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Confirmation of Capacity and Capability to Deliver Research at Imperial College Healthcare NHS Trust

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Version	Date	Reason for Change
Version 1.0	14 Jul 2011	New Procedure
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 6.0	21 Mar 2019	New Procedure
Version 7.0	11 Jun 2019	Updates to the use of Organisation information document
Version 8.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP.

		JRCO name change to RGIT
Version 9.0	12 Jan 2022	Update made to the appendices for the DRM and Feasibility officers contact details
Version 10.0	04 Dec 2024	3yr SOP review

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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 (C&C). The management's confirmation of capacity and capability (C&C) is mandatory when research is being undertaken in the Imperial College Healthcare NHS Trust (ICHT) premises, or involving ICHT participants, premises and resources. That is, before that the project can start at the Trust, a C&C needs to be attained in addition to the research ethics committee (REC) and healthcare research authority (HRA) approvals (and any other necessary approvals, such as the MHRA[1] approval). Therefore, this procedure is specifically concerned with obtaining management confirmation of capacity and capability for research that has been, or is being, submitted for HRA approval as well as ethical approval, and it should be used in conjunction with relevant SOPs, such as RGIT_SOP_002 and RGIT_SOP_003, which can be found on the SOP, Associated Documents & Templates webpage.

2. INTRODUCTION

The HRA approval process is the formal approval by the NHS that often comprises also a review by an NHS REC along with regulatory compliance and governance assessments. In England, the HRA approval has replaced the need for local legal compliance checks and any related matters that were previously known as the local governance review. Therefore, for proposed research studies, the NHS Trusts in England will not issue an NHS permission, but a confirmation of capacity and capability.

As a result of the above, the HRA has defined a list of stages that sponsors and participating organisations (such as, the Trusts) need to go through to provide evidence that they have mutually agreed on the study initiation at a given organisation.

1. **Assessing**: this stage is to assess whether a Trust has the capacity and capability to participate in a study; though, this stage may not be required, or become less time-consuming for some types of studies where the Trust is expected to participate in automatically (unless there is a significant reason why it shouldn't). These study types include: emergency public health research studies involving minimal local activity (such as distributing questionnaires and/or online surveys or supplying previously collected clinical data where consent is in place already), and studies where the clinical pathway is such that a patient has been transferred for on-going clinical care, though any research related responsibility remains with the principal investigator of the original study.

2. **Arranging**: this stage is about putting in place any practical arrangements necessary to provide the capacity and capability that is required to deliver the study.

3. **Confirming**: this stage is to confirm that the Trust has in place the capacity and capability necessary to deliver the study and will deliver the study. This confirmation is given through the mutual confirmation of the contents of the Organisation Information Document (for non-commercial studies) or the sign-off of an agreement.

[1] Medicines and Healthcare products Regulatory Agency

The research management's confirmation of capacity and capability (C&C) at ICHT must be obtained for all ICL/ICHT[2] research studies that involve ICHT participants, staff, premises, and resources. Such confirmation of capacity and capability is needed in addition to the HRA approval (together with other necessary approvals such as the MHRA approval) and REC approval (if relevant), before that the project can start at the Trust.

3. C&C CONFIRMATION OBJECTIVE

The C&C confirmation stage is the ultimate feasibility assessment stage within the research study lifecycle. This is better detailed in the college website for both ICL and ICHT sponsored studies. The objective of the C&C process (that is in place within ICH) is to assess that the Trust has the capacity and capability that is necessary to deliver a proposed research study and maintain an oversight of the agreements between the parties that have participated in the capacity and capability confirmation process. Therefore, it is instructed that this procedure should be used in conjunction with the RGIT_SOP_002 and RGIT_SOP_003.

4. RESPONSIBILITIES

The Sponsor

The sponsor is the organisation/institution with overall responsibility for the conduct of the clinical trial in the UK. That is, the sponsor will have to arrange:

- The indemnity, financial and contractual arrangements for the whole study.
- All necessary approvals required to be in place by the start of the study.
- The study setup, trial documentation and study training to local research-teams.
- Continued communication on study updates and documentation to the local site.

