ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

Manual 29

ARIC Publication Guidelines and Procedures

Version 2.2

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ARIC Coordinating Center

Collaborative Studies Coordinating Center (CSCC) Department of Biostatistics

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http://www.nhlbi.nih.gov/

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1. INTRODUCTION

This document is intended to help investigators who are interested in submitting proposals for manuscripts/abstracts using ARIC data understand and comply with publications guidelines and procedures established by ARIC. The document also provides additional information for new investigators who are interested in using ARIC data to launch new collaborative projects. The ARIC Publications Committee is responsible for reviewing and approving proposals for all manuscripts/abstracts. To be considered for Publications Committee calls, which occur on the second Tuesday of each month, manuscript proposals are due the Wednesday before at 12:00 noon E.T.

Appendix A provides an overview of the lifecycles of ARIC Ancillary and Manuscript Proposal. For a more detailed process flowchart on the Publications Committee manuscript proposal process, please see Appendix B.

2. New Investigators

The ARIC Study welcomes new investigators, particularly those early in their careers. This includes NIH K-awardees, scientists who are seeking their first R01 grant, and other researchers who are interested in using the ARIC data for the first time to answer important scientific questions.

Opportunities for new investigators to become involved include:

- Obtaining ARIC data to prepare a new scientific manuscript on a topic that has not been addressed previously in the ARIC study.
- Receiving limited ARIC data summaries for use in preparing a proposal for funding or secondary data analysis (e.g., R03 or K-award).
- Obtaining biospecimens (e.g., blood, urine) for new assays that have not been previously conducted in the ARIC study. Such projects require an ancillary study proposal and typically are funded by an outside source (e.g., NIH, a foundation grant, institutional internal funding).
- Obtaining other information either directly from ARIC participants (e.g., interview, adding information to existing questionnaires), from medical records, or review of existing data (e.g., MRI scans). Such ancillary studies with participants burden must be approved by the ARIC OSMB in addition to the ancillary and steering committees.

Please note that projects that involve the use of stored specimens, or additions or modifications to existing ARIC protocols require close collaboration with ARIC investigators, approval by the ARIC Steering Committee, the NHLBI from the NIH, and institutional review boards at participating institutions. Such projects must not duplicate work already completed or proposed by other investigators using ARIC data. All projects that lead to external funding should submit an ancillary study.

2.1. Proposing a manuscript using ARIC data – Overview

Please read detailed policies and procedures outlined in Section 3 of this manual before initiating or submitting a new ARIC manuscript proposal. The key steps in this process are to:

1) Identify a current ARIC investigator who will serve as the senior ARIC author on the project and can help guide the process of submitting the manuscript proposal. The

senior ARIC author is a contact point for ARIC, but the paper can have a different senior author.

2) Review the existing approved ARIC manuscript proposals to ensure that the project is novel and does not duplicate an existing approved manuscript proposal. All related ARIC manuscript proposals should be referenced in the proposal. (In the secure section of the **website**, ARIC investigators can search the full database of over 5000 manuscript proposals.)
3) Work with the senior ARIC author to identify co-authors and assemble a writing group for the paper. We encourage inclusion of investigators from multiple ARIC field centers to foster collaboration and facilitate communication. Consulting with leaders of workgroups in the relevant scientific area is helpful. Information regarding ARIC working groups is located on the ARIC website, under About→ARIC Structure.
4) Develop and write the manuscript proposal with input from the ARIC author and writing group, and using the ARIC manuscript proposal form that can be downloaded from the ARIC website, under Publications →Publications Policies, Forms and Guidelines→Manuscript Proposal Form. All members of the writing group must approve the final version of the manuscript proposal.
5) Submit the proposal to the ARIC Coordinating Center for review by the ARIC Publications Committee for approval.

Authors in the writing group either get access to the data from the ARIC PI who should have them sign a local data use agreement, or they submit a request for the CC to prepare the analysis files for them (with a cost associated). A third way to get access to data is through BioLINCC.

