National Research Ethics Service

NHS Health Research Authority

Does my project require review by a Research Ethics Committee?

This algorithm is designed to assist researchers, sponsors and R&D offices in determining whether a project requires ethical review by a Research Ethics Committee under the UK Health Departments' Governance Arrangements for Research Ethics Committees (GAfREC), a harmonised version of which came into effect on 1 September 2011. It encompasses the requirements for ethical review under both the policy of the UK Health Departments and legislation applying to the UK as a whole or to particular countries of the UK.

Researchers requiring further advice should contact their R&D office in the first instance. Further advice may also be sought from a REC office or the NRES Queries Line at queries@nres.nhs.uk by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location.

GAfREC is available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474. This updated version of the algorithm takes account of paragraph 2.3.8A of GAfREC which was re-included in February 2012 following publication of an erratum.

In this document the term "Research Ethics Committee' means a REC within the UK Health Departments' Research Ethics Service, i.e. the National Research Ethics Service (in England) and the equivalent Research Ethics Services in Scotland, Wales and Northern Ireland. It does not include other RECs such as university RECs.

A. Is the project research?

A1	Is the project classified as research, or is it another type of activity such as clinical audit, service evaluation, public health surveillance, case study, satisfaction survey or equipment/systems testing? *Please refer to our leaflet "Defining Research" at http://www.nres.npsa.nhs.uk/applications/is-your-project-research/* *Specific guidance on the classification of post-market surveillance of CE marked medical devices is available within our guidance on approval for medical devices research at http://www.nres.npsa.nhs.uk/applications/guidance/guidance-and-good-practice/?esctl1507888_entryid62=66940*

If the project is not classified as research, review by a REC is not required. Host care organisations may have other arrangements in place to review the activity. Please seek advice from the R&D office or clinical governance office in the first instance.

If the project is research, proceed to Section B.

B. Is there a legal requirement for REC review of this research?

The requirements in Section B apply *whether or not* the participants are patients or service users within the services for which the UK Health Departments are responsible.

The requirements apply to the whole of the UK except where stated.

Ref.	*Question*	*Relevant legislation*
B1	Is the research a clinical trial of an investigational medicinal product? *Refer to the MHRA algorithm at http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/IsaclinicaltrialauthorisationCTArequired/index.htm#1 to determine whether the trial is subject to the Clinical Trials Regulations. Contact the MHRA Clinical Trials Helpline for further advice.*	Medicines for Human Use (Clinical Trials) Regulations 2004
B2	Is the research a clinical investigation of a non-CE Marked medical device, or a device which has been modified or is being used outside its CE Mark intended purpose, conducted by or with the support of the manufacturer or another commercial company to provide data for CE marking purposes? *Refer to our guidance on approval for medical devices research* at http://www.nres.nhs.uk/applications/guidance/guidance-and-good-practice/?esctl1507888_entryid62=66940 or MHRA guidance at http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/index.htm *Contact MHRA Devices Division for further advice.*	Medical Devices Regulations 2002
B3	Does the research involve exposure to any ionising radiation? *Refer to our guidance on research involving radiation at*	Ionising Radiation (Medical Exposure) Regulations 2000

	http://www.npsa.nhs.uk/applications/guidance/research-guidance/?esctl1428683_entryid62=67014	
B4	Will the research involve at any stage intrusive procedures with adults who lack capacity to consent for themselves, including participants retained in the study following loss of capacity? *An adult is any living participant aged 16 or over. Intrusive procedures are those requiring consent in law, including use of identifiable tissue samples or personal information.* *Applies in England, Wales and Scotland only.*	Section 51 of the Adults with Incapacity (Scotland) Act 2000 Sections 30-33 of the Mental Capacity Act 2005
B5	Will the research involve storage of relevant material from the living or the deceased on premises without a storage licence from the Human Tissue Authority (HTA)? *Relevant material means any material from a human body consisting of or including cells, except for hair or nail from the living or embryos outside the body.* *Includes storage of imported material. Does not include 'storage incidental to transportation' or temporary storage pending extraction of aceullar material for research provided that residual relevant material is disposed of within hours or days (or at most a week).* *Applies to England, Wales and Northern Ireland only.*	Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006