The Chief Investigator (CI)

The chief investigator (CI) is the lead researcher with overall responsibility for the conduct of the clinical trial across different sites, which includes but is not limited to:

- Qualifications and agreements: GCP training and delegation of trial-related duties.
- Adequate study resource arrangements: time, funding, recruitment ability (via pilot etc).
- On-going communication with the research approving bodies throughout the trial.

The Principal Investigator (PI)

The principal investigator (PI) is the person that has delegated duty for the conduct of the research study at each individual participating research site. Their duties will include:

- Identifying co-investigators as required for each research study.
- Contributing to the study feasibility assessment at ICHT.
- Assessing potential recruitment numbers.
- Highlighting any difficulties or challenges in the study delivery.
- Assessing training needs and organising training for the research team(s).
- Attending site selection, setup, and initiation visits.

The Research Team: RN/CRP/RA

The research team comprises any member involved in the research work, including the Research Nurse (RN), Clinical Research Practitioner (CRP) and Research Assistant (RA),

[2] ICL and ICHT stand for Imperial College London and Imperial College Healthcare Trust respectively.

who may be delegated to carry out specifically allocated duties as identified in the delegation log. Their duties include, but may not be limited to:

- Input on study feasibility and capability as required.
- Organising training and attending study setup meetings as required.
- Identifying any delivery challenges of the study, based on prior experience.
- Communicate with the PIs and co-investigators about the study feasibility & setup.

The Supporting Services

The ICHT supporting services are services (such as histology, information governance and tissue bank) that are responsible for reviewing study protocols that require their input, as part of the capacity and capability assessment process. They may also be responsible for recommending whether or not such studies can be carried out, following an assessment of the required study targets and timescales. Therefore, they may have a pivotal role when deciding that a particular study cannot be supported on the basis of the capacity/capability as well as cost assessment.

The Divisional Research Management Teams (DRM)

The DRM teams review the local feasibility for conducting research studies in the relevant NHS premises. Their duties include, but may not be limited to:

- Leading on capacity and capability assessment on behalf of the organisation.
- Agreeing potential participant numbers and targets with the PI, CI and/or sponsor.
- Assigning research team members to support the PI.
- Agreeing outsourcing arrangements for clinical support services.
- Costing commercial studies.
- Confirming capacity and capability on behalf of the organisation.

The Joint Research Office (JRO)

The joint research office (JRO) is responsible for executing the contract on behalf of ICHT and can be contacted via the following email address:
imperial.admin_trustresearchcontracts@nhs.net
Their duties include, but may not be limited to:

- Agreeing contractual terms and conditions.
- Agreeing legal wording on the financial annex.
- Costing non-commercial studies.
- Validating/checking the eligibility of costs included in commercial costing templates (in parallel to feasibility).
- Managing the clinical research studies financially (including account setup, invoicing, recharging, reconciliation).

The Research Governance and Integrity Team (RGIT)

The research governance and integrity team (RGIT) is responsible for undertaking sponsorship reviews for Imperial College and ICHT sponsored studies only. Also, the RGIT advises on all research governance and regulatory matters.

5. THE PROCEDURE

Site Invitation

To invite the ICHT to act as a research site, it is expected that the sponsor should contact the ICHT via the dedicated officer (imperial.research_feasibilityofficer@nhs.net), the study

investigator or the relevant DRM team (with contact details as per appendix 1 - RGIT_TEMP_009). Although the full study documentation is not required at this stage, a final draft protocol or study summary would be necessary for site invitation. The invitation will provide an opportunity to initiate the early feasibility assessment and start the engagement and discussion with the clinical and research teams across the Trust.

Site Selection

Once the sponsor has selected the ICHT as a Research Site, they should send the minimum set of documents to the ICHT generic inbox (imperial.research_feasibilityofficer@nhs.net) or to the relevant DRM team (by means of the contact details as per appendix 1- RGIT_TEMP_009). Once the minimum set of documents is received, the ICHT will proceed by assessing, arranging and confirming the study capacity and capability. From that point, the Trust will work towards the agreed sponsor's expected CCC date.

