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Imperial College Healthcare NHS Trust

Research Governance and Integrity Team

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Sponsorship and Insurance Approval

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Version	Date	Reason for Change
Version 1.0	14 Sep 2006	Annual review
Version 2.0	25 Jun 2007	Annual review, change in practice post MHRA inspection
Version 3.0	02 Jul 2008	Annual review
Version 4.0	08 Feb 2010	Formation of Joint Research Office
Version 5.0	14 Jul 2011	Annual Review
Version 6.0	30 Nov 2012	Annual Review
Version 7.0	18 Feb 2015	Scheduled Review and addition of communication with Sponsor's Representatives
Version 8.0	25 Oct 2017	Scheduled Review, Addition of Legal Representative Risk assessment tool, factors posing risk on sponsorship. CI Agreement for CTIMP and Guide on sponsorship has been updated Minor/administrative changes
Version 9.0	18 Feb 2019	Sponsorship and Insurance registration form appendix addition
Version 10.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes JRCO name change to RGIT.
Version 11.0	21 Oct 2020	Amended section 4.4.2.1 for further clarifications
Version 12.0	05 Jul 2021	Minor change made to the to the Appendices/Templates section
Version 13.0	02 Nov 2021	Inclusion of CWOW IRAS form
Version 14.0	04 Jun 2024	Scheduled Review
Version 15.0	02 May 2025	Addition of Risk Assessment for College sites
Version 16.0	27 Apr 2026	Updated for Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

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1. PURPOSE

This SOP describes the process for obtaining sponsorship approval from Imperial AHSC (Imperial College London or Imperial College Healthcare NHS Trust) and registering a project for insurance cover. It applies to all studies falling under the UK Policy Framework for Health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the Clinical Trials Regulations"), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538) which reform the UK clinical trial regulatory framework.

The SOP also outlines the process for Clinical Trials of Investigational Medicinal Products (CTIMPs) where Imperial College London or Imperial College Healthcare NHS Trust may agree to act as UK Legal Representative instead of, or on behalf of, a Lead sponsor based outside of the UK. For CTIMPs conducted in the UK, sponsors not established in the UK must appoint a legal representative in the UK. This representative, who may be an individual or a corporate entity, acts as an agent for legal proceedings and should be established in the UK.

For clinical investigations of medical devices in Northern Ireland under the EU Medical Device Regulation 2017/745, a legal representative of the sponsor based in Northern Ireland or the EU is required. However, for studies other than CTIMPs, a UK legal representative for the lead sponsor is not mandated under the UK Policy Framework.

For further information please refer to HRAs guidance on Sponsor's legal representative . Please also refer to section 4.3 below.

For a proposed Imperial AHSC sponsored study with international sites please discuss with RGIT prior to submission so that we can advise on any specific requirements (e.g. confirmation of insurance of overseas sites).

2. INTRODUCTION

Every clinical trial/research study must have a named sponsor. A sponsor is defined by the HRA as "The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project" (Roles and responsibilities - Health Research Authority).

The UK Policy Framework for Health and Social Care states that for non-commercial research, the sponsor is normally expected to be the employer of the chief investigator. For commercial research, the funder is usually the sponsor. It defines the sponsor as having responsibility for ensuring effective arrangements are in place to set up, run and report a research project.

All Imperial College Academic Health Sciences Centre (AHSC) healthcare research projects which involve humans, their tissue and/or data must be registered and assessed for sponsorship with the Research Governance and Integrity Team (RGIT). This applies to studies funded by Imperial College AHSC or another organisation (including a commercial company); whether it is a CTIMP, Device or Combined products; human tissue or data project; observational or epidemiological study; or physiological study.

Please note, for Imperial College AHSC studies where the only research being undertaken at Imperial is tissue collection (e.g. collecting biopsies, blood only, etc.), registration and ethics approval may be obtained from the Tissue Bank, who have been delegated authority from the REC to approve this type of project. Contact the Imperial Tissue Bank for advice.

Registration allows the RGIT to:

- Assess the project for AHSC sponsorship
- Confirm or arrange appropriate insurance cover for the study
- Discuss research governance issues, if required
- Have sponsor oversight
- Ensure the study has the necessary regulatory, ethics and HRA approvals
- Have an overview of the AHSC's clinical research portfolio
- Respond to monitoring/audit requests by regulatory authorities

The table in Appendix 1 of this SOP contains a guide to help determine who should act as the study Sponsor.

