# Standard Operating Procedure

**Number:** UM/UoM Sponsorship of Study/SOP03/4.0  
**Title:** Processing requests for confirmation of sponsorship for funding applications for CTIMPs and trials of medical devices  
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1.0 Background

The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union. It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as the Regulations in the rest of this document.

Regulation 3, as amended by Statutory Instrument 2006/1928, requires that a Clinical Trial of an Investigation Medicinal Product (CTIMP) has to have a named Sponsor. As stated in the Regulations, the role of the Sponsor “in relation to a clinical trial, [is] the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial”. Therefore all proposed research which falls within the scope of the Regulations will require a formal confirmation from the Sponsor.

This SOP describes the processes that are involved for obtaining University of Manchester (UoM) sponsorship approval, for research projects led by staff from the UoM and where funding bodies require a Sponsor to be identified as part of the application; and which fall under the UK Policy Framework for Health and Social Care Research, and the Medicines for Human Use (Clinical Trials) Regulations 2004.

The Chief Investigator (CI) of a proposed CTIMP or trial of a medical device, who wishes the UoM to consider Sponsorship of the trial, must approach the Research Governance Ethics and Integrity Team (Clinical Trials Officer) prior to funding submission. Where an external organisation will be the likely Sponsor of a research project, (this includes all non-commercial and commercial entities), the investigator must register the proposed research project with the Research Governance, Ethics and integrity team (See SOP Registration of non-UoM CTIMP). Even if not required by the proposed funder, the UoM expects that all proposed CTIMPs have written confirmation of Sponsorship in principle prior to the submission of any funding application.

Generally speaking the University is only able to consider Sponsoring Trials which are run with the involvement of a UK registered clinical trials unit (CTU).

2.0 Purpose

This SOP ensures compliance with Sponsorship processes and allows the UoM to:
- Risk assess the proposed research for Sponsorship purposes
- Discuss UoM processes with the CI
- Discuss research governance issues with the CI
- Ensure that all necessary regulatory approvals are in place, before the project starts
- Allow the UoM, as the employer of the CI, to have oversight of the research activities
- Ensure that the Chief Investigator has suitable insurance in place before the project starts
3.0  Roles and Responsibilities

Whilst the Sponsor is responsible for the initiation, management and financing of the clinical trial, the Sponsor holds the CI to account via the investigator agreement although there can be no diminution of the Sponsor’s responsibility. The Sponsor requires a deputy CI to be nominated in the case that the original CI has to step down or is away for a prolonged period of time. An investigator agreement must be signed by the CI and Sponsor before Sponsor greenlight to start the trial can be issued.

The Clinical Trials Management Group (CTMG) is empowered by the University to determine if the UoM can act as Sponsor and oversee all such trials. Post funding, all CIs/Trial teams will be required to report quarterly on the progress of their trial. This will increase to monthly once the trial is open to recruitment, subject to risk.

In addition to the regulatory requirement to register all clinical trials on a public database (EudraCT is mandatory for CTIMPs), all finalised protocols will be uploaded onto the relevant trial portfolio page on the Research Governance, Ethics and Integrity webpages.

4.0  Procedure

In order for the University to consider sponsorship requests, the CI must be substantively employed by the University of Manchester or hold an Honorary contract with the University.

4.1  Pre-Funding

The CI must contact the Research Governance, Ethics and Integrity team to discuss sponsorship before submitting any funding application, if the proposed research project is a CTIMP or a medical device. It is the responsibility of the CI to liaise as early as possible with the Research Governance, Ethics and Integrity team with the UoM requiring a lead time of 12 weeks in order for the Sponsor to risk assess the study, provide guidance and make a decision whether to provide Sponsorship in principle.

The CI must contact the Research Governance, Ethics and Integrity team (Clinical Trials), where a proposed research project is a CTIMP/Medical Device, and forward a copy of the research protocol. For CTIMPs, the University expects both the HRA protocol template (https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/) and PIS/consent guidance (http://www.hra-decisiontools.org.uk/consent/) to be used during document development. Where there is a doubt as to whether the proposed research project falls under the Regulations, the MHRA Clinical Trials algorithm should be consulted. If it is still not clear whether the proposed research will be subject to the Clinical Trial Regulations, the protocol should be referred to the MHRA (clintrialhelpline@mhra.gsi.gov.uk) with the question “Is this research subject to the clinical trial regulations?”
The Research Governance, Ethics and Integrity team (Clinical Trials) will require evidence of the proposed research having undergone internal (where necessary external) peer-review, before undertaking a risk assessment based on the research protocol.