B6	Will the research involve storage or use of relevant 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? *Does not include imported material.* *Applies to England, Wales and Northern Ireland only.*	Section 1(9) of the Human Tissue Act 2004
B7	Will the research involve analysis of DNA in material from the living, collected on or after 1 September 2006, and the analysis is not within the terms of consent for research from the person whose body manufactured the DNA?	Section 45 of the Human Tissue Act 2004
	For further guidance on B5-B7, refer to http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/requirements-for-ethical-review-under-legislation/human-tissue/ or the HTA Code of Practice on Research at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm *Guidance on defining 'relevant material' is available from the HTA at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policiesandpositionstatements.cfm*	
B8	Will the research involve either of the following: (a) organs retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal (b) organs, tissue blocks or slides retained from a hospital post-mortem	Human Tissue (Scotland) Act 2006

	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? *Applies in Scotland only.*	
B9	Will the research involve access to, or processing of, the confidential information of patients or service users by researchers outside the normal care team without consent? *Applies in England and Wales only.* *In addition to REC review, application must be made to the National Information Governance Board's Ethics and Confidentiality Committee (NIGB ECC). Refer to http://www.nigb.nhs.uk/s251 for further guidance. Specific advice may be sought from the NIGB http://www.nigb.nhs.uk/contact-us*	Health Service (Control of Patient Information) Regulations 2002 Section 251 of the NHS Act 2006
B10	Will the research involve processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers without consent? *Authorisation for the research is required from the Human Fertilisation and Embryology Authority (HFEA). A favourable opinion from a REC is a required condition of authorisation. The NIGB ECC advises the HFEA on applications for authorisation. Please contact the NIGB for further advice http://www.nigb.nhs.uk/contact-us.*	Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010

B11	(a) Will the research involve patients (or information about patients) receiving treatment in or for the purposes of an independent hospital or independent clinic? *Applies in Wales and Northern Ireland only*. (b) Will the research involve patients (or information about patients) receiving treatment in or for the purposes of an independent medical agency? *Applies in Northern Ireland only*. *(Note: The Private and Voluntary Health Care (England) Regulations 2001 were revoked by the Health and Social Care Act 2008 (Commencement No. 16) Transitory and Transitional Provisions Order 2010 (SI 2010/87)*	The Independent Health Care (Wales) Regulations 2011 The Independent Health Care Regulations (Northern Ireland) 2005
B12	Will the research involve residents (or information about residents) at a residential care home or nursing home? *Applies in Northern Ireland only.*	Residential Care Homes Regulations (Northern Ireland) 2005 Nursing Homes Regulations (Northern Ireland) 2005
B13	Is the research a clinical trial involving the participation of practising midwives?	Nursing and Midwifery Council (Midwives) Rules Order of Council 2004
If the answer to any of the questions in Section B is Yes, application for ethical review should be made to a Research Ethics Committee within the UK Health Departments' Research Ethics Service, except for research recruiting through the UK Armed Forces or otherwise within the remit of the Ministry of Defence Research Ethics Committee (MoDREC).		

Specific requirements apply to the allocation of certain types of application. Further guidance is available from http://www.nres.nhs.uk/applications/booking-and-submitting-your-application/ or from the NRES Central Allocation System or Local Allocation Systems (see link for contact details).

If the answer to all the questions in Section B is No, please proceed to Section C to check whether any other policy requirements for ethical review apply to the study.

C. Is there a policy requirement for REC review of this research?

The requirements in Section C apply to the whole of the UK.

