Ethical approval

2.8 Under Section 40 of the Act, research must be approved in writing by such persons or groups as the Scottish Ministers may specify where it involves the use of an organ retained from a post-mortem examination carried out on or after 1 September 2006 on the instructions of the Procurator Fiscal. Under the Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specification of Persons) Scotland Order 2006 such approval must be given by a Research Ethics Committee. The Order also requires Research Ethics Committee approval for new research on organs retained from a post-mortem examination that took place before 1 September 2006. A "research ethics committee" is defined in the Order as:

- Any ethics committee established or recognised under the Medicines for Human Use (Clinical Trials) Regulations 2004, or
- Any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State or the Scottish Ministers. This means all NHS RECs in Scotland and England.

2.9 The Human Tissue (Scotland) Act 2006 does not require REC approval where the research involves tissue blocks and slides retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal, or tissues and organs retained from a hospital post-mortem examination, and there is authorisation for its use in research (see below). However, under guidance issued on the Act in Scotland those responsible for the research project would be expected to obtain REC approval.

2.10 Section 48 makes transitional provision for research using organs removed from the deceased during a post-mortem examination carried out on the instructions of the Procurator Fiscal before 1 September 2006 and held for research purposes. Provided that the organ is held for research approved by a REC prior to 1 September 2006, this research may lawfully continue without the need to obtain authorisation in the terms of the Act or any further approval. It may also be used for new research approved by a REC after 1 September 2006 (see paragraph 2.8).

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ANNEX J

RESEARCH TISSUE BANKS

Model conditions of approval by Research Ethics Committees

Research Ethics Committee:	
Research Tissue Bank:	
REC reference number:	
Name of applicant:	
Date of approval:	

Ethical approval is given to the Research Tissue Bank ("the Bank") by the Research Ethics Committee ("the Committee") subject to the following conditions.

1. Further communications with the Committee

1.1 Further communications with the Committee are the personal responsibility of the applicant.

2. Duration of approval

2.1 Approval is given for a period of 5 years, which may be renewed on consideration of a new application by the Committee, taking account of developments in legislation, policy and guidance in the interim. New applications should include relevant changes of policy or practice made by the Bank since the original approval together with any proposed new developments.

3. Licensing

[Note: Omit this section if the RTB is in Scotland or the material to be stored by the Bank is entirely outside the definition of "relevant material" in the Human Tissue Act]

3.1 A copy of the Licence from the Human Tissue Authority (HTA) should be provided when available (if not already submitted).

3.2 The Committee should be notified if the Authority renews the licence, varies the licensing conditions or revokes the Licence, or of any change of Designated Individual. If the Licence is revoked, ethical approval would be terminated.

[Note: Use one of the following versions of Section 4, depending on whether the Bank has applied for and received generic approval for projects receiving tissue]

4. Generic ethical approval for projects receiving tissue

[Option A: For Banks receiving generic approval]

4.1 Samples of human tissue or other biological material may be supplied and used in research projects to be conducted *[within the establishment responsible for the Bank] and/or [by researchers and research institutions external to the Bank within the UK] [and in other countries]* in accordance with the following conditions.

4.1.1 The research project should be within the fields of medical or biomedical research described in the approved application form.

4.1.2 The Bank should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add something useful to existing knowledge.

4.1.3 Where tissue samples have been donated with informed consent for use in future research ("broad consent"), the Bank should be satisfied that the use of the samples complies with the terms of the donor consent.

4.1.4 All samples and any associated clinical information must be non-identifiable to the researcher at the point of release (i.e. anonymised or linked anonymised).

4.1.5 Samples will not be released to any project requiring further data or tissue from donors or involving any other research procedures. Any contact with donors must be confined to ethically approved arrangements for the feedback of clinically significant information.

4.1.6 A supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with the HTA Codes of Practice, the terms of the ethical approval and any other conditions required by the Bank.

4.2 A research project in the UK using tissue provided by a Bank in accordance with these conditions will be considered to have ethical approval from the Committee under the terms of this approval. In England, Wales and Northern Ireland this means that the researcher will not require a licence from the Human Tissue Authority for storage of the tissue for use in relation to this project.

4.3 The Bank may require any researcher to seek specific ethical approval for their project. Such applications should normally be made to the Committee and booked via the NRES Central Allocation System.

4.4 A Notice of Amendment form should be submitted to seek the Committee's agreement to change the conditions of generic approval.

4. Ethical approval for specific projects

[Option B: For Banks where the applicant has not applied for generic ethical approval for projects receiving tissue or such approval has not been given by the Committee]

4.1 The approval for the Bank does not confer generic ethical approval for specific research projects using tissue supplied by the Bank. Where project approval is required, either under the Human Tissue Act or NHS research governance, a specific application should be made by the researcher. Such applications should normally be made to the Committee.

4.2 To request generic ethical approval for projects to which tissue is supplied, the Bank should submit a new application rather than a Notice of Amendment.