2.1.1. Procedures for TOPMed Proposals using ARIC data

TOPMed Proposals should go through the TOPMed publication committee review process to receive a proposal number. TOPMed proposals should never come to the ARICpub email from authors directly (TOPMed proposals are not reviewed by ARIC).

2.1.2. Procedures for ACHIEVE Proposals

ACHIEVE Proposals and Publications process is located on the ARIC website, under ACHIEVE → Publications→ ACHIEVE Publications Process.

2.2. Proposing an Ancillary Study to the ARIC cohort – Overview

An ARIC ancillary study is a research project based on information from ARIC participants that is not described in the current ARIC protocol. ARIC ancillary studies typically involve use of existing stored specimens (e.g., blood, urine, DNA), interviewing participants via telephone, and may involve new contact with ARIC participants. In general, ancillary studies require external (non-ARIC) funding that must cover the costs incurred by ARIC laboratories and to the coordinating center for the conduct of the study. Detailed policies have been developed to help guide investigators who are interested in proposing an ancillary study to the ARIC cohort, please see the *Ancillary Studies* section of the ARIC website. The key steps in this process are to:

1) Identify a current ARIC investigator or investigator who will help guide the process.

2) Review existing ARIC ancillary studies to ensure that the project does not duplicate ongoing work or a previously approved ancillary study.
3) If proposing use of specimens, confirm that the assays are valid in the ARIC specimen that the volume used is reasonable with the amount left in the proposed visit, and that costs are covered. (Synchronizing multiple assays often provides the most efficient use of specimen) Studies proposing additional participant burden need ARIC Monitoring Board approval.
4) Work with existing ARIC investigators to assemble an appropriate research team. We encourage inclusion of investigators from multiple ARIC Field Centers.
5) Develop and write the ARIC ancillary study with input from collaborators. All collaborators must approve the final version of the ancillary study proposal.
6) Submit the ARIC ancillary study for review by the ARIC Steering Committee.

The ARIC investigators and the coordinating center are dedicated to working with new investigators to help them become active parts of the ARIC Study. Please contact coordinating center or ARIC investigators with relevant expertise for additional information on how to become involved.

3. PROCEDURES FOR SUBMITTING AN ARIC MANUSRIPT PROPOSAL

1) Once you have completed the steps described in Sections 2.1.1) – 2.1.2), start with item 1 below to submit the proposal. Once you have completed the form in its entirety, and it is approved by all listed co-authors, send an electronic copy to the ARIC Coordinating Center (CC) at aricpub@unc.edu.
2) The CC will assign the manuscript proposal an ARIC MS Proposal number, add it to the agenda for the next monthly Publications Committee call, and input it into the Manuscript Tracking system (NewT). The proposals are available to PIs on the main ARIC website, under the Publications tab. The CC will email you with the ARIC MS Proposal number, which you must use for any future correspondence regarding this manuscript proposal.
3) Once the Publications Committee has reviewed the manuscript proposals, they will be assigned a status (approved, conditionally approved, deferred, or rejected) and priority, and the notes are then sent to the Steering Committee for final approval (3-day comment period).
4) Once the Steering Committee completes the review process, you will receive an official letter with the Committee's decision from ARIC CC (aricpub@UNC.edu).
    - Conditionally approved and deferred proposals require revision and resubmission prior to approval.
    - Requirements for revisions: Letter addressed to the committee stating the revisions made, a revised version of the proposal with all the changes made using tracked changes and a clean version of the revised proposal.

