Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Roles and Responsibilities for University of Liverpool Sponsored Research

SOP006

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1. Introduction

The UK Policy Framework for Health and Social Care Research defines the sponsor as the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

The Sponsor is responsible for ensuring that the proposed research respects the dignity, rights, safety and well-being of participants. The UK Policy Framework requires that all research projects must have a sponsor identified and declared prior to the commencement of the project.

In addition, the The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025requires that all Clinical Trials of Investigational Medicinal Products (CTIMPs) must have the sponsor declared to the Competent Authority. The Competent Authority in the UK is the Medicines and Healthcare products Regulatory Agency (MHRA).

This standard operating procedure (SOP) has been produced in accordance with the requirements laid out in relevant regulations. This includes, but is not limited to the UK Policy Framework for Health and Social Care Research, The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025and subsequent amendments (the Regulations), The Medical Devices Regulations 2002, the Principles of Good Clinical Practice, the Data Protection Act 2018, UK General Data Protection Regulation (UK GDPR), the Mental Capacity Act 2005, the Human Tissue Act 2004 and Good Clinical Practice (GCP) guidelines.

2. Scope of Procedure

The purpose of this SOP is to outline the responsibilities undertaken as part of University of Liverpool (University) sponsorship for clinical research.

3. Who

This SOP is aimed at staff within the University Clinical Directorate as well as Chief Investigators, students, trial coordinators and other members of University Staff involved in University Sponsored research.

4. When

This SOP should be referred to during study set-up, during the course of the study and at study completion.

5. Pre-study set-up responsibilities

The following must be in place before a study begins:

Sponsorship Approval

It is the CI's responsibility to ensure that appropriate Sponsorship has been obtained before the start of the research. See SOP004 for further details on applying for and obtaining University sponsorship. If University sponsorship is approved, the CI will be asked to sign and date a 'Sponsorship agreement' to confirm that they understand the delegated roles and responsibilities taken on behalf of the University as a sponsor. The Liverpool Health Partners (LHP) Joint Research Office (JRO) Sponsorship Committee/Non-Interventional Sponsorship Sub-Committee (NISSC) and the Sponsorship Team will ensure through liaison with the CI that there are sufficient resources, including staff, facilities and finances, in place for the duration of the study.

Peer review

All studies must undergo scientific peer review. This is either completed by the funder or by experts' independent to the research. It is the responsibility of the CI to ensure peer review is provided to the JRO Sponsorship Committee or NISSC and it is the responsibility of the Sponsor to ensure the review is appropriate. Where it is deemed necessary the committee may request further review. If the peer review is unfavourable or raises issues the CI should submit a response letter along with the Sponsorship Application for the committee's consideration. Ethics Committee approval is not peer review and should not be submitted as such. It should be noted that where a funder has undertaken peer review for a programme grant, independent peer review for each individual project must be obtained. See SOP004 for more information on peer review requirements.

Research Ethics Committee (REC) Approval

Once Sponsorship Approval or Intention to Sponsor has been issued the CI may proceed to obtaining the required approvals for the research.

For studies involving NHS Patients, their tissues or data, the CI is responsible for obtaining Health Research Authority (HRA) REC approval for the study (see also SOP013). The CI can delegate the responsibility to a suitably qualified member of the research team. The CI must oversee this process, check and sign off the application and obtain favourable opinion from the relevant REC. The CI is responsible for responding to any REC conditions of approval.

Obtaining other Ethical Approvals

If the proposed study involves recruitment of participants outside of the HRA REC remit the CI must ensure that the correct Ethical Approvals are applied for and obtained prior to the commencement of the research. The Sponsorship Team will assist with identification of required approvals at Sponsorship approval.

