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<h2>Confirmation of Capacity and Capability to Deliver Research at Imperial College Healthcare NHS Trust</h2>	
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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

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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. **If research is being undertaken in Imperial College Healthcare NHS Trust (ICHT) premises, or involving ICHT participants, premises and resources Management confirmation of capacity and capability is mandatory. It is needed in addition to the Research Ethics Committee (REC) approval** and the HRA approval (and any other necessary approvals e.g. MHRA approval) before the project can start at the Trust. This protocol is concerned with obtaining Management confirmation of capacity and capability for research that has been, or is being, submitted for ethical approval and HRA approval and should be used in conjunction with RGIT_SOP_002 'Ethics Approval for Health-Related Research' and RGIT_SOP_003 'NHS REC Applications', this SOP which can be found on the [SOP, Associated Documents & Templates page](#)..

2. INTRODUCTION

HRA Approval is the process for the NHS in England that comprises a review by an NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA Staff. In England, it replaces the need for local checks of legal compliance and related matters previously known as local governance review.

This allows NHS organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study. Thus, NHS Trusts in England will not issue NHS permission, but instead provide confirmation of capacity and capability for a proposed research study.

The HRA has defined the different stages that sponsors and participating organisations (the Trust) go through on the way to mutually agreeing that the study can open at that organisation (the Trust).

1. **Assessing:** Assessing whether or not the Trust has the capacity and capability to participate in the study. NB this stage will not be required, or will be minimal, for some types of studies where it is automatically expected that the Trust will participate unless there is a significant reason why not. These study types include emergency public health research, studies involving minimal local activity such as distributing questionnaires, on line surveys or supplying previously collected clinical data where consent is already in place, and studies where the clinical pathway has meant that a patient has been transferred for on-going clinical care but the responsibility for the research remains with the original Principal Investigator.
2. **Arranging:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study
3. **Confirming:** Confirming that the Trust has the capacity and capability in place 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 sign-off on an agreement.

ICHT Research Management confirmation of capacity and capability must be obtained for all research studies that involve ICHT participants, staff, premises and resources. This confirmation of capacity and capability is needed in addition to the Research Ethics Committee (REC) approval (if relevant) and the HRA approval (and any other necessary approvals e.g. MHRA approval) before the project can start at the Trust.

3. OBJECTIVE

This SOP describes the process within Imperial College Healthcare NHS Trust to assess and confirm capacity and capability (C&C) of the trust to deliver a proposed research study.

This procedure should be used in conjunction with RGIT_SOP_002 'Ethics Approval for Health-Related Research' and RGIT_SOP_003 'NHS REC Applications'.

4. RESPONSIBILITIES

4.1. Sponsor

The organisation/Institution with overall responsibility for the conduct of the clinical trial in the UK. The sponsor will arrange:

- Indemnity, financial and contractual arrangements for the whole study.
- Necessary approvals required to be in place by the start of the study.
- Study set-up and provide full trial documentation and study training to local research teams.
- Continued communication about updates to study and documentation to the local site.

4.2. Chief Investigator

The lead researcher with responsibility for the conduct of the clinical trial across all research sites, including but not limited to the following areas.

- Qualifications and agreements (Good Clinical Practice (GCP) Training, delegation of trial-related duties)
- Arrange adequate resources to conduct the overall study – time, funding, demonstrate ability to recruit (via pilot etc)
- On-going communication with research approving bodies throughout the trial.

4.3. Principal Investigator (PI)

A person that has overall delegated duty for the conduct of the research study at each individual participating research site.

Duties will include:

- Contribution to the study feasibility at ICHT
- Reasonable assessment of potential recruitment numbers
- Highlighting any difficulties or challenges in delivering the study.
- Assessing and organising training needs of the supporting research team.
- Attending site selection, set-up and initiation visits.
- Identify co-investigators as required for each research study.

4.4. Research Nurse (RN), Clinical Research Practitioner (CRP)/Research Assistant (RA)

A member of the research team with delegated duties to carry out specific allocated duties as identified in the delegation log.

Duties could include:

- Input on study feasibility and capability as required.
- Organising training and attending study set-up meetings as required.
- Identifying any delivery challenges of the study, based on prior experience.
- Communicate with PI and Co-Is about study feasibility and set-up.

