Imperial College London

Research Governance and Integrity Team

Imperial College Healthcare NHS Trust

This is a controlled document.
The master document is posted on the RGIT website and any print-off of this document will be classed as uncontrolled.

Researchers and their teams may print off this document for training and reference purposes but are responsible for regularly checking the RGIT website for more recent versions

HRA/Ethics Approval for Health-Related Research

SOP Reference: RGIT_SOP_002	
Version Number: 9.0	
Effective Date: 19 Oct 2020	Review By: 19 Oct 2023
Author: Naomi Gardner, Research Facilitator	
Approved by: Ruth Nicholson, Head of Research Governance and Integrity	Date: Ruth Nicholson Digitally signed by Ruth Nicholson Date: 2020.10.13 16:04:54 +01'00'

Version	Date	Reason for Change
Version 1.0	14 Jul 2006	
Version 2.0	25 Jun 2007	Update
Version 3.0	24 Jun 2008	Annual Review
Version 4.0	08 Feb 2010	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 2015	Scheduled Review
Version 8.0	25 Oct 2017	Scheduled Review
Version 9.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP. JRCO name change to RGIT.

Table of Contents

1. PURPOSE

This Standard Operating Procedure (SOP) explains what research should be reviewed by a Research Ethics Committee (REC) and/or Health Research Authority (HRA) and describes where to apply for REC/HRA review for different types of research projects.

It should be used in conjunction with the RGIT_SOP_003 on 'Applying for NHS REC Approval' and RGIT_SOP_004 'Application for Gene Therapy Advisory Committee Approval', where relevant.

2. INTRODUCTION

Most health-related research projects, which involve humans, their tissue and/or data, must be reviewed by a Research Ethics Committee (REC) prior to commencing. On 31 March 2016, the HRA Approval process was introduced for all studies led from England, involving National Health Service (NHS) and Health and Social Care (HSC) organisations in England. From 16 April 2018 this was extended to include all research studies in the NHS in England or Wales and is now referred to as HRA and HCRW Approval.

HRA and HCRW (Health and Care Research Wales) approval is required, along with the REC review, for research studies described by any of the IRAS filter question 2 categories, except those for "Research Tissue bank", "Research Database" and studies taking place outside of the NHS where there is a legal or policy requirement for ethical review under GAfREC such as Phase 1 trials in health volunteers. It is an approval undertaken by dedicated HRA/HCRW staff, which brings together the assessment of governance and legal compliance with the independent REC opinion, provided through the UK Research Ethics Service.
For any new studies led from Scotland or Northern Ireland, but with English and/or Welsh sites, the national R&D coordinating function of the lead nation will share information with the HRA/HCRW assessment teams, who can issue HRA and HCRW approval for English and Welsh sites. For studies led from England or Wales with sites in North Ireland or Scotland, support will be provided through existing UK compatibility systems, by which the country accepts the centralised assurances from the national coordinating functions.

Research studies that have previously sought or gained NHS Permission for participating NHS organisations in England, or applied for REC review will come under HRA approval

The following projects need HRA approval and management permission from host care organisations, but are excluded from REC review:

- Research limited to secondary use of non-identifiable data previously collected during usual care with no intention to use it for research at the time of collection.
- Research limited to secondary use of non-identified tissue samples previously collected during usual care with consent for research
- Research limited to use of non-identified acellular material (e.g. plasma, serum) extracted from tissue previously collected during usual care
- Research involving health or social care services staff, who are recruited by virtue of their professional role (no patient involvement)

Researchers undertaking the above studies should apply for HRA approval through IRAS and contact the R&D Trust where they wish to conduct their study.

All other projects need to be reviewed by a REC.

This applies whether the project is to be externally or internally funded, and whether the project is to be conducted in the UK or overseas. A REC will review the research protocol, and other relevant project documentation, to provide an assurance that the dignity, rights, safety and well-being of research subjects will be protected in a research study.

In the UK, it is against the law, under the Medicines for Human Use (Clinical Trials) Regulations 2004, to start, recruit for or conduct a clinical trial of an investigational medicinal product (CTIMP) until there is a favourable opinion from a recognised REC (and authorisation from the licensing authority – the Medicines and Healthcare Products Regulatory Agency, MHRA).

Furthermore, the UK Policy Framework for Health and Social Care Research states that a research project can start only if a research ethics committee and any other relevant approval body have favourable reviewed the research proposal or protocol and related information, where their review is expected or required.

Research within the NHS requires ethical approval form an NHS Research Ethics Committee (unless covered by the exceptions above). Such research could involve:

1. NHS patients/service users (including potential participants recruited by the patient or user's past or present treatment and NHS patients treated under contracts with private sector institutions)
2. Potential participants identified because of their status as relatives/carers of patients and users of the NHS
3. Access to data (unless anonymised), organs or other bodily material (including DNA extracted from acellular material) of past and present NHS patients
4. Foetal material and IVF involving NHS patients
5. Recently dead in NHS premises
6. Healthy volunteers where a drug or device is being tested within the NHS
7. Research tissue bank
8. Research Database

Similar local regulations and requirements are in place in other countries across the world.

