COPE – Consortium on Organ Preservation in Europe

Authorship and Publicatoin Policy

Contents

1. Introduction

Publications are a vital part of communicating research findings to the wider scientific community allowing further research ideas to evolve and contributing to the continuous growth of knowledge and deepening of scientific and medical understanding. Ultimately, each published research finding can create better evidence-based clinical practice benefitting patients and health systems alike. However, research does not happen in isolation and many groups and research teams contribute to jointly analyse and interprete research data. COPE is a good representation of the large networks involved in research with a total of 13 partner institutions and over 25 involved recruiting hospitals across many European countries. To ensure that the collaborative nature of the research is reflected while also giving due recognition to the scientific contribution of each individual involved, the COPE consortium has outlined the authorship policy at hand.

2. Policy Background

This policy is based on a variety of COPE Management Board discussions held and decisions taken throughout the years of project implementation since 2013. The stipulations and guidelines defined in the authorship policy at hand were confirmed by the COPE Consortium members in the Annual Meeting on 6-7 April 2017 in Oxford (UK). Additionally to the decisions taken by the COPE governing bodies, this authorship policy is also informed by the COPE grant agreement, the COPE consortium agreement as well as the EU Commission's FP7 guidelines. The timing of the authorship policy is derived from the fact that first results of the COPE clinical trials start to emerge based on the completion of six months and twelve months patient follow-up.

3. Aim

The purpose of this document is to enhance transparency and to facilitate the dissemination of published materials produced by the COPE Consortium or produced by external groups using data or samples collected or results and analyses created within the COPE Consortium. We encourage all Consortium members and external groups to contribute to our dissemination efforts to maximise the project's outputs and impacts. The authorship policy's main aims are to provide clear and transparent guidance to scientists and clinicans working with COPE data or samples and to ensure compliance with EU rules as laid out in the grant agreement and FP7 guidance documents.

4. Scope and Applicability

This policy applies to all scientists, clinicians or researchers or research groups using COPE samples, COPE data or results and analyses derived from COPE data and samples. It applies to groups internal to the COPE consortium members as well as external groups, who are not grant beneficiaries or recruiting trial centres in the COPE clinical trials. The policy at hand furthermore applies to manuscripts, abstracts and all other types of written and publishable documents.

5. Relevant governance structure in COPE

COPE Management Board (MB): The COPE Management Board is the main decision-making body of the consortium as stipulated in art. 6 of the Consortium Agreement. The Management Board consists of the COPE Coordinator, COPE Work Package Leaders (x 6), a representative of each COPE beneficiary who is not also a Work Package Leader (x 7), the COPE Scientific Secretary and the COPE Translational Research Coordinator.

Trial Monitoring Committee (TMC): COPE has three TMCs; one for each of the three clinical trials carried out in the project. The TMCs are the executive body of the respective clinical trial and the discussion forum for trial progress, trial implementation, governance issues, reporting of trial events, research ideas and other relevant topics specific to that Work Package. Each TMC consists of the respective Work Package Leader who chairs the TMC, representatives of the Work Package's partners, representatives from the recruiting trial centres that are not beneficiaries in the COPE grant, the Central COPE Trials Development Lead and the COPE Coordinator.

Scientific Monitoring Committee (SMC): COPE has two SMCs; one for each of the experimental work packages in the project. The SMCs are the executive body of the respective clinical trial and the discussion forum for trial progress, trial implementation, governance issues, reporting of trial events, research ideas and other relevant topics specific to that Work Package. Each SMC consists of the respective Work Package Leader, representatives of the Work Package's partners, COPE Scientific Secretary and the COPE Coordinator.

6. Authorship handling

General

Principle authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Principle authors should meet all three conditions outlined. Co-authors, on the other hand, are those who have substantially contributed to the publication, but may not have responsibility for one section of the work. Co-authors may not meet criteria 2 outlined for authorship above, but would have to meet criteria 1 and 3. Should a journal limit the list of possible co-authors or should the list of co-authors be deemed too long by the Trial Monitoring Committee or COPE Management Board, the most visible other form of recognition should be found for contributors to the work. This could include listing involved team members in the acknowledgments to ensure they can be found on pub med.

