Ethics Approval for Health-Related Research

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Author: Becky Ward, Research Governance Manager
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<tr>
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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 (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:

- Research involving health or social care services staff, who are recruited by virtue of their professional role (no patient involvement)
- Studies involving anonymised data collection

Researchers undertaking the above studies should 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

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 system 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

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 which combines the ethics application with other regulatory forms such as MHRA applications. All UK studies must apply through this system. For further
guidance on IRAS, please see the JRCC SOP on applying to ethics – JRCC/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 NRES website at: http://www.nres.nhs.uk/contacts/nres-committee-directory/advanced-search

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 our practical guide on 'How to Apply for NHS REC Approval' for more information: http://www.imperial.ac.uk/clinicalresearchgovernanceoffice/projectplanning/ethicsapproval/howtoapplyforNHSRECapproval

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**

Responsibilities:

- South Kensington Campus
- St Mary’s Hospital
- Imperial College London campuses based at:
  - Royal Brompton and Harefield Foundation Trust
  - North West London Hospitals NHS Trust

Tel: +44(0)203 311 0212Email: r.nicholson@imperial.ac.uk

**Becky Ward, Research Governance Manager**

Responsibilities:

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

Tel: +44(0)203 311 0205Email: becky.ward@imperial.ac.uk

**CTIMP studies:**

**Tharani Thurairajah, Clinical Trials Manager:**

Responsible for CTIMP studies at all above listed sites/campuses
## 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>Ethics Approval Route</th>
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<tbody>
<tr>
<td>CTIMP in patients</td>
<td>NHS REC System (via the Centralised Booking System)</td>
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<tr>
<td>CTIMP in healthy volunteers only</td>
<td>Type 1 NHS REC (via the Centralised booking system 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>
</tr>
<tr>
<td>Other health-related research <em>within</em> NHS (non CTIMP)</td>
<td>NHS REC System (via the Centralised Booking System)</td>
</tr>
<tr>
<td>Studies for Proportionate Review</td>
<td>NHS REC System (subcommittee, rather than full REC meeting) – Book via the Centralised Booking System</td>
</tr>
<tr>
<td>Other health-related research <em>outside</em> NHS (non CTIMP) if CI is ICL contract holder</td>
<td>ICREC</td>
</tr>
<tr>
<td>Research involving tissue only collected at Imperial</td>
<td>Contact Joint Research Compliance Office or Tissue Bank Manager. Tissue Bank Manager contact details: Sarah Chilcott-Burns</td>
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<tr>
<td>Research involving NHS staff only</td>
<td>R&amp;D permission from Trust where you are undertaking the research</td>
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| Overseas projects (including EU)  | Various routes  
(Ensure compliance with local rules, if UK approval required can use ICREC if CI is ICL contract holder) |