5. Records

5.1 The Bank should maintain a record of all research projects to which tissue has been supplied. The record should contain at least the full title of the project, a summary of its purpose, the name of the Chief Investigator, the sponsor, the location of the research, the date on which the project was approved by the Bank, details of the tissue released and any relevant reference numbers.

5.2 The Committee may request access to these records at any time.

6. Annual reports

6.1 An annual report should be provided to the Committee listing all projects for which tissue has been released in the previous year. The list should give the full title of each project, the name of the Chief Investigator, the sponsor, the location of the research and the date of approval by the Bank. The report is due on the anniversary of the date on which ethical approval for the Bank was given.

6.2 The Committee may request additional reports on the management of the Bank at any time.

7. Substantial amendments

7.1 Substantial amendments should be notified to the Committee and ethical approval sought before implementing the amendment. A substantial amendment generally means any significant change to the arrangements for the management of the Bank as described in the application to the Committee and supporting documentation.

7.2 The NRES Notice of Amendment form should be used to seek approval. The form is available at http://www.nres.npsa.nhs.uk.

7.3 The following changes should always be notified as substantial amendments:

7.3.1 Any significant change to the policy for use of the tissue in research, including changes to the types of research to be undertaken or supported by the Bank.

7.3.2 Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.

7.3.3 Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.

7.3.4 A change to the conditions of generic approval. *(Omit if not applicable).*

7.3.5 Any other significant change to the governance of the RTB.

8. Serious adverse events

8.1 The Committee should be notified as soon as possible of any serious adverse event or reaction, any serious breach of security or confidentiality, or any other incident that could undermine public confidence in the ethical management of the tissue. The criteria for notifying the Committee will be the same as those for notifying the Human Tissue Authority in the case of research tissue banks in England, Wales and Northern Ireland.

9. Other information to be notified

9.1 The Committee should be notified of any change in the contact details for the applicant or where the applicant hands over responsibility for communication with the Committee to another person at the establishment.

10. Closure of the Bank

10.1 Any plans to close the Bank should be notified to the Committee as early as possible and at least two months before closure. The Committee should be informed what

arrangements are to be made for disposal of the tissue or transfer to another research tissue bank.

10.2 Where tissue is transferred to another research tissue bank, the ethical approval for the Bank is not transferable. Where the second bank is ethically approved, it should notify the responsible Research Ethics Committee. The terms of its own ethical approval would apply to any tissue it receives.

11. Breaches of approval conditions

11.1 The Committee should be notified as soon as possible of any breach of these approval conditions.

11.2 Where serious breaches occur, the Committee may review its ethical approval and may, exceptionally, suspend or terminate the approval.

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Note: Please note that any page numbers and references given below apply to version 3.0 of SOPs and may differ from this version.

Governance arrangements

for NHS

Research Ethics Committees

July 2001

Governance arrangements for NHS Research Ethics Committees

July 2001

PREFACE

1. For many years the NHS has had the benefit of a generally high standard of advice from its Research Ethics Committees (RECs), which were formally established in England under cover of HSG(91)5 for Local Research Ethics Committees (LRECs) and HSG(97)23 for Multi-centre Research Ethics Committees (MRECs).

2. The Department of Health (DH) has also established additional committees that offer an ethical opinion on research proposals within certain very specialist areas. These include the Gene Therapy Advisory Committee (GTAC), and the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA).

3. The recently published DH *Research Governance Framework for Health and Social Care*[1] (RGF) indicated a need for a review of LRECs and MRECs. There are also new developments in the national and international legal and regulatory framework in which research must in future be conducted. In particular, significant changes are required in order to respond to the rigorous standards set by European Directive 2001/20/EC.

4. The accountability for the various aspects of research was clarified in the RGF. The current document describes the role and remit of RECs as part of this overall governance framework.

5. Whilst the research environment itself is changing, the need for a prior favourable ethics opinion before the categories of research defined later in this document may be started is central to Research Governance. The provision of this opinion will remain the prerogative of Research Ethics Committees.

6. This document provides a standards framework for the process of review of the ethics of all proposals for research in the NHS and Social Care which is efficient, effective and timely, and which will command public confidence. It sets out general standards and principles for an accountable system of RECs, working collaboratively to common high standards of review and operating process throughout the NHS. It should be read in conjunction with the *Research Governance Framework for Health and Social Care*.

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[1] The *Research Governance Framework for Health and Social Care* also contains comprehensive references to other documents relevant to this guidance. It may be found on the Department of Health website: http://www.doh.gov.uk/research

7. This guidance replaces the previous guidance issued under cover of HSG(91)5 and HSG(97)23. It is Section A of a suite of documents. The topics to be covered are as follows:

    - Section A concentrates on general principles and standards, and is based on previous DH guidance, on guidance published by the World Health Organisation, and on the current regulatory standards pertaining to pharmaceutical and other research.
    - Section B offers more detailed and timely guidance on operating procedures and the requirements for general support for RECs. It will be up-dated as new or modified operating procedures are required, particularly in order to implement new European legislation.
    - Section C is a regularly up-dated resource for RECs and others, collating current advice on particular ethical issues, as issued by the Department of Health itself, or by august bodies such as Royal Colleges, Research Councils or appropriate professional organisations.

