**CI agreement for CTIMPs**

**DELEGATION OF RESPONSIBLITIES BETWEEN**

**Imperial College London / Imperial College Healthcare NHS Trust (Sponsor)**

**&**

**Chief / Principal Investigator**

**for CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS**

This form acts to identify and acknowledge sponsor responsibilities between Imperial College London/Imperial College Healthcare NHS Trust and the designated Chief Investigator undertaking clinical trials Involving Medicinal Products (IMPs) as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004.

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| **Title of Research****Project:**  |  |
| **Chief Investigator:** |  | **EudraCT:** |  |
| **Principal Investigator:**  |  | **RGIT Ref:**  |  |

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| RESPONSIBILITIES **OF IMPERIAL COLLEGE LONDON /HEALTHCARE NHS TRUST** |
| Joint Research Office (JRO) – Pre-award section | All grant and funding administration including study costs assessment and approval |
| All trial related contract negotiations and sign-off (i.e. with pharma company, funders, 3rd party suppliers) |
| Research Governance and Integrity Team (RGIT) | Project review, organisational risk assessment and Sponsor approval  |
| Confirmation of indemnity (in conjunction with Insurance Manager) |
| Conduct audit as per DoH target of 10% of all projects |
|  |  |
| **RESPONSIBILITIES OF CHIEF / PRINCIPAL INVESTIGATOR** |
| General | Compliance with all College/Trust Policies and Procedures relating to human research, and contracting process |
| Ensure all team members have read and understood RGIT SOPs (Appendix 1)  |
| CI/PI to be trained in ICH-GCP before study commencement |
| Pre-study commencement | Protocol written to ICH-GCP standards and appropriate data management systems in place |
| Peer review of project has taken place and documents provided to RGIT  |
| Internal authorisation given by Head of Division or nominee |
| Ethics, MHRA and HRA approval R&D approval (and GTAC/ARSAC as applicable) are obtained |
| R&D or RGIT’s approval (capacity and capability confirmation) is obtained |
| Submit responses to CTA Conditions and Assumptions to MHRA and RGIT |
| Study submitted to public database (e.g. [ClinicalTrials.gov](http://www.clinicaltrials.gov)) |
| Ensure arrangements are in place to adhere to principles of ICH-GCP |
| Ensure pharmacy arrangements in place |
| Ensure INFORM/OPENCLINICAdata management system in place |
| Ensure all trial documents are maintained in a Trial Master File  |
| During the study | Ensure appropriate monitoring procedures are in place for all trial sites and provide monitoring plan to RGIT (if not included in protocol) |
| Adhere to IMP Management and Accountability SOP (RGIT/SOP/026) |
| All IMPs meet GMP requirements |
| Defined process for continued safety monitoring of IMP in study |
| Document all adverse events in study |
| Ensure reporting and recording of SUSARs to MHRA, RGIT and Ethics  |
| Provide annual safety or Development Safety Update Report (DSUR) report to MHRA, RGIT and Ethics |
| Give notice of trial amendments to MHRA, RGIT, HRA and Ethics as applicable |
| Complete annual progress report for ethics, RGIT |
| End of study | Give notice that research has ended to MHRA, RGIT and Ethics |
| Archiving of Investigator site file and associated documents |
| Ensure that end of trial summary results (CSR) are uploaded to EudraCT and give notice to MHRA via email @ CT.Submission@mhra.gov.uk  |

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|  | **Signature** | **Print Name** | **Date** |
| CI |  |  |  |
| Signed on behalf of Imperial College London |  |  |  |

The agreement must be received by the Clinical Trials Manager before Sponsorship can be confirmed. Please e-mail the agreement to: RGIT.ctimp.team@imperial.ac.uk after CI sign off with Acrobat or Adobe reader e-signature (refer to [RGIT/SOP/043/Electronic Signature](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/joint-research-compliance-office/public/JRCO_SOP_043_Electronic-Signature_V1.0_21April2020.pdf)). The agreement will be counter-signed by the Clinical Trials Manager.

**Appendix 1: CTIMP SOP reference**

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|  | **Relevant SOP(s)** |
| **Pre-study – project design** |
| Protocol (template available) | RGIT/SOP/012 |
| Patient Information Sheet and Consent Form | RGIT/SOP/016 |
| CRFs designed and checked by statistician | RGIT/SOP/007 |
| Peer Review | RGIT/SOP/040 |
| Incidental Findings | RGIT/SOP/042 |
| Research Fraud and Misconduct | RGIT/SOP/036 |
| **Pre-study – regulatory** |
| Ethics approval | RGIT/SOP/002RGIT/SOP/003 |
| MHRA CTA approval | RGIT/SOP/008 |
| HRA Approval | RGIT/SOP/039 |
| GTAC approval (if applicable) | RGIT/SOP/004 |
| Sponsorship and insurance approved by RGIT | RGIT/SOP/009 |
| R&D and SSA approval for all local sites | RGIT/SOP/002RGIT/SOP/003 |
| All contracts signed by pre-Award in the JRO (i.e. pharma company, funder, other 3rd party suppliers) |  |
| Study submitted to public access database | RGIT/SOP/022 |
| **Pre-study – management** |
| Pharmacovigilance plan in place | RGIT/SOP/001 |
| Trial specific SOPs and TMF in place  | RGIT/SOP/005 |
| Data Management procedures in place | RGIT/SOP/020 |
| Computerised system for clinical trials | RGIT/SOP/030 |
| IMP Management procedures in place | RGIT/SOP026 |
| Monitoring procedures in place | RGIT/SOP/015 |
| Laboratory Procedures in place | RGIT/SOP/029 |
| Electronic Signature | RGIT/SOP/043 |
| **Pre-Study – studies occurring at Imperial College Healthcare NHS Trust** |  |
| Confirmation of Capacity and Capability in place | RGIT/SOP/031 |
| NIHR approval in place (if applicable) | RGIT/SOP/033 |
| Letter of Access or Honorary Research Contracts in place (if applicable) | RGIT/SOP/034 |
| **During Study** |
| Amendments advised to REC, MHRA, RGIT | RGIT/SOP/006 |
| Amendment Approval for ICHT located studies **(if applicable)** | RGIT/SOP/032 |
| SUSARs advised within timelines to REC, MHRA, RGIT | RGIT/SOP/001 |
| Incidental Findings | RGIT/SOP/042 |
| Development Safety Update Report (DSUR) submitted to REC, MHRA, RGIT | RGIT/SOP/001RGIT/SOP/035 |
| Annual progress report submitted to REC, RGIT | RGIT/SOP/002RGIT/SOP/003RGIT/SOP/035RGIT/SOP/041 |
| Allow College/Trust auditors to attend as required | RGIT/SOP/018 |
| TMG, DMC and TSC meet regularly (if applicable) | RGIT/SOP/015 |
| Essential documents stored in TMF | RGIT/SOP/005 |
| Training file maintained for all members of trial staff | RGIT/SOP/024 |
| Notification of serious breach of GCP or Trial Protocol | RGIT/SOP/021 |
| Management of protocol deviations, violations and urgent safety measure | RGIT/SOP/037 |
| Managing research participants complaints | RGIT/SOP/013 |
| Equipment Maintenance  | RGIT/SOP/027 |
| **Completion of Study** |
| Database Lock | RGIT/SOP/046 |
| End of study report submitted to Ethics, MHRA and RGIT | RGIT/SOP/028 |
| Copy of publication sent to RGIT |  |
| Archiving of TMF and associated documents arranged | RGIT/SOP/019 |