Data Transfer Agreement

IMPORTANT: All principal investigators and their research team/collaborators must read these guidelines prior to starting the study.

1. Authorship Guidelines

1.1 Introduction

In accordance with the mission of uCARE, the guidelines for authorship were developed to keep the goals of uCARE and the interests of participants in mind. Time consuming disputes, even legal action, can be avoided with fair, watertight, practical guidelines for authorship.

1.2 Why is authorship important?

As authorship is used to measure academic success, it has significant implications. Authorship trans- poses responsibility and accountability on the listed authors. While guidelines for authorship aim to ensure that those credited have made substantial scholarly contributions, authors are responsible for the published work credited to their name.

1.3 Potential conflicts in authorship:

1. Principal investigators (PIs) and uCARE committee members;
2. PIs and subinvestigators who are PIs for a country or region;
3. PIs and subinvestigators for a region.

1.4 Who is an author?

uCARE supports the International Committee of Medical Journal Editors (ICMJE) guidelines for Authorship. The ICMJE recommends that authorship should be based on four criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
2. Drafting the work or revising it critically for important intellectual content;
3. Final approval of the version to be published;
4. 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.

Authors should meet all four criteria, and importantly, all contributors who meet these requirements should be listed as authors. Contributors who do not meet all four criteria will be included in the Acknowledgements/Appendix section.

The corresponding author is the person who takes primary responsibility for communication with the journal during the review to publication process and has a responsibility to communicate the information to co-authors.

Authorship, in large and small groups, should be decided before the work starts, with the provision that the four named ICMJE criteria should be adhered to during the research project and the submission of the manuscript to the journal.

1.5 Non-author contributors

Contributors who do not meet all four criteria should not be listed as authors. However, they should be acknowledged as non-author contributors. It is essential that authors get written agreement from those recognized before publication. In Medline, the byline of the article identifies who is directly responsible for the manuscript and lists as authors whichever names appear on the byline. If the byline includes a group name, Medline will list the names of the individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the by-line clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators. Definitions are reported in: https://jamanetwork.com/journals/jama/fullarticle/2667044.

1.6 A stepwise approach to determine authorship

The following is the stepwise approach to determine authorship:

1. PIs should register their new trial with uCARE. They must accept PI responsibilities and assume authorship of all publications using their protocol, as long as the four criteria are met. Potential PIs must sign an agreement that only authors who meet the four criteria will be listed as authors.
2. PIs must document a discussion and agreement on authorship at the time of enrolling a subinvestigator. PIs can decide on the first, second, and last author. The order of the rest of the authors will be decided by uCARE, with the wishes of the PIs kept in mind.
3. uCARE will evaluate the protocol and may suggest co-authors who will be able to meet the ICMJE four-point criteria.
4. Subinvestigators must declare their role at the time of publication—those who do not meet the ICMJE criteria should be acknowledged for their contributions as discussed (in the Acknowledgements/Appendix section), but not listed as authors.
5. uCARE committee members helping with publications will make sure that they adhere to the ICMJE four-point criteria, which will enable them to become authors.
6. In case of a dispute, this should be brought to the attention of the Executive Board of SIU. They will oversee the uCARE-related communications and provide suggestions for

resolution.

2. uCARE Publication Guidelines

2.1 Introduction

uCARE provides the infrastructure and support to conduct global multicentre studies and facilitates the design and evaluation of studies, as well as the administration of protocols. Upon completion of the study, uCARE will perform the analysis of the data and help support the preparation of abstracts and manuscripts. We recognize the importance of the communications derived from the different studies and have therefore developed the following guidelines for publications.

The purpose of the uCARE publication guidelines is to provide important information and guidance to our uCARE Council members, the lead investigators, as well as their study team members who participate in uCARE research studies. These guidelines will cover important information regarding the reporting of complete, balanced, and accurate information about uCARE studies. The aim of these guidelines is to ensure that we consistently produce publications in a responsible and ethical manner. These guidelines are designed to be applied in conjunction with our authorship guidelines and apply to ALL uCARE studies sponsored by SIU.

2.2 Guidelines

1. uCARE will communicate on the progress and outcomes of their projects via:
2. Manuscripts prepared under the responsibility of the uCARE Council members.
3. Abstracts submitted to national and international meetings under the responsibility of the uCARE Council members.
4. PowerPoint presentations prepared under the auspices of the uCARE Council members.
5. Webpage of uCARE under the auspices of the uCARE Council
6. Please see the Appendix for definitions regarding the above communication channels outlined in a to d.
7. The first paper prepared from each project should be a descriptive one authored by the members of the uCARE Council who participated in the study. As a first publication, a design paper from each study protocol will be developed and authored by all council members.[1]
8. Subsequent manuscripts will be authored by up to 7 co-authors selected from all the contributors. The first three authors will be selected based on their contribution to the preparation of the manuscript and active input in the data collection. The exact sequence will be decided by the Re- search Council at the beginning of each study. The senior author is the Principal Investigator (the PI brings in the idea and preferably also the financial support) who is responsible for initiating the project. For information about authorship, please refer to the authorship guidelines.
9. At the end of every manuscript, all other contributors will be included in an appendix. One contributor from each center can be included and the name of the contributor is to the discretion of the participating center.
10. The supporter of each project will be acknowledged at the end of the manuscript.
11. Each abstract submitted to an international meeting will follow the same sequence for authorship, but the presenting author may differ from the first author and is identified as

such on the abstract.

