Imperial College London and Imperial College Healthcare NHS Trust Sponsorship and Confirmation of Capacity and Capability Guide

There are 3 main stages of approvals before you can start recruitment to a research project running in the NHS. These are Sponsorship approval, Research Ethics Committee (REC) and Health Research Authority (HRA) Approval and Confirmation of Capacity and Capability (CCC). The guide below provides details on how best to gain Sponsorship approval and CCC where the study is ICHT or College sponsored and ICHT is a study site.

Sponsorship:

All research projects running in the NHS require a formal research sponsor. A sponsor has overall responsibility for initiation, management and financing of the research. For studies where the Chief Investigator (CI) is employed by the College or the Trust and any funds are based with the College or the Trust then the Research Governance and Integrity (RGIT) will undertake sponsorship review and will sign off as sponsors representative of the study. Whether the College or the Trust is the organisation who sponsors will depend on where funding for the project is based, and who the CI is employed by.

The first stage of setting up your project is to fill in any appropriate forms and documentation. Please ensure you give yourself enough time to undertake this, writing a protocol can be a time-consuming process, along with all the other documentation required. A study can take around 3 weeks for sponsorship review (depending on the speed of response), up to 60 days for REC review and up to 40 days for CCC to be issued, so any timelines should take the set-up times into account.

The Research Governance and Integrity team have standard operating procedures which include templates for protocols, information sheets and consent forms which can be found here: https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/sop-associated-documents--templates-/

For RGIT sponsorship review please submit the following documentation to rgit@imperial.ac.uk:

- Draft pdf of IRAS form: https://www.myresearchproject.org.uk/
- Protocol
- Participant information sheet and consent forms
- RGIT sponsorship registration form: https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/sop-associated-documents--templates-/
- Participant facing documentation including recruitment adverts, questionnaires or emails
- And Organisation Information Document (OID): https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/
- If your study involves sites outside of ICHT you will require either a Schedule of Events or a Schedule of Events Cost Attribution Template depending on if your study will be adopted by the National Institute of Health Research:

https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-SoE-SoECAT

Once submitted the RGIT will review the project to ensure that we are able to take on the role of sponsor and to ensure that the study will be run in line with all appropriate policies, framework and regulations. The RGIT will also ensure that the documentation is up to appropriate standards for REC and HRA review. The aim is to review within 5 working days. Please respond to any changes promptly and with tracked changes if possible. If changes are requested, then these are for a reason and to ensure that there are no additional delays with HRA and REC also requesting these. The faster these are returned the faster sponsorship approval can be given.

Further guidance:

Below is some guidance on the main queries we have regarding completing the IRAS form, and the most common mistakes that occur at sponsorship review stage:

Main questions on the IRAS form:

1. Project filter questions: These generate the rest of the form so make sure they are correct. Especially in regard to study type, and if this is a student project.
2. A4: You can leave this blank, when your study is allocated for sponsorship review you will be advised of who to include.
3. A6-1/A6-2/A12 and A13: All of these questions request that information is given in lay persons terms. Pleas ensure this is the case.
4. A27 1-4 to A30: These questions deal with recruitment and consent. It needs to be clear exactly how you will identify, approach and consent participants. And recruitment materials i.e. posters or email advertisements needs to be submitted as part of sponsorship review.
5. A76-1/2/3: Insurance and indemnity questions. For College sponsored studies then tick 'Other' to A76-1 and A76-2 and state that Imperial College indemnity applies. A76-3 should be ticked as NHS. For NHS sponsored studies, NHS should be ticked for all 3.

Common mistakes with documents for sponsorship review:

1. Lack of consistency between documentation. You will need to ensure that all documents have the same information, common issues are length of time that an interview or questionnaire takes, or the number of participant visits.
2. Spelling mistakes and grammatical errors. These are surprisingly common! If not picked up at sponsorship review, then the Ethics Committee or HRA will request these are changed.
3. No version number, date or IRAS number on documents. This is a requirement for your protocol, and all participant facing documentation (excluding validated questionnaires).
4. Data should be pseudonymised as soon as possible during the study. Please note data is rarely fully anonymised, especially if you have consent forms and a code linking this to the participant.
5. Transparency wording in the information sheet should be updated as per what will happen in the study, including any 3rd party access.

6. Participants outside the direct care team of patients should not access data without consent.
7. The patient information sheet should be in lay person terms and refer directly to the participant i.e. 'you will sign the consent form', not 'the participant will sign the consent form'.

If you have any questions on the sponsorship process then please contact the Research Governance and Integrity team: https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/about-us/staff-list/

Confirmation of Capacity and Capability:

Before Confirmation of Capacity and Capability can be issued at Imperial College Healthcare NHS Trust, the following documents/approvals must be in place:

- REC approval (if applicable)
- HRA approval and all associated documents
- Copy of Investigator Brochure (IB)
- 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
- Fully executed Clinical trial site agreement signed off by ICHT and sponsor organisation (if applicable) or completed SoA.
- 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

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.

Once the assessment process is completed and it is determined that there is sufficient capacity or capability to deliver the study, ICHT is required to confirm organisational readiness. Relevant DRM teams will confirm ICHT's capacity and capability with the sponsor via email, 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.

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 formal "clock start" 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.

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 which 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 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.

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.