of members

- 4.2.5 Appointment of members should be by an open and fair process, compatible with the Nolan standards. Vacancies should be filled following public advertisement in the press, and/or by advertisement via local professional and other networks as most appropriate to the vacancy to be filled. Potential candidates should be required to complete an application form and be interviewed. There should be standard written procedures for application and selection, which should comply fully with equality and human rights legislation.

Expert and lay members

- 4.2.6 Each REC should have expert members to ensure methodological and ethical expertise about research in care settings and in relevant fields of care, as well as professional expertise as care practitioners. This expertise should be appropriate to the types of research proposal the REC reviews.
- 4.2.7 Lay members are people who are independent of care services, either as employees or in a non-executive role. Their primary professional interest is not care-related research. At least a third of each REC's membership should be lay. At least half the lay membership should comprise people who have never been care professionals, researchers in a care field, or chairs, members or directors of care service bodies or organisations providing care.
- 4.2.8 The Research Ethics Service head offices should adopt and publish operational definitions of expert and lay members, taking into account other applicable requirements (see paragraph 4.2.12), and support RECs and their appointing authorities to ensure an appropriate balance of members.

Affiliations

- 4.2.9 RECs are constituted, and operate, independently of organisations that sponsor, conduct or host research. Members absent themselves during consideration of research proposals that could be seen to create a conflict of interest. REC meetings should be attended so as to accommodate these absences while remaining quorate.

Quorum

- 4.2.10 For the purpose of effective debate, a REC normally has no more than 18 members in total. A quorate meeting is one attended by no fewer than seven members, including:

- (a) the chair or other officer;
- (b) at least one expert member; and
- (c) at least one lay member who is not, and never has been, a care professional or a chair, member, director, officer or employee of a care service body.

4.2.11 Each REC should be constituted so that it can function quorately for the duration of its scheduled meetings.

4.2.12 Where other membership, composition or attendance criteria are specified, e.g. in law, for RECs reviewing certain types of research proposal, guidance enabling RECs to convene in accordance with the requirements set out in this document as well as the additional specifications is available from www.nres.npsa.nhs.uk [8].

Officers

4.2.13 Each REC has a chair, a vice-chair and an alternate vice-chair. If all three are unavailable, another member will be acting chair. These officers are appointed from among the REC's members by the REC's appointing authority, after consulting the REC.

4.2.14 Candidates for office are expected to have at least one year's experience as a member of a REC. Appointees should receive any necessary supplementary training (e.g. in chairing skills) prior to taking office.

4.2.15 Officers are appointed for a specified period not exceeding five years. An acting chair's appointment ceases when one of the other officers becomes available again or when his or her term as a member expires (see paragraph 4.3.2), whichever is sooner.

4.2.16 Officers may resign from office at any time. They may continue as members of the REC, subject to the disqualification and resignation procedures of its appointing authority.

Deputies

4.2.17 REC members may have deputies to enable the REC to perform its duties and meet quorately, while accommodating absences.

4.2.18 Deputies of expert members must be eligible for appointment in their own right as expert members. Deputies of lay members must be eligible for appointment in their own right as lay members. Deputies are appointed by the REC's appointing authority.

4.2.19 Deputies do not count towards the quorum or vote on decisions unless the members for whom they deputise are absent.

Referees

- 4.2.20 RECs may seek advice from specialist referees on any aspects of a research proposal that fall beyond the members' expertise. RECs may seek referees' advice at their discretion or because the law requires them to do so. Referees' advice should only be sought on issues material to the REC's review of the research proposal, i.e. issues of research ethics.
- 4.2.21 Terms of reference for referees should be established. Referees do not count towards the quorum or vote on decisions. They are not involved in any REC business apart from advising on the issues put to them. Their advice is recorded in the minutes of the relevant REC meeting.

Observers

- 4.2.22 REC meetings are not public meetings. External observers may attend following a written invitation which states the terms and conditions of their attendance. Attendance will be agreed by the REC and minuted accordingly. Representatives of the relevant Research Ethics Service head office may attend and observe meetings at any time, with prior notification.
- 4.2.23 Observers play no part in the deliberations of the REC.

Advice to applicants

- 4.2.24 RECs should take steps to facilitate communication with their potential or actual applicants. A REC may designate a point of contact for more detailed discussion. This includes advice about whether a proposed activity requires REC review, or the content, submission or review of an application. The point of contact may be any of the REC's members (including those appointed as officers) or administrative staff.

