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<b>Obtaining ICHT confirmation of continued Capacity and Capability for Amendments to Healthcare Research</b>	
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Version	Date	Reason for Change
Version 1.0	18 Jul 2011	New SOP
Version 2.0	03 Dec 2012	Annual Review
Version 3.0	18 Feb 2015	Scheduled Review
Version 4.0	25 Oct 2017	Scheduled Review
Version 5.0	30 July 2019	DRM team to take over Amendment CCC process Trust approval of Substantial Amendments Annual Review
Version 6.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP.

		RGIT name change to RGIT.
Version 7.0	25 Mar 2021	Remove of Annex 2 requirements for CTIMP amendments

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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 RGIT\_SOP\_006 Amendments to Healthcare Research this SOP which can be found on the [SOP, Associated Documents & Templates page](#).

**If your study is sponsored by Imperial College London, or Imperial College Healthcare NHS Trust, your amendment must be sent to the RGIT, prior to submission to ethics/HRA, for sponsor approval.** The RGIT 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.

Category:	This category includes any amendment to a research project that has:
A	<p><b>Amendment to a research study that has implications for, or affects, <u>ALL</u> participating NHS organisations hosting the research study.</b></p> <p><i>Note - The applicant should send the amended documentation, to the research management support offices and local research teams at your participating NHS organisations in England. The organisation will then make the necessary arrangements to implement the amendment</i></p>
B	<p><b>Amendment to a research study that only those participating NHS organisations affected by the amendment are expected to consider</b></p> <p><i>Note - This category includes any amendment to a research study that has implications for, or affects, SPECIFIC participating NHS organisations hosting the research study. The applicant should send the amended documentation, to the research management support offices and local research teams at the relevant participating NHS organisations in England. These organisations will then make the necessary arrangements to implement the amendment</i></p>
C	<p><b>Amendment to a research study that participating NHS organisations are <u>NOT</u> expected to consider.</b></p> <p>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. The participating organisations do not need to put any arrangements in place for the amendment. However, the local research team still need to be aware of the amendment so the applicant should send the amended documentation, to the research management support offices and local research teams at the participating NHS organisations in England.</p> <p>Non-substantial amendments which do not require study wide review will only receive an automated response from the HRA, and do not require HRA approval.</p> <p><i>Note - Updated Investigator Brochure (IB; Clinical Trials of Investigational Medicinal Products (CTIMPs) only):</i> Where the IB update, annual or otherwise, constitutes a non-substantial amendment for REC and MHRA <u>and</u> 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</p>

	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 <a href="#">local study set-up</a> for the nation where the new site is located.

### 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 all supporting documents and amended documents for continued CCC, for example:

- Updated protocol
- Updated patient information sheets and consent forms
- Any other study specific documentation approved by the REC
- Signed .pdf copy of the completed amendment tool [Amendment Tool v1.2 \(11 Jun 2020\).xlsm](#) submitted .via the [online amendment submission portal](#) applicable to all project-based research except Research Tissue Banks (RTBs) and Research Database (RDBs) which continue to use the Notice of Substantial Amendment Form. For CTIMP studies a copy of the European Commission form available under the 'Annex 2' tab of the Amendment Tool as required prior to 25th March 2021 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 contracts team in place before final CCC approval. Contracts review is required for the following criteria:
  - Change of sponsor or legal representative

- Change to insurance or indemnity arrangement
  - Change to procedures undertaken by participants that may affect the budget
  - Other changes to funding arrangements.
  - Changes to logistical arrangements for storing or transporting samples.
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- 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 (DRM) 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. To arrange please contact Liam Greenshields [liam.greenshields@imperial.nhs.uk](mailto:liam.greenshields@imperial.nhs.uk) or Charlie Clemoes [charlie.clemoes@imperial.nhs.uk](mailto:charlie.clemoes@imperial.nhs.uk)
  - Pharmacy 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.

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 or acknowledged by the HRA. The DRM The divisional 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

[HRA NHS - Amending an approval](#)

[HRA Website](#) (cited on 30/06/2020) [MHRA Website](#) (cited on 30/05/2020)

[Amendment guidance](#) - all review bodies (*cited on 03/06/2020*) [JRO Websites](#) [New HRA Amendment Process](#) (*cited 9/07/2020*)  
[IRAS Amendment Website](#) (*Cited 09/07/2020*) Amendments to healthcare Research, ref: RGIT\_SOP\_006, this SOP which can be found on the [SOP, Associated Documents & Templates page](#).  
NIHR studies RGIT\_SOP\_033