Obtaining ICHT approval for Amendments to Healthcare Research

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1. PURPOSE

This SOP describes the procedure for obtaining Imperial College Healthcare NHS Trust (ICHT) Joint Research Compliance Office (JRCO) approval of non-CSP 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 approval (and any other necessary approvals e.g. MHRA approval) 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 AHSC, your amendment must be sent to the JRCO, prior to submission to ethics, 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 approval, it also needs final ICHT Trust approval before the amendment can be implemented (unless the amendment was implemented as an urgent safety measure, in which case the JRCO office 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 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.

• Category A – Amendment to a research study that ALL participating NHS organisations are expected to consider:
  This category includes any amendment to a research study that has implications for, or affects, ALL participating NHS organisations hosting the research study. All participating NHS organisations will be informed of, and have access to the amendment.
All participating NHS organisations are expected to consider the amendment to determine whether they are able to continue NHS research permission.

- **Category B – Amendment to a research study that only those participating NHS organisations affected by the amendment are expected to consider:**
  This category includes any amendment to a research study that has implications for, or affects, SPECIFIC participating NHS organisations hosting the research study. Only those participating NHS organisations affected by the amendment will be informed of the amendment. However, all participating NHS organisations will have access to the amendment through the relevant national coordinating function. Only those participating NHS organisations affected by the amendment are expected to consider the amendment to determine whether they are able to continue NHS research permission.

  Note: Where the amendment is the addition of a new research site, the submission of a SSI application for a new research site should proceed through the NHS permission process appropriate to the addition of a new site in accordance with the requirements of the nation where the new research site is to be added.

- **Category C – Amendment to a research study that participating NHS organisations are not expected to consider:**
  This category includes any amendment to a research study that has no implications that require management or oversight by the participating NHS organisations hosting the research study. All participating NHS organisations will have access to the amendment. Participating NHS organisations are NOT expected to consider the amendment or give continued permission for these amendments. There may be amendments of a confidential nature that the Sponsor is required to submit to the MHRA. Such amendments will have no implications for, or affect, the participating NHS organisations hosting the research study. Therefore these amendments will not be notified to the NHS organisations.

The ethics approval letter 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 who originally approved your study and has been categorised as requiring NHS approval, please send the JRCO a copy of the REC favourable opinion letter approving the amendment, 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

Final Trust 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 JRCO approval
- 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 Trust approval can be issued.**
- Any study which 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
- If your study has been adopted by NIHR we have to wait for the system to complete the checks before we can sign off Trust approval for the amendment. For further information on NIHR studies, please see JRCO/SOP/033.

JRCO will then assess the project for Trust approval. Please note that if documents with tracked changes have been sent to the ethics committee, these should also be supplied to the JRCO.

When everything is in place, a Trust approval letter will be issued for the amendment. 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 do not need to be reported to or approved by the REC and/or the MHRA. However, it is best practice to update the REC and the MHRA (for CTIMPs) with the non-substantial amendments to your study by letter, and copy in the JRCO. The Joint Research Compliance Office will send you a
letter/e-mail (depending on how you submitted the non substantial amendment) acknowledging 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