# Does my project require review by a Research Ethics Committee?

The Health Research Authority (HRA) provides two linked, online decision tools to assist you in determining whether your project is classified as research and whether it requires ethical review by a NHS Research Ethics Committee (REC). These tools are available at:

- **Is it research?**
- **Do I need NHS REC review?**

As long as the information you enter is correct, the outcome of these decision tools can be taken as authoritative, and you do not need to seek further confirmation. The decision obtained from the decision tools should not be interpreted as giving a form of ethical review or endorsement to your project on behalf the HRA. However, it may be provided to a journal or other body as evidence if required.

This algorithm is designed to complement these tools by providing more detailed information and guidance to assist researchers, sponsors and R&D offices in determining whether a project requires ethical review by a Research Ethics Committee under the Devolved Administrations' and the Health Research Authority's Governance Arrangements for Research Ethics Committees (GAfREC). This document 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.

**Please note:** responsibility for determining if an activity is research and which regulatory approvals are needed sits with the sponsor.

In this document the term 'Research Ethics Committee' means a REC within the UK Health Departments' Research Ethics Service, i.e. a REC in the Health Research Authority (in England) and the equivalent Research Ethics Services in Scotland, Wales and Northern Ireland. It does not include other RECs such as university RECs. Where the NHS is referenced throughout this document, this refers to Health and Social Care (HSC) in Northern Ireland.

This document uses the following abbreviations to explain which nations the information provided is applicable to:

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| E | England |
| W | Wales |
| S | Scotland |
| NI | Northern Ireland |
| UK wide | Applies to England, Wales, Scotland and Northern Ireland |

## A. Is the project research?

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| A1 | **Is the project classified as research, or is it another type of activity such as clinical audit or service evaluation, public health surveillance, case study, or a satisfaction survey?**<br><br>*Please refer to our 'Is it research?' decision tool.*<br><br>*For the purpose of the UK Policy Framework for Health and Social Care Research "research is defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research."* | **UK-wide** |

**If the project is not classified as research**: Review by a REC is not required. Where a research study does not require review by a research ethics committee within the Research Ethics Service under GAfREC, review may be undertaken by another appropriate committee. The Economic and Social Research Council's Framework for Research Ethics sets out principles, requirements and standards for university committees that are compatible with those set out in this document.

**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 | |
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| B1 | **Is the research a clinical trial of an investigational medicinal product?**<br><br>Please refer to the MHRA algorithm to determine whether the trial is subject to the UK Clinical Trials Regulations:<br><br>https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#when-a-clinical-trial-authorisation-cta-is-needed | Medicines for Human Use (Clinical Trials) Regulations 2004 | UK-wide |
| B2 | **Is the research a clinical investigation of a non-CE Marked medical device, or a CE-Marked device, that has been modified, or is being used, outside of its' current intended purpose?**<br><br>Please refer to the MHRA guidance on approval for medical devices research at https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety<br><br>MHRA guidance on software applications is available here: https://www.gov.uk/government/publications/medical-devices-software-applications-apps<br><br>REC review is also required for post market surveillance studies involving a CE-marked device used within its' intended purpose but involving a change to standard care. 'Change to standard | Medical Devices Regulations 2002<br><br>EU Regulation on Medical Devices 2017/745 (applies from May 2020) | UK-wide<br><br>UK-wide |

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| | care' means that there could be a change to the patient's treatment if they opt to take part in the study, compared to the treatment normally provided outside the study. | | |
| B3 | **Does the research involve exposure to ionising radiation?**<br><br>The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) apply to the exposure of ionising radiation to patients or other persons participating in medical or biomedical, diagnostic or therapeutic research (this includes sports science studies).<br><br>Please refer to the HRA guidance on research involving radiation at:<br><br>*https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/ionising-radiation/* | Ionising Radiation (Medical Exposure) Regulations 2017<br><br>Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 | E+W+S<br><br>NI |
| B4 | **Will the research involve at any stage procedures (including use of identifiable tissue samples or personal information)involving adults who lack capacity to consent for themselves, including participants who would be retained in the study following loss of capacity?**<br><br>For the purposes of the Mental Capacity Acts (MCA) and Adults with Incapacity Act (AWI), an adult is any living participant aged 16 or over.<br><br>Approval under the MCA and AWI Acts may also be required where the research involves procedures with adults whose capacity is likely to fluctuate during the study. | Section 51 of the Adults with Incapacity (Scotland) Act 2000<br><br>Sections 30-33 of the Mental Capacity Act 2005 (England and Wales)<br><br>Mental Capacity Act (Northern Ireland) 2016 | S<br><br>E&W<br><br>NI |
| 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)?**<br><br>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.<br><br>Includes storage of imported material. | Human Tissue Act 2004 | E+W+NI |

