1. Introduction

This Standard Operating Procedure (SOP) describes the requirements for ensuring all research results and findings are appropriately reported and disseminated.

Investigators have an obligation to the scientific community, and current and future patients, to provide full and open disclosure of research project results, whatever the findings. Research projects with null results, those which failed to recruit to target, and those which were unexpectedly terminated all need to be reported. Research outputs can be disseminated via a variety of mediums, one of which is peer reviewed academic journals and publications. Research results must also be published in accordance with regulatory requirements and the Health Research Authority research transparency strategy.

2. Scope

This SOP applies to all researchers and any external individuals who are involved in drafting reports, publications and other methods used to disseminate results relating to research sponsored by University Hospitals of Leicester (UHL).

3. Responsible Personnel

The Chief Investigator (CI) will be responsible for ensuring that study findings are reported and disseminated as appropriate and in accordance with national requirements and their study protocol. It is the CIs responsibility to be aware of the funder requirements in respect of study reports / publications and to inform them of any impending publications.

It is the responsibility of all authors to declare all relevant conflicts of interest as specified by individual funder and/or journal policies.

It is the Sponsor's responsibility to ensure that the CI uploads the clinical trial summary results in EudraCT (European Union Drug Regulating Authorities Clinical Trials) where applicable and /or any research database to which the study has been registered (e.g., ISRCTN - International Standard Randomised Controlled Trial Number, Clinical Trials.gov).

4. Requirements

4.1 Results and final study reports

Results of all studies must be reported within 12 months of the published definition of the end of the study. This may be defined as 'Last patient, Last Visit (LPLV), but it may also be the completion of any follow-up monitoring and data collection, as described in the protocol. Where a definition has not been provided, the date of the End of Study Declaration will be taken as the end of the study date.

Where applicable, results and/or final study reports should be uploaded to the publically accessible platform detailed in the initial application e.g. clinical trials.gov/ISRCTN/EudraCT. For clinical trials (CTIMPs, clinical investigations of medical devices, clinical trials of novel interventions or randomised clinical trials to compare interventions in clinical practice), not registering within six weeks of recruiting the first patient is a breach of approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee.

In addition many funding bodies will require a final report. The format and deadline for these may differ depending on the funder.

4.2 Publications

In addition to the results and final study report, many CIs and funders will submit to peer-reviewed scientific journals.

Publications may occur at any time point during the lifetime of a trial. For example, protocols may be published at an early stage. If a trial is closed prematurely, it may still be published, giving such results and conclusions as possible and discussing why the trial was closed. This ensures that data is still available for subsequent meta-analysis. The benefits and hazards of treatment policies are equally important; both must be reported. Publication should be no later however than 24 months after study completion.

All publications, notably those funded by the NIHR, should be open access publications. Failure to facilitate open access publication may be a breach of funding contractual arrangements. Where possible and applicable, funds for open access should be included in grant funding awards.

The format and deadlines for these publications may differ depending on the requirements of the journal. Publications of trials should conform to the CONSORT (Consolidated Standards of Reporting Trials) statement guidelines http://www.consort-statement.org/. The CONSORT statement is a research tool to improve the quality of reports of randomised controlled trials (RCTs). CONSORT comprises a checklist and flow chart to provide a standard way for researchers to report trials. Full details, including a downloadable checklist and flow diagram, may be found on the CONSORT website.

4.2.1 Acknowledgement of Contributors for Publication

4.2.1a) Funders

The contribution of funders should be clearly acknowledged. Where the format of this acknowledgement has been specified by the funder(s), the CI must ensure that this is followed. The CI must also ensure that any contractual obligations to the funder relating to publications are met. This may include prior notification of the publication.

4.2.1b) Disclaimers

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

4.2.1c) Sponsor & Regulatory Bodies

The publication must include details of the Sponsor, any ethics committee and other regulatory bodies such as the MHRA within the manuscript. Where applicable all study reference numbers i.e., IRAS, REC, MHRA, EudraCT, ISRCTN etc. should be stated in the publication.

4.2.1d) Affiliated institutions

All publications that have an author who is affiliated to an institution (e.g. BRC, CRF, CRN, ARC) should acknowledge the institution in author affiliations, funding and by a disclaimer. If acknowledgements are omitted, this will mean your publication will not be included as an output in the returns to the NIHR, which may form part of the contractual reporting process.

4.2.1e) Trial steering committees and data monitoring committees

To maintain strict independence, independent members of the trial steering committee and /or independent monitoring committee members should not gain any academic credit by being a co-author on study publications.

4.2.2 Submission of Publication

The CI or delegate (e.g., Lead Author) must on acceptance of publication to a journal, provide a copy of all publications to the Sponsor and file a copy in the Trial Masterfile/Investigator Site File.

4.3 Authorship

There should be a clear statement of authorship policy included in the study protocol. Authorship should include all individuals who have made a substantial contribution. According to the guidance and recommendations of the International Committee of Medical Journal Editors (ICMJE) http://www.icmje.org all individuals who have made a substantial contribution to the research project, without fulfilling the authorship criteria, should be clearly acknowledged, detailing their contributions.

4.4 Dissemination to participants

The process for dissemination of results to participants will have been addressed at the time of ethical approval and detailed in IRAS/the protocol. Evidence of completion should be filed in the Trial Master File. Any deviations from this should be discussed and agreed with the Sponsor.

5. Education and Training

None

6. Supporting Documents and Key References

Research transparency - Health Research Authority (hra.nhs.uk)

NIHR Open Access policy - articles submitted before 1 June 2022 | NIHR

7. Key Words

Research, Innovation, EudraCT, Transparency, ISRCTN, Clinicaltrials.gov, open access policy

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

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