Delegation

- 4.2.25 A REC may appoint sub-committees consisting of its members. Executive sub-committees may exercise any of the REC's functions on its behalf, in accordance with standard operating procedures. In particular, executive sub-committees may review and give an opinion of:
- (a) research proposals that present no material ethical issues;
 - (b) information further to earlier review in full committee;
 - (c) substantial amendments; and
 - (d) annual progress reports (see paragraph 3.2.17).

- 4.2.26 If a REC issues a provisional opinion reached in full committee, it may delegate the responsibility for determining its final opinion to the chair or other officer, or to an executive sub-committee of specified members.
- 4.2.27 Responsibilities of REC officers may be delegated to administrative staff where the matters are administrative, in accordance with standard operating procedures. In particular, office staff may check evidence provided by applicants in response to requests for further information and issue letters confirming the REC's opinion.

4.3 Conditions of membership

Terms of appointment

- 4.3.1 Written terms of appointment for REC members should include the following:
- (a) duration of appointment;
 - (b) renewal policy;
 - (c) disqualification and resignation procedures;
 - (d) policy concerning declaration of interests; and
 - (e) details of allowable expenses.
- 4.3.2 REC members are appointed for fixed terms not exceeding five years. Appointments may be renewed. However, members should not normally serve more than two consecutive terms of five years on the same REC. Where a member is appointed as an officer during their second term, their membership may be extended until the completion of their term as an officer. See paragraph 4.2.15. Where the normal period of membership has expired, the appointing authority may exceptionally extend a member's term while new members are appointed. Such extension should be for no longer than a year unless the member has rare expertise that is essential for the work of the REC, in which case the appointment may continue to be renewed until a suitable replacement is found.
- 4.3.3 Former members may be reappointed to the same REC no sooner than two years after the end of their last term, or to another REC without interval.
- 4.3.4 Attendance at meetings of other RECs as a co-opted member, referee or observer is encouraged, in the interests of training and consistency.
- 4.3.5 Simultaneous membership of more than one REC is permitted with the approval of the appointing authorities concerned, as is deputy membership of other RECs.

- 4.3.6 REC members are normally required to attend in full at least two thirds of all scheduled REC meetings in each year, barring exceptional circumstances. Attendance at scheduled sub-committee meetings should be taken into account. With the approval of the appointing authority, a REC member and his or her deputy may make arrangements to share responsibility for attendance. In this case, the REC member should attend at least half of all scheduled meetings and the deputy should attend the remainder.
- 4.3.7 REC members may resign at any time.
- 4.3.8 REC members should normally allow publication of their full name and, if applicable, their profession and institutional affiliation. In the interests of transparency and probity, any potential conflict of interest should be recorded and published with these personal details.
- 4.3.9 REC members are unpaid volunteers. RECs may not charge an application fee or seek any other financial contribution or donation for or on considering a research proposal for which their review is required by Section 2. Members receive no payment for contributing to the review of applications at scheduled meetings or for attending such meetings.
- 4.3.10 Expenses incurred during the course of a REC member's duties are reimbursed. These may cover travel, subsistence, domestic care and locum arrangements, but do not normally cover loss of earnings. Except in Scotland, allowances may be offered to REC members for additional activities, e.g. appointment as an officer, acting as a point of contact to advise applicants or providing expert critique of research proposals as a referee.

Training

- 4.3.11 As a condition of appointment, REC members must agree to take part in initial and continual training appropriate to their role.

Confidentiality

- 4.3.12 REC members must maintain confidentiality regarding applications, meeting deliberations, information about research participants and related matters.

Indemnity

- 4.3.13 Each REC member must be supplied with a personal statement regarding the indemnity provided by the appointing authority and its conditions.

Conduct

- 4.3.14 The meetings and proceedings of RECs and their sub-committees are conducted in accordance with standard operating procedures.

5 Requirements of research ethics committee review

5.1 Summary

5.1.1 There is a standard process for applying to a research ethics committee. Research ethics committees (RECs) also review applications in accordance with standards.

5.2 Applying for research ethics committee review

5.2.1 Applications to RECs should be made in accordance with a process set out in standard operating procedures for RECs and in written guidance for applicants. This process covers the application from submission to opinion and on to subsequent notification of substantial amendments, annual progress reporting etc.

5.2.2 The Research Ethics Service should be prepared to offer accurate advice and guidance to potential and actual applicants. See paragraphs 3.3.8 and 4.2.24. This includes being able to answer queries about whether REC review is required (see Section 2), the application process (including the requirements for a valid application) and the review process (including the issues RECs consider before reaching an opinion).

