Obtaining ICHT confirmation of continued Capacity and Capability for Amendments to Healthcare Research

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<th>Version</th>
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<td>Version 1.0</td>
<td>18 Jul 2011</td>
<td>New SOP</td>
</tr>
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<td>DRM team to take over Amendment CCC process</td>
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1. PURPOSE

This SOP describes the procedure for obtaining Imperial College Healthcare NHS Trust (ICHT) Confirmation of continued Capacity and Capability of amendments (both substantial and minor) to healthcare research. If your research is being undertaken in ICHT premises, or involving ICHT participants, this approval is mandatory, in addition to the REC and HRA approvals for substantial amendments (and any other necessary approvals e.g. MHRA approval) and HRA approval only for non-substantial amendments before any changes can be made to your project.

2. INTRODUCTION

Amendments are changes (substantial or minor) made to a research study after a favourable ethical opinion or approval has been given by a regulatory body. They can be made to a protocol, other essential documentation, or other aspects of a study’s arrangements. This protocol is concerned with obtaining Trust approval for amendments to healthcare research that have received or do not require ethical approval. For further information on making amendments to healthcare research, please refer JRCO/SOP/006 Amendments to Healthcare Research.

If your study is sponsored by Imperial College London, or Imperial College Healthcare NHs Trust, your amendment must be sent to the JRCO, prior to submission to ethics/HRA, for sponsor approval. The JRCO can help to determine whether an amendment is substantial or non-substantial and will assess for implications arising from the amendment (e.g. costing, contracts, imaging implications). When you have received sponsor approval of the amendment, it can then be sent to ethics.

Once your study amendment has received ethical and Health Research Authority (HRA) or HRA only approval (if exempt from REC approval), it also needs final ICHT Trust confirmation of continued Capacity and Capability approval before the amendment can be implemented (unless the amendment was implemented as an urgent safety measure, in which case the DRM team should be contacted as soon as possible after the event).

All notifiable amendments to your study must also be notified to each applicable R&D office, at each NHS Trust, where the study has been approved subject to the categorisation guidance listed below. This approval is in addition to the approval from the NHS REC or HRA who approved your study. All amendments must also be submitted to the host Trust of any participant identification centres (PIC sites).

Categorisation of Amendments
Amendments are grouped into three different categories for the purpose of handling them in a manner appropriate to the amendment.

<table>
<thead>
<tr>
<th>Category</th>
<th>This category includes any amendment to a research project that has:</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>Implications for, or affects, all participating NHS/HSC organisations hosting the research project.</td>
</tr>
<tr>
<td>B</td>
<td>Implications for, or affects, specific participating NHS/HSC organisations hosting the research project.</td>
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No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. However the amendment should still be submitted for information.

*Note* - *Updated Investigator Brochure (IB; Clinical Trials of Investigational Medicinal Products (CTIMPs) only):* Where the IB update, annual or otherwise, constitutes a non-substantial amendment for REC and MHRA and this is the only amendment (e.g. the update to IB does not give rise to updated pharmacy manual or protocol) the updated IB should not be submitted for categorisation. These amendments will always be category C and they will not be assessed by NHS/HSC if submitted. The IB should be provided to each participating NHS/HSC organisation.

| New NHS/HSC site | Where the amendment is to add a new NHS/HSC site to the project, the set-up of this new site should proceed according to the process for [local study set-up](#) for the nation where the new site is located. |

The HRA categorisation email for the amendment will identify which category applies.

### 3. PROCEDURE

#### 3.1 Trust approval of Substantial Amendments

When the substantial amendment has been approved by the REC and HRA or HRA only where REC exempt that originally approved your study and has been categorised as requiring NHS approval, please send the DRM team a copy of the HRA categorisation email, with all supporting documents and amended documents, for example:

- Updated protocol
- Updated patient information sheets and consent forms
- Any other study specific documentation approved by the REC
- Signed Substantial Amendment Form (IRAS form), as submitted to the appropriate approval committee. Depending on your study this may be one or a combination of the following:
  - REC
  - MHRA
  - Confidentiality Advisory Group
- Letter from the MHRA confirming acceptance of the amendment (if applicable)
- Confirmation from support departments that their involvement is agreed
- ARSAC certificate (if applicable)
- Any other approval documentation that is relevant to the study
- HRA approval email

Please note that the clock for 35 days to raise objection does not start until the amendment categorisation email has been received.

Final continuation of capacity and capability sign off of the amendment is also dependent on the following documents/approvals being in place, if applicable:
• Any contract implications being approved by the Joint Research Office to the contract being approved and in place before final CCC approval. Contracts review is required for the following criteria:
  o Change of sponsor or legal representative
  o Change to insurance or indemnity arrangement
  o Change to procedures undertaken by participants that may affect the budget
  o Other changes to funding arrangements.
  o Changes to logistical arrangements for storing or transporting samples.

• Any amendments or updated clinical trial agreements being signed off by Pre-award Imperial AHSC JRO and sponsor organisation. **Fully signed contracts need to be in place before CCC can be issued.**

• Divisional Research Manager approval

• Any study that involves Trust imaging facilities being reviewed with regards to the amendment by the Trust Research Imaging Committee. You should contact Liam Greenshields at the earliest possible opportunity, if the changes to your project involve Imperial College Trust imaging equipment and facilities. Such projects require review by the Imaging Research Committee, which meets once per month. Contact here is Liam Greenshields liam.greenshields@imperial.nhs.uk

• Pharmacy approval (for all CTIMP studies).

• Pathology approval (if changes to lab arrangements or tests)

• IG approval (any changes that require CAG approval).

• Other approvals depending on study support, i.e. CRF, CIF and Imanova.

The DRM team will then assess the project for CC confirmation. Please note that if documents with tracked changes have been sent to the ethics committee, these should also be supplied to the DRM team.

When everything is in place, a Trust Confirmation of continued capacity and capability approval email will be issued for the amendment. An acknowledgement email will be sent for Category C or Category B amendments which do not require formal notification. A copy of this should be placed in your site file and you may then implement the amendment.

3.2 Trust approval of Minor (‘Non-Substantial’) Amendments.

A CI can make a non-substantial amendment at any time but must keep records of these amendments. Non-substantial study amendments need to be approved by the HRA. The DRM team will follow the process above as required and will send you an e-mail confirming continued capacity and capability. An acknowledgement email will be sent for Category C/Category B amendments which do not require formal notification. A copy of this should be placed in your site file and you may then implement the amendment.

4. References

http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
http://www.mhra.gov.uk;
Amendments to healthcare Research, ref: JRCO/SOP/006
NIHR studies JRCO/SOP/033