Obtaining ICHT approval for Healthcare Research

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<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Reason for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final 1.0</td>
<td>14/07/2011</td>
<td>New Procedure</td>
</tr>
<tr>
<td>Final 2.0</td>
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<td>Annual Review</td>
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<tr>
<td>Final 3.0</td>
<td>18 Feb 2015</td>
<td>Scheduled Review</td>
</tr>
</tbody>
</table>

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## Table of contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Purpose</strong></td>
<td>3</td>
</tr>
<tr>
<td>2. <strong>Introduction</strong></td>
<td>3</td>
</tr>
<tr>
<td>3. <strong>Procedure</strong></td>
<td>3</td>
</tr>
<tr>
<td>3.1 Divisional Approval</td>
<td>3</td>
</tr>
<tr>
<td>3.2 Required Documents</td>
<td>4</td>
</tr>
<tr>
<td>3.3 Participant Identification Centres</td>
<td>5</td>
</tr>
<tr>
<td>4. <strong>References</strong></td>
<td>6</td>
</tr>
</tbody>
</table>
1. PURPOSE

This SOP describes the procedure for obtaining Imperial College Healthcare NHS Trust (R&D) approval of healthcare research. If research is being undertaken in Imperial College Healthcare NHS Trust (ICH) premises, or involving ICHT participants, Trust approval is mandatory. It is needed in addition to the Research Ethics Committee (REC) approval (and any other necessary approvals e.g. MHRA approval) before the project can start. This protocol is concerned with obtaining Trust approval for research that has been, or is being, submitted for ethical approval and should be used in conjunction with JRCO/SOP/002 ‘Ethics Approval for Health-Related Research’ and JRCO/SOP/003 ‘NHS REC Applications’.

2. INTRODUCTION

Any study sponsored by Imperial College AHSC should be sent to the Joint Research Compliance Office (JRCO), prior to submission to ethics, for sponsor approval. The JRCO can help to determine who the sponsor for the study should be (College or Trust) and will assess the project to ensure that it fulfils sponsor requirements. JRCO will review the project prior to submission to ethics and can advise whether there are any implications arising from the application (e.g. costing, contracts, imaging implications). Sponsor approval (and an accompanying sponsor letter) is required before the project can be booked in to ethics.

NHS RECs will review all research conducted within the NHS. As well as obtaining ethical approval, a research project being conducted at ICHT sites or involving ICHT participants must also be given Trust approval before it commences. A researcher can start applying for Trust approval as soon as the ethics application has been submitted.

Trust approval must be given by each R&D office, at each NHS organisation, where the study is due to start. This approval is in addition to the approval from the NHS REC who approved your study.

3. PROCEDURE

If your study is on the NIHR portfolio or is possibly eligible and is being considered for adoption, please refer to JRCO SOP 033 instead of this SOP

Please note that we only accept one investigator for Imperial College Healthcare NHS Trust. So if the Chief Investigator is based at Imperial College Healthcare NHS Trust, they must also be named as the Principal Investigator. Other researchers can be named as co-investigators.

3.1 Divisional Approval:

To initiate the JRCO approval process (for Trust or PIC approval), please contact the Feasibility Officer/Research Manager for your ICHT Trust division. They will assess your study for feasibility in the Trust and advise on the submission of the documents for Trust approval.

The Research Managers/Feasibility Officers are:
Studies can only be accepted by the JRCO after feasibility assessment has commenced and the Divisional Research Manager has confirmed the submission.

3.2 Required Documents

The documents required to give Trust approval to a study are:

1. IRAS REC form, preferably pdf. **Must be the final signed version.** JRCO will accept electronic copy.
2. IRAS Site Specific Information form for Imperial College Healthcare site, preferably in pdf format. **A final signed copy is required.**
3. Signed and dated copy of the Principal Investigator’s C.V.
4. CVs for the research team listed in the SSI. Signed and dated.
5. Protocol (final REC approved version).
6. Patient information sheet and consent form (final REC approved version on Trust headed paper).
7. Study specific documentation approved by the REC (e.g. patient diary cards)
8. Certificate of ARSAC (if applicable).
9. REC favourable opinion letter.
10. Confirmation of REC favourable opinion for any substantial amendments (if applicable).
11. MHRA CTA approval (if applicable).
12. Confirmation of authorisation from MHRA for any substantial amendments (if applicable).

13. Any other approvals documentation that is relevant to the study (e.g. Confidentiality Advisory Group (CAG) formerly known as NIGB approval) Divisional authorisation – an email is sufficient evidence.

14. Confirmation from support department that their involvement is agreed (e.g. pharmacy is applicable).

Once all of this has been received, the JRCO will be able to carry out the appropriate governance checks. Final approval is also dependent on the imaging committee approval, pharmacy approval, pathology assessment (if applicable) and any contracts required being signed off by all parties.

Final JRCO sign-off is also dependent on the following documents/approvals being in place internally:

1. Clinical trial site agreement signed off by Pre-award Imperial AHSC JRCO and sponsor organisation (if applicable). **Fully signed contracts need to be in place before Trust approval can be issued.**

2. Approval by Research Imaging committee, including IRMER approval (if applicable). You must contact Liam Greenshields liam.greenshields@imperial.nhs.uk at the earliest possible opportunity, if you have a project that utilises Imperial College Trust imaging equipment/facilities. Such projects require review by the Imaging research Committee and they only meet once a month.

3. Imperial College Healthcare NHS Trust Safety Committee approval (if the study involves a Gene Therapy study being carried out in the Trust) Contact: Sharon Wood, Director of Safety Services, Imperial College Healthcare NHS Trust 020 331 17477; sharon.wood@imperial.nhs.uk

4. New Interventions Committee approval for device studies being conducted at the Trust (Contact: Professor Onn Min Kon; 020 331 21244; onn.kon@imperial.nhs.uk).

When everything is in place, a Trust approval letter will be issued for the study and the project can commence. A copy of the Trust approval letter should be placed in the site file.

**3.3 Participant Identification Centres (PICs)**

Participant Identification Centres (PICs) are organisations which refer potential participants to a research team at another organisation, but do not conduct trial related activity themselves. If consent or screening will take place, then the site would not be classed as a PIC and you will need to complete a SSI form in IRAS.

You must ensure that all PICs are listed in the part C of the IRAS form and send the JRCO details of what activity will take place at ICHT and a copy of the protocol. You will receive confirmation from the JRCO that you may use the site as a PIC. You cannot commence the study at any ICHT site until you receive this confirmation.
4. REFERENCES

http://www.hra.nhs.uk/
http://www.nres.nhs.uk/
http://www.mhra.gov.uk;

Amendments to healthcare Research, ref: JRCO/SOP/006
NHS REC applications, ref: JRCO/SOP/003
Ethics Approval for Health-Related Research, ref JRCO/SOP/002