Ref.	*Question*	*Explanatory comments*
C1	Will the research involve research participants identified from, or because of their past or present use of, services for which the UK Health Departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls?	The relevant services are: • Adult and children's healthcare within the NHS/HSC (UK-wide) • Adult social care (England, Wales, NI) • Children's social care (Wales, NI) Refer to Supplementary Note 7 below for further guidance on social care research.
C2	Will the research involve research participants identified because of their status as relatives or carers of past or present users of	

	these services?	
C3	Will the research involve collection of tissue or information from any users of these services, including those who have died within the last 100 years?	Tissue means any material consisting of or including cells. Includes tissue or information collected in the course of normal care, where research use is intended at the time of collection.
C4	Will the research involve use of previously collected tissue or information from which the research team could identify individual past or present users of these services, either directly from that tissue or information, or from its combination with other tissue or information in or likely to come into their possession?	Tissue means any material consisting of or including cells. Refer to Supplementary Notes 1-3 below for further guidance on circumstances where REC review is not required for secondary use of tissue or information previously collected in the course of normal clinical care.
C5	Is this a health-related research project involving prisoners?	A prisoner for this purpose means a person in the custody of the National Offender Management Service (i.e. the Prison Service in England and Wales), the Scottish Prison Service or the Northern Ireland Prison Service?
C6	Does this research involve xenotransplantation?	Xenotransplantation means putting living cells, tissue or organs from animals into people.
C7	Is this a social care research project funded by the Department of Health?	
If the answer to any of the questions in Section C is Yes, application for ethical review should be made to a Research Ethics Committee within		

the UK Health Departments' Research Ethics Service.

Where research approved by the Ministry of Defence Research Ethics Committee (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.

Specific 'flags' apply to the allocation of certain types of application. Further guidance is available from http://www.nres.nhs.uk/applications/booking-and-submitting-your-application/ or from the NRES Central Allocation System or Local Allocation Systems (see link for contact details).

Supplementary notes on research not requiring REC review

The following types of research do not normally require review by a REC within the UK Health Departments' Research Ethics Service. Alternative sources of ethical review may be available in some cases, e.g. from a university REC (UREC).

Researchers should note that, where the Research Governance Framework for Health and Social Care applies, research will continue to require management permission from host care organisations ("R&D approval"). For NHS/HSC care organisations, researchers should seek advice from relevant R&D offices about arrangements to seek permission for such research. Within the Integrated Research Application System (IRAS), it is possible to indicate in the Filter that a research project requires review by R&D only, and this produces a simplified version of the application form.

1. Research involving previously collected, non-identifiable information

Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research (see C4 above).

This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research.

2. Research involving previously collected, non-identifiable tissue samples

Research limited to use of previously collected, non-identifiable material consisting of or including cells in accordance with the terms of donor consent is generally excluded from REC review.

However, REC review would be required if any of the following applied:

(a) Consent for research has not been given, or the research is not within the terms of the consent (see B6 above)
(b) The samples will be held on premises in England, Wales or Northern Ireland without a licence from the Human Tissue Authority to store relevant material for scheduled purposes (see B5)
(c) The research also involves removal, storage or use of new samples from the living or the deceased (see C3)
(d) The research also involves use of identifiable information held with the samples (see C4).

Researchers are encouraged to consider making a voluntary application for REC review where the exclusion applies but the study raises significant ethical issues, in particular where a generic consent given previously may not be adequate in the circumstances of the current study. For example, where a study could generate sensitive and clinically relevant information for the donors and/or their relatives, and the samples are linked anonymised potentially enabling donors to be re-contacted, it would be appropriate to apply to a REC to seek ethical advice on whether further specific consent should be sought and/or how feedback of results would be handled. The Research Ethics Service will accept voluntary applications raising ethical issues of this nature. It is helpful if researchers indicate clearly in their application why they are seeking voluntary review.

Research teams undertaking a programme of research with stored samples are also encouraged to make use of the NRES voluntary scheme of generic ethical review for Research Tissue Banks / Biobanks. Further guidance is at http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/.

In cases where review by a REC is not necessary, academic researchers are recommended to seek ethical review by a university REC as an alternative. The Code of Practice on Research from the Human Tissue Authority (HTA) recommends that any research with human tissue is conducted with ethical approval and that a HTA storage licence should not be seen as an alternative.

Researchers should always seek advice from the local R&D office (and from the Designated Individual in the case of HTA licensed institutions) on the appropriate arrangements for review of their research.

3. Research involving acellular material

Research limited to acellular material (e.g. plasma, serum, DNA) extracted from tissue previously collected in the course of normal care is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research.