4. PROCEDURES FOR SUBMITTING AN ARIC MANUSCRIPT

After the manuscript proposal has been approved, the main steps for preparing and submitting the manuscript are as follows:

a. If the lead author or other investigator who will be conducting the analyses does not already have access to the necessary data, an ARIC data and materials distribution form (DMDA) will need to be completed before the Coordinating Center will supply a dataset for

the manuscript. (The Coordinating Center will usually charge for creation of a dataset. The DMDA form is available on the ARIC website at Researchers→Obtain/Submit Data→Data and Materials Distribution Agreement (DMDA).

b. The writing group prepares and communicates computational specifications to the CC, or it prepares statistical computations using the data set distributed by the CC.
c. The CC, when requested, prepares statistical computations according to priorities specified by the Publications Committee.
d. Once the lead author and the rest of his or her writing group agree upon the contents of the manuscript, the lead author must send their manuscript **along with the ARIC MS number** to aricjhu@jhu.edu. To expedite processing of the manuscript, authors should provide relevant information by completing this form. The manuscript, along with supplementary documents, should be sent as email attachments because the manuscript will eventually be circulated to the Steering Committee, NIH Project Office, the CC (for statistical review), and possibly other reviewers.
e. Once the aricjhu@jhu.edu administrator has received a manuscript, they will send the lead author an email with the following message, "We have received your manuscript [####] entitled [XXXX] for review by the ARIC Steering Committee. Please contact us if you do not hear from us in five weeks."
f. The editorial office will send the manuscript to the primary reviewer with a cover letter with a due date and will send the manuscript to the CC to begin the process of assigning a statistical reviewer. He will also send the manuscript to the ARIC Steering Committee members for critical comments along with a cover letter with a due date. When there is an NIH co-author, the editor will confirm with the NIH-co-author that NIH clearance has been received. Expedited review could be granted for ARIC papers that meet certain criteria. Please refer to section 4 for details.
    - Sponsors of certain types of data may have specific requirements (e.g., Cancer data, Soma Logic Data) for the administrator to include when sending out the manuscript for review.

g. The primary and statistical reviewers have two weeks to return his or her review to the editor by email (aricjhu@jhu.edu.)
h. Once all the reviews have been turned into the editor, he will compile all the comments and suggestions into a letter. The letter will then be sent by email to the lead author of the manuscript along with email attachments of the statistical reviewer's comments, the primary reviewer's comments, the statement of acknowledgement of the ARIC staff, and a copy of the policy regarding approval of manuscripts.
i. The manuscript is formally submitted to a journal or scientific meeting selection process. However, upon receiving Steering Committee approval to submit a manuscript to a journal, the lead author must follow the instructions in the ARIC approval letter.
j. If the manuscript is accepted in a journal, it is required that the lead author send acceptance notice to aricjhu@jhu.edu with the MS number.
k. The ARIC study endorses the NIH Public Access Policy that requests authors submit an electronic version of the author's final manuscript to the NIH upon acceptance of publication. The manuscript will be made available to the public at the NIH National Library of Medicine's (NLM) **PubMed Central (PMC)** after the final date of journal publication. Files about the public access policy from http://publicaccess.nih.gov/ are posted on the ARIC website, under Publications →Publications Policies, Forms and Guidelines. http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to PubMed central. Authors are encouraged to

notify the Coordinating Center via email (aricpub@unc.edu) of their submission status.

The overall responsibility for managing the entire process lies ultimately with the Steering Committee; however, for some steps a subgroup may be given responsibility. Further, the nature of the approval process varies according to the type of document. These issues are outlined below.

4.1. Types of Publications and Presentation

ARIC publication and presentations approval procedures apply to all national and international presentations and all publications. Presentations at informal settings and seminars do not require formal approval. Likewise, summaries of published data do not require re-review. The Publications Committee can be consulted to resolve any uncertainties.

4.2. Authorship

ARIC strongly believes that authorship should follow scientific contributions and endorses established publication policies (e.g., ICMJE). For some publications, the author is listed as the "The ARIC Study Investigators," with the preparers clearly indicated. In other cases, the persons preparing the manuscript are listed as authors followed by the words, "for the ARIC Study Group." Similarly, for some presentations, the paper is listed as presented by someone for the ARIC Study. In other cases, the individual is listed as the lead author. In all cases, however, the person who assumed the lead responsibility for a particular publication or presentation is to be listed as the first author or preparer. In addition, the phrase "ARIC Study" is to be included in the title or abstract when possible. Consortium papers will generally follow the consortium policies and ICMJE.