The minimum set of documents required consists of:

- The IRAS form (combined REC and R&D forms) as submitted for HRA approval.
- The protocol.
- Any amendments.
- The participant information sheet (PIS) and informed consent documents (ICFs).
- The complete ICHT set-up form.
- The organisation information document (OID) relevant to the participating NHS organisation(s); this isn't necessary for Trust sponsored single centre ICHT studies.
- The relevant template-contract/model-agreement (if needed in addition to the OID).
- The costing template (this is necessary only for commercially sponsored studies).
- Any funding/loan, collaboration, or material transfer agreements (if applicable).
- The schedule-of-events cost-attribution template (for non-commercially sponsored only) or SoECAT (for NIHR and NIHR non-commercial partner research funders); again, this is not required for single centre studies.
- Any other documents that the sponsor wishes to provide to the site to support the setup and delivery of the study (such as relevant support department manuals etc)
- Copies of the HRA initial assessment and approval letters, and final versions of all enclosed documents (if these have been issued).

In the case of studies that are participating in the combined review scheme, the minimum set of documents remains the same, apart from the *signed IRAS form*, which is replaced with the following documents:

- Recruitment and informed consent procedure.
- Ethical considerations form.
- Payment of compensation.
- Study wide review form.

N.B. The DRM team can also download some of the key documents from the HRA portal at the HRA approval portal login (Cited on 03 Dec 2024).

Assessment of Capacity and Capability

ICHT notified studies not requiring C&C review

Following the application to the HRA some research may be assessed as not requiring C&C review by the local NHS organisations or/and as having the ICHT listed as a participating

site on the IRAS form. In such cases, the HRA will email the study team and confirm whether the research can be implemented immediately at site or whether further review is required (that is, whether a 35 day review for 'no objection' is required).

In the latter case, the clinical research facilitator (who monitors the generic inbox) will notify the relevant DRM team who will review the research project within the agreed timescale, so as to assess any objection to the research taking place at ICHT. The review by the DRM team will involve assessing the documentation provided in the email by the HRA to establish whether any resource or funding needs have been identified. Where applicable, the DRM team will liaise with the local teams/services (which are located where the research is supposed to take place) to discuss whether there are any objections. If it is confirmed that a C&C is not required, the DRM team will register the study on Edge by indicating that a 'C&C is not required' (CCC). Also, where the outcome of the review is 'no objection', the relevant DRM team will email the outcome to the CI, sponsor and relevant local team. Please note that there is no template for this communication, and it may be shaped differently on a study-by-study basis.

ICHT notified studies with ICHT as a PPS (Host) requiring C&C review

When projects are sponsored by organisations other than the ICHT, the ICHT may simply be a potential participating site (PPS). In this case, the study sponsor will have to submit the minimum document set to the ICHT generic email address or to the appropriate DRM team. Following submission, the sponsor will be notified within 2 working days of receipt and agree on the expected date of confirmation of capacity and capability (C&C). That is, on receipt of the minimum set of documents, the DRM team will liaise with local research team, relevant supporting departments, and JRO[3] to confirm the commencement of the capacity and capability assessment.

Please note that, before that the C&C confirmation can be issued, the following documents/approvals must be in place:

- Final versions of all supporting documents including the IRAS form, protocol, and participant information sheets.
- The HRA approval letter and all the associated documents, including the REC approval letter (if applicable).
- A copy of the IB/IMPD/SmPC/MDTF[4] (depending on the trial type) (if applicable).
- The divisional approval.
- The confirmation of pharmacy's capacity and capability (if applicable).
- The confirmation of imaging department's capacity and capability, including the IRMER[5] approval (if applicable).
- The confirmation of the pathology department's capacity and capability (if applicable).
- Any confirmation of capacity and capability from other applicable supporting services.
- All the relevant speciality committee/feasibility team approvals (if applicable).
- A fully executed clinical trial site agreement (which has been signed off by the ICHT and sponsor organisation) (if applicable) or a completed OID.

[3] JRO stands for Joint Research Office

[4] IB, IMPD, SmPC, MDTF stand for investigator's brochure, investigational medicinal product dossier, summary of product characteristics and medical device technical file respectively.

[5] IRMER stands for ionising radiation (medical exposure) regulations.