In order to reach a final decision about new sponsorship requests the University requires the following information related to the trial. In order to minimise delays the CI should start gathering the information as soon as possible. There is no need to delay contacting the Clinical Trials team until all the information is available, but a decision about Sponsorship cannot be reached until all this has been completed (even if the deadline for grant submission is imminent):

1. Confirmation of who the CI is and a copy of their CV (updated within the last 2 years)
2. Confirmation of the clinical trial phase for the trial
3. Confirmation that the proposed study is classed as a CTIMP if applicable
4. A trial protocol to enable the sponsor to risk assess the trial and categorise the potential risk associated with the IMP (Type A, B or C) [http://www.ct-toolkit.ac.uk/routemap/risk-assessment/](http://www.ct-toolkit.ac.uk/routemap/risk-assessment/)
5. Confirmation of engagement with a statistician and statistical review
6. Confirmation of a data management plan
7. Confirmation of peer-review and Faculty approval
8. Details of costings carried out to date: costings must include costs for a clinical trials unit involvement, costs for MHRA fee, archiving costs, costs for the IMP and placebo, pharmacy costs, Sponsorship costs – please provide copy of the Costings/Pan Man form (FBMH)
9. An outline of trial timelines from idea to archiving, including all submission deadlines
10. Confirmation that the lead NHS R&D site has agreed to host the CTIMP(s) and confirmation of other host organisations
11. The name of the proposed lead pharmacist and evidence of in principle acceptance by the pharmacist and the pharmacist’s employer
12. Confirmation of vendors likely to be used in the trial and confirmation (at least in principle) of what activity they will be providing (e.g. CTU, IMP distributor, randomisation service, GMP facility, Laboratories) – each vendor to be listed separately
13. Proposed archiving arrangements and costs

If a CTU is being used, the University will require the following information:

1. A complete list of activities the CTU has agreed to provide for the trial (please point out any cost related activities the CTU has not agreed to carry out)
2. Confirmation regarding the level of trial management that the CTU will provide and what the CTU expects the Sponsor/CI to undertake
3. Confirmation of the IMP costs, including any manufacturing, labelling, distribution and storage costs the CTU has provided for this trial
4. Confirmation of who the lead pharmacist for this trial is, as agreed with the CTU, including their role and responsibility
5. Confirmation of the proposed level of monitoring for this trial as agreed with the CTU
6. Any issues the CTU has raised for this application that remain unresolved
7. Any issue where in the opinion of the CTU there is a lack of clarity e.g. is there an activity that hasn’t been considered or costed or is there uncertainty about who is or should be providing the activity
The UoM follows a risk based approach and will not usually sponsor studies which are classified as high risk following a risk assessment.

The in-principle agreement, stating that the UoM is prepared to undertake responsibility as a Sponsor, will be given in writing before the funding application can be submitted.

4.2 Post-Funding
Once funding is secure, the CI should contact the Sponsor immediately. The Sponsor will perform a further risk assessment (including a separate IMP risk assessment if applicable) based on both the original and any updated information. The study team will also be asked to complete a Study Risk Assessment/Management Plan and a Risk Categorisation Template.

A final UoM decision to Sponsor a trial is dependent on HRA/MHRA and other relevant approvals. The HRA Approval process was implemented in March 2016 for all studies in the NHS in England (see https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/). Before submission to the HRA/REC (via the Integrated Research Application System) the UoM will issue a Sponsor letter and both indemnity and insurance cover. This written confirmation of full Sponsorship needs to be obtained prior to application submission for the HRA and MHRA.

All documentation should be sent to the Sponsor for review before permission to submit to the HRA and MHRA is granted. All documentation will be cross referenced and must be version controlled. The Sponsor requires evidence of statistical and pharmacy input as appropriate.

Following review by the relevant bodies, any conditions set out for each approval will also be reviewed by the CI, trial team and Sponsor before a final response is generated and submitted. Final approvals must be in place before the Sponsor will give ‘greenlight’ for a study to open to recruitment.

Upon study completion, it is the responsibility of the Chief Investigator (Delegated from the Sponsor) to notify the competent authorities and the REC within 90 days of the trial end as defined in the protocol.

The CTMG has the power to withdraw Sponsorship if deemed necessary/appropriate.

Please see Appendix I for the process map illustrating the process detailed above.

5.0 Appendices

Appendix I - Overview of the CTIMP/Medical Device Approval Process at the Pre Funding Stage

Appendix II - Overview of the CTIMP/Medical Device Approval Process at the Post Funding Stage

UoM/UoM Sponsorship of Study/SOP03/4.0
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6.0 References

- UK Policy Framework for Health and Social Care Research
- UK Clinical Trial Regulations
APPENDIX I: Overview of the CTIMP Approval Process at the Pre-Funding Stage

Sponsorship request from CI → Sponsor Review → Decision

- Faculty Approval
- PartMan/Coding

Sponsor review

- Protocol
- Sponsor list including investigators
- Contracts
- Consent
- CTU
- Pharmacy
- CMI

YES

- Sponsorship agreed

NO

- Sponsorship declined

In principle agreements with sponsor
T&Cs
APPENDIX II: Overview of the CTIMP Approval Process at the Post-Funding Stage

Cl contacts Sponsor → Sponsor Review → Decision

- Pan Man
- Protocol
- Vendor full including labs
- Contracts
- Conting
- CTU
- Pharmacy
- GMT

GO
Submit full application to HRA/REC/MHRA

NO GO
Sponsorship removed

Final agreement to Sponsor T&Cs

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