Imperial College London

Research Governance and Integrity Team

NHS Imperial College Healthcare NHS Trust

NHS REC Applications	
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Author: Naomi Gardner, Research Facilitator	
Approved by: Ruth Nicholson, Head of Research Governance and Integrity	Date:

Version	Date	Reason for Change
Version 1.0	14 Jul 2006	
Version 2.0	25 Jun 2007	Update
Version 3.0	28 Jun 2008	Annual Review
Version 4.0	08 Feb 2010	Update and Formation of Joint Research Office
Version 5.0	14 Jul 2011	Annual Review
Version 6.0	29 Nov 2012	Annual Review
Version 7.0	18 Feb 2014	Scheduled Review
Version 8.0	25 Oct 2017	Scheduled Review
Version 9.0	11 Jun 2019	Updates to the use of Organisation information document and SoECAT
Version 10.0	19 Oct 2020	Scheduled Review. Templates removed and administrative changes to SOP. JRCO name change to RGIT

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1. PURPOSE

This SOP details how to apply for NHS Research Ethics Committee (REC) approval for health-related research projects. It provides general information on the NHS REC system and outlines each step that should be completed in the application process.

Please note the information within this SOP is only a summary. For more detailed guidance see the Standard Operating Procedures for RECs: HRA - Research Ethics Committee – Standard Operating Procedures. The SOP should also be used in conjunction with RGIT_SOP_002 'Ethics Approval for Health-Related Research'.

The application form for UK REC review can be obtained via the Integrated Research Application System (IRAS) which combines the ethics application with other regulatory forms such as MHRA applications. The IRAS application form replaces the NRES form. All UK studies must apply through this system.

2. INTRODUCTION

2.1. NHS REC Review

NHS RECs will review most research conducted within the NHS. Such research could involve:

- Clinical Trials of Investigational Medicinal Products
- NHS patients/service users (including potential participants recruited by their past or present treatment and NHS patients treated under contracts with private sector institutions)
- Potential participants identified because of their status as relatives/carers of patients and users of the NHS
- Access to data (except anonymised data – see alternatives to NHS REC section below), organs or other bodily material of past and present NHS patients
- Foetal material and IVF involving NHS patients
- Recently dead in NHS premises
- Use of/access to NHS premises or facilities
- Healthy volunteers, where a drug or device is being tested within the NHS

A different ethics application route may be needed if your project involves gene therapy, is a Phase I CTIMP in healthy volunteers outside the NHS and/or only being conducted overseas. This is outlined further throughout this SOP and in RGIT_SOP_002 'Ethics Approval for Health-Related Research'.

2.2. Alternatives to NHS REC:

2.2.1. Non-NHS resources/Overseas research

If your research involves:
- Non NHS resources
- Overseas research

Then your project may be eligible for review by the Imperial College Research Ethics Committee (ICREC) – For further information please contact Nooreen Shaikh , RGIT Co-

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ordinator
Email: researchethicscommittee@imperial.ac.uk Tel: +44 (0)20 7594 9484

2.2.2. Studies needing confirmation of capacity and capability:

Following changes (Sept 2011) to the remit of RECs in the UK, the following projects need management permission from host care organisations, but are excluded from REC review: From March 2016 studies that involve NHS staff, or the use of pre-collected anonymised tissue or data only do not need to be reviewed by the REC, but will require HRA approval via IRAS. In all cases if the IRAS form is used HRA approval will be required.

- Research involving health or social care services staff, who are recruited by virtue of their professional role (no patient involvement)
- Studies involving retrospectively collected anonymised data
- Research limited to use of previously collected, non-identifiable material consisting of, or including, cells in accordance with the terms of donor consent

Researchers undertaking the above studies should contact the Trust R&D department where they wish to conduct their study. The documents that will need to be submitted for this type of project are:

- IRAS form and the local document pack. Further guidance can be found on the HRA website.
- by email to the R&D departments.
  If you complete the IRAS filter questions in IRAS as normal and only tick IRAS to Q4 if sites in England are involved, this will ensure it is submitted to the HRA.

Prior to submitting your application for confirmation of capacity and capability, please contact your Divisional Research Manager (DRM) who will assess the study for feasibility approval confirmation and register it on the DOCUMAS database. They will also advise when to submit the documents to the RGIT. Please do not start your research until you have confirmation from the RGIT that the study has been registered and you are in receipt of the Trust confirmation of capacity and capability.

