MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

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Title:	Processing Requests for Sponsorship (CTIMPs, Medical Device and other studies)		
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Version	Date	Summary of Changes
2.0	January 2013	Update of weblinks and office details
2.1	March 2014	Review
3.0	August 2016	Update of weblinks, office details and minor changes to text
4.0	March 2018	Update to reflect changes to processes
5.0	March 2020	Corrections and clarifications to process. Scope extended to ATIMPs & Medical Device trials.
6.0	March 2025	Updates to align with: UoM Policy on CTIMPS and Medical Devices DoH updates – Subject to participant? ICH-GCP changes HRA (CWoW), MHRA guidance (Is it a CTIMP?)

When using this document please ensure that the version you are using is the most up to date either by checking on the Research Governance, Ethics and Integrity Team website for any new versions or contacting the author to confirm the current version.

1.0 Background

All clinical trial activities conducted under this SOP are in line with the applicable UK legislation governing clinical trials of investigational medicinal products and/or medical devices. This includes, but is not limited to, the Medicines for Human Use (Clinical Trials) Regulations 2004 and any subsequent amendments or replacement legislation, such as the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, effective from 28 April 2026. All procedures will be carried out in accordance with current guidance issued by the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Research Authority (HRA), relevant Research Ethics Committees (RECs), and updated GCP standards. This SOP will be reviewed as detailed above or upon significant changes to the regulatory framework to ensure continued compliance.

Regulation 3, as amended by Statutory Instrument 2006/1928, requires that a Clinical Trial must 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 formal confirmation from the Sponsor.

2.0 Purpose and Scope

This SOP describes the process for obtaining University of Manchester (UoM) sponsorship approval, for CTIMPs/ATIMPs/Medical Device trials or other research deemed high risk, led by staff from the UoM and which may fall under the UK Policy Framework for Health and Social Care Research, the Medicines for Human Use (Clinical Trials) Regulations 2004, Medical Devices Regulations 2002 (SI 2002 No 618, as amended and compliance with good clinical practice standards (ISO 14155). This SOP describes the standard procedure for the review of trials on behalf of the sponsor by the UoM Research Governance, Ethics and Integrity Team (RGEIT) (Clinical Trials) to ensure they are appropriate for UoM Sponsorship and to agree ongoing oversight of trial activities prior to granting Sponsor approval.

Even if not required by the proposed funder, the UoM expects that all proposed Clinical trials have written confirmation of sponsorship in principle prior to the submission of any funding application.

3.0 Roles and Responsibilities

Whilst the Sponsor is responsible for overseeing the initiation, management and financing of the clinical trial, some responsibilities (including management) may be delegated to other persons or organisations where skills and facilities are in place to support this, and

there can be no diminution of the Sponsor's responsibility. An investigator agreement must be signed by the CI and Sponsor, and a signed delegation of duties in place before Sponsor approval is granted to commence the trial.

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.

4.0 Procedure

The procedure for obtaining UoM Sponsorship is split into two stages; pre and post funding.

4.1 Pre-Funding

The CI is required to contact the RGEIT (Clinical Trials; Email: clinicaltrials@manchester.ac.uk) to discuss sponsorship of a trial before submitting the funding application. The CI should allow six weeks for RGEIT to collaborate effectively with them on risk assessment, design and the decision whether to sponsor. The RGEIT adopts a risk-based approach to trial sponsorship, where Sponsorship in principle is decided on the outcome of the completed **Sponsor Pre-funding Risk Assessment Template.**

The RGEIT will request the information listed below to provide an in-principle decision on Sponsorship prior to the funding application submission. To minimise delays the CI should start gathering the information as soon as possible. There is no need to delay contacting the RGEIT until all the information is available, but an in-principle decision about Sponsorship may not be reached until all the below has been received (even if the deadline for grant submission is imminent):

1. Confirmation of who the CI is (the CI must be substantively employed by the University of Manchester or hold an honorary contract with the University) and a copy of their CV (updated within the last 2 years).
2. Confirmation of the clinical trial phase for the trial/medical device classification.
3. IMP Risk Categorisation Template (not relevant for Medical Devices).
4. Confirmation that the proposed study is classed as a CTIMP/ATIMP/Medical Device trial if applicable (where there is doubt as to whether the proposed research project falls under the Regulations, the MHRA Clinical Trials algorithm should be consulted (see references). If there is uncertainty, the sponsor (RGEIT and a Clinical Trials Pharmacist) will make the final decision.
5. A trial protocol or outline.
6. Confirmation of engagement with a statistician and statistical review (if CTU not used) (some studies e.g. small pilot studies may not be required).

7. Evidence of the proposed research having undergone internal (where necessary external) peer-review
8. Completed UoM Insurance Assessment form (if required) to be sent to Insurance Office.
9. Faculty approval email from the Research Support Manager)
10. Costings confirmation, generating research proposal in PURE to include details of costings for CTU involvement (or project manager salary), MHRA fees, archiving (paper and electronic – clinical trials need to be archived for up to 30 years), the IMP and placebo, pharmacy, and Sponsorship.
11. An outline of trial timelines/Gantt chart.
12. Confirmation that the lead NHS R&I location has agreed to host the trial and confirmation of other host organisations.
13. For CTIMP trials, the name of the proposed lead pharmacist and evidence of in principle acceptance by the pharmacist and the pharmacist's employer.
14. List 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).
15. Checklist for clinical trial 3rd party contracts.

