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HRA/Ethics Approval for Health-Related Research

SOP Reference: JRCO/SOP/002

Version Number: 8.0


Author: Tom Lazenby, Trial Monitor

Approved by: Gary Roper          Date: 24 Oct 2017

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1. PURPOSE

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

It should be used in conjunction with the JRCO/SOP/003 on ‘Applying for NHS REC Approval’ and JRCO/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.

Following changes effective from 31 March 2016, HRA Approval process is now in place for all studies lead from England and involves the National Health Service (NHS) organisations in England and this approval (HRA) must be sought before REC review for research studies described by any of the IRAS filter question 2 categories, except those for “Research Tissue bank” and “Research Database”

HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK research ethics service.

If a research study also involves NHS/HSC organisation(s) elsewhere in the UK (i.e. other than in England) the study will be supported through existing UK-wide compatibility systems, by which each country accepts the centralised assurances, as far as they apply, from 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

In the new approval process, 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, DNA) 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)
• Studies involving the use of or access to NHS organisation’s premises or facilities but no involvement of patients or service users.

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 Department of Health’s Research Governance Framework for Health and Social Care requires that research involving humans, their tissue and/or data in the NHS (unless covered by the exceptions above) must be ethically reviewed. 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 of past and present NHS patients
4. Foetal material and IVF involving NHS patients
5. Recently dead in NHS premises
6. Use of/access to NHS premises or facilities
7. Healthy volunteers where a drug or device is being tested within the NHS
8. Research tissue bank
9. 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 Joint Research Compliance Office (JRCO), see Appendix 1, 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.

A centralised booking service is now in operation, 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: [http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-central-booking-service-cbs/#sthash.Oprk1mnv.dpuf](http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-central-booking-service-cbs/#sthash.Oprk1mnv.dpuf)

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) found at: [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk) 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 JRCO SOP on applying to ethics – JRCO/SOP/003.

3.3.1 **UK-Based Projects**

3.3.1.1 **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 website at:
http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-directory/

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.

See more at: http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/#sthash.e1YyvbBk.dpuf

Professor Andrew George is available to provide advice to applicants before submission of their applications for ethical review. Initial contact should be made via: nrescommittee.london-westlondon@nhs.net and the email marked for the attention of Andrew George.

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. See the following Imperial College web link for more information:
www.imperial.ac.uk/joint-research-compliance-office/project-planning/ethics-approval/

3.3.1.4 Studies for Proportionate Review

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 JRCO SOP on applying to ethics – JRCO/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.

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. APPENDICES

4.1 Appendix 1 – Joint Research Compliance Office Contact Details

Joint Research Compliance Office Contacts:

Non-CTIMP studies:

Ruth Nicholson, Research Governance Manager

Responsible for following hospital campuses:

- St Mary’s Hospital and
- Royal Brompton and Harefield NHS Trust
- North West London Hospitals NHS Trust.
- Western Eye Hospital

Tel: +44 (0)20 7594 1862
Email: r.nicholson@imperial.ac.uk

Becky Ward, Research Governance Manager

Responsible for following hospital campuses:

- Hammersmith Hospital,
- Charing Cross Hospital
- Imperial College London campus based at Chelsea and Westminster NHS Foundation Trust

Tel: +44 (0)20 7594 9459
Email: becky.ward@imperial.ac.uk

CTIMP studies:

Gisela Barreto, Clinical Trials Manager

Responsible for CTIMP studies at all above listed sites/campuses

Tel: +44 (0)20 7594 9480
Email: g.pereira-barreto@imperial.ac.uk
4.2 Appendix 2 - Summary of Where to Apply for Ethics Approval

- All NRES studies should now be booked via a Centralised Booking System, which identified and allocates applications to the appropriate REC

<table>
<thead>
<tr>
<th>Type of Research</th>
<th>HRA/Ethics Approval Route</th>
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<tr>
<td><strong>UK Projects</strong></td>
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<tr>
<td>CTIMP in patients</td>
<td>NHS REC System (via the Central Booking Service)</td>
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<tr>
<td>CTIMP in healthy volunteers only</td>
<td>Type 1 NHS REC (via the Centralbooking Service or can be booked directly with the REC)</td>
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<tr>
<td>Medicinal product for gene therapy</td>
<td>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.</td>
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<tr>
<td>Other health-related research within NHS (non CTIMP)</td>
<td>NHS REC System (via the Central Booking Service)</td>
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<tr>
<td>Studies for Proportionate Review</td>
<td>NHS REC System (subcommittee, rather than full REC meeting) – Book via the Central Booking Service</td>
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<tr>
<td>Other health-related research outside NHS (non CTIMP) if CI is ICL contract holder</td>
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<tr>
<td>Research involving tissue only collected at Imperial</td>
<td>Contact Joint Research Compliance Office or Tissue Bank Manager.</td>
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<td></td>
<td>Tissue Bank Manager contact details:</td>
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<tr>
<td></td>
<td>Dr George Gveric</td>
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<tr>
<td></td>
<td>Tissue Bank Manager</td>
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<td></td>
<td>Imperial College London</td>
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<tr>
<td></td>
<td>11L05 Laboratory Block</td>
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<td></td>
<td>Charing Cross Hospital</td>
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<td></td>
<td>W6 8RF</td>
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<td></td>
<td>Tel 0203-311-7342</td>
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<td></td>
<td>Fax 0203-311-7175</td>
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<td>NHS England Led</td>
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<tr>
<td>Research involving anonymised data, tissue and acellular materials</td>
<td>NHS REC System (via the Central Booking Service for HRA Approval)</td>
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<td>Overseas projects (including EU)</td>
<td>Various routes (Ensure compliance with local rules, if UK approval required can use ICREC if CI is ICL contract holder)</td>
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