RESEARCH & ENTERPRISE SERVICES
RESEARCH ETHICS, INTEGRITY & GOVERNANCE

UNIVERSITY OF SUSSEX

Standard Operating Procedures - CTIMP Reporting, Project Publication and Dissemination

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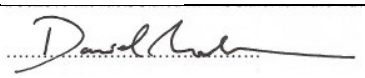
Authorised by: Dr Daniel Michelson **Designation:** SSC Chair		11 June 2021

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Acknowledgement – University of Aberdeen

[1] http://www.sussex.ac.uk/staff/research/governance

1 Purpose

1.1 This SOP describes the processes that are involved in the reporting of results for a Clinical Trial of an Investigational or Medicinal Product (CTIMP).

1.2 The scope of the document is for all schools at the University of Sussex, all members of staff with substantive employment and students registered at the University (including Brighton and Sussex Medical School).

1.3 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 1 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.

2. Introduction

2.1 As of 21 July 2014, it has been mandatory for sponsors to post clinical trial results in the European trials Database (EudraCT), managed by the European Medicines Agency (EMA). This is stipulated in Directive 2001/20/EC and the Paediatric Regulation. It is expected to be replaced by Regulation EU No 536/2014 in the course of 2019.

2.2 Under these regulations, Sponsors have 12 months to post results (6 months for paediatric clinical trials) following the end of trial.

3. Responsibilities

Chief Investigator (CI)

3.1 The Chief Investigator (CI) should approve all submitted trial reports (and trial publications), in particular by guaranteeing their clinical and methodological validity. They will ensure that study findings are published and disseminated appropriately and maintain awareness of funder requirements in respect of study publications and the need inform the funder of any impending publications.

All authors

3.2 All authors should Declare relevant conflicts of interest as specified by funder/journal policies.

The Sponsor

3.3 The Sponsor will identify any issues which must be reflected in the publication and ensure CI posts clinical trial summary results in EudraCT.

4. Procedure

4.1 There is an obligation to full and open publication of research project results, regardless of findings. Research projects with null results, those which failed to recruit to target and those which were unexpectedly terminated, all need to be published. In so far as possible, CTIMPs should be reported to their planned intentions and as soon as is practicable.

4.2 The results of all CTIMPs and Medical Device trials shall be appropriately disseminated through publication in peer-reviewed scientific journals.

4.3 Many funding bodies will publish a final report upon completion of the research project. The format and deadline for these reports will differ depending on the funder. If a final report is required the CI must ensure that they complete these reports accurately and submit within the specified time frame.

Registration of CTIMP Prior to Recruitment of first participant

4.3 It is a condition of University of Sussex Sponsorship that **before the first participant is recruited**, the *study shall be registered with a summary of the approved trial protocol on a recognised clinical trials database*.

4.4 If the study is registered on the Central Portfolio Management System (CPMS) the trial should be registered on the International Standard Randomisation Clinical Trial Number (ISRCTN) http://www.isrctn.com/page/faqs#aboutISRCTN. It is free to use via the CPMS system https://www.nihr.ac.uk/documents/ISRCTN-registration/11585#What_if_my_study_has_an_ISRCTN_reference_or_is_registered_with_another_registe [2]

Authorship

4.5 There shall be a clear statement of authorship policy included in the study protocol. This shall include all individuals who have made a substantial academic contribution according to the guidance and recommendations of the International Committee of Medical Journal Editors (ICMJE) http://www.icmje.org/

4.6 Authorship should be based on the following **four** criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- Drafting the work or revising it critically for important intellectual content;
- Final approval of the version to be published;
- 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.

4.7 The University of Sussex requires that all research and its associated conduct (including the attribution of authorship) meets the standards of the *Code of Practice for Research*[3].

Acknowledgement of funders and any disclaimers

4.8 The contributions of funders should be clearly acknowledged. Where a format for this acknowledgement has been specified by the funder(s) the CI must ensure this is followed. The CI must also ensure that any contractual obligations to the funder relating to publications are met including any requirements for prior notification of the publication of project outputs.