<u>If a CTU/CRO is being used, the University will require the following information in addition to the above</u>:

16. A complete list of activities the CTU/CRO has agreed to provide for the trial.
17. Confirmation regarding the level of trial management that the CTU/CRO will provide and what the CTU/CRO expects the Sponsor/CI to undertake.
18. Confirmation of the IMP costs, including any manufacturing, labelling, distribution and storage costs the CTU/CRO has provided for this trial
19. Confirmation of the proposed level of monitoring for this trial as agreed with the CTU/CRO.
20. Confirmation of the proposed level of safety monitoring and data collection for this trial as agreed with the CTU/CRO
21. Confirmation of who the lead pharmacist for this trial is, as agreed with the CTU/CRO, including their role and responsibility.

Where there is no CTU/CRO involvement the above information will need to be provided by the CI.

<u>To be completed by Sponsor:</u>

22. Sponsor pre-funding risk assessment.

Once the above information has been received, the in-principle agreement, stating that the UoM is prepared to undertake responsibility as a Sponsor, must be communicated before the funding application can be submitted.

4.2 Post-Funding

The Sponsor must be informed of the status of the funding application. Once funding is secured, the CI should contact the Sponsor immediately. The Sponsor should also be informed if the funding application is unsuccessful or if the trial is abandoned.

4.2.1 Sponsor review prior to regulatory submission

All final application documentation must be submitted to the Sponsor for review prior to the Sponsor granting permission to proceed with submission to the HRA and MHRA via the combined ways of working scheme (CWoW).

Part 1 of the Sponsor Greenlight checklist must be completed to confirm that the Sponsor has received and reviewed all documents intended for submission to the Regulatory Authorities. This review ensures that the information is consistent across all documentation, is compliant with GCP principles, and meets both regulatory and Sponsor requirements. It also confirms that the Chief Investigator is a University of Manchester employee, is appropriately qualified to lead the trial, and that suitable funding, trial management arrangements, and oversight structures are in place. Any risks identified during the pre-funding risk assessment must be mitigated to an acceptable level.

The RGEIT requires 10 working days from receipt of the complete document package to carry out this review. Once part 1 of the Sponsor Greenlight checklist is completed, the UoM will issue a Sponsor letter and both indemnity and insurance cover to the trial team. This written confirmation of full Sponsorship needs to be obtained prior to submission of application to the HRA and MHRA.

4.2.2 Sponsor Greenlight for trial to begin

Following review by the relevant bodies, any conditions set out for each regulatory approval will also be reviewed by the CI, CTU trial team/Project Manager and Sponsor before a final response is generated and submitted. A UoM decision to Sponsor a trial is conditional on the trial receiving HRA/MHRA and other relevant approvals.

Once all relevant approvals are in place, part 2 of the Sponsor Greenlight Checklist can be completed with support from the trial manager. The RGEIT requires 10 working days from receipt of the last complete document package to carry out this review.

Alongside the regulatory obligation to register all clinical trials on a publicly accessible database, a summary of the trial will be published on the Research Governance, Ethics and Integrity webpages.

4.3 Ongoing Sponsorship

Where the University of Manchester is the sponsor of CTIMPs/ATIMPs/Medical Device trials or other research deemed high risk, such trials will come under the Clinical Trials Management Group (CTMG) authority. The CTMG is empowered by the University of Manchester to oversee all sponsorship responsibilities.

The CI is required to submit Sponsor Quarterly reports throughout the lifecycle of the study, starting from the point when funding has been confirmed and until archived (UoMSOP20 Archiving). The Sponsor must be kept informed of progress with applications, approvals, and planned amendments. Further conditions of Sponsorship are detailed in the Investigator Agreement.

5.0 References

UK Policy Framework for Health and Social Care Research
The Medicines for Human Use (Clinical Trial) Regulations and subsequent amendments
MHRA Clinical Trials Algorithm
UoMSOP20 Archiving
Investigator Agreement
SOP Risk Assessment
UoM Insurance Assessment Form

6.0 Appendices

Appendix 1: Overview of Sponsorship process.

APPENDIX 1

Overview of Sponsorship process

1) Pre-funding stage:
   - Minimum information from CI (listed within this SOP, Section 4.1)
   - Sponsor pre-funding RA completed
   - Risk categorisation template (for CTIMPs)
   - Checklist for clinical trial 3rd party agreements

➔ Sponsorship in principle provided

If the funding application is successful,

1. Inform the Sponsor.
2. Quarterly Reporting will begin (RGEIT will provide the template) to keep Sponsor informed of progress.

If the funding application unsuccessful or the trial is abandoned, please inform the Sponsor.

2) <u>MHRA/HRA/REC Pre-submission stage:</u>
Sponsor green light part 1 completed
➔ Sponsorship letter and insurance certificate provided

3) <u>Pre-trial green light stage:</u>
Sponsor green light part 2 completed
➔ Sponsor green light form signed off indicating green light for trial to begin participant recruitment.