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| | 'Storage' does not include:<br><br>• storage incidental to transportation –where relevant material is only being held temporarily, in transit, while it is being conveyed from one place to another - provided that relevant material is moved from the premises within hours or days (or at most a week), or<br><br>• where relevant material is being temporarily held whilst it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular). The HTA views this as analogous to the incidental to transportation exception above. If there is no intention to use or store relevant material for research, and the only holding of relevant material is temporary and for the purpose of obtaining material which does not contain cells, then no HTA storage licence is required.<br><br>Applies to England, Wales and Northern Ireland only. | | |
| 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?**<br><br>Does not include imported material.<br><br>Where a researcher holds relevant material for a short period for the purpose of a project to conduct analysis prior to discarding the relevant material, this is storage for a scheduled purpose (i.e. research). Such storage requires either a licence from the HTA or a favourable ethical opinion for the project.<br><br>In the HTA Code of Practice and Standards on Research (Code E) there are several examples where a HTA storage licence would and would not be required.<br><br>Applies to England, Wales and Northern Ireland only. | Section 1(9) of the Human Tissue Act 2004 | E+W+NI |
| B7 | **Will the research involve analysis of human DNA in cellular material collected on or after 1 September 2006 where appropriate consent for the research is not in place?**<br><br>If you are using DNA that has already been extracted and isolated from human cells, the answer to this question is NO. | Section 45 of the Human Tissue Act 2004 | E+W+NI |

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| | For further guidance on B5-B7, refer to: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/<br><br>or the HTA Code of Practice on Research at: https://www.hta.gov.uk/hta-codes-practice-and-standards-0 | | |
| B8 | **Will the research involve either of the following:**<br><br>**(a) organs retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal**<br><br>**(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?**<br><br>For further guidance please refer to Health Department Letter (HDL) – reference NHS HDL (2006) 46 – paragraph 49 www.sehd.scot.nhs.uk | Human Tissue (Scotland) Act 2006 | S |
| B9 | **Will the research involve processing of the confidential information of patients or service users by researchers outside of the care team without consent?**<br><br>"Processing" in this context means the use, disclosure or obtaining of the information or the doing of such other things in relation to it as may be prescribed, as defined in s251(13) NHS Act 2006.<br><br>In addition to REC review, an application must be made to the Confidentiality Advisory Group (CAG). Any research application applying to the CAG must always obtain a favourable ethical opinion.<br><br>Please refer to: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/ for guidance.<br><br>Applies in England and Wales only. | Health Service (Control of Patient Information) Regulations 2002<br><br>Section 251 of the NHS Act 2006 | E+W |

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| B10 | **Will the research involve processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority (HFEA) by researchers without consent?**<br><br>Disclosable protected information means identifying information held by the HFEA, on a database register, about patients who have undergone assisted reproduction treatments and services and any resulting children. "Processing" in this context means using this information, as defined in regulation 2 of the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010. Answer YES to this question if it is not practicable to obtain consent for the disclosure of this information.<br><br>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.<br><br>The HFEA and the HRA's Confidentiality Advisory Group have put in place coordinated arrangements for the processing of applications to access identifiable HFEA Research Register information without consent. | Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 | UK-wide |
| B11 | **(a) Will the research involve patients, or tissue or information relating to patients, being treated in an independent establishment in Wales or for the purposes of an independent establishment in Wales?**<br><br>*Applies in Wales only. 'Establishment' means an independent hospital or independent clinic.*<br><br>**(b) Will the research involve patients (or information about patients) in or for the purposes of an independent establishment or independent agency in Northern Ireland?**<br><br>*Applies in Northern Ireland only. 'Agency' means an independent medical agency. 'Establishment' means an independent hospital or independent clinic.* | The Independent Health Care (Wales) Regulations 2011<br><br>The Independent Health Care Regulations (Northern Ireland) 2005 | (a) W<br><br>(b) NI |
| B12 | **Will the research involve residents or patients (or information about them) in or for the purpose of residential care homes or nursing homes in Northern Ireland?**<br><br>*Applies in Northern Ireland only.* | Residential Care Homes Regulations (Northern Ireland) 2005 | NI |

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| | | Nursing Homes Regulations (Northern Ireland) 2005 | |

## If the answer to any of the questions in Section B is 'Yes':

An application for ethical review must be made to an appropriate Research Ethics Committee within the UK Health Departments' Research Ethics Service.

Research recruiting through the UK Armed Forces or otherwise within the remit of the Ministry of Defence Research Ethics Committee (MoDREC) should be submitted to 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.

