The University of Manchester

Standard Operating Procedure

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Version	Date	Summary of Changes
1.0	March 2018	First Version
2.0	March 2024	Update of weblinks and minor changes to text

MANCHESTER 1824
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1 Introduction

All Clinical Trials of Investigational Medicinal Products (CTIMPs) must be compliant with The Medicines for Human Use (Clinical Trials) Regulations (2004 and subsequent amendments). These trials also fall under the RUK Policy Framework for Health and Social Care Research, which states that the Sponsor, Chief Investigator and Funder should ensure appropriate arrangements for making data accessible in a timely manner after the study has finished. Moreover, there is a recent strategy by HRA and the UK Policy Framework for Health and Social Care Research to 'Make it public; transparent and open.

The ICH harmonised Guideline for Good Clinical Practice (GCP) also states that "the contents of a clinical trial protocol should generally include [a] publication policy, if not addressed in a separate agreement".

2 Purpose and Scope

The purpose of this SOP is to ensure that the University of Manchester, when acting as Sponsor, follows best practice and fulfils its obligation to publish and disseminate all clinical trial study results. This includes conference abstracts, presentations, peer reviewed journals and any other types of dissemination. Dissemination of any data must be in accordance with relevant prior agreements with e.g. Funder.

3 Responsibilities

The author/authors of any publication (journal, abstract etc.) must ensure that the information included is accurate and original, with any co-authors having made a significant contribution listed. Following ICMJE guidelines for journal publication, authorship is dependent on the following criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Contributors who do not meet the aforementioned criteria should be appropriately acknowledged.

Any conflicts of interest, across any contributors, should be declared.

4.1 Chief Investigator (CI)

In addition to the above, the CI has the responsibility to ensure that all data emerging from their study is published in a timely manner and that all contributors are adequately acknowledged.

The CI should also ensure that the trial statistician has had appropriate input into any publication/data set and that manuscripts have been reviewed by the TSC, IDMC and other relevant parties e.g. IMP manufacturer, Contract Manager where applicable. The CI should be aware of all stipulations detailed in any agreements and adhere to them.

4.2 Sponsor

The RGEIT monitors deadlines for publication of final reports (where this is needed for a journal, this should be done within 1 year of the end of the study.
MHRA requires that Sponsor has oversight the standards of the Publishing data (primary and secondary). Assurance need to be provided, whether the data is or is not analysed to GCP standards.
For CTIMPs a medical device trials a summary of results should be published within one year of the end of study via chosen registry as declared in trial submission.
All manuscripts must be provided to the Sponsor for review by the University's Clinical Trials Management Group before submission. All publications must adhere to all agreements where publication rights are detailed.

4 Related Documents

No related documents in place for this SOP

Reference Number	Document Title

5 Procedures

The Participant Information Sheet (PIS) of each trial should address what will happen to the results at the end of the study. The PIS, along with the informed consent form, should explain how the confidentiality of participants will be maintained throughout the dissemination of such results. HRA/REC submission documents should also explain whether and how a summary of trial outcomes will be available to participants. These documents will be reviewed and approved by the relevant research ethics committee.
Publication plan details must also be clearly documented in the protocol. It is good practice to agree an authorship policy well before the trial analysis commences, either as a separate document or as an annex to the protocol.

5.1 Publicly Accessible Databases

UK Policy Framework for Health and Social Care Research now requires "information about the research [to be] publicly available before it starts". All

CTIMPs Clinical Trials must be registered on the EudraCT ClinicalTrials.gov database as a minimum. From 1 January 2022 the Health Research Authority (HRA), as part of the Combined Review Process, will automatically register clinical trials with ISRCTN Registry as one of the steps to ensure research transparency. The final protocol will also be made available on the University's externally facing website.

6 References

HRA Research transparency:
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/
MHRA guidance:
https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk
ICMJE guidelines for journal publication:
https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html