

Policy and procedure

NHS permission for research studies

1 Scope

This policy and procedure is for use by research staff from any organisation undertaking research activity involving Cambridge University Hospitals NHS Foundation Trust (CUH) staff or patients, their organs, tissue and/or data and/or facilities. It also applies to studies involving healthy volunteers that are taking place within Trust facilities.

2 Purpose

Following the publication of the *Research Governance Framework for Health and Social Care by the Department of Health* (version 2) in 2005, all researchers are required to know and follow 'the law and the principles of good practice relating to ethics, science, information, health and safety, and finance' set out in the Research Governance Framework.

This policy and procedure is based on the guidance of the Research Governance Framework. Its purpose is to provide a clear and concise guide for issuing NHS permission for proposed research studies.

3 Definitions

3.1 Valid application

A valid application includes all documents listed under the [application process](#) section below, including the required signatures.

3.2 Integrated Research Application System (IRAS)

IRAS is an application system used by researchers to apply to ethics, MHRA ([Medicines and Healthcare products Regulatory Agency](#)), R&D and other regulatory boards.

4 Responsibilities

4.1 Researchers

Researchers are responsible for ensuring that correct and complete information is provided to the R&D Department in order to determine whether NHS permission can be issued. Deliberate submission of false information will be classed as fraud and may lead to a misconduct hearing.

Research and Development (R&D) Department

Corporate Development Directorate

4.2 R&D officer

The R&D officer will be responsible for reviewing research documents and determining if all information is present and correct and adheres to relevant research legislation.

4.3 R&D manager

The R&D manager will review studies once the R&D officer has obtained all relevant details and will sign off the study on behalf of the Trust.

4.4 Data protection officer

The data protection officer will review studies in relation to data protection issues, ensuring researchers are compliant with data protection laws.

4.5 Research Advisory Committee

The Research Advisory Committee will, where applicable, review research projects in order to carry out the peer review process.

4.6 Risk Management Department

The Risk Management Department will follow up on a quarterly basis those studies that will use human tissue to ensure that Trust procedures are followed for the destruction or retention of tissue.

4.7 Ionising Radiation (Medical Exposure) Regulations (IRMER) practitioner

The IRMER practitioner will review studies involving ionising radiation in relation to radiation issues.

4.8 R&D solicitor and solicitor/ contracts manager

The R&D solicitor and solicitor/ contracts manager will ensure that a suitable contract/ agreement has been agreed by all parties and that the Trust is protected.

4.9 R&D director

The R&D director reports to the medical director and will lead on any misconduct issues.

5 Undertaken by

All research staff across the Trust, the University and from external organisations.

6 The application process

Applicants will use the IRAS form to make a submission to all regulatory bodies including R&D. Failure to submit the required paperwork will lead to a delay in issuing NHS permission.

Researchers wishing to undertake a new research study must submit one copy of each of the following documentation to the R&D Department, Box 277, Addenbrooke's Hospital:

- IRAS R&D form
- IRAS site specific information (SSI) form
- protocol
- proof of sponsorship* (when the sponsor is different from Cambridge University Hospitals NHS Foundation Trust)
- evidence of peer review
- consent form and patient information sheet
- Copy of MHRA clinical trials authorisation letter [for clinical trials of investigational medicinal products (CTIMPs) only].

* Proof of sponsorship includes a signed sponsor letter on headed paper or an agreement which outlines sponsor responsibilities.

Submission of a protocol or R&D form only does **not** provide the R&D Department with sufficient information to determine whether NHS permission can be given.

Signatures will be required from the following people before NHS permission can be issued:

- the **clinical director, deputy divisional director, divisional director or head of department** in which the study will take place. This is to ensure that the people responsible for the department are aware of the study taking place in their area and that there is suitable space and resources to support the study. Advice will be given by the R&D Department on who should sign the form.
- the **associate director of nursing**, when the chief investigator (CI) is a nurse, midwife or an allied health professional (arts therapies, chiropody or podiatry, dietetics, operating department practice, orthoptics, occupational therapy, physiotherapy, prosthetics and orthotics, psychology, psychotherapy, radiography, speech and language therapy)
- **chief pharmacist** for studies in which the Pharmacy Department will manage and dispense medicinal products. This includes those studies that fall out of the Clinical Trials of Investigational Medicinal Products category, but may involve the use of drugs

- **IRMER practitioner** for studies that involve the use of ionising radiation
- any other relevant area as advised by the R&D Department.