3. RESPONSIBILITIES

This SOP must be followed by the RGIT, Chief Investigators (CI) and clinical trial teams of all proposed Imperial College AHSC sponsored studies. RGIT staff members must comply with this SOP when assessing, reviewing and providing sponsorship for a project.

For any studies coming into RGIT for sponsorship, the RGIT Quality Assurance Facilitator (QAF) will check if the CI is up to date with final reporting requirements on public databases for previous Imperial College AHSC studies. This must be confirmed before the sponsor review starts. Final reporting requirements refers to when a previously sponsored study has been registered on a public database, the results for that trial must have been reported within 1 year of study completion.

The Head of Research Governance and Integrity or a delegate is responsible for ensuring that this SOP is updated by the review date, or as necessary.

4. PROCEDURE

4.1. WHEN TO REGISTER WITH THE RGIT

All research projects sponsored by Imperial College AHSC must be registered with the RGIT. Registration must occur **prior** to the submission of the application for approval to REC/HRA/MHRA (as applicable to the study). The approvals required will vary according to type of study being submitted. The RGIT will assess which approvals are needed.

For projects occurring within Imperial College Healthcare NHS Trust (ICHT), registration will form part of the Confirmation of Capacity and Capability (CCC) process, which must be in place before the study starts (see RGIT_SOP_031). For studies sponsored by Imperial AHSC 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 in a streamlined way. Documents should be sent to RGIT for sponsor review in finalised form, after PPI and other required reviews (e.g. statistician) have been undertaken. Major changes to documentation during sponsor review, or following a modification straight after sponsorship review has been undertaken, will result in a delays to document review and study set up.

If undertaking student research, before sending to the RGIT for review, please refer to the HRA's Student Research pages and Student Research Toolkit guidance to check whether your study is eligible for HRA review and what else might be needed (e.g. supplementary declaration form).

4.2. FOR PROJECTS TO BE SPONSORED BY IMPERIAL COLLEGE AHSC

4.2.1 Send the following to RGIT@imperial.ac.uk:

- A completed RGIT Sponsorship and Insurance Request Form
- CV for Chief/Principal Investigator
- Protocol, Participant Information Sheet and Informed Consent Form in Word format following SOP, Associated Documents & Templates | Research and Innovation | Imperial College London.
- Any other patient facing documents (e.g. questionnaires)
- Ethics application form (full IRAS dataset or ICRE C/SETREC)
- For CTIMP studies the Combined Ways of Working (CWOW) Step by step guide to using IRAS for combined review - Health Research Authority (hra.nhs.uk) IRAS form should be completed and the RGIT notified when it is ready to review in the system
- Non-commercial Organisational Information Document (OID) or model non-commercial agreement (mNCA) if applicable. See Appendix 5 for guidance on which one to use.
- Schedule of Events or Schedule of Events Cost Attribution (if applicable)
- Funding letter or funding agreement, if applicable
- A completed RGIT TEMP 082 College or College Associated Sites Interventional Risk Assessment form if the study has interventional research taking place outside NHS site as per the RGIT Sponsorship Form. This includes taking of samples. See the form for full details of what is included.

Additional documentation required for CTIMP studies:

- CTIMP addendum Risk Assessment (RA) and provide confirmation that the College's approved Electronic Data Capture (EDC) system (currently OPENCLINICA) for CTIMPs will be used or if other validated EDC system to be used this should assessed by RGIT. See RGIT SOP 030 for details. Trial risk classification (if applicable)
- Confirmation whether the study may qualify as a notifiable clinical trial under the MHRA guidance.
- Cover letters for the MHRA and REC submissions. For the MHRA cover letter please see all details of what to include here
- https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-approval-in-the-ukAll IMP and NIMP related documentation – IB/IMPD/SMPC as required. Non-medicinal products do not necessarily require their own dossier but must, as a minimum, be listed in the cover letter and included in an IMP dossier with information

about their properties, labelling, manufacture, stability and safety controls, as appropriate to the product.

- Manufacturer's authorisation for IMP and NIMP, including the IMP importer's authorisation [MIA (IMP)] and Qualified Person (QP) declaration on Good Manufacturing Practice (GMP) for each manufacturing site if the product is manufactured outside the EU (this should be provided to you by the IMP supplier)
- Labelling documentation: In line with RGIT SOP IMP Management including for NIMPs if applicable.
- Confirmation that trial monitoring will be in place for non-ICHT sites where relevant
- Any previous correspondence with the MHRA, or any other Competent Authorities (CAs) for international studies, regarding the study

4.2.2 What happens next?

If the study is a CTIMP it will go to the CTIMP RGIT Clinical Trials Manager (CTM) leading on the CTIMP sponsorship review.

