Standard Operating Procedure
Research Governance

Title:	**Publication and Dissemination of Study Outcomes**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Final v 1.0
Final v 1.0	09/09/11	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	21/08/2012	Periodic Review	Final v 3.0
Final v3.0	31/01/2014	Update of ICMJE Guidelines, CONSORT statement and inclusion of reference to COPE and authorship dispute resolution	Final v4.0
Final v 4.0	06/10/2014	Periodic Review	Final v 5.0
Final v 5.0	18/01/2017	Periodic Review	Final v 6.0

1. Purpose

This Standard Operating Procedure (SOP) provides guidance for the publication and dissemination of study outcomes involving human participants, in particular, clinical trials.

2. Introduction

The International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP) states that the clinical trial protocol should contain a "publication policy, if not addressed in a separate agreement" (GCP 6.15).

There is also a requirement for the publication and reporting of the findings of a randomised controlled trial to be in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement. The CONSORT Statement provides a minimum standard to enable readers to understand the trial design, conduct, analysis and interpretation, which in turn assists the author in ensuring transparency and helps the reader with assessing the validity of the results.

In addition, researchers who involve human participants in their studies will have prepared a participant information leaflet. The leaflet may well make reference to how the results will be shared. Sometimes these leaflets state that each research participant will receive a summary of the results. It should be noted that these information leaflets will have received formal approval by either a NHS/HSC Research Ethics Committee or a School Research Ethics Committee (SREC), therefore, they have become part of the ethical agreement for the research study. The Committee on Publication Ethics (COPE) also provides Guidance on publication and dissemination of research results.

In 1978 the International Committee of Medical Journal Editors (ICMJE) published guidelines providing uniform requirements for manuscripts being submitted to biomedical journals. Although this guidance, last updated in December 2013, was prepared for one particular research community, the good practice outlined within it can be applied by all.

It should also be noted that under ICMJE guidelines that, from 1 July 2008, any research studies that "prospectively assign human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcome" (World Health Organisation) are required to be registered on an acceptable internet based registry, before they can be considered for publication in any of the member journals. The ICMJE has not advocated the use of any one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria (e.g. accessible to public at no charge, managed by a not-for-profit organisation etc).

3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are conducting research within or on behalf of the University.

4. Responsibilities

4.1 Chief Investigator

It will be the responsibility of the Chief Investigator (CI) to ensure that study outcomes are disseminated in accordance with the ethical approval for the study. The CI should endeavour to publish the results from the study in sources such as journals, conferences and scientific meetings, where their work can be scrutinised by peers.

4.2 Author

The person(s) to whom responsibility is delegated to author journal articles, conference presentations, presentation abstracts and posters must ensure their writing is original, accurate, and presented in an objective, balanced manner. Anyone named as an author should have made a substantive intellectual contribution.

5. Procedure

The following procedure has been taken from the ICMJE guidelines.

5.1 Authorship and Contributorship

Authorship credit should be based on all four of the following conditions being met:

- Substantial contributions to conception and design, or acquisition of data, or analysis of interpretation of data;
- Drafting the article 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.

The above criteria are not intended to be used to deny authorship to those who deserve credit and individuals who meet the first criterion should have the opportunity to participate in the review, drafting and final approval of the article or manuscript.

It should be noted that the acquisition of funding, collection of data, or general supervision of the research group alone, does not justify authorship.

Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Increasingly, authorship of multi-centre trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributorship.

All contributors, who do not meet the criteria for authorship, should be listed in an acknowledgements section.

The practice of honorary authorship is unacceptable.

5.2 Conflicts of Interest

In order to ensure transparency it is necessary to disclose any conflicts of interest that may be present in the research, for example if research into a particular drug has been sponsored by the manufacturing pharmaceutical company. Other considerations should include the financial relationships such as employment, consultancies, stock ownership, honoraria, paid expert testimony or personal relationships that may have biased the work. The University's Register of Interests Policy must be adhered to.

5.3 Study Participants

The privacy of study participants should not be infringed without their informed consent. Therefore, all identifiable information such as hospital numbers, names, initials etc

should not be published in written descriptions, photographs and genetic pedigrees unless the information is essential for scientific purposes and the research participant (or parent or legal guardian) gives written informed consent for publication.

Authors also need to indicate whether the ethical standards of the National Research Ethics Service, or appropriate similar body, and with the Helsinki Declaration of 1975, as revised in 2000, were followed.

In addition, authors have an obligation to ensure that study participants are provided with a summary of the outcomes of the study, if they indicated their intention to do so when applying for ethical approval.

5.4 Reporting and Dissemination of Study Findings

In order to ensure that important information is not omitted, authors should ensure, where possible, to provide the results on the following:

- Title Page;
- Conflicts of Interest Notification Page;
- Abstract and Key Words;
- Introduction;
- Methods;
- Results;
- Discussion;
- References;
- Tables, Illustrations (figures), legends for illustrations, units of measurement, abbreviations and symbols.

Further information on Reporting Guidelines can be found in the following websites (last accessed January 2017):

Initiative	Type of Study	Source
CONSORT	Randomized controlled trials	http://www.consort-statement.org/
STARD	Studies of diagnostic accuracy	http://www.stard-statement.org/
PRISMA	Systematic reviews and meta-analysis	http://www.prisma-statement.org/
STROBE	Observational studies in epidemiology	http://www.strobe-statement.org/
MOOSE	Meta-analysis of observational studies in epidemiology	http://jamanetwork.com/journals/jama/fullarticle/192614

5.5 Authorship Disputes

In order to minimise authorship disputes occurring it is good practice to discuss authorship, including order of authorship, at the start of projects rather than at the time of submission of the research to a journal or conference.

Where an internal authorship dispute occurs, involving research that is not yet published or presented researchers should attempt to resolve the dispute at a local level. Where it is not possible for the researchers to resolve the dispute, the matter should be referred to the Head of School or Institute Director to review and mediate an agreed solution. Manuscripts for which there is an unresolved authorship dispute should not be submitted

for publication before consulting with the Head of School or Institute Director. Where there is a conflict of interest for the Head of School or Institute Director, an alternative Head of School or Institute Director or the relevant Dean may be asked to consider the dispute.

Authorship disputes involving published manuscripts may be considered under the procedures detailed in the Regulations Governing Investigation into Allegations of Research Misconduct. An individual or individuals with concerns regarding authorship of published works by a member of the University should raise the issue in writing to their Head of School, Centre Director or the Head of Research Governance.

When an external authorship dispute involves collaborators or contributors from another institution, the procedures for dispute resolution at the lead author's institution will be followed.

6. References

Consolidated Standards of Reporting Trials (CONSORT) Website http://www.consort-statement.org/ (last accessed January 2017)

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332.

Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG, for the CONSORT Group. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trial. BMJ 2010;340:c869.

Committee on Publication Ethics (COPE) Website http://publicationethics.org/ (last accessed January 2017)

ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, Updated December 2013 Website: http://www.icmje.org/icmje-recommendations.pdf (last accessed January 2017)

Queen's University Belfast Register of Interests Policy Website http://www.qub.ac.uk/home/RegistrarsOffice/RegisterofInterests/ (last accessed January 2017)

7. Appendix

QUB Guidance on Authorship and Publication (http://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Policies-procedures-and-guidelines/) last accessed January 2017