An R&D Officer will provide the signature sheets that need to be signed.

7 Application review process

The R&D officers can assist with the completion of the IRAS application.

For any Trust sponsored studies, draft applications must be reviewed by the R&D Department before they are printed for submission.

Once all documents are submitted the application is reviewed against set criteria to ensure compliance with current research legislation, Trust policies and procedures and the Research Governance Framework. A decision will then be made as to whether the study can commence or if any changes need to be made.

A favourable ethical opinion is conditional on receiving NHS permission. Therefore, failure to obtain NHS permission will invalidate the favourable opinion.

Below are details of some of the issues considered during the study review.

7.1 Sponsorship

All research studies must have a sponsor. The sponsor is the 'individual, company, institution or organisation responsible for the initiation, management and/or financing of the research' (Research Governance Framework).

- The Trust is willing in principle to sponsor all studies initiated by its employees or by university employees with an honorary contract.
- The Trust and the University of Cambridge (UoC) are willing in principle to jointly sponsor studies. The R&D Office will advise when this applies on receipt of a draft application.

The Trust and UoC each reserve the right to refuse sponsorship for research led by its respective employees. This decision will be made after a thorough review of all documentation; however, all efforts will be made by all parties to resolve any issues identified before undertaking this decision.

Submission to regulatory and/or funding bodies may require a pre-sponsorship letter which accompanies the submissions. The R&D Department can provide this.

Agreement to sponsor a study may be terminated if during the course of a study:

- the safety of participants is at risk
- the CI is no longer employed by the Trust or UoC and/or
- a breach of any existing research standard operating procedures (SOPs) or policies and procedures is identified.

7.1.1 Sponsor declaration page

Before the ethics application form can be submitted to a research ethics committee (REC) it needs to be signed by the sponsor. For studies sponsored solely by the Trust or jointly with the UoC, the Trust R&D Department will sign the form.

The process is as follows:

1. ensure your study has been peer reviewed (please see below paragraph about peer review)
2. submit your **draft** application for review by an R&D officer to the r&denquiries@addenbrookes.nhs.uk email address
3. when the form has been finalised, obtain a REC number, add it to the form and print it for submission
4. email the final form to the R&D officer
5. within two days an R&D officer will sign the form and notify the researcher when it can be collected.

Researchers **must** ensure that the R&D Department has sufficient time to review the study in order to sign it.

Please **do not** book a slot with the ethics committee until an R&D officer has reviewed your application and sponsorship has been confirmed.

The paperwork for the study can then be submitted to an ethics committee as normal. **Please note:** the signatures from the clinical director, divisional director or head of department on the SSI form can be obtained at a later stage.

7.2 Site specific assessment

From April 2009 the responsibility of carrying out an assessment of an NHS site for a study transferred from the research ethics committees to R&D departments. SSI forms must now only be sent to the R&D Department for when a study will involve the Trust as an NHS site.

The same checks that are carried out by the ethics committees will be undertaken by the R&D Department. The most recent version of the ethics SOPs will therefore be followed for this process.

SSI forms for non-NHS sites must still be submitted to ethics for review.

7.3 Peer review

All proposals must have a suitable review of scientific quality **before submission to an ethics committee**. Studies may already have undergone peer review as part of a competitive funding process in which case a duplicate review is not required.

The Trust **only** accepts peer review undertaken by:

- government organisations, eg:
 - Medical Research Council,
 - National Institute for Health Research (NIHR)
- charitable organisations:
 - Wellcome Trust
 - Cancer Research UK
 - British Heart Foundation
 - all other charities listed on the Association of Medical Research Charities
- pharmaceutical companies
- Scientific Advisory Board which reviews studies to be carried out within the Addenbrooke's Clinical Research Centre
- Trust Research Advisory Committee
- the educational supervisor in the case of student research projects.

7.3.1 Oncology R&D Committee

Peer reviews for studies involving oncology patients will be carried out by the Oncology R&D Committee, which meets fortnightly. Please contact the Cancer Clinical Trials Centre for details on how to apply.

If a study has not been peer reviewed, the R&D Department can arrange this. Please contact the department for guidance.