5.2.3 There is a managed process for allocating REC applications to an appropriate REC. See paragraph 3.3.3. As far as possible, it takes into account what will be convenient to the applicant.

5.3 Requirements for a favourable opinion

5.3.1 A REC gives a favourable opinion if it is assured about the ethical issues presented by the proposed research. These issues may vary, depending on the research in question. REC members receive training and guidance (available from www.nres.npsa.nhs.uk) about the issues they should consider, both in general and in particular cases. The training and guidance reflect recognised standards for ethical research, such as the Declaration of Helsinki [9], and take account of applicable legal requirements.

5.4 Principles of research ethics committee review

- 5.4.1 RECs receive training, guidance, standard operating procedures and quality assurance (including appraisal and accreditation) in order to support them to identify the relevant issues and consider them appropriately.
- 5.4.2 RECs should receive guidance on the wider regulatory and governance environment for research and its reliability so that they can assess the assurances they receive. RECs will accept credible assurances that others will do what is expected of them.
- (a) A REC need not reconsider the quality of the science, as this is the responsibility of the sponsor and will have been subject to review by one or more experts in the field (known as 'peer review'). The REC will be satisfied with credible assurances that the research has an identified sponsor and that it takes account of appropriate scientific peer review.
 - (b) A REC can expect to rely on established mechanisms for ensuring the proper conduct of the research at individual sites. Organisations providing care that are subject to the UK Health Departments' *Research Governance Framework* are responsible for the management, governance and monitoring of the research they host. Other standards assurance processes, such as inspection or accreditation of sites by regulators, may also be adequate for the REC to be assured about the suitability of those sites.
 - (c) Where others have a regulatory responsibility, a REC can expect to rely on them to fulfil it. If the law gives another body duties that are normally responsibilities of a REC according to this document, RECs do not duplicate them. For example, the Medicines and Healthcare products Regulatory Agency has the primary legal responsibility for considering the safety of the research it regulates.

5.5 Expedited review

- 5.5.1 Some research requiring REC review in accordance with Section 2 may be suitable for expedited review, e.g. because of a public health emergency or because the proposal presents no material issues of research ethics.
- 5.5.2 Standard operating procedures for expedited review of research proposals should specify:
- (a) the nature of the applications, amendments or other considerations that are eligible for expedited review;
 - (b) the application and review process;
 - (c) the quorum requirements; and
 - (d) the status of decisions (e.g. whether they require ratification in full committee).

5.6 Transparency

5.6.1 RECs should publish a summary of their opinions, whether favourable or otherwise.

6 Standard operating procedures

6.1 Summary

6.1.1 Common working practices promote efficiency and enable research ethics committees (RECs) to work together as part of a consistent Research Ethics Service. Published standards allow researchers and the public to expect transparent accountability.

6.2 Purpose

6.2.1 Standard operating procedures for RECs are essential to an efficient, consistent and accountable Research Ethics Service.

6.3 Content

6.3.1 Standard operating procedures take account of applicable laws and national guidance, advice and exemplars. They also reflect relevant internationally recognised principles and standards.

6.3.2 Standard operating procedures provide the operational detail for meeting the principles, requirements and standards set out in this document.

6.4 Compliance and accountability

6.4.1 Each REC must adopt standard operating procedures approved by or on behalf of its appointing authority, as well as by any other body whose approval is required by law. The head offices of the Research Ethics Service enable adoption by all RECs of standard operating procedures and other common working practices.

6.4.2 RECs act in accordance with their standard operating procedures and are ultimately accountable to their appointing authorities for their governance in this respect.

6.4.3 Standard operating procedures are publicly available from www.nres.npsa.nhs.uk [10].

Glossary

HSC	Health and Social Care, the name for health and personal social services in Northern Ireland
intrusive research	<p>Section 30 of the Mental Capacity Act defines ‘intrusive research’ as research that (a) is carried out on, or in relation to, a person who lacks capacity to consent to it and (b) would be unlawful if it were carried out on, or in relation to, a person who had capacity to consent to it, but without his or her consent. Intrusive research involving people who lack the capacity to consent to it requires a favourable REC opinion before it may begin.</p> <p>NB Section 30 of the Mental Capacity Act does not apply to clinical trials of investigational medicinal products (CTIMPs). CTIMPs involving people who lack the capacity to consent are covered separately by Clinical Trials Regulations.</p>
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
MoDREC	Ministry of Defence Research Ethics Committee
NHS	National Health Service, the name for health and adult social care services in England, health and social care services in Wales and health and community care services in Scotland
NRES	National Research Ethics Service, which is the research ethics committees and the head office (see Annex C) of the Research Ethics Service in England. The NRES head office also performs some functions (see Annex E) on behalf of the other nations’ head offices, as well as acting for the UK Health Departments and UKECA in respect of some UK-wide functions.
REC	<p>research ethics committee, specifically one within the UK Health Departments’ Research Ethics Service</p> <p>NB The term ‘REC’ in this document should not be interpreted as referring to any other body that reviews the ethics of research.</p>

