

NHSBT Clinical Trials Unit Publication policy

1. Policy

All clinical trials, studies and other research protocols conducted by NHSBT CTU must be published in a peer reviewed journal, irrespective of the outcome of the research. In addition, trial protocols and statistical analysis plans should be published at an early stage in the research, and certainly before completion of recruitment. This will ensure transparency and inspire confidence in the trial results when they are published. Where appropriate, publications should be in open access journals to ensure access to the widest possible audience.

2. Defining manuscript authorship

The choice of authors of manuscripts should conform with the International Committee of Medical Journal Editors (ICMJE) guidelines (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) to qualify for authorship, contributors should meet the following criteria:

- I. Substantial contributions to study conception and design, or acquisition, analysis and interpretation of data, and
- II. drafting the article or revising it critically for important intellectual content, and
- III. final approval of the version to be published, and
- IV. agreement to be accountable for all aspects of the work to ensure its accuracy and integrity.

All four conditions should be met. Members of the CTU team who do not meet criteria for authorship but who contributed materially to the manuscript will be recognised in the acknowledgments section (as below) when the manuscript is published.

For a manuscript the NHSBT CTU expects the following:

- a) As a minimum, authorship of manuscripts should meet the criteria laid out by the ICMJE and transcribed above.
- b) If the main publication for a large study is to be published under the author name of “Study name Collaborative group” or similar collective name, with a full list of collaborators, this should include all the Clinical Trials Unit members who have been involved in the design, conduct or analysis of the study (including statisticians, data managers, trial managers and coordinators, QC checks, admin team, IT, etc).
- c) The main author should request a list of all members of the CTU to be named as authors from a senior member of the CTU team.
- d) The main author should keep the trial team informed of progress when a publication is submitted or accepted by a journal. A copy of the published paper should be provided to the CTU so it can be kept for the records.

3. Acknowledgement Statement

These following statements should be included in the acknowledgement section of the publication:

“This [project or study or research] was supported by the NHSBT Clinical Trials Unit, including: [list members of CTU who are not study authors and who were involved in the study, could also add their role in the study support e.g. data manager]”.

“The study was adopted onto the [UK’s National Institute for Health Research (NIHR) Clinical Research Network Portfolio]. This report/ manuscript is independent research funded by the [National Institute for Health and Research or NHS Blood and Transplant, or other]. The views expressed in this publication are those of the author(s) and not necessarily those of the [NHS, the National Institute for Health Research or the Department of Health or NHS Blood and Transplant, or other].” *(delete organisations in square brackets as appropriate and add others if necessary).*

The publication should also acknowledge the members of the Trial Steering and Data Management Committees and the research teams at the participating sites by name. It is also good practice to acknowledge the participants for taking part in the study.

4. Data sharing

The data from completed clinical trials must be managed and shared in accordance with our policy on data sharing which follows the ICMJE’s recommendations as below:

<http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>

- a) As of 1 July 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement.
- b) Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript and updated in the registry record.

5. References

1. ICMJE. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals Boston, USA: International Committee of Medical Journal Editors, December 2017. Available at <http://www.icmje.org/>