7.4 Indemnity

All research studies must have insurance for harm to participants arising from:

- the **management** of the research; this is provided by the **sponsor** of the study
- the **design** of the research; this is provided by the **substantive employer** of the CI;
- the **conduct** of the research.
 - Where **NHS patients** are participants, NHS indemnity applies.
 - For **all other participants**, the sponsor or employing organisation will provide insurance.

Commercially sponsored studies require indemnity provided by the Association of British Pharmaceutical Industries (ABPI) or Association of British Healthcare Industries (ABHI) guidelines (for medical devices).

Such indemnity covers legal claims made by study participants resulting from non-negligent harm.

7.4.1 NHS Indemnity

NHS Indemnity is a form of insurance for negligent harm provided via the NHS Litigation Authority (NHSLA).

NHS Indemnity covers **negligent harm** caused to people whenever they are:

- receiving an established treatment
- receiving a novel or unusual treatment
- a subject of clinical research.

NHS Indemnity does not offer cover for **non-negligent harm**, in exceptional circumstances (and within the delegated limit of £50,000) NHS bodies may consider an ex-gratia payment.

7.5 Researcher contracts

The Research Passport system was implemented by the NIHR in 2008. The system aims to standardise the process for obtaining an honorary contract with an NHS Trust.

The Research Passport is the application form which a researcher and substantive employer completes; this is then submitted to the relevant Trust. When the Trust is satisfied that relevant checks have been carried out, an honorary contract or letter of access will be issued.

The Trust's [research passport, honorary research contracts and letters of access policy and procedure](#) should be followed for Cambridge University Hospitals NHS Foundation Trust ([this document is also available on the CUH website](#)).

7.6 Data protection

The R&D Department will arrange for the data protection signature.

The data protection officer will review the application and discuss any concerns with individual researchers before sign off.

Note: all computerised systems used for clinical trials should be validated* and there should be a documented fitness-for-purpose assessment to ensure that the system in use does what is required. The security of the data and quality control should be considered in all cases.

* Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes as expected.

7.7 Radiation protection

All studies involving ionising radiation require assessment by the radiation protection officer (even if this procedure is part of the participant's routine care). Researchers are advised to contact the **IRMER practitioner** as early as possible in the development of their study for a successful ethical submission. Studies sponsored by other institutions/ organisations also require assessment by the IRMER practitioner.

7.8 Human Tissue Act (HTA)

Tissue transferred from or to the Trust requires a tissue transfer agreement. The sponsor of the research will be responsible for initiating this document.

On a quarterly basis a list of studies that involve tissue which falls under the HTA and where the end date has passed, will be sent on to the Risk Management Department, which will ensure that samples are held or disposed of in compliance with the HTA guidelines.

7.9 Legal contracts and agreements

Legal agreements are needed when a study involves collaborations with other organisations for example when:

- the study is multi-centre: participating site agreements need to be in place before the study starts at the site to ensure compliance with current legislation
- data, human tissue, blood samples etc are transferred to other organisations
- the trial is co-sponsored with other organisations
- another organisation provides funding for the study.

This is to ensure that other organisations carry out the study according to current legislation and good clinical practice standards.

The R&D team and in particular the contracts manager and consultant solicitor will be able to advise about such agreements in conjunction with the University Research Services Division and will ensure that they are in place before NHS permission is given.

Note: Individual researchers **should not sign** such agreements as this implies assuming the liability involved in the contract. Legal agreements should be signed by the Trust and UoC authorised signatories and acknowledged by the investigators.

8 Participant identification centres (PICs)

PICs are responsible for the identification of potential participants who are subsequently invited to take part in research through a different site which takes on responsibility for seeking consent and undertaking research procedures. The PIC retains responsibility for the healthcare of the patient outside the research, but the research site takes on the duty of care for the patient in relation to the research study.

The term 'referral' is used here to describe the process whereby a care clinician provides information about a research study to a potential participant who is the clinician's patient, and either invites the patient to contact the research team, or obtains appropriate agreement to pass on the relevant details of the patient to the research team.

All the documents outlined above should still be submitted to the R&D Department with the exception of the SSI form.

Appropriate checks will be carried out and a letter will be issued by the department giving NHS permission.