8. Plans for implementation of these Governance Arrangements for NHS Research Ethics Committees should start now, with a view to establishing the necessary REC structures and procedures from April 2002. As an interim measure, existing RECs – and their membership and administration – may continue after that date, but should operate according to this new guidance. All new appointments and new operational and management arrangements made after that date should conform to these new governance arrangements. Implementation of new structures and processes should be complete by April 2003.

Further information may be obtained from:

Central Office for Research Ethics Committees (COREC)
Room 76 Block B
40 Eastbourne Terrace
London W2 3QR

Email: ***tstacey@doh.gsi.gov.uk***

SECTION A: Statement of General Standards and Principles

1. Introduction
2. The role of Research Ethics Committees
3. The remit of an NHS REC
4. Establishment and support of NHS RECs
5. Membership requirements and process
6. Composition of an REC
7. Working procedures
8. Multi-centre research
9. The process of ethical review of a research protocol
10. Submitting an application
11. Glossary

1 Introduction

1.1 Research is essential to the successful promotion and protection of health and well-being and to modern and effective health and social care. It also contributes to the efficiency and effectiveness of the content, planning, delivery and monitoring of health and social care. The National Health and Social Services have a key role in enabling relevant research of good quality, and as part of the NHS, Research Ethics Committees (RECs) share in this duty.

1.2 There is now a quality and accountability framework within which research is to be undertaken in the NHS. This framework is described in the DH *Research Governance Framework for Health and Social Care.* In that guidance, particular reference is made to the duties and accountability of all NHS organisations that agree to host any research, whether undertaken by its own employees or by others. The *Guide to collaboration in Research between the NHS and other research funders* sets out additional factors relevant to collaboration on R&D in the NHS.

1.3 The Research Governance Framework states that the dignity, rights, safety and well-being of participants must be the primary consideration in any research study. The Department of Health requires that all research falling within certain categories *(set out in 3.1)* is reviewed independently to ensure it meets the required ethical standards.

1.4 For research in the NHS, this independent review must be obtained from a Research Ethics Committee recognised for that purpose by the Department of Health. For research in Health and Social Care occurring outside the NHS, it is recommended that an opinion should be obtained from an NHS REC, or from an REC meeting the general standards for NHS RECs laid down in this document.

1.5 The decision that a research project may proceed is an important management responsibility involving the availability of resources, financial implications, and ethical issues. Before undertaking or hosting any research, an NHS organisation must ensure that a favourable opinion on the ethics of the proposed research has been obtained from an appropriate REC. Research may not be started until this has been obtained.

1.6 The research sponsor is also required to ensure that a favourable opinion on the ethics of the proposed research has been obtained from an appropriate REC.

1.7 Irrespective of the host or sponsor of the proposed research, it is the responsibility of the named principal investigator to apply for approval by the REC. This person retains responsibility for the scientific and ethical conduct of the research.

1.8 The requirements concerning application to RECs set out in this document apply to all research conducted within the NHS. This includes research

conducted by those already having clinical responsibility for the research participants, by other NHS staff, and by those who have no other association with the NHS beyond the particular research project.

1.9 Should it wish to do so, an NHS organisation itself may corporately seek advice directly from an REC about ethical issues relating to research that it wishes to commission or host.

1.10 The protection of research participants is best served by close co-operation and efficient communication amongst all those who share the responsibility for it. Whilst not sacrificing the independence of their decision on the ethics of a proposal, RECs should, where appropriate, work closely with actual and potential participants, researchers, funders, sponsors, employers, care organisations and professionals - and each other - in order to achieve this goal.

2 The role of Research Ethics Committees

2.1 Research Ethics Committees are the committees convened to provide the independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for research studies comply with recognised ethical standards.

2.2 The purpose of a Research Ethics Committee in reviewing the proposed study is to protect the dignity, rights, safety and well-being of all actual or potential research participants. It shares this role and responsibility with others, as described in the *Research Governance Framework for Health and Social Care.*

2.3 RECs are responsible for acting primarily in the interest of potential research participants and concerned communities, but they should also take into account the interests, needs and safety of researchers who are trying to undertake research of good quality. However, the goals of research and researchers, while important, should always be secondary to the dignity, rights, safety, and well-being of the research participants.

2.4 RECs also need to take into consideration the principle of justice. This requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account in particular age, gender, economic status, culture and ethnic considerations. In this context the contribution of previous research participants should also be recalled.

2.5 RECs should provide independent, competent and timely review of the ethics of proposed studies. Although operating within the Governance Framework determined by the Department of Health, in their decision-making RECs need to have independence from political, institutional, profession-related or market influences. They need similarly to demonstrate competence and efficiency in their work, and to avoid unnecessary delay.

2.6 In common with all those involved in research in the NHS and Social Care environments, RECs should have due regard for the requirements of relevant regulatory agencies and of applicable laws. It is not for the REC to provide specific interpretation of regulations or laws, but it may indicate in its advice to the researcher and host institution where it believes further consideration needs to be given to such matters.