[2] Contact the Sponsor's Representative via researchsponsorship@sussex.ac.uk for further information.
[3] https://www.sussex.ac.uk/webteam/gateway/file.php?name=code-of-practice-for-research-june-2018.pdf&site=377

4.9 It is often necessary to include an appropriate disclaimer (e.g. funder's disclaimer) when reporting research findings or opinions.

Acknowledgement of regulatory bodies and Sponsor

4.10 Authors must include details of the Sponsor, any ethics committee and other approvals (e.g. Medicines and Healthcare products Regulatory Agency (MHRA)) within the manuscript. Where applicable all study reference numbers (e.g. Research Ethics Committee (REC), MHRA, etc.) shall be stated in the publication.

Acknowledgement of Trial Steering Committee and Data Monitoring Committee as relevant

4.11 To maintain their strict independence, independent members of the Trial Steering Committee (TSC) and independent Data Monitoring Committee (DMC) members should not gain any academic credit by being a co-author on study publications.

4.12 The role of individual members of the TSC and DMC should be gratefully acknowledged unless they request otherwise.

Dissemination

4.13 There shall be a commitment to disseminate outputs from the research project to study participants, the general public, internally within the University, and to professional and lay publications when appropriate.

Dissemination to participants

4.14 The process for disseminating results to participants shall have been addressed at the time of ethical approval and detailed in the protocol. Any deviations from this should be discussed and agreed with Sponsor.

Dissemination to the public

4.15 Consideration shall be given to issuing a press release. It is advisable that research personnel contact the appropriate communication/press office teams in the University. If the press release contains research project results the press release should be embargoed until the day of publication. The CI must also ensure that any contractual obligations to the funder are met including any requirements for prior approval of press releases or other media material. All relevant parties including the funder and Sponsor shall be informed in advance of any press release.

4.16 It is mandatory for the Clinical Trial summary results to be posted in EudraCT and subsequent MHRA stipulated systems within a specific period following the end of the trial (six months for paediatric and twelve months for other trials).

5. Training

5.1 This is a 'read and understand' SOP. Please note that the Research Governance Office discourages the retention of hard copies of SOPs and can only guarantee that the most up-to date version is on the University website.

6. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational or Medicinal Product
CTU	Clinical Trials Unit
CV	Curriculum Vitae
EU	European Union
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GP	General Practitioner
HRA	Health Research Authority
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IMP	Investigational or Medicinal Product
ISF	Investigative Site File
IRAS	Integrated Research Application System
JCRO	Joint Clinical Research Office
MHRA	Medicine and Healthcare Products Regulatory Agency
NHS	National Health Service
PI	Principal Investigator
PIS	Patient Information Sheet
R&D	Research and Development
REC	Research Ethics Committee
REIGO	Research Ethics and Integrity Office
SOECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reactions)
TMF	Trial Master File
US	University of Sussex

7. Cross Referenced SOPs

SOPRG01 Sponsorship approval - CTIMPs

8. References

EUDRACT Database - https://eudract.ema.europa.eu/

Clinical Trials.gov database - https://clinicaltrials.gov/

HRA Publication and dissemination of research findings

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/publication-and-dissemination-research-findings/

ICMJE Defining the Role of Authors and Contributors

http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

NIHR How to disseminate your research: Getting your message heard - and used

https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/manage-my-study/how-to-disseminate-your-research

Clinical Trials Regulations 2004 (SI 2004/1031)
http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

Clinical Trials Regulations 2006 (SI 2006/1928)

http://www.legislation.gov.uk/uksi/2006/1928/pdfs/uksi_20061928_en.pdf *UK*

Policy Framework Health and Social Care Research

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/ukpolicy-framework-health-social-care-research/

Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

NIHR Clinical Trials Toolkit - http://www.ct-toolkit.ac.uk/

Code of Practice for Research, University of Sussex
https://www.sussex.ac.uk/webteam/gateway/file.php?name=code-of-practice-for-research-june-2018.pdf&site=377

Good Clinical Practice, International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use

https://www.ich.org/page/efficacy-guidelines