

Title: Study Dissemination	
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Approver: University Research Ethics Committee	

Document History

Version	Description of update	Date Effective
1.0	Minor typographical errors updated	25/11/2020

1. Scope

This Standard Operating Procedure (SOP) outlines the requirements and methods for dissemination and publication of study results, in addition to good practice in sharing the results of the research to the participants that have contributed.

2. Responsibilities

The *Chief Investigator (CI)/Researcher* is responsible for ensuring that study findings are 'open access', by publishing and disseminating appropriately, whilst maintaining awareness of funder requirements with regard to study publications and impending publications. They should make their publications and reports to the funder by the stipulated deadline. They are also responsible for depositing their research on Bournemouth Online Research Data Repository (BORDaR) and on Bournemouth University Research Online (BURO).

All *authors* are responsible for declaring any relevant conflicts of interest as specified by the funder or within any journal policies.

The *Sponsor (Clinical Governance Advisor [CGA])* is responsible for providing researchers with access to the ClinicalTrials.gov website so that they may register and publish their research. For some kinds of health research it may be difficult to publish the results in a journal unless the study has been registered in a timely manner.

3. Procedure

Under BU policy, in order to be eligible for submission to the [Research Excellence Framework](#), authors' peer-reviewed outputs must have been deposited in an institutional or subject repository, on acceptance for publication (BU, Library & Learning Support, 2018).

3.1 There is an ever increasing obligation within the research community, for clinical research results and findings to be openly published and disseminated, even if the research did not produce any, or it produced unfavourable results. Similarly, studies terminated early should be published.

3.2 Clinical Trials of Investigational Medicinal Products (CTIMPs) and trials investigating medical devices should be appropriately disseminated through publication in peer-reviewed scientific journals.

3.3 The funding body may require the Researcher to make the research available in an Open Access source. Bournemouth University has a publications policy that requires Researchers to deposit a version of their work in the open access institutional repository, BURO.

3.4 The Governance Advisors within Research Development & Support (RDS) hold administrator's access to Clinicaltrials.gov and will provide researchers with a user account, so that they may register and subsequently publish their research study.

3.5 If known at the time of protocol development, the study protocol should set out the key study contributors, and a statement/description of those that will be granted authorship on the final study report: those that have made a substantial contribution, in line with the guidance and recommendations of the International Committee of Medical Journal Editors (ICMJE) - <http://www.icmje.org/>. In the case of student research, the supervisors should be listed as co-authors.

The protocol should likewise detail the roles and responsibilities of the Sponsor, and any funders with regard to study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

3.6 The individuals that made a substantial contribution to the study, who did not meet authorship criteria, should be acknowledged, within an *Acknowledgments* section. This should include details of their contributions.

3.7 The details of the funder and Sponsor should be clearly set out, and the contributions they made to support the study, both financially and in kind. The CI/Researcher must ensure that any contractual obligations to the funder in terms of publication are met.

3.8 The publication must likewise include details of any ethics committee that was involved in the study, as well as other approvals granted (e.g. MHRA). And registration numbers (e.g. clinicaltrials.gov). The authors should include study reference numbers relating to these approvals.

3.9 Independent members of the Trial Steering Committee, and Data Monitoring Committee should be gratefully acknowledged within the publication (unless requested otherwise), but not listed as a co-author, so as to maintain their independent status.

3.10 In reporting, researchers are encouraged to following the reporting guidelines provided by the Equator Network (Enhancing the Quality and Transparency of health Research), found on <http://www.equator-network.org/>.

3.11 Any issues raised by the Sponsor should be appropriately addressed within the publication by the CI/Researcher.

3.12 Approval of the final publication will be granted from within the authorship team, followed by a review by the journal. Any Intellectual Property concerns should be discussed with BU Legal Services, as soon as possible.

3.13 Study results should be disseminated to study participants, the general public, and the research community, both within and outside of BU. Informing participants of the results, shows respect and gratitude for their contribution and the time they donated to help answer the research question.

3.14 Disseminating results to participants will have been discussed at the time of ethics approval. Any deviation to what was discussed and agreed should be agreed with the Sponsor.

3.15 In the case of CTIMPs, it is mandatory for the Clinical Trial summary results to be posted in EudraCT, twelve months following the end of the trial (six months for paediatric trials).

4. Abbreviations and definitions

BORDaR	Bournemouth Online Research Data Repository
BURO	Bournemouth University Research Online
CGA	Clinical Governance Advisor
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
EudraCT	European Clinical Trials Database
ICMJE	International Committee of Medical Journal Editors
MHRA	Medicines and Healthcare products Regulatory Agency
RDS	Research Development & Support

5. Related documentation and references

England, H. (2018). Home - REF 2021. [online] Available at: <http://www.ref.ac.uk/> [Accessed 13 Jul. 2018].

equator-network.org. (2018). The EQUATOR Network | Enhancing the QUALity and Transparency Of Health Research. [online] Available at: <http://equator-network.org> [Accessed 18 Jul. 2018].

icmje.org. (2018). ICMJE | Home. [online] Available at: <http://www.icmje.org/> [Accessed 16 Jul. 2018].

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