

CARRA PUBLICATION AND PRESENTATION GUIDELINES

Version October 1, 2017

1. Introduction

The goals of the CARRA Publication and Presentation Guidelines are to:

- a) Promote timely and high-quality presentation and publication of findings.
- b) Support broad and equitable participation by CARRA investigators in presentations and publications.
- c) Define prospectively a set of equitable rules and guidelines that can be used to determine authorship and the order in which authors are listed.
- d) Provide editorial support and timely review for presentations and publications.

2. Scope of Guidelines

These guidelines apply to publications and presentations which include results derived from data and bio specimens collected via the CARRA Registry protocols and sub-studies, or other studies which have been authorized to be managed by the CARRA Publications Committee after completion of the primary study. A sub-study is any study that makes use of a CARRA study infrastructure or database for recruitment, information collection, and information storage. All data and bio specimens that are shared via the CARRA Registry Data and Sample Share Committee application process are subject to these guidelines. These guidelines also apply to surveys and other publications related to the use of CARRA infrastructure for mailing lists, conference time, or funding.

3. Publications Committee

The CARRA Publications Committee will consist of:

- a) The CARRA Registry Scientific Director
- b) The CARRA Informatics Director
- c) 1 elected chairperson

Publications Committee Chair

Candidates for Publications Committee chair will be self-nominated, voted upon by the voting members CARRA, and serve a term of three years. The timing of this election will be coordinated by CARRA and occur to ensure that the new chairperson is in place to assume responsibilities on July 1st of the election year. The number terms that a Chair may serve will be limited to two consecutive terms. After two consecutive terms, an individual may re-run after sitting out for at least one full term.

Chairperson Responsibilities:

1. Oversees CARRA Publications Committee.
2. Selects reviewers for abstracts, posters, and manuscripts. Reviewers may be chosen from the CARRA Registry Data and Sample Share Committee, or from the CARRA membership at large as needed.
3. Serves as resource/point of contact for investigator questions and disputes regarding publications
4. In conjunction with CARRA staff, assist with cataloging and archiving of all abstracts and publications completed and in progress.
5. Provide semi-annual reports to the CARRA Steering Committee on the progress of all study publications.

This position will receive 5% effort in salary support.

CARRA Publications Committee Responsibilities:

- Review publications/presentations for correct attributions
- Review publications/presentations for adherence to the original research proposal accepted by the CARRA Registry Data Sample Share committee before the manuscript is submitted for publication.
- Review the policy (at minimum) on annual basis and amend as necessary
- Adhere to CARRA Publications Policy Review Timelines:

Type of Publication	Time Needed for Review by Publications Committee
Abstracts	7 days
Papers/Manuscripts	3 weeks
Posters	7 days
Slides	7 days
Meeting Proceedings	7 days
Press Releases	7 days

4. Types of Publications

Publication and Presentation types under consideration by the CARRA Publications Committee include:

1. All manuscripts, publications, proceedings, abstracts, or presentations that represent reports of the main results, findings, etc., of the CARRA Registry, based on analysis of study-wide data.
2. Secondary publications or presentations that address issues more peripheral to the main CARRA Registry study outcome but that are based on data collected as part of the main study. This would include ancillary studies that involve all study sites.
3. Methodology/Validation Papers describing statistical procedures and other methodological issues associated with the design, execution and analysis of these studies.
4. Press Releases concerning CARRA Registry activities or studies.
5. Reviews that contain unpublished CARRA Registry data presented at national and international meetings
6. Publications and presentations that include results derived from data and bio specimens collected via the CARRA Registry protocols and sub-studies. A sub-study is any study that makes use of the CARRA Registry infrastructure or database for recruitment, information collection, and information storage.
7. Any manuscript, publication, proceeding, abstract, or presentation resulting from a secondary analysis of data or biospecimens from a study that has been authorized to be managed by the CARRA Registry Data and Sample Share Committee and CARRA Publications Committee after completion of the primary study.
8. Any manuscript, publication, proceeding, abstract, or presentation resulting from a project supported or advanced by contributions from CARRA infrastructure or the CARRA membership, this includes surveys of the CARRA membership.