If you are unsure whether your project requires ethical approval, you are strongly advised to contact the Research Governance and Integrity Team (RGIT), see Appendix 1 RGIT_TEMP_007, or to contact a relevant ethics committee, in order to cover yourself.

3. PROCEDURE

3.1. Responsibilities

It is the responsibility of the Chief Investigator to ensure that a health-related research project has been reviewed by a REC. If a project is to occur in the UK, the Chief Investigator must be professionally based in the UK.

3.2. Project Specific

Ethics approval is project specific. If, for example, a research project has separate protocols governing one or more sub-studies in addition to the main study, ethics review should be conducted for each protocol.

3.3. Where to Apply for Ethics Approval

The route for applying for REC approval for your project will differ depending on where your research is to be conducted and the specific nature of your study, for example, whether it is a clinical trial of an investigational medicinal product (CTIMP), involves gene therapy or is a human tissue/epidemiological study, as detailed below.

The HRA operates a centralised booking service, which identifies and allocates applications to the appropriate REC. You may request a review by a named committee, but if you choose this option, the 60-day clock will start from the submission date for the REC and not the date of application receipt. For further information, please refer to **the** online booking service) on how to apply to a research ethics committee. cited on 11 August 2020

Importantly, for international studies, an ethics application must always be made to a REC in each country in which the study is to be conducted, whether or not the project already has a favourable ethical opinion from another REC outside a particular country.

The application form for UK REC review can be obtained via the Integrated Research Application System (IRAS), (cited on 15 May 2020) which combines the ethics application with other regulatory forms such as MHRA applications. All UK NHS studies must apply through this system. For further guidance on IRAS, please see the RGIT SOP on applying to ethics – RGIT_SOP_003.

3.3.1 UK-Based Projects

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 Appendix 2). This type of approval can only be considered if tissue collection is the only component of the research being undertaken. If other research procedures are involved (e.g. questionnaires, scans) then a REC review will be needed.

3.3.1.2 CTIMPs

CTIMPs in Patients (any Phase):

Ethics approval should be sought *via* the **NHS REC system (see SOP on 'Applying for NHS REC Approval'.**

CTIMPs in Healthy Volunteers only (Phase 1):

Ethics approval should be sought from what is known as a Type 1 REC, which should be an NHS REC. A full list of Type 1 RECs can be obtained from the HRA/REC directory. (cited on 15 May 2020)

Trials involving Gene Therapy:

You may book applications 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.

For further information, please visit the Gene Therapy Advisory Committee (GTAC) website. (cited on 15 May 2020)

You are no longer required to seek pre-application regulatory advice from GTAC. The MHRA will continue to provide this service to commercial companies and will consider requests for advice from academic researchers.

3.3.1.3 Other Health-related Projects *within* the NHS (non-CTIMP)

For all other healthcare research within the NHS, ethics approval must be sought you will need to apply for ethics review *via* the NHS REC system. For more information go to the RGIT webpage and search for ethics approval.

3.3.1.4 Studies for Proportionate Review

Your study may be eligible for proportionate review. If this is the case then you will be notified when you book your application in through the Online Booking Service.

The Proportionate Review Service (PRS) provides for expedited, proportionate review of research studies which raise no material ethical issues, which have minimal risk, burden or intrusion for research participants. These include anonymous tissue studies and non-sensitive questionnaire and interview studies

For further guidance on applying for a project for proportionate review, please refer to the RGIT SOP on applying to ethics – RGIT_SOP_003.

3.3.1.5 Other Health-related Projects *outside* the NHS (non-CTIMP)

For those projects which fall outside the remit of the NHS REC system, ethics approval should be sought from the Imperial College Research Ethics Committee (ICREC), if the Chief Investigator is employed by Imperial College. This does not include research involving relevant material under the Human Tissue Act, which must go through the NHS REC system.

Please note that if you have a healthy volunteer study, involving tissue collection, it may be possible for this to be considered by ICREC. Please discuss with the RGIT Coordinator RGITcoordinator@imperial.ac.uk.

3.3.2 Ethics Approval for Overseas Projects (including EU)

The process of ethical review projects to be conducted overseas is not always straightforward. It is essential that local ethics approval systems are complied with, and these can vary.

Certain countries may require that UK ethics approval is obtained, even if the project will have no UK component, if their regulatory environment is, for example, not well-developed. In such cases, the ICREC can be approached (see 3.3.1.4).

4. REFERENCES

HRA and HCRW Approval

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) Regulations 2004

HRA NHS - Research Ethics Committee – Standard Operating Procedures

HRA NHS - Governance arrangements for Research Ethics Committees

HRA NHS - What approvals and decisions do I need?

Imperial College Healthcare Tissue Bank

RGIT SOP on applying to ethics – RGIT_SOP_003.

EU Clinical Trials Directive 2001/20/EC

5. APPENDICES

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

Appendix 1 – Research Governance and Integrity Team Contact Details - RGIT_TEMP_007
Appendix 2 - Summary of Where to Apply for Ethics Approval RGIT_TEMP_008