12. Suggestions for analysis and a subsequent manuscript preparation will be put forward by the UCARE Council member of the project. Six months after closing the study all contributors may propose to the uCARE Council topics for analysis. Upon receiving approval by the uCARE Council, this proposal can be further worked out. The contributor will be responsible for preparing the manuscript in due time.
13. uCARE publications will be highlighted on the uCARE website with a link to the abstract of the publications.
14. A complete slide set will be made available on the website. Contributors have access to this via a login code.
15. Contributors may present their center/country's results or share global data results via abstracts at national meetings after approval by the uCARE Council, and in agreement with the guidelines for uCARE communications.
16. In case of a disagreement regarding issues related to these guidelines, the uCARE Council would take the final decision. In the rare case in which a further appeal is made, then the issue will be placed before the Executive Board of the Société Internationale d'Urologie.

These guidelines outline in a transparent way the recognition in publications and presentations by the contributors of the study. The participants transfer their data to uCARE to allow data collection, analysis, and preparation of manuscripts without impairment by the participating center. On the other hand, participation in uCARE projects does not hinder the independent publication of data from contributing sites. To ensure quality of the data and for the protection of patients and adherence to uCARE clinical research standards, the uCARE Council will ask each participating site to provide confirmation of IRB approval or a similar document.[1]

Moreover, uCARE will implement tools for data validation and quality control via random data checks of patient data, as well as full project audits.

In addition to the above, the following addresses some of the issues that may be encountered during the publication of the studies:

- Study design and ethical approval;
- Data analysis;
- Conflict of interests;
- Peer review process;
- Redundant publication;
- Plagiarism;
- Media relations.

[1] Example of a design paper: Swann et al. JMIR Res Protoc 2018;7(5):e132;pp1-11.

2.3 Study Design and Ethical Approval

2.3.1 Definition

Good research should be well justified, well planned, appropriately designed, and ethically approved. To conduct research to a lower standard may constitute misconduct.

2.3.2 Guidelines:

- Laboratory and clinical research should be driven by protocol; pilot studies should have a written rationale.
- Research protocols should seek to answer specific questions, rather than just collect data.
- Protocols must be carefully agreed by all contributors and collaborators, including, if appropriate, the participants.
- The final protocol should form part of the research record.
- Early agreement on the precise roles of the contributors and collaborators, and on matters of authorship and publication, is advised.
- Statistical issues should be considered early in study design, including power calculations, to ensure there are neither too few nor too many participants.
- Formal and documented ethical approval from an appropriately constituted research ethics committee is required for all studies involving people, medical records, and anonymized human tissues.
- The principal investigator must adhere by the uCARE Data Access and Transfer Guidelines. It is the principal investigator's responsibility to supervise research projects, this includes ensuring high-quality data collection, and frequent review and long-term retention (for an unlimited time) of all primary records and outputs.

2.4 Data Analysis

2.4.1 Definition

Data should be appropriately analyzed, but inappropriate analysis does not necessarily amount to mis- conduct. However, **fabrication and falsification of data** do constitute misconduct.

2.4.2 Guidelines

1. All sources and methods used to obtain and analyze data, including any electronic pre-processing, should be fully disclosed; detailed explanations should be provided for any exclusions.
2. Methods of analysis must be explained in detail, and referenced, if they are not in common use.
3. The post-hoc analysis of subgroups is acceptable, as long as this is disclosed. Failure to disclose that the analysis was post-hoc is unacceptable.
4. The discussion section of a paper should mention any issues of bias, which have been considered, and explain how they have been dealt with in the design and interpretation of

the study.

2.5 Authorship

2.5.1 Definition

uCARE has developed its **Authorship Guidelines**, which are based on the ICMJE guidelines for authorship. These are separate from these publication guidelines and therefore, will not be discussed here. Please refer to the uCARE Authorship Guidelines for more information.

2.6 Conflicts of interest

2.6.1 Definition

Conflicts of interest comprise those which may not be fully apparent, and which may influence the judgement of author, reviewers, and editors. They have been described as those which, when revealed later, would make a reasonable reader feel misled or deceived. They may be personal, commercial, political, academic, or financial. “Financial” interests may include employment, research funding, stock or share ownership, payment for lectures or travel, consultancies and company support for staff.