Non-CTIMPS will be allocated for review to the next available person at RGIT (Clinical Trials Manager (CTM), Research Governance Manager (RGM) or Clinical/Research Facilitator (RGF)).

The CTM/RGM/RGF allocated the study will check if it has already been registered by ICHT on the Sponsor's electronic database during a grant application process and if not, they will register the study on the database.

Prior to any sponsor review activities occurring, the CTM/RGM/RGF allocated the study will check with the Quality Assurance Facilitator (QAF) at RGIT to ensure that the CI has completed all final reporting requirements for public databases (e.g. CT.gov) and the Peer Review Officer will ensure that all studies with outstanding EoS reporting are first resolved. The CI will be notified of any gaps in reporting by the QAF/PRO, who will be able to advise the study team on resolving reporting issues. The CTM/RGM/RGF reviewing the study will let the CI/study team know that the study is on hold for sponsor review until confirmation of DB clearance is confirmed to them by the QAF. All final reporting requirements must be resolved by the study team and confirmation of resolution confirmed to the CTM/RGM/RGF by the QAF before the sponsor review can proceed. The only exception to this will be for Master's students' studies, which have short timelines and should not be held up due to any CI failure to meet public database reporting requirements.

Following registration, if the study is running at ICHT, the CTM/RGM/RGF reviewing for sponsorship will send the completed RGIT form (signed by the CI) with the Sponsor's Database reference number and the initial study documents received for sponsor review to the relevant Divisional Research Manager (DRM), Feasibility Lead to facilitate feasibility checks and set up at ICHT. A list of the DRMs for the different divisions can be found in RGIT_SOP_031. A copy of these documents will also be forwarded to imperial.admin_trustresearchcontracts@nhs.net to facilitate their assessment of ICHT costing and contracts.

If the study is unfunded and due to run at ICHT, the CTM/RGM/RGF will check with the ICHT relevant DRM, prior to commencing the sponsor review, that the Trust (ICHT) will be able to support the research. This confirmation must be received in writing before the

sponsor review can start. Unfunded research due to run at Imperial College London should have authorisation in writing from the relevant College Head of Department.

Immediately following registration on the Sponsor's Database, the CTM/RGM/RGF will send the study to the RGIT Peer Review Office for peer review assessment/certification, in accordance with the procedure set out in RGIT_SOP_040. Please note that PRO request that clean copy protocols are sent to reviewers and also that peer reviews are received with sufficient time for a certificate to be issued prior to REC/HRA submission, with the documents for peer review being sent to the PRO prior to the initial sponsor review being returned to the applicant.

The CTM/RGM/RGF will aim to provide the initial sponsor review, following receipt of all relevant documents listed in 4.2.1, and provide the initial response within 10 working days. They will advise on research governance issues, if needed and can meet with the study team to discuss the study.

4.2.2.1 Assess for Imperial College AHSC Sponsorship, where applicable

In order for Imperial College London or Imperial College NHS Trust to act as the research Sponsor, the CTM/RGM/RGF will assess the project for risk to College or Trust and participants, using risk assessment tool templates. A decision on sponsorship will then be made, in consultation with the Head of Research Governance and Integrity if needed.

Factors that are likely to pose a risk in the conduct of a trial include, but are not limited to:

- Insufficient funding
- CI's lack of experience
- Certain groups of patients e.g. pregnant women, children, vulnerable adults
- Trials that are excluded or restricted in terms of insurance
- Trial complexity in terms of design, size and involvement of multi-centre and/or multinational trials
- Eligibility for risk-proportionate regulatory pathways, including notifiable trials
- Involvement of Advanced medicine therapy product (ATMP)
- For CTIMP trial - Involving a medicinal product not licensed in any EU Member State or Phase 1-first in man- CTIMP or ATMP trials.

4.2.2.2 Assess and confirm insurance cover

Appropriate insurance must be in place for each research project undertaken in order to cover against harm to a research participant. There are two types of possible harm: negligent and non-negligent.

Negligent Harm: Any action or process that is held by a court to have caused harm because of a lack of due diligence, lack of care, omission of duty or an act of carelessness towards a participant in a research project.

Non-Negligent Harm: Circumstances where there is no specifically identified causative factor relating to the harm of a participant in a research project, but harm is likely, on the balance of probabilities, to have arisen from the participant taking part in the research.