Obtaining approvals from the MHRA

For CTIMPs, the Sponsor is responsible for obtaining a Clinical Trial Authorisation (CTA) from the MHRA. This function is delegated to the CI, with the help of the Sponsorship team. The CI is responsible for paying the registration fee for CTA applications. The CI is responsible for responding to any MHRA remarks. Further guidance is available at http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Clinicaltrialsformedicinalproducts/index.htm

For studies which involve the Clinical Investigation of a Medical Device the CI, with the help of the Sponsorship Team, is responsible for obtaining a Notification of No Objection from the MHRA. The CI is responsible for paying any fee associated with the application. The CI is responsible for responding to any MHRA remarks. Further guidance is available at http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/

Obtaining further Regulatory Approvals

As well as REC and MHRA approval studies may also require approval from other Regulatory committees, including but not limited to;

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Confidentiality Advisory Group (CAG)
- Her Majesty's Prison and Probation Service (HMPPS)
- Health and Social Care Research Ethics Committee (HSC REC)

The Integrated Research Application System (IRAS) will assist in identifying where further approvals are required, but it is the responsibility of the CI to ensure that these are appropriately applied for, and approvals gained before beginning the research. The Sponsorship Team can provide further information and guidance where required.

Site Agreements

The Sponsorship Team will advise the CI on any required contracts or agreements that need to be put in place on the advice of the University's Research Contracts Team (part of the Legal & Governance Department). Template agreements will be provided to the CI by the Legal, Risk and Compliance Department. It is the CI's responsibility to ensure that all agreements are processed and signed off by relevant parties, and the Sponsor will ensure this is completed as part of the Sponsor Permission to Proceed process (see SOP016 and SOP004). The CI can contact the Sponsorship Team or the Research Contracts Team for assistance.

Obtaining HRA Approval

HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that researchers only need to submit one application. It applies where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers. References to participants include people whose data or tissue is involved in a research project.

The CI is responsible for ensuring that HRA approval is obtained for research carried out in the NHS in England. HRA approval can be applied for via the IRAS system.

Site Confirmation of Capacity and Capability

Following receipt of HRA Approval the CI must provide each proposed NHS research site with a copy of the 'Local Information Pack' and await site Confirmation of Capacity and Capability using the Organisation Information Document relevant to the research being carried out at that site. IRAS provides more detail on this process and the required documents here;

Contents of the UK Local Information Pack;

- Covering email using standard template format.
- Localised Organisation Information Document
- UK Statement of Events / Schedule of Events Cost Attribution Tool (SoECAT)
- Delegation Log (A delegation log is appropriate for studies that are clinical trials where the local study activities are managed by a Principal Investigator (PI))
- Relevant supporting documents.
  These will include some of the documents that have been submitted/approved with the IRAS Form submission and other documents to support study set up at the participating NHS/HSC organisation(s) for example;
- Copy of submitted IRAS Form
- All REC approved documents including Protocol and Participant information and consent documents
- Copy of HRA Initial Assessment Letter and HRA Approval Letter and final documents.

Insurance

Studies Sponsored by the University will be covered by the University's Clinical Trials Insurance, but there are some cases where pre-approval is required from the Insurers, or where extra insurance cover will need to be purchased. Please see SOP030 for full details. The Sponsorship Team is responsible for ensuring studies are referred where required. The CI is responsible for ensuring any additional insurance policies are purchased.

6. During the study responsibilities

Master Files

For CTIMPs the Sponsor is responsible for the creation and maintenance of a Trial Master File (TMF). This function is delegated to the CI or CTU managing the CTIMP. Creation and maintenance of a TMF is a requirement under the Regulations for all CTIMPs and must contain all the essential documents for the project as described in Good Clinical Practice (GCP) guidelines. Please see SOP015.

For all other studies the CI is responsible for the creation and maintenance of a Study Master File which will contain all essential study documents. Please see SOP005.

Delegation at site

The CI or Principal Investigator (PI) at each site must ensure each member of the research team is qualified by education, training and experience to fulfil their role in the study. All delegation of duties must be documented on the study specific delegation logs and filed in the Investigator Site File and TMF or SMF.