Specific requirements apply to the allocation of certain types of application. Further guidance is available from: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

## If the answer to all the questions in Section B is 'No':

Please proceed to Section C to check whether any 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 following areas of the UK Health Departments' responsibility (including services provided under contract with the private or voluntary sectors):

| Nation | Health Department | Services |
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| England | Department of Health and Social Care (England) | NHS and adult Social Care |
| Northern Ireland | Department of Health (Northern Ireland) | Health and Social Care |
| Scotland | Scottish Government Health Directorates | NHS and adult Social Care |
| Wales | Department for Health and Social Services | NHS and Social Care |

| Ref. | Question | Explanatory comments | |
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| C1 | **Will the research involve potential research participants identified in the context of, or in connection with, their past or present use of these services, including participants recruited through these services as healthy controls?** | Excludes research where participants have been identified because they have a condition that was diagnosed by the NHS in the past but where the research is being conducted independently of the NHS. For example, patients with cancer which may have been diagnosed by the NHS but who are identified from a cancer charity's contact list to be participants in a research project that is otherwise being conducted independently of the NHS. | UK-wide |

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| | | **Research involving NHS staff**<br>REC review is not normally required for research involving NHS or social care staff recruited as research participants by virtue of their professional role. Section F includes some scenarios of projects involving staff which would and would not require REC review.<br><br>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.<br><br>Agreement should be sought from the Research Ethics Service prior to submission of the application. Requests should be sent to the HRA Queries Line.<br><br>**Social Care Research**<br><br>Under paragraph 2.3.9 of GAfREC, social care 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:<br><br>(a) The research involves deviating from standard social care.<br><br>(b) The research involves NHS patients or service users as research participants;<br><br>(c) The research is a social care research project funded by the Department of Health & Social Care in England; involving adult social care service users as participants. | |

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| | | (d) There is a legal requirement for REC review of the research (i.e. <u>any</u> requirement under Section B of this guidance)<br><br>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 - UREC). Projects meeting these criteria should normally be reviewed by a UREC or another appropriate committee where possible. However, an application may be made to a REC where review by another committee is not available.<br><br>In Wales and Northern Ireland, social care research applications may be submitted to any NHS REC.<br><br>In Scotland, GAfREC does not normally require REC review of research in the social care setting. It would only be required, exceptionally, where:<br><br>(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.<br><br>(ii) the study involves NHS patients, or a mix of NHS patients and social care users.<br><br>NHS RECs in Scotland will generally accept voluntary applications for review of social care research which is related to healthcare. | |
| C2 | **Will the research involve potential research participants identified because of their status as relatives or carers of past or present users of these services?** | | UK-wide |

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| C3 | **Will the research involve prospective collection of tissue (i.e. any material consisting of or including human cells) from any users of the services listed above identified in the context of, or in connection with, their past or present use of these services, including participants recruited through these services as healthy controls?**<br><br>*"Tissue" means any material consisting of or including human cells, as defined in GAfREC 2.3.5.c* | This includes those who have died within the last 100 years.<br><br>Includes tissue collected in the course of standard care, where research use is intended at the time of collection. | UK-wide |
| C4 | **Will the research involve prospective collection of information from any users of the services listed above identified in the context of, or in connection with, their past or present use of these services, including participants recruited through these services as healthy controls?** | Includes information collected in the course of normal care, where research use is intended at the time of collection. | UK-wide |
| C5 | **Will the research involve use of previously collected tissue from which individual past or present users of these services are likely to be identified by the researchers either directly from that tissue or from its combination with other tissue or information in, or likely to come into, their possession?** | **<u>Research involving previously collected, non-identifiable tissue samples</u>**<br><br>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 <u>excluded</u> from REC review.<br><br>However, REC review would be required if any of the following applied:<br><br>(a) Consent for research has not been given, or the research is not within the terms of the consent (see B6 above)<br><br>(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) | UK-wide |

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| | | (c) The research also involves removal, storage or use of new samples from the living or the deceased (see C3)<br><br>(d) The research also involves use of identifiable information held with the samples (see C4).<br><br>**<u>Voluntary Review</u>**<br><br>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. | |
| C6 | **Will the research involve use of previously collected information from which individual past or present users of these services are likely to be identified by the researchers either directly from information in, or likely to come into, their possession?** | **<u>Research involving previously collected, non-identifiable information</u>**<br><br>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 <u>excluded</u> from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research. | UK-wide |

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| | | 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 in conducting the research.<br><br>Research involving information which has been anonymised by an intermediary (such as NHS Digital) before its onward release to the researchers is excluded from REC review provided that there is a legal basis for the anonymisation. | |
| C7 | **Will the research involve analysis of human DNA in acellular material AND the analysis is not within the terms of consent for research from the person whose body manufactured the DNA?** | For further guidance on C7, please refer to paragraphs 70–79 of the Human Tissue Authority's Code of Practice E: https://www.hta.gov.uk/<br><br>*If you are using DNA that has already been extracted and isolated from human acellular material (e.g. serum, processed plasma or processed semen), the answer to this question is NO.*<br><br>**Research involving acellular material**<br><br>Research limited to acellular material (e.g. plasma, serum) 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.<br><br>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 in conducting the research.<br><br>However, REC review would be required if the research involved:<br><br>(a) Collection of tissue samples from patients in order to extract acellular material for the research (see C3) | UK-wide |