Not all projects will need cover against both types of harm. The RGIT are responsible for determining what insurance is relevant to a research project. The insurance assessment should provide the CI with the reassurance that the study has the appropriate level of protection. Evidence of appropriate insurance or indemnity must be included within the regulatory application submitted to MHRA and REC where required.

Due to certain exclusions in Imperial College policies, the study team must not assume that insurance will apply to a project until it has been confirmed to the CI in writing. Where necessary, the RGIT may need to refer to the College's Insurance and Indemnity Manager at insurance@imperial.ac.uk (including c.coulson@imperial.ac.uk) or Insurers for further assessment.

As it can be complicated to arrange insurance for overseas research, the study team should contact RGIT as early as possible to discuss this. As there will likely be additional premiums per country (and per individual site) the IC Insurance Manager at c.coulson@imperial.ac.uk will need to confirm insurance for international sites.
Indemnity arrangements for a study need to be explained in the IRAS application (Questions A76 and A77) or Section E (Questions 3, 4,5 and 6) in the Project Study Information form for applications in CWOW. RGIT can provide a standard statement if required.

4.2.2.3 Provide PI/CI with agreement for all Clinical Trials of Investigational Medicinal Products (CTIMPs)

Upon receipt of the items indicated in section 4.2.1, the RGIT will send the Chief Investigator an agreement (appendix 2) that must be fully signed prior to the study start, which will be checked and confirmed at the site initiation visit.
For CTIMPs managed by the Imperial College Trials Unit (ICTU), the ICTU RGIT CTIMP Delegation of Responsibilities must be fully signed prior to the study start.

4.2.2.4 Agreement of Sponsorship

The Research Governance and Integrity (RGIT) Team will confirm Imperial College London or Imperial College Healthcare NHS Trust sponsorship to the Chief Investigator.

For Imperial College London sponsored projects, sponsorship will be confirmed to the CI by email with the signed sponsor letter attached. This will be accompanied by a copy of the Imperial College London insurance certificate for the study, for submission to HRA.

For Imperial College Healthcare NHS Trust sponsored projects, confirmation to the CI will be by email with the signed sponsor letter attached only.

For studies occurring at ICHT, the relevant DRM and Feasibility Lead will be copied into the sponsor letter. This is to facilitate liaison between the DRM and the study team for study CCC at ICHT.

The Quality Assurance Facilitator will be copied into any sponsor letters for studies that have public database reporting requirements, so that RGIT can assist with registration and maintain oversight of reporting. The Research Governance and Peer Review Officer will be copied into all sponsor letters to assist with tracking end of study and final reports.

For all College sponsored studies involving personal data where the PI is based in the Faculty of Medicine (FoM), the FOM Data Protection Office (DPO) will also be copied into the sponsor letter by email to Faculty of Medicine GDPR Coordination. For the avoidance of doubt, personal data includes identifiable and pseudonymised (coded) data. The only time that the FoM DPO won't be copied into a College sponsor letter will be if the study involves only the use of fully anonymised data (no link or code back to the patient).

The CI/study team must not assume that the College or ICHT will sponsor a project until written confirmation is received.

The email accompanying sponsor letter, Appendix 6 - RGIT_TEMP_057, must be read fully as it contains essential information relevant to the study being undertaken. This includes information about booking via the online booking service or via CWOW in IRAS, along with instructions to:

- Register any Faculty of Medicine (FOM) Imperial College London sponsored study using personal (includes pseudonymised) data on the DART (any queries contact FOM GDPR Office).
- Register any study requiring registration at clinicaltrials.gov as soon as possible by contacting Quality Assurance Facilitator. The Sponsor must ensure that the trial is registered on an appropriate public registry (e.g. ClinicalTrials.gov or ISRCTN) and that summary results and a lay summary of results are published within 12 months of the end of the trial, unless otherwise justified.
- Register any study involving human tissue on the Sponsor's Database by ensuring the relevant Tissue Bank information is completed so tissue can be brought under the HTA licence as appropriate at the end of the study.
- Liaise with the Divisional Research Manager/Feasibility Lead if the study is taking place at ICHT, to facilitate study set up and the CCC process, which must be confirmed before the study can start at ICHT.
- Send any updated documents where changes are requested by the REC, HRA, MHRA to the RGIT in order that RGIT has the most up to date versions of all study documents (also refer to section **4.4.2.1)**.
- Contact any external sites involved in the study to start the approvals process there. The study team should liaise with the relevant R&D departments according to HRA process.