The Steering Committee is responsible for resolving any conflicts or confusion that occur with respect to appropriate recognition of authorship.

4.3. Acknowledgements

Acknowledgements should include the recommended language in the Acknowledgement Statements document located on the ARIC website, under the Publications →Policies, Forms and Guidelines tab. The document is updated with new ancillary studies which support specific components of ARIC (e.g. ARIC NCS for most data after visit 5; genetic grants for GWAS and sequencing; pharmaceutical support for reagents – hs-troponin, NT-proBNP, hyperglycemia, FGF23, Soma Logic for proteomics; imaging studies – MRI, PET; biomarker grants – hyperglycemia for visit 7 phlebotomy; cancer ancillary). Notably, industry funders and cancer registries perform a pre-review of ARIC papers before submission to a journal. The goal of pre-review is usually to assure compliance with regulatory policies and intellectual property. ARIC investigators are expected to have the scientific freedom to publish valid results regardless of the implications for or against any entity.

4.4. Manuscript and Abstract Generation

Under normal circumstances, the lead author of the writing group will be listed as the first author for those manuscripts where individual recognition is appropriate or as the first preparer for those where the ARIC Study is listed as the author. The lead author also has the responsibility

for listing the co-authors in the appropriate order. As indicated above, the Steering Committee advised by the publications committee serves as final arbitrator of any conflicts.

Individuals interested in preparing a manuscript or abstract on a specific topic must submit their proposals, which must include the names of the writing group members, to the Publications Committee for approval. The proposal must include a clear statement of the nature of the publication, the hypotheses to be addressed, and the types of statistical computations or data summarizations likely to be required. For consortia, ARIC will accept proposals on the parent consortium forms to enhance collaboration and productivity.

The Publications Committee has the responsibility for reviewing and approving these proposals, both for appropriateness and for a priority designation. The Committee also ensures that the different participating centers and groups are appropriately represented and that appropriate recognition is provided. The Steering Committee has final authority over publications decisions.

Once the specifications for the manuscript have been approved, any requirements for statistical computing can be formally communicated to the Coordinating Center. Requests will be processed according to the priorities specified by the Publications Committee. The Coordinating Center has representation on the writing group whenever central analyses are conducted and this person serves as the liaison to the writing group, both for communications about computing issues and for providing or obtaining appropriate statistical input.

The Publications Committee reviews the progress that each writing group is making toward the completion of its task and makes changes required for the timely completion of each manuscript or abstract.

4.5. Approval Procedures

A manuscript stemming from the ARIC study is submitted to the ARIC editor, who sends copies of the manuscript to a primary reviewer, a coordinating center's statistical reviewer and Steering Committee members for their critiques. A detailed critique is expected from the primary reviewer(s). Upon receiving the critiques, two courses of action are possible: (1) If the editor deems the reviewers' suggestions to be mainly editorial in nature, he may approve the manuscript and request that the authors incorporate suggested changes to the final version or submit in writing reasons for not doing so. No further action is needed from the Steering Committee; or (2) If, in the editor's judgement, critiques entail substantive changes, the revised manuscript must be re-submitted and reviewed by the editor or their designee before approval is granted. The goal is to complete routine reviews within 2-6 weeks. Multi-cohort papers receive limited review by the editor and a coordinating center representative (with steering committee circulation for comment). The goal is to complete limited review within 1 week.

The approval procedures are presented separately for various type of publication including:
1. Peer reviewed papers with original data
2. Methods papers which include data from ARIC or describe the design of original data collection in ARIC.
3. Consortium papers which include ARIC data including individual data meta-analysis.

