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

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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	Removal of Annex 2 requirements for CTIMP amendments
Version 8.0	25 Nov 2024	Scheduled Review
Version 9.0	27 Apr 2026	Updates following legislative changes.

Table of Contents

Contents

1. PURPOSE....4
2. INTRODUCTION....4
Categorisation of Modifications....5
3. PROCEDURE....5
3.1. Trust approval of Substantial Modifications (Route A & Route B)....5
3.2. Trust approval of Minor (Non-Substantial) Modifications....7
4. REFERENCES....7

1. PURPOSE

This SOP describes the procedure for obtaining Imperial College Healthcare NHS Trust (ICHT) Confirmation of continued Capacity and Capability of modifications (substantial (Route A & B), Modifications of an Important Detail & Minor) to healthcare research. If your research is being undertaken in ICHT premises, or involves ICHT participants, this approval is mandatory. Receipt of this approval should also be alongside REC & HRA approvals, for substantial modifications, as well as any other necessary approvals (e.g. MHRA approval). For modifications of an Important Detail and minor modifications, only HRA approval may be required before any changes can be made to your project.

2. INTRODUCTION

Modifications are changes made to a research study after an initial favorable ethical opinion has been issued by a Research Ethics Committee (REC) and approval has been given by the regulatory body (in the UK, this is the MHRA). They can be made to a protocol, other essential documentation or other aspects of a study's arrangements. For further information on making modifications to healthcare research, please refer to RGIT_SOP_006_Modifications to Healthcare Research. This SOP 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 modification must be sent to the RGIT for Sponsor review prior to submission to REC, HRA and regulatory authorities (MHRA in the UK for CTIMPs or other regulated studies) for review and approval. The RGIT, in line with the modification category on your modification tool, can help to determine whether a modification is substantial (Route A or B), a modification of an important detail or minor and will assess implications arising from the modification (e.g. costing, contracts, imaging implications, etc.).

Once your study modification has received relevant REC, HRA and regulatory (MHRA) approvals as applicable to your study, it also needs final ICHT Trust confirmation of continued Capacity and Capability (CCC) approval before the modification can be implemented at a specific site (unless the modification was implemented as an urgent safety measure, in which case the Divisional Research Management (DRM) team should be contacted as soon as possible after the event – See RGIT TEMP 009 for details of Divisional Research Managers and Feasibility Facilitators – available from SOP, Associated Documents & Templates page)

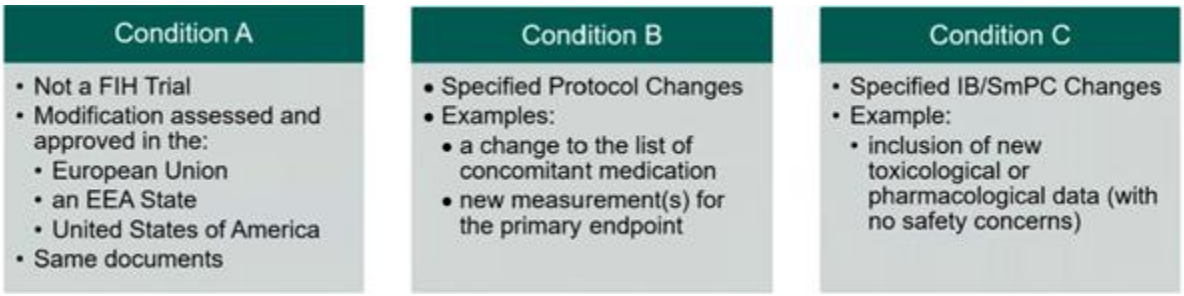
All notifiable modifications to your study must be sent to each applicable R&D office at each NHS Trust where the study obtained initial Trust CCC (Confirmation of Capacity & Capability), subject to the categorisation guidance listed below. This approval is **in addition** to the approval from the relevant regulatory authorities who approved your study. All modifications must be submitted to the host Trust of any participant identification centers (PIC sites).

Categorisation of Modifications

Modifications are classified as follow: **Substantial Modification, Modification of an important detail or Minor Modification.**

Substantial Modifications are categorized into two routes:

- **Route A:** Likely to have a substantial impact on the safety or rights of the participants *or* on the reliability or robustness of the data generated in the trial.
- **Route B:** A modification likely to have a substantial impact on the safety or rights of the participants or on the reliability or robustness of the data generated in the trial but where there are no new significant safety concerns with any of the investigational medicinal products, as far as the sponsor is aware having made reasonable enquiries; and which meets either Condition A, Condition B or Condition C (see figure below). For further details on the conditions, please see the following link: The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 *(cited on 11 March 2026)*. The justification for the decision of a route B modification should be clearly documented by the sponsor.