4.5. Supporting Services

ICHT supporting services are responsible for reviewing study protocols which require their input, as part of the capacity and capability assessment process, and for recommending whether or not they can carry out such studies, taking into account the required study targets and timescales. They may decide they cannot support particular studies on the basis of cost, capacity or capability.

4.6. Divisional Research Management Teams

DRM teams review the local feasibility of conducting research studies in the relevant NHS premises.

Duties Include:

- Lead on capacity and capability assessment on behalf of the organisation
- Agree potential participant numbers and targets with the PI and CI/Sponsor.
- Assign research team members to support the PI.
- Agreeing outsourcing arrangements with partner organisations for clinical support services.
- Responsible for costing commercial studies
- Confirm capacity and capability on behalf of the organisation.

4.7. The Joint Research Office (JRO)

The 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

Duties include:

- Agreeing contractual terms and conditions
- Agreeing legal wording on the Financial Annex
- Responsible for costing non-commercial studies
- Responsible for obtaining ICHT Funding Letters for ICL sponsored studies
- Responsible for validating and checking (in parallel to feasibility) the eligibility of costs included in commercial costing template

- Responsible for the financial management of clinical research studies (account set up, invoicing, recharging, reconciliation).

4.8. Research Governance and Integrity Team

The RGIT is responsible for undertaking sponsorship reviews for Imperial College and ICHT sponsored studies only and advising on all research governance and regulatory matters.

5. THE PROCEDURE

5.1 Site Invitation

It is expected that Sponsors contact ICHT via generic inbox (imperial.research_feasibilityofficer@nhs.net), Investigator or via appropriate Trust DRM team (contact details in Appendix 1) to invite ICHT to act as a research site. A final draft protocol or summary of the study would be expected, but a full study documentation set is not required at this stage. The invitation will provide an opportunity to initiate early feasibility assessment and start engagement and discussion with clinical and research teams across the Trust.

5.2 Site Selection

Once the sponsor has selected ICHT as a Research Site, the sponsor should send the HRA Local Document Pack to ICHT generic inbox (imperial.research_feasibilityofficer@nhs.net) or to the appropriate Trust DRM team (contact details in Appendix 1). The date that the HRA Local Document Pack is received is defined as the 'Clock start Date' for assessing, arranging and confirming capacity and capability of the research study. From this point, the Trust has 40 calendar days to assess, arrange and confirm capacity and capability to the sponsor.

The HRA Local Document Pack consists of:

- Copy of IRAS Form (combined REC and R&D form) as submitted for HRA Approval (must be final, signed version)
- Protocol
- Any amendments
- Participant information and consent documents
- Organisation Information Document relevant to the participating NHS organisation (not applicable if Trust sponsored single centre study)
- Relevant template contract/model agreement (if needed in addition to Organisation Information Document)
- Costing template (commercially sponsored only)
- Schedule of Events Cost Attribution Template (non-commercially sponsored only) or SoECAT (**NIHR** and **NIHR** non-commercial partner research funders) (not applicable if single centre study)
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study

- Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions
- ICHT Funding Letter (for studies sponsored by Imperial College London only) if funding arrangements are not covered in a separate agreement.

In the case of studies that are participating in the Combined Ways of Working (CWoW) pilot, the HRA local document pack mentioned above remains the same, with the exception of 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

DRM team can also find some of key documents from HRA portal [HRA Approval Portal Login](#)

5.3 Assessment of Capacity and Capability

5.3.1. Studies which are notified to ICHT as not requiring C&C review

The HRA will email ICHT generic inbox information about any research which has been assessed as not requiring C&C review by local NHS organisations and where ICHT has been listed as a participating site on the IRAS form.

Within this email the HRA will confirm whether the research can be implemented immediately at site or whether a 35 day review for 'no objection' is required.

The Clinical Research Facilitator, who monitors the generic inbox will notify the relevant DRM team who will review the research project within the 35 day timescale to determine whether there is any objection to the research taking place at ICHT. The review by the DRM team will involve assessing the documentation provided by the HRA in the email to establish whether any resource needs or funding is identified. Where applicable the DRM team will liaise with the local team/service where the research will take place and discuss whether there are any objections. The DRM team will register the study on Documas and complete Documas field to indicate 'CCC not required'.