Substantial and Non-substantial Modifications

If the CI makes a major Modification to the study, it is the responsibility of the CI to submit the relevant documents firstly to the Sponsor(s), then REC, MHRA and any other regulatory bodies required and finally, once all approvals have been gained, to participating sites. Modifications to the protocol cannot be put into practice until approval has been given by all authorities (see SOP018).

If a minor Modification is required, it is the responsibility of the CI to submit the relevant documents firstly to the Sponsor(s), then any ethical or regulatory bodies required and finally, once all approvals have been gained, to participant sites.

Examples of modification types can be found on the HRA website[1].

Annual Reports

The CI is responsible for submitting all relevant annual reports.

Research sponsored by the University are required to submit a Sponsor Annual Report annually from the date of Sponsorship Approval using FORM006[2]. CTIMPs and Research Tissue Banks are exempt from this requirement.

[1] https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/

[2] https://www.liverpool.ac.uk/intranet/health-and-life-sciences/clinical/clinical-research-governance/sponsorship-approval/#annual%20reports

CTIMPs in the UK are required to submit a Development Safety Update Report (DSUR) to the MHRA[3] annually from the date of the CTA.

CTIMPs are required to submit a bi-annual oversight reports to the Sponsor, as detailed in the delegation or communication plan for the specific trial[4].

Other regulatory approval bodies may also require an annual report, the CI is responsible for ensuring all such requirements are met.

Research sponsored by the University being conducted at International sites are required to adhere to the reporting requirements of the relevant international ethical and regulatory bodies as applicable.

Copies of all the above reports must be submitted to the Sponsor.

Safety Reports

Where required, the CI/PI is responsible for documenting and reporting all adverse events that occur during the study. The PI must report all Serious Adverse Events (SAE) to the CI or CTU or responsible sponsor according to the process documented in the REC approved Protocol. If a CTU is not managing the study and the CI has been delegated the responsibility of Pharmacovigilance, the CI must send a copy of the SAE reports to the responsible sponsor as required by their processes.

The Co-Sponsorship Agreement, Internal Delegation Plan, or External Communication Plan will define the party that is responsible for reporting all Suspected Unexpected Serious Adverse Reactions (SUSARs) relating to a CTIMP or medical device to the MHRA, REC, (or international equivalents) and sponsor within the set time period; this is usually the CTU managing the trial.

All sponsored CTIMPs are required to provide a summary safety report to the Sponsorship Team on a biannual basis for review by the JRO Sponsorship Committee.

Breaches of GCP

The CI is responsible for reporting all serious breaches, relating to studies involving CTIMP or medical device, to the MHRA in collaboration with the sponsor, within 7 days of becoming aware of the breach (see SOP017).

The CI should inform the sponsor as soon as a Serious Breach is suspected and notify the co-sponsors of how this is being investigated/managed.

[3] https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#submit-development-safety-update-reports-dsurs

[4] TEM022 Non CTU Sole Sponsorship Internal Delegation Plan / TEM033 LCTC Sole Sponsorship Internal Delegation Plan / TEM034 External CTU Communication plan and division of responsibilities and functions

Publications

The CI should notify the Sponsorship Team of all publications, guidelines etc. which are related to the study.

SOPs

The CI must follow the agreed set of SOPs provided by the Clinical Research Governance Team, the NHS co-sponsor or the managing CTU for the duration of the study. If the Quality System to be used to manage a CTIMP differs from those mentioned the Sponsorship Team will undertake an audit of these SOPs to ensure suitability and adherence with the appropriate regulation and legislation.

International Research

For healthcare-based research taking place at International Sites, it is the CI's responsibility to remain up to date with any legislative changes in the country of the research and inform the Sponsorship Team of any changes that effect the Governance arrangements for the research. Where appropriate the CI will need to ensure any study documentation is updated to reflect the legislative changes.