relevant material	<p>Section 53 of the Human Tissue Act defines ‘relevant material’ as any material consisting of or including human cells, apart from (a) hair and nails from living people, (b) embryos outside the human body and (c) gametes (i.e. sperm and unfertilised egg cells).</p> <p>NB Embryos and gametes are covered separately by the Human Fertilisation and Embryology Act.</p>
UKECA	<p>UK Ethics Committee Authority, which is the statutory body that, among other functions (see Annex F), recognises research ethics committees for the review of clinical trials of investigational medicinal products and approves their standard operating procedures for that review.</p>

References

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http://www.esrcsocietytoday.ac.uk/esrcinfocentre/opportunities/research_ethics_framework/
- 2 *Research Governance Framework for Health and Social Care* (2nd edn). Department of Health, Apr 2005.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962
- 3 Wales Office of Research and Development for Health and Social Care. *Research Governance Framework for Health and Social Care in Wales* (2nd edn). National Assembly for Wales, Sep 2009.
<http://wales.gov.uk/topics/health/research/nischr/publications/researchgovernance/?lang=en>
- 4 *Research Governance Framework for Health and Community Care* (2nd edn). Scottish Executive Health Department, Feb 2006.
<http://www.cso.scot.nhs.uk/publications/ResGov/Framework/RGFEEdTwo.pdf>
- 5 R&D Office. *Research Governance Framework for Health and Social Care*. Department of Health, Social Services and Public Safety, Dec 2006.
http://www.dhsspsni.gov.uk/research_governance_framework.pdf
- 6 *Xenotransplantation Guidance*. Department of Health, Dec 2006.
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063075
- 7 NRES. *Defining Research*. National Patient Safety Agency, Dec 2009.
<http://www.nres.npsa.nhs.uk/applications/guidance/research-guidance/?entryid62=66985>
- 8 *Medicines for Human Use (Clinical Trials Regulations) 2004: Membership of Research Ethics Committees v4.1*. NRES, Jul 2009.
<http://www.nres.npsa.nhs.uk/applications/guidance/clinical-trials/?entryid62=66829>

- 9 *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. World Medical Association, Oct 2008¹³. <http://www.wma.net/en/30publications/10policies/b3/index.html>
- 10 NRES. *Standard Operating Procedures for Research Ethics Committees v4.1*. National Patient Safety Agency, May 2010. <http://www.nres.npsa.nhs.uk/news-and-publications/publications/standard-operating-procedures/>

¹³ The latest version of the Declaration should normally be used, insofar as it is compatible with UK law. NB:

- The Medical Devices Regulations 2002 implement Council Directive 93/42/EEC, which specifies the September 1989 version.
- The Medicines for Human Use (Clinical Trials) Regulations 2004 specify the October 1996 version.
- The Department of Health statement, 'Registration of clinical trials and public access to findings' (<http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/index.htm>), relates to interpretation in the UK of Article 19 of the October 2008 version. The Freedom of Information Act 2000 exempts from disclosure information intended for future publication and information whose disclosure would be likely to prejudice commercial interests.

Annex A: Legal requirements for research ethics committee review

An up-to-date version of this list will be maintained and published at www.nres.npsa.nhs.uk.

Legislation	Extent of legal requirement for research ethics committee review			
	England	Wales	Scotland	Northern Ireland
Adults with Incapacity (Scotland) Act 2000 §51			✓	
Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002, as amended 2007			✓	
Health Service (Control of Patient Information) Regulations 2002	✓	✓		
Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010	✓	✓	✓	✓
Human Tissue Act 2004 §1	✓	✓		✓
Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006	✓	✓		✓
Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006	✓	✓	✓	✓
Human Tissue (Scotland) Act 2006 §40, 48			✓	
Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006			✓	