5. Authorship Priorities

Authors should participate in the writing of the paper according to guidelines of the International Committee of Medical Journal Editors (N Engl J Med 1991; 324:424-8). Those who participated in conception and design, analysis and interpretation of data, drafting of the manuscript, critical revision of

the manuscript relating to important intellectual content, and final approval of the manuscript should be included as authors. Statistical, epidemiological, genetic, or other expertise that relates directly to the conduct of the study are additional criteria for authorship. Honorary authorship will not be considered. For each publication or presentation, the writing will be accomplished by a Writing Group, a member of whom will be designated the Responsible author. The Writing Group will be determined from the investigators that have applied to use the data or samples from the CARRA Registry Data and Sample Share Committee.

Selection of first authors: Unless he/she delegates otherwise, the Responsible author will be the first author.

For CARRA studies which are authorized to be managed by the CARRA Publications Committee after completion of the primary study, masthead authorship (i.e. for the APPLE investigators), grant acknowledgements and investigator acknowledgements will be dictated by the publication rules of the original study.

For non-CARRA Registry studies supported or advanced by contributions from CARRA infrastructure or the CARRA membership, the selected list of masthead authors will end in “for the CARRA Investigators”, or in “for the CARRA Subcommittee,” if the study was carried out on behalf of CARRA or a specific subcommittee. In the event that a study is considered sufficiently independent of CARRA support by the Publications Committee, then this requirement for masthead acknowledgement may be waived on a case by case basis.

(Note: for non-CARRA-Registry studies, the publication should include an acknowledgment of CARRA, Inc. and its underlying support from the Arthritis Foundation. Additional funding sources should be acknowledged as deemed necessary by the CARRA Publications Committee – see section 7. “Acknowledgements”.)

For CARRA Registry papers, the list of authors should be limited to those investigators that developed the specific study or substudy question and analysis. The primary investigators of the CARRA Registry will not automatically be included in the list of authors unless they are involved in the specific manuscript being produced. Because many individuals from each study center are participating in the collection of data for the CARRA Registry, including all personnel is impractical and contrary to journal guidelines and limitations. The selected list of masthead authors will end in “for the CARRA Registry Investigators.” All CARRA Registry study sites including site investigators and coordinators should be listed in an appendix or footnote that identifies study centers and study site personnel to be acknowledged. All CARRA Registry funding must be acknowledged as well. In case of limited authorship, the following order of authorship will apply until the journal’s limit is reached:

5.1 The Writing Group:

Investigators felt by the Writing Group to have made special contributions to the concept, design, or analysis of the study (often these will already be included in the Writing Group). Investigators felt by the Writing Group to have contributed special effort to the execution of the study (often these will already be included in the Writing Group).

5.2 Order of Authorship:

For all manuscripts, factors to be included in decisions about order of authorship are contribution

to concept, design, and analysis; role in drafting of the manuscript and/or revising it critically for important intellectual content; number of study subjects enrolled; completeness/integrity of the data and specimens from the investigator's site; and leadership role.

A plan for authorship should be included in any application for data or samples from the CARRA Data and Sample Share Committee. If the Writing Group does not complete its work on a manuscript or fails to meet timeline milestones previously approved in their data application, the Chairperson of the Publications Committee or Data Share Committee may reassign the roles of first author and/or select new Writing Group members. This exigency will be exercised if no draft is produced within 6 months of the availability of a clean data set for the manuscript.

5.3 Investigators who have left the CARRA Registry:

Over the multi-year course of the CARRA Registry, one or more Investigators or Co-Investigators are likely to relocate to new institutions, change primary interest, or terminate their roles in the CARRA Registry for a variety of professional or personal reasons.

Because such Investigators will have to be replaced, the new Investigators may assume the masthead or contributor authorship role for the sites at which this occurs. Ordinarily, the role of Investigators contributing to but withdrawing from a project can be acknowledged in an appendix or acknowledgement section. For some studies, for example ancillary studies in which the former Investigator may have played a primary or very strategic role, the CARRA Publications Committee may elect to recognize the important contribution of the former Investigator by including him/her as an author and may appoint him/her to a Writing Group. If there is conflict about authorship in such circumstances, the CARRA Publications Committee would be the entity who would review a petition from the former Investigator to be included as an author. If the former Investigator meets the criteria for authorship, as defined above, the CARRA Publications Committee will have the discretion to direct inclusion of him/her as an author.