Please note that if you have an R&D confirmation of capacity and capability only study that is being sponsored by Imperial College London/Imperial College Healthcare NHS Trust, then you may submit it directly to the RGIT for sponsor review. However, for the Trust capacity and capability confirmation stage, Divisional Research Manager confirmation of feasibility approval will be required before final Trust capacity and capability can be issued.

A list of the Research Managers for each division can be found in Appendix 1.

2.2.3. Tissue Bank Approval:

Tissue only studies: For Imperial College studies where the only research being undertaken at Imperial is tissue collection (e.g. collecting biopsies, blood only), ethics approval may be obtained from the Tissue Bank, who have been delegated authority from the REC to approve this type of project. You are advised to contact the Tissue Bank for advice (see contact details in the table in section 3.3). This type of approval can only be considered if tissue collection is the only component of the research being undertaken. If

there are other research procedures involved (e.g. questionnaires, scans) then a REC review will be needed.

Key characteristics of the NHS REC system are that:

- All applications must be made by the Chief Investigator (CI) for the study.
- The CI must be professionally based in the UK.
- For international studies:
  - An application must be made to an ethics committee in the UK whether or not the study has a favourable ethical opinion outside the UK, and;
  - If there is a coordinating investigator outside the UK, a health professional based in the UK **must** be nominated as CI and take responsibility for the conduct of the research in the UK.
  - CTIMP Studies must have a Legal Representative in place to represent the sponsor in the UK. At Imperial College Healthcare NHS Trust this is delegated to the CI of the study. They do not undertake any sponsorship duties but are the contact for the study in the UK.
- The REC must give an opinion on a project **within 60 days** of receiving a valid application as required in law for CTIMPs and the Research Governance Framework for all other research in the NHS (unless it is a trial of a medicinal product for somatic cell therapy or the product contains a genetically modified organism, in which case the time limit is 90 days).
- A single ethical opinion will be given for a project, regardless of the number of sites at which it is to be conducted. A 'main REC' will be responsible for all aspects of the ethical review.
- The suitability of a research site and investigator taking part in the research will be made by the Organisational Information Document and the Schedule of Events (or Schedule of Events Cost Attribution Template (SoECAT)) submitted to each participating site and forms part of the single ethical opinion.
- Each research site should have a PI responsible for the management and conduct of research at that site.

Participant Identification Centres

If research participants are being identified at another organisation this organisation may be classed as a Participant Identification Centre (PIC). A PIC is an NHS Trust where participants are identified and given information on a research project but **no** research activity (consent, medical screening, blood tests etc.) is taking place.

An NHS/HSC organisation is operating as a PIC when it meets the following three criteria:

- identifies potential research participants by processing personal data (e.g. through carrying out a search of a patient records database to identify individuals that meet a study's eligibility criteria)
- is following the sponsor(s) instructions in identifying potential research participants
- directs these potential participants elsewhere without undertaking any further research activity for that study (i.e. the research occurs at another legal entity).

If research activity is to occur at an NHS Trust it must be identified as a research site and complete the site specific assessment process by submitting the Organisational Information Document and the Schedule of Events (or SoECAT) to the participating site for feasibility review and management confirmation of capacity and capability.

NHS/HSC PICs should be set up by through a sub-contracting arrangement with the participating NHS/HSC organisation that the PIC supports. Appropriate data processing arrangements should be put in place by using the appropriate model agreement

- model Commercial PIC agreement (m-C-PICA)
- model Non-Commercial PIC agreement (m-NC-PICA)

Further guidance can be found on the IRAS website.

3. PROCEDURE

The procedure for applying for NHS REC approval can be divided into the following steps. More detailed information on each step is given below.

1. Complete the online Application Form
2. Complete the Applicant's Checklist
3. **Online submission**
4. **After booking**
5. Validation
6. Review/Notification of Decision
7. Request for Further Written Information
8. After Approval

3.1. Complete the Online IRAS Application Form

All applications to conduct research in or through NHS/HSC organisations use the IRAS online application form. which If you are a first-time user, you will need to register for an account online, which is activated immediately. This involves a single electronic submission of the IRAS Form and associated supporting documentation. You do not have to complete the application form in one go – work can be saved and reloaded for further editing.

The process for submission is the same regardless of which UK nation the research is led from and whether or not NHS/HSC Research Ethics Committee (REC) review is required.

The form is designed to save you time completing it. When you fill in certain answers, information will automatically populate in other relevant places, and your answers to certain questions will deactivate or activate other sections of the form. As a result, you are never likely to complete every single page – the average is around 20 pages long.

The application form is structured as in the table below. For a breakdown of each question topic see Appendix 2.