This exception applies to research undertaken by staff within a care team using samples previously collected for clinical purposes from their own patients or clients, provided that the samples/data are anonymised or pseudonymised in conducting the research.

However, REC review would be required if the research involved:

(a) Collection of tissue samples from patients in order to extract acellular material for the research (see C3)
(b) Collection of information from patients (see C3)
(c) Use of previously collected information from which patients could be identified by the researchers (see C4)
(d) Analysis of DNA in material from the living, where consent for research is not in place from the person whose body manufactured the DNA (see B7)

Researchers are encouraged to consider making a voluntary application for REC review where the exclusion applies but the study raises significant ethical issues; or when undertaking a programme of research with stored samples in, e.g. a DNA Bank. See guidance under 2 above.

4. Research involving staff

REC review is not normally required for research involving NHS or social care staff recruited as research participants by virtue of their professional role.

Exceptionally, the Research Ethics Service may accept an application for review of research involving staff at the request of the sponsor, chief investigator or host organisation, where it agrees that the proposal raises material ethical issues. Agreement should be sought from the responsible operational manager for the local REC centre prior to submission of the application. Requests should be sent by email, including a summary of the research proposal (maximum one page) and explanation of why the project raises significant issues which cannot be managed routinely in accordance with established guidelines and good practice, and requires ethical consideration and advice from a REC. Further guidance on research involving staff is set out in the Annex to this document.

Contact points for REC operational managers are at http://www.nres.nhs.uk/contacts/nres-office-and-departmental-contact-details/

5. Healthcare market research

REC review is not normally required for healthcare market research conducted by professional market researchers in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA).

Exceptionally, the Research Ethics Service may accept an application for review of healthcare market research at the request of the sponsor, chief investigator or host organisation, where it agrees that the proposal raises material ethical issues. See guidance under paragraph 4 above.

6. Research involving the premises or facilities of care organisations

REC review is not required for research involving use of or access to a care organisation's premises or facilities, provided that review is not required under any other applicable legal or policy requirement. For example, a Phase 1 clinical trial undertaken by a Contract Research Organisation on premises rented from a NHS Trust would legally require REC review under the Clinical Trials Regulations. But research undertaken by a university department on NHS premises, involving healthy volunteers not recruited as NHS patients and not subject to any

legal requirements, would not require review by a REC within the UK Health Departments' Research Ethics Service and could be reviewed by the university's research ethics committee.

7. Social care research

Under paragraph 2.3.8A of GAfREC, research does not require review by a REC within the UK Health Departments' Research Ethics Service if it is reviewed by another committee operating in accordance with the Economic and Social Research Council's *Framework for Research Ethics,* unless any of the following apply:

(a) The research involves withdrawing standard care;
(b) The research involves NHS patients or service users as research participants;
(c) The research is a social care research project funded by the Department of Health in England; or
(d) There is a legal requirement for REC review of the research (i.e. <u>any</u> requirement under Section B of this guidance)

The effect of this exception is that some social care research does not require REC review, provided that it is reviewed by a committee operating in accordance with the ESRC Framework (for example, a UREC). Projects meeting these criteria should normally be reviewed by a UREC or another appropriate committee where possible. However, application may be made to a REC where review by another committee is not available.

Researchers should note that REC review for social care research in **England** (adult social care only), **Wales and Northern Ireland** (adult and children's social care) is still required where:

(i) a legal requirement applies (e.g. under the Mental Capacity Act);
(ii) the study has DH funding;
(iii) the study involves withdrawing any aspect of standard care from social care users;
(iv) the study involves NHS patients recruited in the social care setting, or a mix of NHS patients and social care users; or
(v) review by another REC operating in accordance with the ESRC Framework is not available.

For further guidance about the remit of the Social Care Research Ethics Committee in England, refer to http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/social-care-research/ or to http://www.screc.org.uk/. In Wales and Northern Ireland, social care research applications may be submitted to any REC.

In **Scotland**, GAfREC does not normally require REC review of research in the social care setting. It would only be required, exceptionally, where:

(i) the study falls within the scope of Section 51 of the Adults with Incapacity (Scotland) Act, e.g. it is medical, nursing or psychological research involving adults unable to consent for themselves.
(ii) the study involves NHS patients, or a mix of NHS patients and social care users.

