



Standard Operating Procedure

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Title:	Processing Requests for Sponsorship		
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Version	Date	Reason for change
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	July 2020	Corrections and clarifications to process. Scope extended to ATIMPs & Medical Device trials.

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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. Regulatory requirements for Sponsorship of CTIMPs also apply to Medical Device trials and trials of Advanced Therapy Investigations Medicinal Products (ATIMPs).

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, and the Medicines for Human Use (Clinical Trials) Regulations 2004. This SOP describes the standard procedure for the review of trials 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.

Where an external organisation will be the Sponsor of a trial, but the Chief Investigator (CI) is an employee of the UoM (this includes all non-commercial and commercial entities), the investigator must still register the proposed trial with the RGEIT (See SOP Registration of non-UoM CTIMP). Even if not required by the proposed funder, the UoM expects that all proposed 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 the initiation, management and financing of the clinical trial, some responsibilities 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.

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), however any decision to Sponsor a trial that does not involve a CTU must be justified and this justification documented in the Sponsor pre-funding risk assessment. 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 must contact the RGEIT (Clinical Trials) to discuss sponsorship of a trial before submitting the funding application. It is the responsibility of the CI to liaise as early as possible with the RGEIT. The RGEIT requires a lead time of 12 weeks to risk assess the study, provide guidance and make a decision whether to provide Sponsorship in principle. The UoM follows a risk based approach.

The RGEIT will request the following information in order to provide an in-principle decision on Sponsorship prior to the funding application submission. In order 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 of 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 it is still not clear, the MHRA should be contacted for advice at clintrialhelpline@mhra.gsi.gov.uk).
5. A trial protocol or outline.
6. Confirmation of engagement with a statistician and statistical review (if CTU not used)
7. Evidence of the proposed research having undergone internal (where necessary external) peer-review
8. Faculty approval (evidenced by completed Pan Manchester Notification (PanMan) Form)
9. Costings/PanMan Form to include details of costings for CTU involvement, MHRA fees, archiving, the IMP and placebo, pharmacy, and Sponsorship.
10. An outline of trial timelines.
11. Confirmation that the lead NHS R&D site has agreed to host the trial and confirmation of other host organisations.
12. The name of the proposed lead pharmacist and evidence of in principle acceptance by the pharmacist and the pharmacist's employer.
13. 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).
14. Checklist for clinical trial 3rd party contracts.

15. UoM Insurance Assessment form to be completed by the CI if any of the insurance conditions apply, or at the RGEIT's request if the trial is considered high-risk.

If a CTU is being used, the University will require the following information in addition to the above:

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

To be completed by Sponsor:

21. Sponsor pre-funding risk assessment.
22. Completed UoM Insurance Assessment form (if required) to be sent to Insurance Office.

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 given in writing before the funding application can be submitted.

4.2 Post-Funding

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 should be sent to the Sponsor for review before permission to submit to the HRA and MHRA is granted.

Part 1 of the Sponsor Greenlight checklist must be completed to ensure Sponsor receipt and review of all trial documents that will be submitted to the Regulatory Authorities. The purpose of this review is to ensure information is consistent across documentation, compliant with GCP principles and relevant regulatory and Sponsor requirements that the CI is an employee of the University of Manchester and is suitably qualified to run the trial, and that appropriate funding, trial management and oversight is in place. Any risks identified during the pre-funding risk assessment must be mitigated to an acceptable level.

The RGEIT require 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 application submission to the HRA and MHRA (see UoMCTSOP07 Clinical Trial Authorisation).

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, trial team 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, the Sponsor will complete part 2 of the Sponsor Greenlight Checklist with support from the trial manager, in order to ensure that all relevant approvals have been received, all required agreements are in place, final versions of approved documents have been received, and all management procedures are in place, prior to giving 'greenlight' for a trial to open to recruitment. The RGEIT require 10 working days from receipt of the complete document package to carry out this review.

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

All Greenlight decisions must be subsequently endorsed by CTMG, which has the power to withdraw Sponsorship if deemed necessary/appropriate.

4.3 Ongoing Sponsorship

From the point where funding has been confirmed, all CIs/trial teams will be required to report quarterly on the progress of their trial to the Sponsor. Quarterly reporting should continue throughout the trial until the end of the trial report is submitted to regulatory authorities and the data is published. The Sponsor should 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
EU Good Clinical Practice (GCP) Directive 2001/20/
The Medicines for Human Use (Clinical Trial) Regulations and subsequent amendments
MHRA Clinical Trials Algorithm:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf

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 SOP)
- Sponsor pre-funding RA completed
- Risk categorisation template
- Checklist for clinical trial 3rd party contracts

➔ Sponsorship in principle provided

Funding application successful? ➔ Inform Sponsor
➔ Quarterly Reporting to begin (RGEIT will provide template) to keep Sponsor informed of progress.

Funding application unsuccessful or trial abandoned? ➔ Inform Sponsor

2) MHRA/HRA Pre-submission stage:

Sponsor green light part 1 completed

➔ Sponsorship letter and insurance certificate provided

3) Pre-trial green light stage:

Sponsor green light part 2 completed

➔ Sponsor green light form signed off indicating green light for trial to begin