When sponsorship is confirmed and the CI is ready to submit the project to the HRA, the RGM/CTM or the Head of Research Governance and Integrity can sign the Sponsor Declaration or submit the study in CWOW IRAS. The sponsor representative should be copied into all approval letters by the REC/HRA/MHRA.

To facilitate set up of studies at ICHT, the RGIT staff who carried out the sponsor review will send the REC validation letter, provisional, conditional and favourable REC opinion letters (as applicable) and HRA initial assessment letter (if received) to the DRM generic inbox. The RGIT staff who carried out the sponsor review will send the HRA approval letter to both the relevant DRM and Feasibility Lead. If the study was reviewed by the Clinical Trials/Research Facilitator, they will be responsible for forwarding these on to the DRM

generic inbox and DRM/Feasibility Lead (as detailed above) when received via the RGM/CTM.

For studies with external sites, HRA process should be followed and the documents provided to the R&D offices by the study team.

For studies with non-NHS sites, the approval letters must be provided by the study team to the sites. Prior to study start up all approvals any contracts must be in place.

4.2.2.5 Continued review of sponsorship

The review of sponsorship is a continuous process and is dependent on the study having the appropriate approvals in place for the project to start up and for duration of the study.

If the required approvals are not in place for the start-up duration of the study, RGIT can suspend sponsorship and inform the relevant regulatory bodies and ethics committees.

Under regulation 26 of the Clinical Trials Regulations, a clinical trial approval will lapse two years from the date on which the trial was approved if no participants have been recruited (i.e. have signed the consent form) to take part in the UK trial.

The licensing authority will monitor the status of the trial's approval. If the approval lapses, the sponsor will be contacted via email to confirm this. The sponsor will then need to submit an end of trial notification.

4.2.2.6 Applying for an extension

Sponsors can apply to the authorities for an extension of this period by emailing clintrialhelpline@mhra.gov.uk, explaining both why the extension is needed and the length of the proposed extension.

Sponsorship is also dependant on receipt of:

- all safety reports i.e. Development Safety Update Reports (DSURs) for CTIMPs and Serious Unexpected Suspected Adverse Reactions (SUSARs), see RGIT_SOP_035
- any modifications to the study see RGIT_SOP_006.
- End of study notification and compliance with regulatory transparency obligations, including publication of trial results and lay summaries see RGIT_SOP_028.

4.3. LEGAL REPRESENTATIVE

- The Legal Representative should be willing to act as the agent of the sponsor in the event of any legal proceedings instituted (e.g. for service of legal documents) should be established and contactable at an address in the UK.
- does not assume any of the legal liabilities of the sponsor(s) for the trial by virtue of the role of legal representative and does not therefore require insurance or indemnity to meet such liabilities; but may in some cases enter into specific contractual arrangements to undertake some or all of the statutory duties of the sponsor in relation to the trial, in which case the legal representative would also be regarded as a co-sponsor and would then require insurance or indemnity cover.

In all trials for which Imperial College London agrees to act as UK legal representative, a contract/written confirmation will be put in place with the Lead sponsor to detail the responsibilities the College have agreed to undertake on behalf of the Lead sponsor.

4.4. COMMUNICATION WITH SPONSOR'S REPRESENTATIVES

4.4.1 Sponsor's Representatives - Contacts

Once the study has CCC approval (and sponsor green light, if requested) issued (at any site) or becomes active at any site (if non-NHS sites involved) all queries and modifications will go to the RGM (or delegate) responsible for the site at which the study has been registered under on the Sponsor's Database (or CTIMP Manager if CTIMP study, irrespective of site). You can refer to the RGIT Staff List for more details of who looks after which sites. This person will then be the Sponsor's Representative for the duration of the study. This relevant person will be the Clinical Trial Manager for CTIMP studies and the Research Governance Manager for the Chief Investigator's campus or College site for non-CTIMP studies.

4.4.2 Modification

4.4.2.1 Modifications made to the study during the approvals process

Once the study has been submitted to the REC/HRA/MHRA (as applicable) changes to the documents may be requested during the approvals review process. Any modifications made during this time must come to the RGIT for their agreement of the changes, prior to resubmission. The updated documents should be sent for review with tracked changes to the CTM (for CTIMPs) and RGM (that is responsible for the Chief Investigator's campus or College site campus for non-CTIMP studies) who will then delegate to RGF's for review as deemed necessary.