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| | | (b) Collection of information from patients (see C4)<br><br>(c) Use of previously collected information from which patients could be identified by the researchers (see C6)<br><br>(d) Analysis of human DNA in acellular material where appropriate consent for the research is not in place from or on behalf of the person whose body manufactured the DNA.<br><br>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 | |
| C8 | **Is this a health-related research project involving offenders ?** | Health-related research involving prisoners, for which Her Majesty's Prison and Probation Service, Scottish Prison Service and Northern Ireland Prison Service are responsible require review by a REC as well as compliance with their own approval procedures.<br><br>A prisoner for this purpose means a person in the custody of the Her Majesty's Prison and Probation Service (England and Wales), the Scottish Prison Service or the Northern Ireland Prison Service. | UK-wide |
| C9 | **Does this research involve xenotransplantation?** | Xenotransplantation (i.e. putting living cells, tissue or organs from animals into people), is recommended to take place in a controlled research context, carried out with a research protocol approved by a REC within the UK Research Ethics Service as a matter of Government Policy. | UK-wide |

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| C10 | **Is this a social care research project funded by the Department of Health and Social Care (England)?** | Such projects must always be reviewed by an appropriate REC within the Research Ethics Service for England. | UK-wide |

## If the answer to any of the questions in Section C is 'Yes':

An application for ethical review should be made to a Research Ethics Committee within the UK Health Departments' Research Ethics Service.

Research recruiting through the UK Armed Forces or otherwise within the remit of the Ministry of Defence Research Ethics Committee (MoDREC) should be submitted to 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.

In some instances, particular types of application, either as specified in statute or through recognition by a statutory authority, are reviewed by "flagged" Research Ethics Committees (RECs) designated for review of these applications due to having relevant professional, academic and ethical expertise among the committee's membership, including expertise acquired through training or previous experience in the relevant field of research ethics.

## If the answer to all the questions in Section C and B is 'No':

You do not need approval from a Research Ethics Committee within the UK Health Departments' Research Ethics Service. However, you may need other approvals.

## D - Supplementary notes on research not requiring REC review

Examples of the types of research which do not normally require review by a REC within the UK Health Departments' Research Ethics Service are included in the explanatory notes column in Section C where applicable. Further examples are also listed below.

Where a project does not require NHS REC review it may require other approvals before commencing in the UK. **Researchers should always seek advice from their local R&D office on the appropriate arrangements for review of their research.**

**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).

**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.

**Public Involvement in Research**

Preparatory activities which involve patients and the public contributing to how a future research project will be designed and conducted does not require REC review. When submitting an application, it is important to describe how the public have been involved in the planning of the research in order to support the ethical review of the study. Further information is available on the HRA website: www.hra.nhs.uk

## E - Voluntary REC Review

- **Research Tissue Banks**

Research teams undertaking a programme of research with stored samples are also encouraged to make use of the Research Ethics Service voluntary scheme of generic ethical review for Research Tissue Banks / Biobanks. Further guidance is at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

In Scotland, the network of NRS Biorepositories provides researchers with access to a wide range of tissue from across NHS Scotland for use in research: https://www.nhsresearchscotland.org.uk/research-in-scotland/facilities/biorepositories-and-tissue-services

- **Research Databases**

A research database is a structured collection of individual-level personal information, which is stored for potential research purposes beyond the life of a specific research project with defined endpoints. Research purposes in this context refers to analysis of data to answer research questions in multiple projects.

Organisations responsible for the management of research databases anywhere in the UK may apply on a voluntary basis for ethical review of their arrangements for collection, storage, use and distribution of data, including arrangements for release of non-identifiable data for analysis by external researchers. However, there is no general requirement for research databases to apply for ethical review under the Research Governance Framework for Health and Social Care or GAfREC.

- **Research which does not fall within the remit of GAfREC**

Where there is no legal or policy requirement for ethical review under GAfREC, the research should not be submitted to an NHS REC. In **exceptiona**l circumstances, an application may be accepted on a voluntary basis if it raises significant or novel ethical issues relating to healthcare research. Requests for voluntary review can be submitted to the HRA Queries Line in accordance with SOPs.

## F – Research involving NHS staff scenarios

Under paragraph 2.3.14 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.

**Staff studies NOT requiring ethical review by a REC**

1. A university student is completing a Master's 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 Trust asking them to return the completed questionnaire anonymously to the researcher. 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 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.

   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 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.

3. An NHS 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.

**Staff 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 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 NHS staff in this study is not by virtue of their professional role; they are being recruited through the NHS/ 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).