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Part	Details
Project Filter	Asks a limited number of key questions about the nature of your research. An application form specific to your project will be created from the answers you give. You need to select your answers carefully.
A	Asks for generic information relevant to all research proposals. Certain questions will be deactivated depending on your answers to the project filter.
B	Is divided into several discrete sections, which refer to particular specialist topics. These appear (or disappear) in response to your answers to the project filter.
C	Asks for a list of sites that the study will be conducted at.
D	Declaration and signatory

You can find further advice and guidance for making a valid NHS REC application on the HRA Research Planning and RGIT HRA REC Applying Process webpages.

More detailed information about using the IRAS form is available through the 'help' pages on the IRAS form website. For more information about how to prepare and submit your application please refer to the 'Step by Step Guide' .

3.2. Complete the Applicant's Checklist

You must also complete the online 'Applicant's Checklist' with your IRAS ethics application to ensure that all of the paperwork required to support your application is sent to the REC. A different version of the checklist must be completed depending on the type of research; there is one for CTIMPs and another for any other research in the NHS. The online system automatically generates the relevant checklist depending on your answers to the project filter. You must ensure you have the appropriate copies of any supporting documentation, as outlined in the Applicant's Checklist.

3.3. Online submission

When you finish your application, you need to make an online booking and during the process you will be asked a series of questions to determine which Research Ethics Committees (RECs) (are appropriate for your study.. It is important that you have your

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application in front on your during the online submission as you be asked a series of question to decide on the suitable REC for the study.

You will be offered a slot for a REC which is suitable for the type of study. Where there is more than one suitable REC or meeting date, you will be given a choice to select the one you prefer.

You do not have to choose your nearest REC, although that option may be available, depending on the type of research you plan to undertake. Applicants are strongly encouraged to attend meetings in person, although teleconference facilities can be made available on request

To make your booking, log into IRAS and navigate to the "e-submission" tab of the form you wish to submit. Detailed step-by-step process, and a direct link to the book portal are provided

Opening hours: . The online booking service is available 24 hours a day, 7 days a week.

During the booking process

You will need to:

- make sure you are ready to submit your application on the same day
- have your application with you, including the Integrated Research Application System (IRAS) project ID and contact details of the chief investigator and sponsor contact
- answer a series of questions about your study.

You will be unable to make a booking until all of the electronic authorisations are in place, any relevant verification checks are passed, and the REC IRAS checklist has been completed with the correct subtitles, versions and dates and the corresponding documents have been uploaded to the checklist ready for submission. The process you need to follow is detailed in the step-by-step instructions on the form's e-submission tab in IRAS.

The online booking service is used for all IRAS form applications for project-based research in the NHS (or HSC in Northern Ireland) and for Research Ethics Committee (REC) applications for tissue banks, databases and health research taking place outside of the NHS/HSC

When making your booking, refer to the on-screen guidance which will help you to answer the questions. If you have any problems or queries during the booking process, you can call for support on 0207 104 8008 between 9:30am to 4:30pm Monday to Friday.

Email

General queries on the health research process
HRA.Queries@nhs.net

Integrated Research Application System queries/feedback line
iras.queries@nhs.net

Integrated Research Application System technical queries line
helpdesk@myresearchproject.org.uk
0207 043 0734

General enquiries: **contact.hra@nhs.net or** call our mainline on 020 797 22545. If your study does not need REC approval, it will need HRA approval and confirmation of capacity and capability by the RGIT and DRM/Feasibility Team. Please see the table below for a list of contact details.

Type of Project	NHS REC Booking Route
Audit or Service Evaluation - single or multi-domain	Check with Research Governance and Integrity Team that this is not considered research. If it is not research, no ethical review is required. However, audit or service evaluation running at ICHT must be reviewed by the divisional team for clinical governance. Proposals should be sent to the audit team. Please contact the audit team by email imperial.audit@nhs.net
Gene Therapy or Stem Cell Clinical Trials - single or multi-domain	Applications should be booked to: London – West London and GTAC; South Central – Oxford A; North East – York; or Scotland A REC (based in Edinburgh). Bookings should be made via the Central Booking Service: In addition to GTAC approval, any gene therapy study taking place at Imperial College Healthcare NHS Trust should also go through the ICHT Joint Clinical Research Safety Committee (JCRSC) Contact: Ana Pedrero-Llamas – Deputy Safety Director and Bio-Risk Manager Tel: 020 7594 9573 Mobile: 07517 551 875 (Mobex 51875) e-mail: a.pedrero-llamas@imperial.ac.uk
Research involving tissue only collected at Imperial	Contact Research Governance and Integrity Team or Tissue Bank Manager. Tissue Bank Manager contact details: Sandrine Rendel Telephone; 0203 311 7173 Fax: 0203 311 7175 Email: tissuebank@imperial.ac.uk Lead Research Nurse & Clinical Engagement Lead for Imperial College Healthcare Tissue Bank
Research which involves: Healthy volunteers (except tissue and drug trials) Non-NHS Resources	Apply through Imperial College Research Ethics Committee (ICREC) For further information contact: Research Governance and Integrity Team Co-ordinator: researchethicscommittee@imperial.ac.uk