2.6.2 Guidelines

1. Where relevant, conflicts of interest must be declared to editors by researchers, authors, and reviewers.
2. Editors should also disclose relevant conflicts of interest to their readers. If in doubt, disclose.

2.7 Peer Review

2.7.1 Definition

Peer reviewers are external experts chosen by the authors to provide written opinions, with the aim of improving the study.

2.7.2 Recommendations

1. The duty of confidentiality in the assessment of a manuscript must be maintained by expert reviewers, and this extends to reviewers’ colleagues who may be asked with the author’s permission) to give opinions on specific sections.
2. The submitted manuscript should not be retained or copied.
3. Reviewers and editors should not make any use of the data, arguments, or interpretations,

unless they have the authors' permission and uCARE.

2.8 Redundant Publication

2.8.1 Definition

Redundant publication occurs when two or more papers, without full cross-reference, share the same hypothesis, data, discussion points, or conclusions. In order to avoid this, the uCARE Council must be notified either via the regional member, or via direct email to the Medical Education Manager, Eduardo Gutierrez, to inform the Office of Research of planned publications, either in the form of presentations, abstracts, manuscripts, etc. prior to publishing any data.

2.8.2 Guidelines

1. Published studies do not need to be repeated unless further confirmation is required.
2. Previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, but full disclosure should be made at the time of submission.
3. Re-publication of a paper in another language is acceptable, provided that there is full and prominent disclosure of its original source at the time of submission.
4. At the time of submission, authors should disclose details of related papers, even if in a different language, and similar papers in press.

2.9 Plagiarism

2.9.1 Definition

Plagiarism ranges from the unreferenced use of others' published and unpublished ideas, including research grant applications to submission under "new" authorship of a complete paper, sometimes in a different language.

It may occur at any stage of planning, research, writing, or publication: it applies to print and electronic versions.

2.9.2 Actions

All sources should be disclosed and referenced, and if large amounts of other people's written, or illustrative material are to be used (e.g., figure or tables), permission must be sought from the primary source.

Most journals now utilize a software to check for plagiarism (e.g., iThenticate). Information taken from other references must be properly referenced and re-written. Copy/pasting the exact sentence may be considered plagiarism by most journal publishers.

2.10 Media Relations

2.10.1 Definition

Medical research findings are of increasing interest to the print and broadcast media.

Journalists may attend scientific meetings at which preliminary research findings are presented, leading to their premature publication in the mass media. Prior to providing data or information to the media, the principal investigator or the Council member must inform the uCARE office, who will consult the group and provide a chance for the Council Members to review the information.

2.10.2 Reference

Adapted from Guidelines on Good Publication Practice. *J Urol.* 2000;163:249-252.

2.11 Author Checklist for Preparing Manuscripts for Submission to Journals

Prior to submitting your article to a journal, please inform the uCARE Council regarding your intent to publish your results so that the members are aware of this, and also so that SIU can assist you with obtaining the data you will need for your publication.

The following chapter components must be included for submission:

1. **Cover page:** Chapter title, authors and their titles, and affiliations
2. **Abbreviations:** List of abbreviations used
3. **References: One master list of references for your manuscript.** Please follow the specific journal's guidelines regarding proper formatting of references.
4. **Figures:** Figures and Tables (including location within the text, if sent separately)
5. **Note:** If a figure/image or table was obtained from another source (journal article, textbook, website, etc.), you will need to obtain reprint permissions. We can advise on how this can be obtained.
6. **Images:** We highly recommend sending high-quality figures to the publisher as a separate file, to keep the high-resolution image for the article.

2.12 Appendix

2.12.1 Definitions

- **Abstracts.** Abstracts from completed studies will be submitted for reporting to national and international meetings by the respective project steering committee. In cases where the PI and the project's SC deem that the study's interim results need to be reported as soon as possible, abstracts will also be developed and submitted. Abstracts submitted to national and international meetings must follow the same sequence of authorship according to the authorship guidelines. If the presenting author differs from the first author, it must be identified on the submitted abstract.

- **Progress reports.** Progress reports will be completed annually by the respective project steering committee using the progress report template and style guide. Manuscripts. Manuscripts for journal submission will be prepared by the respective project steering committee using the manuscript template and style guide and should be completed within 12 months of the data analysis being completed. The SIU encourages everyone interested in submitting a manuscript to submit their results via the Société Internationale d'Urologie Journal (SIUJ).

- **PowerPoint Presentations.** Similar to the abstracts, results can also be reported via presentations at national and international meetings using slides. These will be prepared by the respective project steering committee.

- **uCARE website.** Updates to the website will be the responsibility of the uCARE Research Office of the SIU.

3. Agreement

☐ I have read the guidelines and acknowledge that I agree with them.

Signed on:

By:

On behalf of my research centre/institution: