

Accessible Research Commons for Health (ARCH) Publications and Presentations Policy & Procedures

Overview

The success of the ARCH Network will be judged largely on the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that assure appropriate use of any ARCH Network data, timely completion of manuscripts, and adherence to the principles of authorship. The ARCH Study Submission and Review Committee (SSRC) oversees these activities on behalf of the ARCH Governance Committee. While outside collaborators with meritorious proposals are welcome, ARCH requests that individuals working on projects involving ARCH Network data work closely with at least one of the ARCH Network Investigators and follow the policies of the Network.

Publications and Presentations Policy

Goals

- To encourage publication submissions – particularly collaborative works involving multiple sites.
- To enable external groups to collaborate with ARCH.
- To maintain a complete up-to-date list of ARCH presentations, approved manuscript proposals and publications, and to disseminate such lists to ARCH stakeholders and the public, on a regular basis.

Principles & Functions

- All functions will be performed by the ARCH SSRC using the following principles:
 - Promote transparency and inclusiveness
 - Efficiency
- Key functions of the SSRC relative to publications include:
 - Manuscript and publication tracking
 - Adjudication of publication-related conflicts
 - Concept approval for Network-wide projects
 - Manuscript approval only if policy implications or not all sites represented in authorship

Publications

- **Single-site Projects**
Each Principal Investigator has the right to publish data from his/her own population without approval by the SSRC. For informational purposes, the title and author list should be submitted to ARCH when the manuscript is in press. Please note, this clause applies to SSRC-reviewed ARCH studies for which there was opportunity for multi-site participation. Other i2b2-related publications will not require manuscript submission.
- **Multi-site Projects**
Collaborations between two or more sites that are focused on topics relevant to ARCH, involve data from all sites, make extensive use of Network-generated meta-data or procedures/protocols or involve policy/guidelines applicable to more than one site are

considered multi-site projects and must adhere to the publication approval process outlined below.

Proposal Submission and Approval

To initiate the process that leads to a presentation at a scientific meeting or writing a paper for publication, ARCH investigators are invited to submit ideas for papers to the SSRC (see Figure 1). The tentative Lead (first) Author submits a completed Manuscript Concept Sheet (see Appendix 1), which is reviewed and approved by the SSRC before manuscript submission. If more than one person submits the same or similar topic, the SSRC may decide who will assume the project lead.

The Concept Sheet is submitted to the ARCH SSRC coordinator for administrative processing. The proposal is forwarded to the SSRC for review. The Lead Author is responsible for promptly submitting suggested outlines of all proposed analysis projects, approved presentations and publications to ARCH.

For Special Issue Journals the journal organizer will submit a Concept Sheet for the entire Issue, listing proposed articles and lead authors along with abbreviated Concept Sheets for each article. Abbreviated Concept Sheets will contain at a minimum Title, Lead Author, Project Outline and Desired Data. Once the main Concept Sheet and all abbreviated Concept Sheets have been submitted, ARCH SSRC coordinator forwards the proposal as a Special Issue Journal packet to the SSRC for review.

Authorship

The Lead Author or Senior Author of each project writing group, with the concurrence of other members of the group, determines the order of authorship. A major criterion for this determination is the effort and contribution made by the members of the writing group in preparation of the manuscript. Criteria for authorship will follow the recommendations of the International Committee of Medical Journal Editors (<http://www.icmje.org>). ICMJE recommends that authorship be based on the following four criteria:

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

Disagreement about the order of authors, which cannot be resolved by the Lead or Senior Author of the project writing group, is resolved by the SSRC.

PIs will ensure that all members at their site who have contributed to the proposed effort outlined in the Manuscript Concept Sheet will be proposed to the lead author for authorship. Once the concept sheet has been approved by the SSRC it is then the responsibility of all co-authors to communicate directly with the lead author.

Preparation and Submission of Papers

The following steps are followed in the preparation of ARCH manuscripts. The Lead Author of a writing group:

- Contacts the SSRC if a change in Lead Author or Senior Author is necessary (for instance due to workload), and informs them of the request to transfer the lead to another individual.
- Keeps the SSRC and all authors informed of the manuscript's progress.
- Circulates manuscript at least twice for review by full writing group; once in the early stages of drafting the manuscript and again when the manuscript is near completion. Or if the author prefers, the first circulation can be a proposed study design/analysis plan for review and comment. Upon the first manuscript circulation (or analysis plan) the writing group will have no less than one week and no more than two weeks to comment. Upon the second, near completion, circulation to the writing group the group will have no more than one week (longer upon request) for review and comment.