5.4 Non-CARRA Registry Investigators:

For some ancillary studies, CARRA Registry investigators may wish to invite outside experts to participate as scientific collaborators. Such addition of investigators should be presented initially in the CARRA Registry Data and Sample Share application. Ranking of applications based on applicant involvement in the CARRA Registry is addressed in the CARRA Registry Data and Sample Share Policy. If the outside investigator meets the criteria for authorship, as defined above, the CARRA Publications Committee or the Writing Group have the discretion to include him/her as an author.

5.5 Ancillary Study Investigators Who Are Not Members of CARRA: Ancillary studies may involve collaborators who are not part of CARRA. Such investigator groups will follow the CARRA Registry Data and Sample Share policy and the CARRA Publication and Presentation Guidelines. Within the ancillary study group, however, more specific guidelines may need to be developed. The object of such ancillary-study-group-specific guidelines will be to define the conduct of Writing Groups, determine Order of Authorship within the group, and establish timelines for receipt by the Publications Committee of documents and slide material to meet publication, abstract submission, and presentation deadlines.

6. Responsibilities of the Writing Group

Each Writing Group is responsible for development of the manuscript for final approval by the Publications

Committee. The Responsible author will be responsible for assigning tasks to other members of the Writing Group and will oversee the completion of these tasks on schedule. Writing Group members should participate actively in the writing and review of the manuscript. If, during the course of work on a manuscript, the analysis is found to be too broad for a single manuscript, the Writing Group should notify the Publications Committee that they plan to narrow the scope of the manuscript, and/or they can resubmit a new written plan to the CARRA Registry Data and Sample Share Committee for other potential manuscripts. An amended analysis plan should be submitted to the CARRA Registry Data and Sample Share Committee if the analysis evolves or deviates substantially from the most recent plan approved by the CARRA Registry Data and Sample Share Committee.

Manuscripts should be prepared at the office of the Responsible author. The completed manuscript should be submitted for review to members of the Publications Committee prior to submission to the journal of choice.

7. Acknowledgements

All manuscripts and abstracts utilizing CARRA Registry data shall include “for the CARRA Registry Investigators” in the list of authors. All CARRA Legacy Registry manuscripts should include an acknowledgment of NIAMS, Friends of CARRA, and Arthritis Foundation funding, with specific contract numbers. Additional funding sources should be acknowledged as deemed necessary by the CARRA Publications Committee. The Responsible author is required to send a finalized copy of all publications to the CARRA Publications Committee. All manuscripts should adhere to NIH Open Access policies. (<http://publicaccess.nih.gov/>). For abstracts, acknowledgments can be limited to NIAMS funding without fund numbers, which would be too numerous to list. If there is not separate space for grant acknowledgements in the abstract, they must be listed in the poster or oral presentation.

Publications that resulted from research supported by CARRA funding or CARRA infrastructure (including CARRA Registry manuscripts, surveys of the CARRA membership or a subset of the CARRA membership) must include the following statement: “The authors wish to acknowledge CARRA, and the ongoing Arthritis Foundation financial support of CARRA.”

8. Editorial Functions

The CARRA Publications Committee will serve as the editorial review committee for all manuscripts resulting from the analysis of CARRA Registry data and bio specimens, as well as all secondary papers resulting from CARRA studies authorized to be managed by the CARRA Publications Committee after completion of the primary study. For each manuscript prepared, two CARRA Publications Committee members who have not written the paper will be designated to provide a timely review (within three weeks) of the manuscript for correct attributions and adherence to the original research proposal accepted by the CARRA Registry Data Share committee before the manuscript is submitted for publication. The CARRA Publications Committee may suggest modifications before final approval. The CARRA Publications Committee will also ensure that proper funding agency and contributor acknowledgements are listed.

Manuscripts, abstracts, or other publications that involve study-drug treatment or that focus on test results obtained with commercial assays should be submitted to the industrial sponsor for comment at the same time as submission to the CARRA Publications Committee. The industrial sponsor will have no authority to prevent or delay publication. If a dispute occurs between the authors and the Publications Committee, resolution of the dispute should be the responsibility of the CARRA Leadership Team.

