Obtaining ICHT Capacity and Capability Confirmation for Healthcare Research not requiring REC review

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Version	Date	Reason for Change
Version 1.0	18 Feb 2015	New Procedure
Version 2.0	25 Oct 2017	Scheduled Review
Version 3.0	11 Jun 2019	Organisation Information document
Version 4.0	01 Nov 2019	DRM CCC process
Version 5.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP.JRCO name change to RGIT
Version 6.0	29 Aug 2024	Scheduled Review

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1. PURPOSE

This SOP describes the procedure for obtaining Imperial College Healthcare NHS Trust Confirmation of Capacity and Capability for healthcare research which does not require NHS Research Ethics Committee (REC) review according to the Governance Arrangements for Research Ethics Committees (GAfREC) (cited 10 March 2024).

2. INTRODUCTION

Any study sponsored by Imperial College Academic Health Science Centre (AHSC) must be sent to the Research Governance and Integrity Team (RGIT), prior to Confirmation of Capacity and Capability (CCC) at the site.

The Sponsorship procedure for projects that do not require REC review is the same as the process for those requiring REC review. See RGIT_SOP_009 Sponsorship and Approval, which can be found on the SOP, Associated Documents & Template page for Imperial College London and Imperial College Healthcare NHS Trust studies. See RGIT_SOP_031 for further details on the CCC process.

All research undertaken in ICHT premises, or involving ICHT participants, must obtain Confirmation of Capacity and the Sponsor Green Light and before the project can start.

However, REC approval is not required in certain circumstances, including:

- 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 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.
- **Please note:** Further guidance and examples can be found via the following link.

HRA approval must be in place and CCC must be issued by each R&D office, at each NHS organisation, where the study is due to start.

For studies sponsored by Imperial College London or Imperial College Healthcare NHS Trust and taking place at ICHT the CCC process will be carried out in parallel with the RGIT sponsorship review process, so that ICHT is in a position to give CCC within only a few days of the sponsorship decision being confirmed.

3. PROCEDURE

Please note that we only accept **one** investigator for Imperial College Healthcare NHS Trust, as ICHT is regarded as a single site in research. If the Chief Investigator is based at ICHT, they must also be named as the Principal Investigator (PI). Other researchers can be named as co-investigators. However, if a CI is an academic lead without a clinical contract and a clinical lead is required for ICHT, a different PI can assigned, after discussion with the RGIT.

For a study to be assessed for ICHT CCC, the HRA approved local document pack must be submitted to the DRM team generic email address of which the required documents are listed below:

3.1. Required Documents

- Copy of IRAS Form as submitted (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 single centre at ICHT and sponsored by ICHT, otherwise required)
- Relevant template contract/model agreement (if needed in addition to Organisation Information Document)
- Costing template (commercially sponsored only)
- Schedule of Events or SoECAT (non-commercially sponsored only) (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 documents
- ICHT Funding Letter (for studies sponsored by Imperial College London only) if funding arrangements are not covered in a separate agreement.

For ICHT and Imperial College London sponsored studies, details of when OID or mNCA should be used between the College and the Trust and when and SoE/SoCAT is needed can be found in RGIT_TEMP_022_OID-Contracts-Flowchart.

Once all of the local document pack is received, the Divisional Research Manager (DRM) team will carry out the appropriate feasibility checks and follow the process outlined in RGIT_SOP_031 that can be found on the SOP, Associated Documents & Template page.

Final DRM sign-off is also dependent on Clinical trial site agreement signed off by Pre-award Imperial AHSC JRO and sponsor organisation (if applicable). **Fully signed contracts and all applicable internal approvals need to be in place before Capacity and Capability Confirmation can be issued**.

When everything is in place, a Confirmation of Capacity and Capability email will be issued for the study by the DRM team and the Sponsor Green Light will be requested in this email.

Once the Green Light has been confirmed by email by the Sponsor (or authorised Sponsor delegate) the project can commence. A copy of the CCC email and the study documents with applicable internal and external approvals are uploaded to Edge system by the DRM team. A copy of the Green Light email will be uploaded to Edge by RGIT. The study details on Edge are updated accordingly.

4. DEFINITIONS OF RESEARCH TYPE WHICH THIS SOP APPLIES TO

Research involving NHS Staff only

Research involving NHS staff recruited as research participants by virtue of their professional role (or equivalent research involving the staff of social care providers) is excluded from the normal remit of RECs under GAfREC. An application may be reviewed exceptionally by a REC where the Research Ethics Service agrees that the proposal raises material ethical issues.

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 10 Mar 2024)
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 human DNA in acellular materials (e.g. serum, processed plasma and processed serum) where appropriate consent for the research is not in place from or on behalf of the person whose body manufactured the DNA. Additionally, the researcher must not be in possession of, or likely to come into possession of, information from which the person whose body manufactured the DNA can be identified.

Research involving previously collected, non-identifiable information

REC review is 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, GAfREC states REC review is not required 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.

All above study types still require HRA review and approval.

5. REFERENCES

HRA Governance arrangements for Research Ethics Committees (RECs) (cited 10 March 2024)

HRA Approval Guidance (cited 10 March 2024)

HRA NHS Site set up in England (cited 10 March 2020)

HRA Decisions Tools - Does my project require review by a REC?(cited 10 March 2024)

ICO: Code of Practice. Information Commissioner's Office, Nov 2012. (cited 10 March 2024)

RGIT Standard Operating Procedures (cited 10 March 2024)