7. End of study responsibilities

Notification of End of Study

The sponsor is responsible for the notification of the end of a study but the University delegates this responsibility to the CI.

The CI must notify the Sponsorship Team, Participating Sites, REC and MHRA (or international equivalents), where applicable, as well as any other regulatory bodies when the study has ended. This must be completed within 90 days of the conclusion date (see SOP021). A definition of the end of study must be defined in the protocol.

If a study is terminated early then the Sponsorship Team, REC, HRA and MHRA (or international equivalents), where applicable, must be notified within 15 days.

Close Out

The CI is responsible for informing the Sponsorship Team of close out activities.

Archiving

Where applicable the Co-Sponsorship Agreement, Internal Delegation Plan or External Communication Plan with the CTU will outline the procedure for archiving. In other circumstances, the CI will be responsible for archiving all trial related documentation (see SOP020).

8. Roles and Responsibilities

The main roles and responsibilities are outlined above. The below definitions apply to those parties above (taken from the UK Policy Framework for Health and Social Care Research)

Sponsor

The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research (The employer or funder is not automatically the sponsor; they explicitly accept the responsibilities of being the sponsor). The sponsor has overall responsibility for the research.

Please note that the University does not allow individuals to Sponsor a research study.

Chief Investigator (CI)

The chief investigator is the overall lead researcher for a research project. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project.

The CI is responsible for informing the Sponsor of any pertinent information at all stages of the study. This includes any amendments, adverse events, serious breaches, annual reports and End of Study. Any delegated roles and responsibilities will be outlined in the Sponsorship Approval letter or, if applicable, the Co-Sponsorship Agreement, Internal Delegation Plan or External Communication Plan. At all times the Sponsor will maintain oversight of the study to ensure that the CI is undertaking delegated responsibilities.

Principal Investigator (PI)

This is the leader responsible for a team of individuals conducting a study at a research site.

9. Abbreviations

CI	Chief Investigator
CTA	Clinical Trials Authorisation
CTU	Clinical Trials Unit
CTIMP	Clinical Trial of an Investigational Medicinal Product
DH	Department of Health
GCP	Good Clinical Practice
HRA	Health Research Authority
HMPPS	Her Majesty's Prison and Probation Service
HSC REC	Health and Social Care Research Ethics Committee
IMP	Investigational Medicinal Product

IRAS	Integrated Research Application System
JRO	Joint Research Office
LHP	Liverpool Health Partners
MHRA	Medicines and Healthcare products Regulatory Agency
NISSC	Non-Interventional Sponsorship Sub-Committee
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
University	The University of Liverpool

10. Associated Documents and References

Sponsorship SOPs (accessible here)

SOP004	Sponsorship Application and Approval Process
SOP013	Completing an IRAS Application for Regulatory Approval
SOP015	Maintaining a Trial Master File for CTIMPs
SOP016	Production and Management of Contracts for University Sponsored Clinical Research Activity
SOP017	Identification and Notification of Serious Breaches
SOP018	Procedure for the Submission of Modifications
SOP020	Archiving of Essential Documents for University Sponsored Studies
SOP021	End of Study Procedures for University of Liverpool Sponsored Studies
SOP030	Requirements for Insurance for University Sponsored research
FORM006	Sponsor Annual Report

National Legislation and Guidance

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

The Medical Devices Regulations 2002

ICH Harmonised Guideline for Good Clinical Practice E6(R3)

Data Protection Act 2018

UK General Data Protection Regulation (UK GDPR)

Mental Capacity Act 2005

Human Tissue Act 2004

11. Training and Resources

All University of Liverpool Research Support Office Clinical Research Governance staff and all University Staff involved in clinical research sponsored by the University (including CIs and Trial Coordinators) should ensure that they are aware of this procedure. If any further training is required, this can be arranged with the Clinical Research Governance Team.

12. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years on a risk basis.