- The ICHT clinical research safety committee approval (if the study involves work with genetically modified organisms being carried out in the Trust), (contact details: Chris Rubery, chris.rubery@nhs.net)
- The committee for the new intervention approval of device studies at the Trust: all the studies that involve devices (which are being brought into the NHS Trust) need to go through the clinical engineering department (email imperial.clinical.engineering@nhs.net).
- A copy of the PI's CV and GCP certificate for all trials.
- All the relevant post-HRA-approval amendments, that is, prior to CCC.

Once the assessment process is complete, and it is determined that there is sufficient capacity and capability to deliver the study, the ICHT is required to confirm organisational readiness. That is, at this point, the relevant DRM team will confirm ICHT's capacity and capability with the sponsor via email, by copying in it the local PI and research team, DRM, JRO and applicable support departments. A copy of the confirmation of capacity and capability email should be placed in the site file.

Note: the DRM team will also update EDGE to record the date on which the CCC has been issued. That is, a copy of the CCC email and the study documents with applicable internal and external approvals need to be uploaded onto EDGE by the DRM team and the study details on EDGE need to be updated accordingly. Once greenlight is received, the study team must inform the DRM team to have the recruitment tab on EDGE activated.

ICHT/ICL sponsored studies with ICHT C&C review request as a PS (Host)

For studies where either the ICHT or ICL is the sponsor, and the ICHT is a participating site (PS), the RGIT will contact the DRM team at the sponsor assessment stage to begin the preliminary feasibility assessment of ICHT. This process is classified as the site invitation stage, which provides an opportunity to initiate early feasibility assessment and start engagement and discussion with clinical and research teams across the Trust.

When the minimum set of documents is received either via the ICHT generic inbox or relevant Trust DRM team, this will initiate local Trust review. For studies sponsored by the ICL, the minimum set of documents (including the completion of a set-up form) should also include a completed OID, which is issued by ICL JRO and will be either sent to the relevant DRM either directly or through the ICHT JRO. Once the minimum set of documents has been received, the same process (as per the previous section on PPS requiring C&C review) should be followed.

ICHT notified studies with ICHT as a potential PIC

Participant Identification Centres (PICs) are organisations which refer potential participants to a research team at another organisation, but do not conduct trial related activities themselves. Although PICs do not conduct trial activities, they have the same approval process as full sites, therefore also in this instance the minimum set of documents needs to be submitted to the main research site for review as per the current IRAS guidance. Once the minimum set of documents has been received, the same process (as outlined in the previous section on PPS requiring C&C review) should be followed. Please be advised that, as per the above guidance, NHS/HSC[6] PICs sites are not regarded as participating-

[6] NHS/HSC stand for National Health System and Health and Social Care respectively.

organisations or research-sites, therefore, they cannot be set up through the ordinary UK set of documents.

Studies not requiring REC review

Even if a study does not require a REC approval, an HRA approval must be in place and a CCC must be issued accordingly by the ICHT when the research study involve ICHT participants, staff, premises and resources. Indeed, the REC approval may not be required in certain circumstances (see appendix 6 for further information on this), and these include any:

- Research limited to the secondary use of previously collected information (that is data collected during normal care without intention to use them for research purposes), provided that the patients or service users are not identifiable to the research team when carrying out the research.
- Research involving anonymised information released to researchers by their work organisation that might separately hold related information (which even if it was combined with it, there would be no likelihood that it could potentially identify the individual).
- Research limited to the secondary use of previously collected tissue samples (that is, samples collected with consent for research during normal care), provided that the patients or service users are not identifiable to the research team when carrying out the research.
- Research limited to the use of acellular material (e.g., plasma, serum, DNA,) that has been extracted from previously collected tissue samples (that is samples collected with consent for research during normal care), provided that the patients or service users are not identifiable to the research team when carrying out the research.
- Research limited to the involvement of NHS or social care staff recruited as research participants by virtue of their professional role.
- Research involving the use of (or access to) care organisation premises or facilities, but not otherwise involving patients or service users.

Please note that studies that do not require REC approval have the same approval process as studies that require REC approval. Therefore the local HRA document pack minimum set of documents needs to be submitted to the ICHT for review and the same process needs to be followed (as outlined in the above paragraphs), once the minimum set of documents has been received.