Where the outcome of the review is 'no objection', the relevant DRM team will communicate by email the outcome to the CI, Sponsor and relevant local team. There is no template for this communication, and it will be dealt with on a study by study basis.

5.3.2 Studies notified to ICHT where ICHT is a potential participating site (Host) requiring C&C review

For projects sponsored by organisations other than Imperial College Healthcare NHS Trust, the sponsor will submit the valid HRA Local Document Pack to the ICHT generic email address or to the appropriate Trust DRM team.

The sponsor will be notified within 3 working days of receipt of the valid document set and the Trust has 40 calendar days to confirm capacity and capability to the sponsor.

As soon as the valid HRA Local Document Pack has been received, the DRM team will liaise with local research team, relevant supporting departments and JRO to confirm commencement of capacity and capability assessment.

Before Confirmation of Capacity and Capability can be issued, the following documents/approvals must be in place:

- REC approval (if applicable)
- HRA approval and all associated documents
- Copy of Investigator Brochure (IB) (If applicable)
- Divisional Approval
- Confirmation of Pharmacy's capacity and capability to support the study (if applicable)
- Confirmation of Imaging Department's capacity and capability to support the study, including IRMER approval (if applicable)
- Confirmation of Pathology Department's capacity and capability to support the study (if applicable)
- Confirmation of other supporting services' capacity and capability to support the study (if applicable)
- Relevant Speciality Committee/Feasibility Team approvals (if applicable)
- Fully executed Clinical trial site agreement signed off by ICHT and sponsor organisation (if applicable) or completed OID.
- Imperial College Healthcare NHS Trust Clinical Research Safety Committee approval (if the study involves work with Genetically Modified Organisms being carried out in the Trust) Contact: NIHR/Wellcome Trust Imperial CRF; 020 3313 8070; Imperial.CRF@imperial.nhs.uk
- New Interventions Committee approval for device studies being conducted at the Trust (Contact: imperial.clinical.engineering@nhs.net). All studies that involve devices being brought into the NHS Trust need to go through clinical engineering department.
- Copy of PI's CV and GCP certificate for interventional trials
- All relevant amendments post HRA approval and prior to CCC

Once the assessment process is completed and it is determined that there is sufficient capacity and capability to deliver the study, ICHT is required to confirm organisational readiness. Relevant DRM team will confirm ICHT's capacity and capability with the sponsor via email (see Appendices 3, 4 and 5 for email templates for CCC), copying in local PI/research team, DRM, Joint Research Office and applicable support departments. A copy of the confirmation of capacity and capability email should be placed in the site file. The DRM team will also update DOCUMAS to record the date for CCC.

A copy of the Capacity and Capability Confirmation email and the study documents with applicable internal and external approvals are uploaded to DOCUMAS system by the DRM team and the study details on DOCUMAS are updated accordingly.

5.3.3. Studies sponsored by either ICHT or ICL requesting C&C review from ICHT as a participating site (Host).

For studies where either Imperial College Healthcare NHS Trust or Imperial College London is the sponsor, the RGIT will contact the DRM team at the sponsor assessment stage to begin ICHT's preliminary feasibility assessment. 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.

The "clock start date" is triggered when the valid HRA pack is received either via the ICHT generic inbox or via relevant Trust DRM team. For studies sponsored by Imperial College London, the valid HRA Local Document Pack should also include ICHT Funding Letter. ICHT Funding Letter is issued by ICL JRO and will be sent to either the relevant DRM or ICHT JRO, who will then forward the letter to the relevant DRM. Once the Valid HRA Local Document Pack is received, the same process is followed as outlined in section 4.3.2.

