Obtaining ICHT Management confirmation of capacity and capability for Healthcare Research

SOP Reference: JRCO/SOP/031

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Approved by: Gary Roper  Date: 24 Oct 2017

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1. PURPOSE

This SOP describes the procedure for obtaining Imperial College Healthcare NHS Trust (R&D) Management confirmation of capacity and capability of healthcare research. **If research is being undertaken in Imperial College Healthcare NHS Trust (ICHT) premises, or involving ICHT participants, premises and resources Management confirmation of capacity and capability is mandatory.** It is needed in addition to the Research Ethics Committee (REC) approval and the HRA approval (and any other necessary approvals e.g. MHRA approval) before the project can start at the Trust. This protocol is concerned with obtaining Management confirmation of capacity and capability for research that has been, or is being, submitted for ethical approval and HRA 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 and the HRA, **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 the HRA 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 and the HRA for review and approval.

NHS RECs will review all research (apart from those defined as not requiring Ethics, see Ethics Approval for Health-Related Research JRCO/SOP/002) conducted within the NHS. As well as obtaining ethical approval and HRA approval alongside regulatory approvals such as the ARSAC and the MHRA a research project being conducted at ICHT sites or involving ICHT participants, premises and resources must also be given Trust Management confirmation of capacity and capability before it commences at the Trust. A researcher can start applying for Trust Management confirmation of capacity and capability as soon as the ethics and the HRA applications have been submitted.

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

3. PROCEDURE

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 Management confirmation of capacity and capability process (for Trust or PIC confirmation of capacity and capability), please contact the Feasibility Facilitator/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 to the JRCO for Trust Management confirmation of capacity and capability.

The Research Managers/Feasibility Facilitators are:

<table>
<thead>
<tr>
<th>Facilitator</th>
<th>Division, Specialities</th>
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<tbody>
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<td>Ext 37305</td>
</tr>
<tr>
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<td><a href="mailto:Yojna.HandooDas@imperial.nhs.uk">Yojna.HandooDas@imperial.nhs.uk</a></td>
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<td>Louise George</td>
<td>Women &amp; Children’s and Clinical Support</td>
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<td><a href="mailto:Louise.George@imperial.nhs.uk">Louise.George@imperial.nhs.uk</a> AND/OR <a href="mailto:MyResearchWCCS@imperial.nhs.uk">MyResearchWCCS@imperial.nhs.uk</a></td>
<td>Ext 37303</td>
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</table>

Studies are sent to the JRCO by the divisional managers and by the feasibility facilitators so that we can start working on the studies. The feasibility approval is issued when all the support departmental approvals are issued for the study and the REC and HRA approvals are in place along any applicable regulatory approvals, then the JRCO issues Management confirmation of capacity and capability and only then the study can start at the site.

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3.2 Required Documents for Trust Management Confirmation of Capacity and Capability

For projects sponsored by organisations other than Imperial, the sponsor will contact the JRCO or Trust Divisional Research Managers to inform them of the study and its status of approval. For non-commercial projects a Statement of Activities (SoA) and Schedule of Events should be provided by the sponsor for information on what processes will occur at site. For Commercially sponsored studies a study agreement will be provided by the sponsor.

The sponsor will also provide study related documents (valid document set) that are applicable to the site. Submissions will be made via the JRCO generic email address – jrco@imperial.ac.uk or to the appropriate Trust DRM (contact details in Appendix 1).

The sponsor will be notified within 3 working days of receipt of the valid document set, and the Trust has 40 calendar days to confirm capacity and capability to the sponsor.

Once the document set has been received the JRCO and DRM’s will liaise with each other to confirm commencement of capacity and capability assessment.

The DRM’s will liaise with the local research teams, support services such as Pharmacy, Imaging and Contracts (as applicable) as part of the capacity and capability assessment. Upon completing the assessment the DRM will notify the JRCO.

Once the assessment process is completed the JRCO is required to confirm organisational readiness - Management confirmation of capacity and capability with the sponsor via email (this confirmation replaces the Trust R&D approval letter). A copy of the Management confirmation of capacity and capability email should be placed in the site file.

When HRA approval and JRCO confirmation have been completed the CI/PI and DRM will be informed via email and the study can commence.

For studies where Imperial AHSC is sponsor the JRCO will contact the DRM at the sponsor assessment stage to begin our local capacity and capability process.

The documents required to give Trust Management confirmation of capacity and capability to a study are:

- IRAS form **Must be the final signed version.**
- Signed and dated copy of the Principal Investigator’s C.V.
- Protocol (final HRA and REC approved version).
- Patient information sheet and consent form (final REC and HRA approved versions).
- Certificate of ARSAC (if applicable, make sure that this is Local ARSAC approval), CAG approval etc i.e. other IRAS approvals
- REC favourable opinion letter.
- HRA approval letter. And HRA initial assessment letter if one was issued.
• Amendment documentation (minor/substantial amendment forms and REC/HRA/MHRA approval of these if applicable to site, if not confirmation that not applicable to site is acceptable).
• MHRA approval (if applicable).
• Investigator Brochure or SMPC.
• Divisional Approval – an email is sufficient evidence
• Confirmation from support departments that their involvement is agreed (e.g. pharmacy, imaging, pathology, fully executed agreement, tissue bank if applicable)
• Statement of Activity relevant to the participating NHS organisation (non-commercially sponsored only)
• Relevant template contract/model agreement (if needed in addition to Statement of Activity)
• Costing template (commercially sponsored only) or Schedule of Events (non-commercially sponsored only)
• Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study

Once all of this has been received, the JRCO will be able to carry out the appropriate management checks. Final Management confirmation of capacity and capability 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 Management confirmation of capacity and capability 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 Clinical Research Safety Committee approval (if the study involves work with Genetically Modified Organisms being carried out in the Trust) Contact: NIHR/Wellcome Trust Imperial CRF; 020 3313 8070; Imperial.CRF@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).

**3.3 Participant Identification Centres (PICs)**

Participant Identification Centers (PICs) are organisations which refer potential participants to a research team at another organisation, but do not conduct trial related activity themselves. PICs have the same approval process as full sites now with the
HRA process therefore the local documents pack and the Schedule of Activity and the Statement of Events need to be submitted to the site for review. If consent or screening will take place, then the site would not be classed as a PIC.

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 and the local document pack. 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 Management confirmation of capacity and capability.

4. REFERENCES

http://www.hra.nhs.uk/
http://www.mhra.gov.uk
http://www.hra.nhs.uk/about-the-hra/our-committees/res/

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