4.4.2.2 Modifications made to the study following HRA approval for a study

All modifications to study documentations must be reviewed and authorised by the RGIT prior to submitting them online to the HRA/REC and/or regulatory authorities (as applicable to the study).
Modifications are categorised under the amended Clinical Trials Regulations as:

- Substantial modification – Route A
- Substantial modification – Route B
- Modification of an important detail
- Minor modification (internal documentation only)

The Sponsor must review and authorise all proposed modifications prior to submission to regulatory authorities. The appropriate modification category and submission pathway will be determined in accordance with MHRA guidance.
The documents relevant to the modification should be emailed to the Sponsor's Representative for review or submitted in CWOW IRAS which will be undertaken by the CTM/Clinical Trials Facilitator (CTIMP studies) or the RGM/RGF responsible for the Chief

Investigator's campus or College site campus (for non-CTIMP studies). For detailed information, refer to RGIT_SOP_006 and RGIT_SOP_032.

The CTM/RGM/RGF reviewing the modification will acknowledge its receipt and review the changes within 5 working days of the receipt date.

Regulatory authorities (MHRA) will reject any modifications received without Sponsor's Representative authorisation (or authorised delegate from RGIT for minor modifications).
For all studies sponsored by the Imperial College AHSC and taking place at ICHT, the CTM/RGM/RF who has reviewed the modification will forward all validation emails and approvals relating to the modification to the DRM generic inbox. This is to facilitate communications between the study team and the DRM and the continuing CCC process for the modification for all other sites where the modification will be implemented, IRAS guidance should be followed on the provision of modification documents/approvals to sites and this will be the responsibility of the study team.

All required approvals/permissions must be in place before any modification is implemented (HRA/REC/MHRA/CCC as applicable) as detailed in RGIT_SOP_006 and RGIT_SOP_032.

For College sponsored studies, if the modification will have an impact on the GDPR aspects of the study the information provided on the FOM Asset Register must be updated by the study team before implementation of the modification. If a modification is being made and the study team have not yet registered the study on the FOM Asset Register, they will need to do this before implementation of the modification

It is advisable for the CI to inform the Sponsor's Representative of any communication with external parties, as some information may be privileged or may require contractual arrangements.

5. REFERENCESS

UK Policy Framework for Health and Social Care Research (cited 24 Feb 2026)

HRA - Roles and responsibilities (cited 24 Feb 2026)

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (cited 24 Feb 2026)

ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf (cited 24 Feb 2026)
IRAS - Amendement guidance - all review bodies (cited 24 Feb 2026)

HRA NHS Website (cited 24 Feb 2026)

SOPs and Associated Documents-Templates | Research | Imperial College London (cited 24 Feb 2026)

6. 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: Guide to who should take on Sponsorship role

Who developed the project?	Source of Funding		The trial sponsor
	Trust	College	
College substantive employer and honorary contract with ICHT	Yes	No	ICHT
College substantive employer and honorary contract with ICHT	No	Yes	College
ICHT substantive employer and honorary contract with College	Yes	No	ICHT
ICHT substantive employer and honorary contract with College	No	Yes	College
Other Trust Employee *with* Honorary Contract at College (funds would go through College)	-	Funds go through College	College
Other Trust Employee *without* Honorary Contract at College	Funds go through Trust	No	ICHT
College substantive employer, honorary contract with ICHT or vice versa	Yes	Yes	Decision on IP rights and other factors.
College substantive employers and honorary contract with ICHT	No	No	College (but needs to be agreed with HOD prior to sponsor review being initiated)
ICHT substantive employers and honorary contract with College	No	No	ICHT (but needs to be agreed with DRM prior to sponsor review being initiated)

Appendix 2: CI agreement for CTIMPs – RGIT_TEMP_019
Appendix 3: Risk Assessment Tool – RGIT_TEMP_020
Appendix 4: Sponsorship and Insurance Registration Form– RGIT_TEMP_021
Appendix 5: OID Contracts Flowchart (App.5) – RGIT_TEMP_022
Appendix 6: CTIMP Addendum Risk Assessment – RGIT_TEMP_054
Appendix 6: Sponsorship and Insurance Approval email – RGIT_TEMP_057
Appendix 7: Statistical Engagement Letter – RGIT_TEMP_058
Appendix 8: Process Map for OID and SoECATs – RGIT_TEMP_062
Appendix 9: Risk Assessment and Management Plan Clinical Interventions taking place on College or associated premises – RGIT _TEMP_082