

Changes to the remit of Research Ethics Committees (September 2011)

Guidance for researchers, sponsors, R&D offices and RECs

Introduction

A harmonised edition of the Governance Arrangements for Research Ethics Committees (GAfREC) was issued by the UK Health Departments in May 2011 and came into effect from 1 September 2011.

The harmonised GAfREC sets out the requirements for review of research by Research Ethics Committees within the UK Health Departments' Research Ethics Service. These include both policy requirements, and requirements under legislation applicable to the whole of the UK or to certain countries of the UK.

This document is intended to highlight the main changes to the remit of RECs under the harmonised GAfREC, compared to the edition of GAfREC published by the Department of Health in July 2001 ("the 2001 edition").

Please refer to Section 2 of GAfREC itself for a full description of the requirements:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126474

NRES has produced an algorithm ("the NRES algorithm") to help researchers to determine whether their project requires ethical review by a REC:

<http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/>

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.

Note on R&D approval for research not requiring REC review:

Under the harmonised GAfREC, certain types of research no longer require REC review. However, where the Research Governance Framework for Health and Social Care applies, the 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.

Main changes to the remit of RECs

1. Legal requirements for REC review

The harmonised GAfREC updates the remit of REC to include a range of legal requirements for REC review flowing from legislation which has come into force since 2001. These are summarised in paragraphs 2.3.5-2.3.6 of GAfREC and incorporated within the NRES algorithm (see link above).

For more detailed information about each area of legislation (e.g. clinical trials, human tissue, adults lacking capacity, radiation), refer to the algorithm and additional guidance at <http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/requirements-for-ethical-review-under-legislation/>

Under the NRES Standard Operating Procedures, first produced in 2004, RECs have been routinely accepting all applications for ethical review required by legislation, in addition to those required under the policy in the 2001 edition. Therefore the updating of GAfREC will make no difference in practice either to the requirements for application or the service provided to researchers.

2. Social care research

Under the 2001 edition, which applied to NHS RECs, the remit of RECs was limited to research involving the NHS, broadly speaking to projects involving NHS patients or their tissue and data, relatives and carers of NHS patients, NHS staff and NHS facilities.

The harmonised edition extends the potential remit of RECs within the UK Health Departments' Research Ethics Service to research involving other participants who are users of any of the services for which the UK Health Departments are responsible. This includes adult social care in England, and both adult and children's social care in Wales and Northern Ireland.

However, 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.

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 university REC). 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 or Northern Ireland** (adult and children's social care) is still required where:

- a legal requirement applies (e.g. under the Mental Capacity Act; refer to section B of the NRES algorithm for a full list of the legislation);
- the study has DH funding;
- the study involves withdrawing any aspect of standard care from social care users;
- the study involves a mix of NHS patients and social care users; or
- review by another REC operating in accordance with the ESRC Framework is not available.

For further guidance about applications for review of social care research in England and the remit of the Social Care Research Ethics Committee, 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.

3. Research involving staff

Under the 2001 edition, REC review was required for research involving NHS staff recruited as research participants by virtue of their professional role. Such research, or equivalent research involving the staff of social care providers, is excluded from the normal remit of RECs under the harmonised edition of GAfREC. Alternative sources of review may be available, e.g. from a university REC.

Exceptionally, the Research Ethics Service may accept an application for review of such research 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.nhs.uk/contacts/nres-office-and-departmental-contact-details/>

Further guidance with examples of staff-related research not requiring REC review (or, exceptionally, requiring such review) is available in the Annex to the NRES algorithm.

4. 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
- (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
- (c) The research also involves removal, storage or use of new samples from the living or the deceased
- (d) The research also involves use of identifiable information held with the samples.

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.

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.

5. Research involving acellular material

Research limited to use of human biological material not consisting of or including cells (e.g. plasma, serum, DNA) is also generally excluded from REC review.

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
- (b) Collection of information from patients
- (c) Use of previously collected information from which patients could be identified by the researchers
- (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.

Guidance on biological material generally considered to be acellular is available within the guidance issued by the Human Tissue Authority on defining 'relevant material' for the purpose of the Human Tissue Act 2004

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policiesandpositionstatements.cfm>

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 4 above.

6. Research involving previously collected, non-identifiable information

Under the 2001 edition, REC review was required for any research involving the data of NHS patients.

REC review continues to be required for research involving collection of information from patients or service users for research.

REC review is also required for research involving use of previously collected information from which patients or service users could be identified by researchers outside the usual care team (either directly from that information or in combination with other information in, or likely to come into, their possession).

However, REC review is not required under the harmonised GAfREC for research limited to use of previously collected, non-identifiable information. 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. Such research would involve no breach of the duty of confidentiality owed by care professionals.

7. Research involving prisoners

REC review is required for health-related research involving prisoners 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.

Applications should normally be submitted to flagged RECs in England and Wales, or to any REC in Scotland and Northern Ireland.

8. Healthcare market research

Paragraph 2.3.14 of the harmonised GAfREC clarifies that 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 (BHBI).

Exceptionally, such research may be accepted for review by the Research Ethics Service where it is agreed that material ethical issues arise. Pre-application requests should be sent to the responsible operational manager in the same way as for exceptional requests to review research involving staff (see section 3 above).

9. Research involving premises and facilities

Under the 2001 edition, research required REC review if it involved the use of, or access to NHS premises and facilities.

Paragraph 2.3.16 of the harmonised edition clarifies that research limited to use of or access to a care organisation's premises or facilities no longer requires REC review, provided that review is not required under other provisions of GAfREC. 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.

National Research Ethics Service

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