Nevertheless, RECs in Scotland will generally accept voluntary applications for review of social care research which is related to healthcare.

ANNEX

Research involving NHS/HSC staff[1]

Under paragraph 2.3.13 of GAfREC, review by a REC within the UK Health Departments' Research Ethics Service is not normally required for research involving healthcare or social care staff recruited as research participants by virtue of their professional role.

The aim of the scenarios described below is to illustrate a range of studies involving staff which:

- would not require REC review under the harmonised UK-wide edition of GAfREC; or
- would require REC review, exceptionally, because they raise significant ethical issues or because another provision of GAfREC applies.

Studies not requiring ethical review by a REC

1. A university student is completing a Masters degree. The research seeks the views of occupational therapists on use of art as therapy with patients. The student will be sending out a questionnaire to all occupational therapists in a NHS/HSC Trust asking them to return the completed questionnaire anonymously to the researcher using the SAE provided. This research project involves healthcare staff by virtue of their professional role and presents no material ethical issues. It would not require REC review under GAfREC.

2. A NHS/HSC Trust is surveying staff experiences of being gay, lesbian or transgender in the workplace and whether they have been bullied or stigmatized as a result of their sexuality, to inform a programme of staff training and awareness raising. Staff will be invited to take part by virtue of their professional role. The project involves issues around staff disclosure of their own sexual orientation as well as their perception of how this is managed by their employer. Staff are not obliged to participate and confidentiality must be ensured.

[1] NRES is grateful to the Office for Research Ethics Committee and R&D Division within Northern Ireland Health and Social Care, who developed the case studies used in this annex.

These are important issues but REC review is not required as they fall to be managed within the remit of the normal employer/employee relationship and in accordance with routine practice for staff surveys.

3. A group of public health researchers want to study the uptake of influenza vaccine offered to front line NHS/HSC staff by their employers. The vaccine was offered in a health and safety context, to reduce the possibility of staff infecting service users. The researchers wish to survey staff members to investigate how staff attitudes and beliefs influence vaccine uptake and what organisational issues may influence uptake. Trusts are asked to identify members of staff who have not taken up the offer of the vaccine. A questionnaire will be sent to staff members at their home address exploring their attitudes, beliefs and knowledge relating to the vaccine. Return of the questionnaire is voluntary and anonymous. The participants are staff recruited by virtue of their professional role. The research is concerned with issues of employment rather than health and can be managed within the normal employer/employee relationship.

4. A NHS/HSC Trust wishes to undertake a research study looking at two techniques for emergency airway access based on the Difficult Airway Society Guidelines. The protocol involves staff (anaesthetists) in administering the techniques to mannequin dummies (no patients are involved). The staff are research participants by virtue of their professional role. It presents no material ethical issues and does not require REC review.

Studies requiring ethical review by a REC

1. A social worker is researching residential social workers' experience of working with vulnerable 'looked after' children who have a history of being sexually abused. The design of the study is a focus group based interview involving residential social workers and discussion of individual children's cases. It is possible that during the interview the identity of the child/ children may be unintentionally disclosed. This is a study which involves social care staff by virtue of their professional role but there are significant ethical issues involving disclosure and breach of confidentiality, exceptionally justifying an application for ethical review.

2. A researcher working in a NHS/HSC hospital laboratory wishes to conduct research involving the development of a new diagnostic test for lung cancer. The researcher needs access to normal control samples from non-patient volunteers and plans to collect blood and urine samples from all staff in the laboratory with their consent. The hospital does not hold a licence from the Human Tissue Authority. This requires ethical approval under other provisions of GAfREC. Firstly, the involvement of HSC/NHS staff in this study is not by virtue of their professional role; they are being recruited through the NHS/HSC organisation as healthy controls and REC review is required

(see C1 of the main guidance in this document). Secondly, REC approval would be required by law in England, Wales or Northern Ireland to qualify for exemption from HTA licensing to store relevant material for scheduled purposes (see B5).