9 Turnaround time

For valid applications (ie those which are complete and provide all the necessary evidence upon which to decide whether a study should be approved) the applicant will hear whether NHS permission has been granted within four weeks. However, NHS permission cannot be issued before an ethics favourable opinion has been received.

Once the R&D Department is satisfied that a study has met all the requirements, NHS permission in the form of an R&D approval letter and sponsor letter (if applicable) will be issued to the chief/ principal investigator for the Trust.

Please note that this timeline is based on receiving a complete application and any delays submitting the required paperwork to R&D will mean that NHS permission cannot be issued.

10 Amendments

For amendments which are termed 'substantial', the IRAS substantial amendment form should be completed and sent with the relevant documentation to the Ethics Committee, MHRA (if applicable) and the R&D Department.

Minor amendments should also be notified to the sponsor.

11 NIHR coordinated system for gaining NHS permission (CSP)

CSP is the system used to process those studies which will be adopted by the Comprehensive Local Research Network (CLRN). If you decide to apply for adoption, you will receive email correspondence from the CLRN guiding you through the process for submitting your application.

The R&D Department is still responsible for carrying out the governance checks and issuing NHS permission.

12 Student projects – guidance from National Research Ethics Service (NRES)

For all doctoral research, the student should be named as the CI.

For research projects below doctoral level, the named chief investigator should be a senior person who is able to undertake all the responsibilities set out in the Research Governance Framework for Health and Social Care. For projects conducted mainly for educational reasons, the academic supervisor should normally be named as the CI.

Where the student is participating in a project that is not purely educational, the CI may be another experienced researcher such as a health professional or academic researcher.

While non-doctoral students should not be named as the CI, it is expected that the student will complete the application form on behalf of the CI as part of her/his training.

Further advice may be sought from the NHS R&D office at the lead site for the research if necessary. Students are encouraged to discuss their research with the R&D office at an early stage.

The Trust will consider, on a case-by-case basis, sponsoring a study where the CI is an educational supervisor not employed by the Trust or UoC.

13 Annual progress reports

Every year investigators are required to complete an ethics annual progress report form. Failure to submit a report can potentially suspend or terminate the favourable opinion received so please ensure that these are submitted on time.

Researchers should submit a copy of this form to the R&D Department.

14 Study end dates

Due to the reporting requirements of the department to the DH, researchers are required to inform the R&D Department when their study has been completed. They must also ensure that any extensions are notified.

15 Clinical trials under the European Directive

For further guidance on sponsorship and the setup, initiation, and running (including annual reporting requirements, end of trial notification and end of trial report, minor and substantial amendments) of Trust sponsored CTIMPs, including those jointly sponsored with UoC, please contact the Clinical Trials Unit or R&D Department.

16 Commercial studies

Please refer to the [commercial research activity policy and procedure](#).

17 Other conditions

The Trust reserves the right to withdraw NHS permission if:

- the applicant is found to have submitted inaccurate information
- the applicant or chief investigator does not abide by the principles of:
 - good clinical practice
 - the *Human Rights Act*
 - the *Declaration of Helsinki*
 - the *Medicines for Human Use (Clinical Trials) Regulations*
 - the *Data Protection Act*
 - or other applicable legislation
- the R&D director deems that reported adverse events represent a risk to participants
- a commercial organisation is in breach of its responsibilities as defined in the clinical trials agreement (CTA)
- the principal investigator fails to co-operate with a Trust or external audit of the study
- the principal investigator is found to have acted fraudulently or acted in a way that constitutes misconduct in research (see misconduct and fraud [policy](#) and [procedure](#))
- the Trust or an external audit of the study highlights significant concerns about the way in which the study is being conducted
- the applicant fails to send details of any amendments.

18 Monitoring compliance with and the effectiveness of this document

The effectiveness of this policy and procedure will be monitored by reviewing the number of complete applications received for NHS permission and by regular research study meetings which will highlight any issues with this policy and procedure. The R&D manager and R&D officers will be responsible for the above.

19 References

Department of Health Research Governance Framework second edition 2005.

20 Associated documents

- [commercial research activity policy and procedure](#)
- misconduct and fraud [policy](#) and [procedure](#)
- [research passport, honorary research contracts and letters of access policy and procedure](#)
- Relevant R&D Department SOPs

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

Disclaimer

It is **your** responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

Document management

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