Legislation	Extent of legal requirement for research ethics committee review			
	England	Wales	Scotland	Northern Ireland
Independent Health Care Regulations (Northern Ireland) 2005				✓
Ionising Radiation (Medical Exposure) Regulations 2000, as amended 2006	✓	✓	✓	
Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000				✓
Medical Devices Regulations 2002	✓	✓	✓	✓
Medicines for Human Use (Clinical Trials) Regulations 2004, as amended 2006 (twice), 2008	✓	✓	✓	✓
Mental Capacity Act 2005 §30–34	✓	✓		
Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006	✓			
Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2007		✓		
Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007	✓			
Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007		✓		
Nursing and Midwifery Council (Midwives) Rules Order of Council 2004	✓	✓	✓	✓
Nursing Homes Regulations (Northern Ireland) 2005				✓
Private and Voluntary Health Care (England) Regulations 2001	✓			
Private and Voluntary Health Care (Wales) Regulations 2002		✓		

Legislation	Extent of legal requirement for research ethics committee review			
	England	Wales	Scotland	Northern Ireland
Residential Care Homes Regulations (Northern Ireland) 2005				✓

Annex B: Enforcement authorities

An up-to-date version of this list will be maintained and published at www.nres.npsa.nhs.uk.

Activity	Relevant body	Jurisdiction			
		England	Wales	Scotland	Northern Ireland
Protection of service users from unsafe or inappropriate care	Care Quality Commission	✓			
Human embryo research	Human Fertilisation and Embryology Authority	✓	✓	✓	✓
Licensed storage of relevant material for research purposes	Human Tissue Authority	✓	✓		✓
Research exposure to ionising radiation	IR(ME)R Inspectorates ¹⁴	✓	✓	✓	✓
Clinical investigations of medical devices	Medicines and Healthcare products Regulatory Agency	✓	✓	✓	✓
Clinical trials of investigational medicinal products	Medicines and Healthcare products Regulatory Agency	✓	✓	✓	✓

¹⁴ Each nation has its own IR(ME)R Inspectorate. This is a function of the Care Quality Commission in England and of the Welsh Ministers, the Scottish Ministers and Department of Health, Social Services and Public Safety in Wales, Scotland and Northern Ireland.

Annex C: Research Ethics Service head office functions

The head office of the Research Ethics Service in each nation:

- (a) makes arrangements on behalf of appointing authorities for the appointment of such administrative and other staff for their research ethics committees (RECs) as it considers necessary to enable them to perform their functions;
- (b) makes arrangements through their appointing authorities to provide RECs with such accommodation and facilities as it considers necessary to enable them to perform their functions (including arrangements for such administration, maintenance, cleaning and other services as it considers necessary);
- (c) may fund RECs through, or on behalf of, their appointing authorities a sum in respect of each financial year equal to the amount of expenditure which it considers may be reasonably incurred by the RECs in that year for the purpose of performing their functions;
- (d) may pay RECs through, or on behalf of, their appointing authorities such travelling and other allowances as it may determine;
- (e) collaborates with appointing authorities on their behalf to establish sufficient provision for REC review, according to a common administrative structure so that applications are directed to an appropriate and convenient REC;
- (f) ensures on behalf of appointing authorities that a rotation system (e.g. staggered tenure) is in place for REC members so as to achieve business continuity, the development and maintenance of expertise within each REC and the regular refreshment of debate;
- (g) establishes and manages regional centres where appropriate to oversee the activity of RECs;
- (h) supports appointing authorities in ensuring standard practice and a consistent approach, for the benefit of researchers and RECs alike; and
- (i) handles appeals against the unfavourable opinions of RECs on behalf of their appointing authorities.

The distribution of functions may vary between nations and some of these functions may be performed by appointing authorities (see Annex D).

Annex D: Functions of appointing authorities

An appointing authority:

- (a) establishes, on the advice of the relevant head office, research ethics committees (RECs) to act for the whole or part of their geographical area under its jurisdiction, ensuring there is sufficient provision to meet the local demand for REC review;
- (b) establishes, on the advice of the relevant head office, RECs to act in relation to such descriptions or classes of research as are appropriate;
- (c) varies, on the advice of the relevant head office, the extent to which its RECs may act under (a) and (b);
- (d) seeks recognition of its RECs if the law requires it;
- (e) on the advice of the relevant head office and in collaboration with other appointing authorities where appropriate, abolishes RECs it has established, merges them with other RECs and nominates, if required, successor RECs when RECs cease to operate or are abolished or varied under (c) or have their recognition revoked;
- (f) appoints, with support from the relevant head office, the members of its RECs in accordance with *Governance arrangements for research ethics committees* and the law to ensure that its RECs have the required composition;
- (g) indemnifies members of its RECs to relieve them of personal liability in respect of their opinions of the ethics of research;
- (h) facilitates the provision of funds for the operation of its RECs and may recharge these costs to the relevant head office;
- (i) on the advice of the relevant head office, may enter into legal agreements to secure the accommodation and facilities required to support the operation of its RECs
- (j) appoints the officers of its RECs, extends their tenure of appointment and terminates their appointment in accordance with its disqualification and resignation procedures, the requirements of *Governance arrangements for research ethics committees* and the RECs' standard operating procedures;
- (k) approves, with advice from the relevant head office, standard operating procedures for the regulation of the proceedings and business of its RECs;
- (l) approves, with advice from the relevant head office, variations to, or revocation or suspension of, the standard operating procedures of its RECs; and

