National Research Ethics Service

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). 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.npsa.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

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*	Medicines for Human Use (Clinical Trials) Regulations 2004

	http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/IsaclinicaltrialauthorisationCTAreguired/index.htm#1 to determine whether the trial is subject to the Clinical Trials Regulations. Contact the MHRA Clinical Trials Helpline for further advice.	
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.npsa.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 http://www.nres.npsa.nhs.uk/applications/guidance/research-guidance/?esctl1428683_entryid62=67014*	Ionising Radiation (Medical Exposure) Regulations 2000
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)?	Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of

	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.*	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.npsa.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:	Human Tissue (Scotland) Act 2006

	(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 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	Will the research involve patients (or information about patients) receiving care at a nursing home or other independent hospital, clinic or medical agency? *Applies in England, Wales and Northern Ireland only.*	Private and Voluntary Health Care (England) Regulations 2001 Private and Voluntary Health Care (Wales) Regulations 2002

		Independent Health Care Regulations (Northern Ireland) 2005 Nursing Homes Regulations (Northern Ireland) 2005
B12	Will the research involve residents (or information about residents) at a residential care home? *Applies to Northern Ireland only.*	Residential Care 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.npsa.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: • NHS/HSC healthcare (UK-wide) • Adult social care (England, Wales, NI) • Children's social care (Wales, NI)
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 the *"Supplementary notes on research not requiring REC review"* below for further guidance on circumstances where 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.npsa.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.

1. Research involving previously collected, non-identifiable information

Research limited to secondary use of tissue or 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 thej 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).

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)

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. Contact points for operational managers are at http://www.nres.npsa.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 2 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.