Non-Confirmation Status

A non-confirmation status is triggered when the ICHT has assessed that there is insufficient capacity or capability to deliver the study. In so a case, the ICHT will email the sponsor, local PI (if identified) and applicable support departments to notify them of the reasons why a C&C status cannot be confirmed. There is no template for this email correspondence as it will be drafted differently on a study-by-study basis. Once the sponsor has declined the site confirmation, the sponsor is expected to email the ICHT to notify them that the study will not proceed at that site.

6. REFERENCES

HRA NHS website (cited on 21 April 2023).

MHRA website (cited on 21 April 2023).

Research Ethics Service and Research Ethics Committees (cited on 21 April 2023).

SOP, Associated Documents & Templates webpage (cited on 17 Mar 2023).

Assess Study feasibility (cited on 07 Jun 2023)

HRA Approval Portal Login (cited on 17 Mar 2023).

IRAS guidance – PICs (cited on 21 April 2023).

Amendments to healthcare Research, ref: RGIT_SOP_006.

NHS REC applications, ref: RGIT_SOP_003.

Ethics Approval for Health-Related Research, ref RGIT_SOP_002.

7. APPENDICES

The following appendices list the templates associated to this SOP which can be found at the SOP, Associated Documents & Templates page.

Appendix 1 – please note that the contact details of the divisional research managers and feasibility officers are listed in the RGIT_TEMP_009.

Appendix 6 – please see below the definitions of the research studies not requiring REC approval.

Research involving NHS Staff only

Under the 2001 edition, a REC review was required for research involving NHS staff recruited as research participants by virtue of their professional role. At present, such research, or equivalent research involving staff from social care providers, is excluded from the normal remit of the REC under the harmonised edition of the GAf-REC.[7]

Research involving standard social care only or not

Generally, social care research does not require a review by the REC within the UK Health Departments' Research Ethics Service when it is reviewed by another committee operating in accordance with the Economic and Social Research Council's Framework for Research Ethics. However, exceptions to the above can be found at the following link (cited on 21 April 2023). Indeed, a REC review would be required if any of the following applied:

a. The research involves deviating from standard social care.
b. The research involves NHS patients or service users as research participants.
c. The research is a social care research project funded by the Department of Health & Social Care in England; involving adult social care service users as participants.

Research involving acellular material

Research limited to use of human biological material not consisting of (or including) cells (e.g., plasma, serum, DNA) is also generally excluded from REC review.
However, a REC review would be required where the research involved:

a. The collection of patient tissue samples to extract acellular material for research.
b. The collection of information from patients.
c. The use of previously collected information from which patients could be identified by the researchers.
d. The analysis of DNA in material from the living, where consent for research is not in place from the person whose body manufactured the DNA.

[7] GAfREC stands for Governance arrangements for Research Ethics Committees

Research involving previously collected, non-identifiable tissue samples

As mentioned previously, research limited to the use of previously collected, non-identifiable material consisting of (or including) cells in line with the terms of the donor's consent is generally excluded from REC review.
However, a REC review would be required when any of the following applied:

a. A consent for research has not been given, or the research is not within the terms of the consent.
b. The samples will be held on premises in England, Wales or Northern Ireland without a Human Tissue Authority (HTA) licence to store relevant material for scheduled purposes.
c. The research also involves removal, storage or use of new samples from the living or the deceased.
d. The research also involves the use of identifiable information held with the samples.

Research involving previously collected, non-identifiable information

Under the 2001 edition, a REC review was required also for any type of research involving the data of NHS patients. To date, a REC review continues to be required for research involving the collection of information from patients or service users for research purposes. A REC review is especially required for research involving the use of previously collected information from which patients or service users could be identified by researchers outside the usual care team (either directly from that information or in combination with other information in, or likely to come into, their possession). However, under the harmonised GAf-REC, a REC review is not required for any research type that is limited to the use of previously collected, non-identifiable information. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of standard care for their own patients or clients, provided that data is anonymised or pseudonymised when conducting the research. Indeed, such research would involve no breach of the duty of confidentiality, which is generally owed by care professionals. Further guidance can be found at the following link (cited on 21 April 2023). Exceptionally, the REC service may accept applications for the review of research of the second type at the request of the sponsor, chief investigator, or host organisation, where they agree that the proposal raises material ethical issues.

N.B. Please note that, regardless of the different REC review requirements, all of the above study types still require a regular HRA review and approval.