Governance arrangements for research ethics committees
A harmonised edition

- (m) monitors the extent to which its RECs adequately perform their functions, through annual reports from its RECs, notification of their accreditation status and other mechanisms for quality assurance provided by the Research Ethics Service.

The distribution of functions may vary between nations and some of these functions may be performed by Research Ethics Service head offices (see Annex C) on behalf or instead of appointing authorities.

Annex E: National Research Ethics Service head office functions

In addition to its functions as the head office for the Research Ethics Service for England (see Annex C), the National Research Ethics Service head office:

- (a) develops and manages a national training programme for research ethics committee (REC) members and administrative staff and provides resources to support this training within the annual budget for RECs;
- (b) develops, implements and maintains standard operating procedures for RECs and provides advice and support to RECs on procedural issues;
- (c) develops a quality assurance programme to encourage a consistently high level of service to applicants, including accreditation of RECs, based on regular monitoring and audit of their operation and performance, and an appraisal scheme to support committee officers in performing their duties;
- (d) provides guidance and advice to assist RECs in their work and encourage consistency of approach to common issues in research ethics;
- (e) provides advice to the UK Health Departments on the practical implications of implementing legislation, policy and guidance;
- (f) appoints and supports the National Research Ethics Advisers' Panel;
- (g) acts for the UK Ethics Committee Authority (UKECA) to provide a national mechanism for operational advice and assistance to RECs recognised for the purposes of Clinical Trials Regulations;
- (h) acts for UKECA to handle appeals against the unfavourable opinions of RECs in respect of clinical trials of investigational medicinal products;
- (i) acts for UKECA to transfer to a successor REC the functions of a REC that has ceased to operate or that has been varied, abolished or had its recognition revoked; and
- (j) acts for UKECA to reallocate to RECs applications made to the Gene Therapy Advisory Committee which do not require its review.

Annex F: Functions of the UK Ethics Committee Authority

The National Research Ethics Service head office performs some functions on behalf of the UK Ethics Committee Authority (UKECA) (see Annex E). The following functions remain the responsibility of UKECA for the purposes of Clinical Trials Regulations:

- (a) establishing or recognising research ethics committees (RECs) to act for the entirety of the geographical extent of its jurisdiction or such areas thereof as it considers appropriate;
- (b) establishing or recognising RECs to act in relation to such descriptions or classes of research as it considers appropriate;
- (c) varying the extent to or relation in which RECs act under (a) and (b);
- (d) abolishing or revoking the recognition of RECs which it has established or recognised;
- (e) monitoring the extent to which RECs adequately perform their functions, including through annual reports from RECs it has recognised;
- (f) approving standing orders and standard operating procedures for the regulation of the proceedings and business of RECs; and
- (g) approving variations to or revocation or suspension of orders or procedures made or adopted under (f).

Annex G: Annual reports of research ethics committees

A REC's annual report to its appointing authority shall include at least the following:

- (a) the REC's name, address and other contact details;
- (b) the type of REC, including details of any recognition by UKECA and/or designation by the Research Ethics Service for review of certain types of research proposal;
- (c) details of the officers and staff of the REC;
- (d) details of the membership of the REC, including for each member and deputy member their occupation, expert/lay status, initial date of appointment, and where applicable the date on which the term of membership expired or the member resigned;
- (e) the current register of members' interests;
- (f) the attendance record of each member and deputy member during the year;
- (g) a list of full meetings held during the year, including their dates and the number of members attending;
- (h) the training record of each member and deputy member;
- (i) a list of the applications reviewed during the year, including the final decision reached on each application and the time taken to complete the review (or the current status of the review); and
- (j) a report by the chair on the REC's work during the year.