Modifications of an Important Detail do not significantly impact the safety or rights of participants, but the authorities need to be aware of them for administrative or oversight purposes. Instructions for notifying the authorities about a modification of an important detail are provided on completion of the modification tool.

Minor modifications can be defined as a change to the details of a study which have no significant implications for participants or the conduct, management or scientific value of the study. Minor modifications may be implemented at any time and without informing the licensing authority or ethics committee at the point of implementation (however, other approvals may be required (for example HRA approval), which can be determined using the modification tool). The sponsor must keep records of any modifications implemented and, if requested, make them available to the licensing authority or ethics committee.

3. PROCEDURE

3.1. Trust approval of Substantial Modifications (Route A & Route B)

When the Substantial Modification has been approved by the REC, HRA and UK regulatory authority (MHRA) (as applicable), please send the DRM team the approvals

alongside all modification related study documents (in both clean and tracked versions) for them to review and issue continued CCC. Please see below examples:

- Updated protocol.
- Updated patient information sheets and consent forms.
- Other study specific documentation approved by REC, HRA & MHRA where relevant.
- Signed, pdf copy of the completed modification tool submitted via the online modification submission portal applicable to most project-based research except Research Tissue Banks (RTBs) and Research Database (RDBs) which continue to use the Notice of Substantial Amendment Form.
- **Please note:** The HRA is rolling out a new digital service for managing modifications. Initially in private beta, it is available only to invited sponsors and eligible studies (e.g. single-nation, non-NHS REC studies) and will gradually expand. Imperial College London and Imperial College Healthcare NHS Trust are participating in the early roll-out. Researchers should use the new service for eligible studies; all other studies should continue with the standard modification tool. Guidance and eligibility details have been communicated to researchers. If you need these resources, please contact RGIT@imperial.ac.uk.
- Approvals: Depending on your study, this may be one or a combination of the following:
  - REC approval email and/or letter
  - HRA approval email and/or letter
  - Letter from the MHRA confirming acceptance of the modification (if applicable) Confidentiality Advisory Group (CAG)
  - ARSAC certificate (if applicable)
  - Any other approval documentation that is relevant to the study
  - Confirmation from support departments that their involvement is agreed.

Please note that the clock for 35 days to raise objections (Category A & B modifications) does not start until the modification tool and relevant modification documents have been received (e.g. amended contract).

Final continuation of capacity and capability sign off for the modification is dependent on the following documents/approvals being in place (as applicable):

- Any changes to contracts require the relevant Imperial Contracts team to draft the agreement/ addendum. This draft will need to be reviewed by the JRO Contracts team before execution and final CCC approval. Contract 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, including receipt of funding letter.
  - Changes to logistical arrangements for storing or transporting samples.
- Any modifications or updated clinical trial agreements being signed off by post-award, Imperial JRO and Sponsor organisation (RGIT).
- **CCC approval for modifications can be issued in cases where contracts review is required for the above-mentioned criteria.**
- Divisional Research Manager (DRM) approval
- Trust imaging approval
- Pharmacy approval

- Pathology approval (if changes to lab arrangements or tests)
- IG approval for Trust sponsored studies only (any changes that require CAG approval).
- Other approvals depend on study support e.g. CRF, Clinical Imaging Facility (CIF) and Perceptives).

The DRM team will 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 modification. An acknowledgement email will be sent for Category B or Category C modifications which do not require formal notification. A copy of this should be placed in your site file and Trust LPMS (EDGE). The modification may then be implemented at site.

3.2. Trust approval of Minor (Non-Substantial) Modifications

Minor modifications may be implemented at any time and without informing the licensing authority or ethics committee at the point of implementation. However, these need to be approved or acknowledged by the HRA. The DRM team will then follow the process above as required and will send an e-mail confirming continued capacity and capability. An acknowledgement email will be sent for Category B/Category C modifications which do not require formal notification. A copy of this should be placed in the trial's site file and the modification can then be implemented.

4. REFERENCES

- Clinical trials for medicines: modifying a clinical trial approval - GOV.UK
- HRA NHS - Amending an approval
- HRA Website MHRA Website
- Amendment guidance - all review bodies https://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/hrs/stages/recruitmentstage/reviewamendments/
- New HRA Amendment Process
- IRAS Amendment Website
- Modifications to healthcare Research: RGIT_SOP_006
- NIHR studies RGIT_SOP_03