Overseas Research	
Staff only studies or research that involves retrospective data collection of anonymised data	Apply through Research Governance and Integrity Team for R&D management RGIT@imperial.ac.uk. and the Divisional Research Team imperial.research_feasibilityofficer@nhs.net for confirmation of capacity and capability. Please note that these studies do not require REC approval, but they do require HRA approval and must be booked through the CBS for HRA approval

For further information on what constitutes an 'NHS domain' or 'research site', please refer to the NRES Standard Operating Procedures for Research Ethics Committees

3.4. Proportionate Review

If your study has been submitted for Proportionate Review, a REC manager will undertake a thorough pre-screen. If your application is better suited to a Full REC review – because it does not meet the criteria for proportionate review – you will be contacted within two working days and arrangements will be made for the application to be transferred.

The aim with the system of proportionate review is for a project to be reviewed, and a decision letter issued, within 14 working days of receipt of a valid application. However, the project may be referred on to a full committee if necessary (which will extend the timescale to the usual 60 days).

For your application to be considered for proportionate review, it should fit one of the following categories:

- Research using data or tissue that is anonymous to the researcher
- Research using existing tissue samples already taken with consent for research
- Research using "extra tissue" (e.g. further blood taken at time of routine sampling or tissue taken at "clinically directed" operation)
- Questionnaire research or research interview/focus group that does not include highly sensitive areas or where accidental disclosure would not have serious consequences
- Research surveying the safety or efficacy of established non-drug treatments, involving limited intervention and no change to the patients' treatment
- Minimally invasive basic science studies involving healthy volunteer studies or patients (e.g. which involve the taking of a single blood sample or other similarly invasive intervention).
- Studies that do not fit the above categories but do not have any 'Material Ethics Issues'.
- Research involving children may be considered for proportionate review where it meets the above criteria.

For further information on [Appling to a Research Ethics Committee](#) can be found on the HRA website

3.5. After booking your submission

3.6. You will receive an email confirming your booking and REC reference number. You will need to return to the application form in IRAS and add the REC name, REC reference number, and submission date at the start of the form.

Important: Take care not to amend or click in any other fields as this will invalidate your application. Data entry in the REC details fields in IRAS will not invalidate your electronic authorisations, however please note that if you alter any other part of your application electronic authorisations will be invalidated.

3.7. You must then electronically submit your application. This must be done on the same day as making your booking. Return to the form's e-submission tab and click 'e-submit application'.

3.8. Validation

If your application is correct and you have submitted it with all the relevant documents by the closing date, you will be issued a validation letter **within 5 working days**, acknowledging your submission and confirming it is valid. The letter will also provide details (time and venue) of the REC meeting and invite you to attend. It is recommended that you attend the meeting, in order to answer any questions that the REC may wish to address.

If Imperial College AHSC is named as sponsor for your research, the Research Governance and Integrity Team (RGIT) will also receive a copy of this letter.

3.9. Site Specific Information (Organisational Information Document and Schedule of Events or SoECAT)

If your research is multi-site, once you have received the validation letter, studies can be notified to the PI and R&D offices but the clock won't start for approval until you send the local document pack-.(see below), including the HRA initial assessment letter or HRA approval letter if no assessment letter issued in order to instruct the PIs at each site to apply for management confirmation of capacity and capability at each site participating in the study.

Each PI should receive the IRAS Form, the Organisational Information Document, the Schedule of Events (or [SoeCAT](#) and the study documentation ([local document pack](#)):and submit it to the relevant Research and Development (R&D) department, along with a signed and dated copy of his/her CV to start the review.

If the research is single-site, then the CI should complete the IRAS form and submit to the local R&D office with the local document pack and signed and dated copy of his/her CV for review.

Following a favourable ethical opinion, the PI should send to the R&D office a copy of the REC favourable ethical approval letter, the HRA approval letter and all supporting documents approved by the REC and the HRA. Each R&D department will notify the PI

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whether or not there is any objection to the research on site-specific grounds. If there are no objections, the Trust will issue the PI with management confirmation of capacity and capability in order for the study to start at the site.