Ensures that potential authors review and comment on draft manuscripts; failure to do so should be seen as a withdrawal from authorship. Notifies non-respondents and their PIs that they will be removed from authorship list prior to submission.

- Submits the final version of a manuscript for review/approval (if necessary) to the SSRC coordinator before the paper is submitted to a journal for publication.

The role of the SSRC coordinator is to assist with tracking and coordination of papers and presentations for the review process and for reporting to the Network PIs, ARCH sponsor(s), the public, and ARCH stakeholders.

For data submitted to meta-analyses or other large consortia projects, the lead contributor for ARCH is responsible for ensuring that authorship is provided appropriately to participating sites and that the manuscript is circulated to site authors as indicated above for Network manuscripts.

Manuscript Review

The purpose of manuscript review is to evaluate the scientific merit, the clarity of the writing and the consistency with other ARCH Network findings. Full manuscript review is only required if:

- Each site is not represented by a co-author
- The manuscript involves the presentation or discussion of broad policy guidelines

A copy of the manuscript is submitted to the Governance Committee (GC) for circulation to the SSRC and ARCH Central for review. The SSRC discusses the review and manuscript during conference call or by e-mail within two weeks. If no comments are received within this time period, the manuscript is considered approved.

Publication Administrative Items: Acknowledgement Statements, Reprints, Publication Costs

All network-wide papers should include a statement citing the PCORI grant support for the work, listing the appropriate grant numbers (Appendix 2), and acknowledge the ARCH Network.

All requests for reprints of final and network-wide papers are directed to the corresponding author of the paper. The costs of slides for specific presentations, publication of specific manuscripts and reprints are the responsibility of the Lead author.

Abstract Submission for Meetings

Abstracts do not require approval. All presentations should be sent to the ARCH SSRC coordinator so that they may be posted to the ARCH web site. All abstract citations should be sent to the ARCH SSRC coordinator so that the ARCH bibliography can be updated accordingly.

I. Publication Tracking & Reporting

- **Single-site Publications**

As outlined in section II, during the manuscript planning stages, authors should submit the title and author list to ARCH. When the manuscript is in press, a final copy of the manuscript should be submitted to ARCH informational, reporting, and dissemination purposes.

- **Multi-site Publications**

ARCH will provide access to a listing of publications via the Network website. This report lists the Lead Author and Senior Author, working title and journal submission title, date of receipt and approval by the SSRC and proposal status.

The following reports will be distributed at each Governance Committee meeting:

- Manuscript Status List - number, title, lead author, date received, status, date submitted, and date approved.
- Manuscript Publication List - full citation and ARCH Network manuscript number.
- Abstract Presentation List - full citation and ARCH Network manuscript number, date, and meeting.

ACKNOWLEDGEMENTS

This policy was adapted from the eMERGE Network Publication Policy. The eMERGE Network was initiated and funded by NHGRI, in conjunction with additional funding from NIGMS through the following grants: U01-HG-004610 (Group Health Cooperative/University of Washington); U01-HG-004608 (Marshfield Clinic Research Foundation and Vanderbilt University Medical Center); U01-HG-04599 (Mayo Clinic); U01HG004609 (Northwestern University); U01-HG-04603 (Vanderbilt University Medical Center, also serving as the Administrative Coordinating Center); U01HG004438 (CIDR) and U01HG004424 (the Broad Institute) serving as Genotyping Centers.

APPENDIX 1

ARCH Network Proposal for Analysis

Manuscript Concept Sheet

Submission Date	
Project Title	
Tentative Lead Investigator (first author)	
Tentative Senior Author (last author)	
All other authors	
Sites Involved	
Background / Significance	
Outline of Project	
Desired Variables (essential for analysis indicated by *)	
Desired data	
Planned Statistical Analyses	
Ethical considerations	
Target Journal	
Milestones**	

** This section should include: Timeline for completion of project, including approval, project duration, first and second draft of the paper and submission.

APPENDIX 2

ARCH Acknowledgement Text

The ARCH network is funded by: a Patient-Centered Outcomes Research Institute (PCORI) Award CDRN-1306-04608 for development of the National Patient-Centered Clinical Research Network, known as PCORnet.