5.3.4. Studies not requiring REC review

HRA approval must be in place and Capacity and Capability confirmation must be issued by ICHT for all research studies that involve ICHT participants, staff, premises and resources. However, Research Ethics Committee (REC) approval is not required in certain circumstances (see Appendix 6 for further information), these include:

- Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection), provided that the patients or service users are not identifiable to the research team in carrying out the research.
- Research involving anonymised information released to researchers who work in an organisation that might separately hold other information, which if combined could identify the individual, but where there is no likelihood of doing so
- Research limited to secondary use of tissue samples previously collected in the course of normal care with consent for research, provided that the patients or service users are not identifiable to the research team in carrying out the research
- Research limited to use of acellular material (e.g. plasma, serum, DNA,) extracted from tissue previously collected in the course of normal care, provided that the patients or service users are not identifiable to the research team in 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 use of or access to a care organisation's premises or facilities, but not otherwise involving patients or service users.

Studies, which do not require REC approval, have the same approval process as studies that require REC approval, therefore the local HRA document pack need to be submitted to ICHT for review. Once the Valid HRA Local Document Pack is received, the same process is followed as outlined in section 4.3.2.

5.3.5. Studies notified to ICHT where ICHT is a potential Participant Identification Centre (PIC)

Participant Identification Centres (PICs) are organisations which refer potential participants to a research team at another organisation, but do not conduct trial related activity themselves.

PICs have the same approval process as full sites, therefore the local HRA document pack need to be submitted to ICHT for review. Once the Valid HRA Local Document Pack is received, the same process is followed as outlined in section 4.3.2.

5.4. Non-Confirmation Status

If ICHT determines that there is insufficient capacity or capability to deliver the study, ICHT will email the sponsor, local PI (if identified) and applicable support departments to notify them of the reasons why C&C cannot be confirmed. There is no template for this email as it will be on a study by study basis.

If the sponsor declines the site confirmation, the sponsor is expected to email ICHT and the study will not proceed at the site.

6. REFERENCES

[HRA NHS website \(cited 30 May 2020\)](#)

[MHRA website \(cited 30 May 2020\)](#)

[Research Ethics Service and Research Ethics Committees \(cited 30 May 2020\)](#)

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 following Templates associated to this SOP which can be found on the [SOP, Associated Documents & Templates page](#).

Appendix 1 Divisional Research Managers and Feasibility Officers – RGIT_TEMP_009

Appendix 2 – 5 has been combined into RGIT_TEMP_043

Appendix 2 – Email template to notify Sponsor valid HRA pack has been received

Appendix 3 – CCC (without study amendments) email template

Appendix 4 – CCC (with study amendments) email template

Appendix 5 – CCC email template for PIC site

APPENDIX 6 - DEFINITIONS OF RESEARCH STUDIES WHICH DO NOT REQUIRE REC APPROVAL

Research involving NHS Staff only

Under the 2001 edition, REC review was required for research involving NHS staff recruited as research participants by virtue of their professional role. Such research, or equivalent research involving the staff of social care providers, is excluded from the normal remit of RECs under the harmonised edition of GAfREC.

Research involving social care staff only

Social care research does not require review by a REC within the UK Health Departments' Research Ethics Service if it is reviewed by another committee operating in accordance with the Economic and Social Research Council's Framework for Research Ethics, Exceptions to this can be found via the following [link](#).(cited 03/07/20)

However, 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 previously collected, non-identifiable tissue samples

Research limited to use of previously collected, non-identifiable material consisting of or including cells in accordance with the terms of donor consent is generally excluded from REC review.

However, REC review would be required if any of the following applied:

- 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 licence from the Human Tissue Authority 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 use of identifiable information held with the samples

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, REC review would be required if the research involved:

- (a) Collection of tissue samples from patients in order to extract acellular material for the research
- (b) Collection of information from patients
- (c) Use of previously collected information from which patients could be identified by the researchers
- (d) Analysis of DNA in material from the living, where consent for research is not in place from the person whose body manufactured the DNA.

Research involving previously collected, non-identifiable information

Under the 2001 edition, REC review was required for any research involving the data of NHS patients. REC review continues to be required for research involving collection of information from patients or service users for research.

REC review is also required for research involving 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, REC review is not required under the harmonised GfREC for research limited to 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 care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research. Such research would involve no breach of the duty of confidentiality owed by care professionals.

Further guidance can be found via the following [link](#).

Exceptionally, the Research Ethics Service may accept an application for review of such research at the request of the sponsor, chief investigator or host organisation, where it agrees that the proposal raises material ethical issues.

All above study types still require HRA review and approval.