Please note that any studies taking place on Imperial College Healthcare NHS Trust (ICHT) premises or recruiting ICHT Trust patients or staff must go through the ICHT Trust R&D process and obtain Trust feasibility approval and R&D confirmation of capacity and capability, in addition to ethical approval and HRA approval, before they start the study. Please see RGIT_SOP_031 'Trust Confirmation of Capacity and Capability'. All studies should be discussed with your Divisional Research Manager (DRM) and Feasibility Facilitator before confirmation of capacity and capability can be issued.

If studies are taking place at other sites, confirmation of capacity and capability must be obtained from the R&D department at each site, before any research commences there.

3.10. Ethical Review/Notification of Decision

At the REC meeting, the Committee will review the ethics of your research in a completely independent way, free from bias or any conflicts of interest. They will consider such things as:

- Arrangements for the recruitment of subjects
- How informed consent will be obtained, including the adequacy of written information for participants
- Provision for compensation in the event of injury attributable to the research
- Any insurance or indemnity to cover the liability of an investigator or sponsor

The Committee must notify you of their decision **within 60 days of receiving your valid application**. If you find this has not happened, you can complain to the Centre Manager in the first instance

You can also contact:

Complaints Manager
Health Research Authority
Skipton House
80 London Road
London, SE1 6LH

if you would like to provide feedback or raise any concerns of HRA services. You can contact them.

The REC can reach one of five decisions about your application:

- Final decision – which could be favourable, favourable with conditions or unfavourable
- Provisional decision – with a request for further written information
- No opinion – a referee needs to be consulted

You should receive notification of the decision **within 10 working days of the review meeting**. If Imperial College AHSC is named as Sponsor for your research, the RGIT will also be notified of the ethical decision.

3.6 Request for Further Written Information

The REC may make a provisional decision about your research and ask for further information about specific aspects of the project. If this is the case, you may be required to submit further clarification, information or revised documents to the REC which will be reviewed, usually by the REC Chair or a subcommittee of the REC, before confirming a final opinion. Such a request can only be made once and the 60 day clock stops whilst the REC awaits your response.

If Imperial College AHSC is sponsor of your study, you should send a copy of your response to the request for information and any supporting documents to the RGIT.

If your response is not deemed satisfactory, the committee may ask you to respond again to the same questions (no new issues can be raised) or reject your application. The clock only starts again when a complete response is received. A final decision should then be issued.

3.11.   After Approval
Once you have received NHS REC approval, you still must not start your research until you have all the relevant regulatory approvals e.g. MHRA, CAG, HRA, internal College confirmation of capacity, RGIT Greenlight and capability and received R&D confirmation of capacity and capability from the relevant NHS Trust(s) participating in the study.

Your research **must start within 12 months** of the date on which a favourable opinion was given. A study is generally considered to have commenced when the first subject gives written informed consent to participate or, where this does not apply, when any procedures in the protocol are initiated. If your research does not commence within 12 months, please discuss with the Sponsor and inform the REC, who may require you to submit a substantial amendment. If your study does not start within 24 months, you may have to re-apply).

After approval, you will also need to:

- Apply to the main REC for approval of any substantial amendments to the protocol. For any Imperial AHSC sponsored studies, you will need permission from the Research Governance and Integrity Team before submitting any amendments. You must also apply to each Trust for R&D confirmation of continued capacity and capability of any amendment before it is implemented at that site (please see RGIT_SOP_006 'Amendments to Healthcare Research' and RGIT_SOP_032 'Trust Amendments')
- Submit safety reports when appropriate (please see RGIT_SOP_001)
- Apply to the relevant R&D department of any subsequently enrolled research site
- Provide an annual progress report to the main REC each year of the project's duration. Inform the main REC when the project finishes using the end of study declaration form.

Please note that if Imperial is sponsoring your study then you must also copy safety reports, annual progress reports and end of study reports to the RGIT.

4. REFERENCES

Standard Operating Procedures for Research Ethics Committees (Version 7.4 from 5 June 2019)
Medicines for Human Use (Clinical Trials) Regulations 2004
NHS Health Research Authority website
NRES website
IRAS form website

5. APPENDIX

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page.

Appendix 1 - Divisional Research Managers and Feasibility Facilitators - RGIT_TEMP_009
Appendix 2 – IRAS Content Index - Integrated Dataset - RGIT_TEMP_010