The following papers do not require ARIC publications committee review:
A. Review papers with no new data analysis
B. Meta-analyses of published results

Consortia with established publications committee review which includes ARIC representation may be granted streamlined review. For these papers receive limited review but the editor review may rely more heavily on the previous consortium vetting process. Currently, C4R have been granted streamlined review.

4.6. Abstracts and Presentations

Abstracts for presentations should be submitted to the ARIC publications committee at least 1 week prior to the submission deadline. The committee may provide edits for consideration or request the abstract be withdrawn. **If there are no comments, the authors can proceed to submit the abstract**. Authors are also given the option of submitting the abstract before ARIC review if the meeting has a process for withdrawing the abstract in the rare cases where ARIC review subsequent to submission reveals a substantive problem.

For those presentations for which the formal submission of an abstract is not required and for which no proceedings are to be published, there is no formal requirement for ARIC review.

If an abstract is subsequently required, it should be submitted for review as other abstracts are. In a similar fashion, if it should be decided later to publish the proceedings, then the document detailing the presentation is to be submitted for review as are other publications.

4.7. Press releases and media discussions

In general, scientific findings from ARIC made available to the media will involve those findings being presented at scientific meetings and being published in the scientific literature. Such presentations and publications require prior clearance as noted above. Investigators are requested to keep the Project Office informed of contacts with representatives of the major national media and of major national media coverage of information that they have supplied.

Release of general descriptive information about the ARIC Study for local use (such as a local newspaper, university newsletter or state medical society journal) does not require prior approval. Use of centrally prepared materials for such purposes is encouraged. A copy of any resultant article should be sent to the Project Office.

4.8. Lectures and informal presentations

No formal approval is required for lectures and informal presentations so long as they do not constitute the initial public release of ARIC results.

5. PROCEDURES FOR ARIC ABSTRACT REVIEW

A week or more prior to submission of an abstract to a scientific session or conference, the author must submit the abstract for ARIC approval.

a. Once your proposed abstract has been read and approved by all co-authors it should be submitted as an email attachment to the CC (aricpub@unc.edu). It is required that the text of the email include the following:
    1) The name and contact information of the author who plans on presenting the abstract
    2) Title of the conference at which you will be presenting the abstract

3) The date, city, and state of the conference will be held
4) The Organization to which you will be submitting the abstract
5) The deadline for submission to the conference
6) The abstract title and the approved ARIC manuscript number or Ancillary Study proposal number in which the abstract pertains to

b. Sponsors of certain types of data may have specific requirements (e.g., Cancer data, Soma Logic Data) for the administrator to include them when sending out the abstract for review.

c. Upon receipt of your abstract with the above information, the CC will circulate it, via email, to the ARIC Publications Committee for review. The committee members will respond individually to the Chair of the Publications Committee with comments and responses, copying aricpub@unc.edu and aricjhu@jhu.edu on their response. The prescribed deadline for members to respond is typically one week. Note that no comments are interpreted as no objection to the authors proceeding as proposed.

   If an abstract is from an already approved manuscript or the abstract has been previously reviewed by the Publications Committee (e.g., the author is submitting the abstract to a new conference), the abstract will receive an expedited review from the Chair or one other designated member of the Publications Committee only.

d. Approval of abstracts is the fault and requires no action by the Publications Committee. If the committee has suggested comments or in rare instances where an abstract is not approved, the authors will be notified.
   If you have submitted an abstract for review and have not heard back from the committee, do not miss the conference submission deadline. You may still submit your abstract to the conference.

   Please note that submission of an abstract prior to ARIC review is allowable if the abstract can be withdrawn a month or more after the submission deadline. If the abstract as submitted is not approved by the ARIC study, it must be withdrawn.

Procedures for ACHIEVE abstract review can be found on the ARIC website, under ACHIEVE → Publications→ ACHIEVE Abstract Review Process.