Clinical Trials

For the COPE clinical trials, the first author will be determined by the Work Package leader and will represent the junior scientist or clinician having carried out the majority of research work to be published. Lead authorship could be held by a Post-Doctoral Scientist, PhD student, Research Registrar, Academic Clinical Lecturer or other member of staff depending on the nature of the publication. The Work Package Leader will be last author with the COPE Coordinator second to last. The authorship list between first position and second to last as well as last positions needs to be discussed and formulated by the TMC and will then be confirmed and approved by the MB after receiving the TMC's suggestion. Depending on the nature of the research and the nature of the publication, additional authors can include, but are not limited to, representatives from recruiting centres, the COPE statistician, the COPE Health Economist, COPE Scientific Secretary, COPE Translational Research Coordinator, involved radiologists, pathologists, trial device company representatives or external researchers and clinicians who contributed to the research to be published. Authors listed between the first and second to last authorship positions should be listed alphabetically, unless important differences in contributed work require to highlight another individual's position outside of the alphabetical listing. In that case, a short explanation should be provided by the TMC to the MB.

Experimental Work Programmes

For the experimental work packages in COPE, the first author will be determined by the Work Package leader and could represent the junior scientist having carried out the majority of research work to be published. The Work Package Leader will be last author with the COPE Experimental Coordinator second to last.

The authorship list between first position and second to last as well as last positions needs to be discussed and formulated by the SMC and will then be confirmed and approved by the MB after receiving the SMC's suggestion. Depending on the nature of the research and the nature of the publication, additional authors can include, but are not limited to, representatives from the other work package partners, perfusion solution company representatives, COPE Scientific Secretary, COPE

Translational Research Coordinator or possible external groups who contributed to the performed work. Authors listed between the first and the second to last authorship positions should be listed alphabetically, unless important differences in contributed work require to highlight another individual's position outside of the alphabetical listing. In that case, a short explanation should be provided by the SMC to the MB.

Special handling for publications overlapping between different work packages

If a publication uses data or samples collected as part of different COPE Work Packages, this needs to be reflected clearly in the list of authors. In the case of overlapping work package contributions, the involved Work Package Leaders need to determine the main focus of the publication to ascertain second to last and last authorship positions held between them. Equal contributions for first or last author can be stipulated if both data and sample collection alayses are equally relevant to the research at hand. Most cases of overlapping work package contributions are likely to result from publications using patient data collected as part of the clinical trials and patient samples collected as part of the biobank Work Package. However, other constellations of overlapping work package contributions are possible and are not excluded from this handling.

7. Approval processes within COPE

All research ideas requiring COPE data and samples or using results and analyses derived from COPE data and samples need to first be submitted to COPE for approval. This process is outlined in the COPE access policy, which can be downloaded from the COPE website or which can be requested from the COPE project office. Research using COPE samples, data or derived COPE research findings which was not previously submitted as COPE project proposals and which has therefore not been approved by the MB cannot be put forward for publication until the approval process has been completed.

If a manuscript or abstract or other publishable document is derived from an approved research proposal, the SMC or TMC will jointly discuss the authorship list drawn up following the guidelines stipulated in this policy. This discussion can be based on an initial suggestion or proposal made by the Work Package leader. Once the TMC or SMC have jointly approved the authorship list, the respective Work Package leader will inform the MB by email or through the next MB review meeting. Final confirmation of all authorship lists lays with the MB.

8. Logos and texts to be used

Any publication, manuscript, abstract or other written document derived from samples or data in COPE or using results and analyses obtained in COPE need to refer and/or include the below shown COPE logo and EU logo downloadable from the COPE website. The document or publication should also include a reference to the COPE website www.cope-eu.com wherever suitable depending on the nature of the document or publication. Furthermore, the following text has to be included in any written publication using the 'acknowledgement' section: "*This project has received funding from the European*

Union's 7th Framework Programme on research, technological development and demonstration under grant agreement number 305934."

9. Appendix A. Useful Resources

EU Commission – DG Research & Innovation

Information on EC research funding and grant management

http://ec.europa.eu/research/index.cfm?pg=dg

Information Commissioner's Office

Provides information and guidance on the implementation of the Data Protection Act 1998.

www.ico.gov.uk

COPE Access Policy for sample and data access

Provides guidance on the steps necessary to request COPE samples and data and on the approval process applicable to all requests

http://cope-eu.com/work%20programme/biobank.html

EU FP7 Publication Guidelines

Provides in-depth information per relevant FP7 funding stream regarding rules and stipulations on publications derived from EU funding.

https://ec.europa.eu/research/fp7/index_en.cfm?pg=publications

10. Appendix B. Glossary and Abbreviations

EC	European Commission
EU	European Union
FP7	7th Framework Programme for Research, Technological Development and Demonstration of the European Union
MB	Management Board
Organ Donor	An individual who donates an organ for transplantation and provides samples that form part of a collection
Organ Recipient	An individual who receive an organ for transplantation and provides samples that form part of a collection
SMC	Scientific Monitoring Committee
TMC	Trial Monitoring Committee
WP	Work Package

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