9. Abstracts and Presentations

Abstracts should be submitted to the CARRA Publications Committee at least 7 days prior to submission to the organization sponsoring the meeting. A member of the Publications Committee will be selected by the Chair of the Publications Committee for expedited review of the abstract. Slide material (including tables and graphs) to be presented for accepted abstracts and posters should be reviewed by the Publications Committee at least 7 days prior to presentation.

Unpublished CARRA study data presented at national and international meetings must be approved in the same way as abstracts. This may entail review of slides, electronic and printed material by the same mechanism as that used to review abstracts. When previously approved slides or electronic files are to be presented at a national or international meeting, the Publications Committee should be notified at least 7 days in advance, the slides or electronic files should contain an acknowledgment of the original source, but formal re-approval will not be required. Requests for permission by meeting organizers, industrial sponsors, or non-CARRA investigators to reproduce slides, to videotape or audiotape presentations, and/or to publish written summaries of these presentations must be submitted to the Publications Committee, which will review the material to ensure that previously unpublished data are protected.

Investigators are encouraged to consult the Publications Committee chairperson when questions arise. If the chairperson cannot address such questions readily, the issue should be considered by the entire Publications Committee (via conference call or written communication).

Suggested abstract funding acknowledgment: “Funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS for brevity, if needed), Friends of CARRA and the Arthritis Foundation.” Other funding mechanisms specific to each manuscript must also be included as needed.

10. Publications Priorities and Access

No investigator should jeopardize the publication of CARRA Registry or other CARRA study data in a peer-reviewed journal by releasing or presenting data prematurely. Press releases should be timed to coincide with publication of manuscripts, either in print or electronically on the internet, whichever comes first, and should respect any applicable publication embargoes. No individual site will be permitted to publish site-specific results that compete and interfere with the integrity of study-wide reports of the results of the CARRA Registry or other CARRA study protocols. Press Releases should be approved by the CARRA Publications Committee. All manuscripts and abstracts will be stored electronically on a CARRA secure website, to which all CARRA members have access. Slide material or electronic files prepared for presentations should be made available to other CARRA members in electronic format, to be maintained on a CARRA secure website.

11. CARRA Publications Committee Review: Submission Instructions and Review Timelines

All submissions to the CARRA Publications Committee should be submitted via the online publication review form (<https://www.jotform.com/carragroup/publication-review-form>).

Type of Publication	Time Needed for Review by Publications Committee
Abstracts	7 days

Papers/Manuscripts	3 weeks
Posters	7 days
Slides	7 days
Meeting Proceedings	7 days
Press Releases	7 days

12. Disputes/Conflicts

The CARRA Publications Committee will mediate and settle all disputes and conflicts related to publications, including priorities, authorship, and author order etc., among study investigators. Plans for authorship should be addressed from the beginning of application for data to the CARRA Registry Data and Sample Share Committee. Investigators who later perceive inequities in authorship or other problems relating to authorship should discuss these concerns with the Publications Committee chairperson; if the difficulty cannot be settled in this informal manner, the concerned investigator should submit a letter to the Publications Committee chairperson outlining the problem and requesting formal review. The document will be reviewed and discussed by the Publications Committee, and a written reply will be made to the investigator. If the chairperson of the Publications Committee has a perceived or real personal stake in the outcome of the conflict and cannot preside in an unbiased way, he or she should be recused, and another member of the Publications Committee should assume the chairperson’s role in resolution of the dispute. If the Publications Committee deliberations fail to resolve such a dispute, the dispute will be submitted for resolution to the CARRA Steering Committee.

If investigators publish a CARRA-related study without seeking the approval of the publications committee prior to publication, they may be subject to sanctions from CARRA, which may include denial of access to future data or infrastructure support. These sanctions may be imposed by the Publications Committee Chair with the agreement of the CARRA Steering Committee.

13. Resources

Lists of CARRA Legacy Registry and CARRA Registry authors and acknowledgements as well as poster templates can be found on the CARRA website at https://carragroup.org/policies_templates.

14. Future Modifications to this Policy

The CARRA Publications Committee reserves the right to amend the CARRA Publication and Presentation Guidelines as necessary. Any amendments to this policy will require review and approval by the CARRA Registry Leadership Committee and the CARRA Steering Committee.