1. Introduction

This Standard Operating Procedure (SOP) describes the procedure to ensure all research results are appropriately reported and disseminated within the required regulatory timeframe.

1.1)

Investigators have an obligation to the scientific community, 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 in accordance with National transparency requirements.

2. Scope

This SOP applies to all researchers, and any external individual, who are involved in the drafting of reports, publications and dissemination of 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. It is the responsibility of all authors to declare all relevant conflicts of interest as specified
by individual funder/journal policies.

3.1)

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.

3.2)

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 Registered Clinical/Social Study Number, Clinical Trials.gov).

4. Requirements

4.1) Reports

Results of all studies should 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), or any other variation including submission of the 'End of Study Report'. 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.

4.1.1)
Where appropriate reports should be uploaded to the publically accessible platform detailed in the initial application e.g. clinical trials.gov/ISRCTN/ EudraCT. In addition many funding bodies will require a final report. The format and deadline for these may differ depending on the funder.

4.1.2)
Clinical Trials of Investigational Medicinal projects (CTiMPs) must be uploaded to the international register ISCRTN or Clinical Trials.gov. For trials involving both UK and EU sites a record in the EU clinical trials register must also be uploaded.

4.1.3)
The aim is to record information once. It is for this reason that many reports will include Sponsor specific details and those of other Entities and Workflows. This reduces duplication of effort and provides a smooth and more coherent sponsor process.

4.2) Publications

In addition to the 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 e.g. 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.

4.2.1)
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 compromises 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 from the CONSORT website.

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.

5. Acknowledgement of Contributors for Publication

5.1) 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.

5.2) Disclaimers

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

5.3) Sponsor & Regulatory Bodies

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

5.4)

All publications that have an author who is affiliated to an institution (e.g. BRC, CRF, CRN, CLAHRC) 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.

5.5) Trial Steering Committees & 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.

6. Submission of Publication

The CI or delegate (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.

7. Dissemination

7.1) 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.

7.2) Dissemination to the Public

Consideration should be given to the format of dissemination. The CI must ensure that any contractual obligations to the funder are met including any prior approval of press releases or other media material. All relevant parties, including the funder and Sponsor should be approached for approval in advance of any press release(s) being issued. If the press release contains research project results the press release must be embargoed until the date and time of publication. It is strongly advised that research personnel contact the Head of R&I Communications for information and advice prior to a press release being developed.

8. Non Compliance

Failure to demonstrate compliance to this SOP will result in implementation of the SOP S-1016 UHL Non Compliance SOP at a minimum of a CRITICAL Finding.

9. Responsibilities

	Responsibility	Undertaken by	Activity
1	Chief Investigator	Chief Investigator	Ensure that all study findings are reported, published and disseminated in a timely and appropriate manner
2	CI/Author(s)	Author(s)	Ensure that all relevant conflicts of interest are reported as specified by Individual funder/journal policies.
3	CI/Author(s)	Author(s)	Ensure a copy of all reports/publications are made available to the Sponsor and filed in the Trial Master File
4	Chief Investigator/Principal Investigator	Chief Investigator/Principal Investigator	Ensure the posting of clinical trial reports/publications to EudraCT and any relevant research databases.

10. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

11. Guideline Standards and Procedures

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

12. Education and Training

None

13. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Sponsor Audit	Randomly chosen for audit	Carolyn Maloney	As and when	A report will be produced

14. Supporting Documents and Key References

SOP S-1016

15. Key Words

Research, Innovation, EDGE, REC, EudraCT, Transparency

16. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

17.

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NB: Paper copies of this document may not be most recent version. The definitive version is held on Insite in the Policies and Guidelines Library

17.1)

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

17.2)

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Julie James	**Job Title:** Clinical Trials Monitor & Trainer
Reviewed by:	UHL R&I Management Meeting	
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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
November 2019	V2	Carolyn Maloney Julie James	Updated to reflect UHL Transparency responsibilities.
February 2021	V3	CM LW JJ	Clarification of report process to public Research databases, Updating to new trust template

DISTRIBUTION RECORD:			
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