6. PROCEDURES FOR LIMITED AND EXPEDITED REVIEW OF ARIC PAPERS

6.1. Limited Review by the ARIC Editor

At the ARIC Editor's discretion, a full ARIC review which includes a primary reviewer, a statistical review, and an editorial review, will be waived and approval (if warranted) will be granted by the Editor for the following categories of papers:

1) letters to the editor
2) papers relying primarily on ancillary study data or consortia with approved publications committees (e.g., ACHIEVE, C4R)
3) multi-cohort papers where ARIC data are included with other databases or primarily used to illustrate a methodologic development

The paper would still be sent to the ARIC Steering Committee (all PI's and NHLBI) as usual for a 2–3-day comment period. The goal is to complete the limited review within a week.

6.2. Overdue Reviews

In cases when the primary reviewer's review is not received within four weeks, the editor will have the discretion to substitute his own review for the primary review.

6.3. Expedited review of papers

When expedited review is requested in writing by an ARIC principal investigator with a specific reason given, the ARIC Editor would have the discretion to request expedited review with a goal of making a decision within 1-2 weeks. Reviewers will be given 3-5 days to complete their review. It is anticipated that only a few (<10) papers a year will be expedited since this involves greater burden and special treatment compared to other papers. This is in addition to rapidly limited reviews of multi-cohort papers and efforts to accommodate deadlines by engaging diligent fast reviewers who may have others return the favor by reviewing their paper rapidly. The main reason for expediting a review will be time sensitivity of results. This arises for particularly high impact papers or work in a field such as genetic variant discovery where a delay could lead to being scooped by another group at a substantial reduction in the impact of the ARIC paper.

7. ARIC POLICY ON DATASETS FOR REPRODUCING RESULTS

7.1. The issue

An increasing number of journals are requiring authors of manuscripts to commit to making data available for other researchers to try to reproduce the results in the manuscript. A few journals even require data to be made freely available without restrictions. Some others require authors to choose between two statements with wording such as:

> "The data, analytic methods, and study materials will be/have been made available to other researchers for purposes of reproducing the results or replicating the procedure."
>
> OR
>
> "The data, analytic methods, and study materials will not be made available to other researchers for purposes of reproducing the results or replicating the procedure."

Although ARIC has a substantial amount of data in repositories such as BioLINCC and dbGaP, these repositories may not satisfy the needs for reproducing results in a specific ARIC manuscript because: (a) there is a lag between the data being available for use by ARIC investigators and submission to the repositories; (b) because of consent restrictions and recoding of some variables to reduce the risk of identification of participants, the data in the repositories may not be identical to that used in a manuscript; and (c) details of analytic methods used in a manuscript, including computer code, are not included in the material submitted to the repositories.

Some papers have used the following language when ARIC and other data are used but not publicly available:

Data availability statement: Pre-existing data access policies for each of the parent cohort studies specify that research data requests can be submitted to each steering committee; these

will be promptly reviewed for confidentiality or intellectual property restrictions and will unreasonably be refused. Individual level patient or protein data may further be restricted by consent, confidentiality, or privacy laws/considerations. These policies apply to both clinical and proteomic data.

7.2. Reproducing Results

The ARIC Study investigators are committed to efforts to enhance reproducibility of scientific research.

If the authors of an ARIC manuscript are required or requested to provide a dataset and analytic methods for the purposes of reproducing results in the manuscript, the lead author should submit to the Coordinating Center the dataset, a corresponding data dictionary, and any information needed to understand how the data were used. If the journal requires computer code, this should also be submitted to the CC. Submission of material to the CC is needed only when a request for a dataset is received, either from the journal or from an individual after the journal has published the article with a statement that data may be obtained upon request. The CC will ensure personal identifiers are removed. To reduce the risk of deductive disclosure, the dataset submitted to the CC by the authors should contain only the data that were actually used in the analyses for the manuscript.

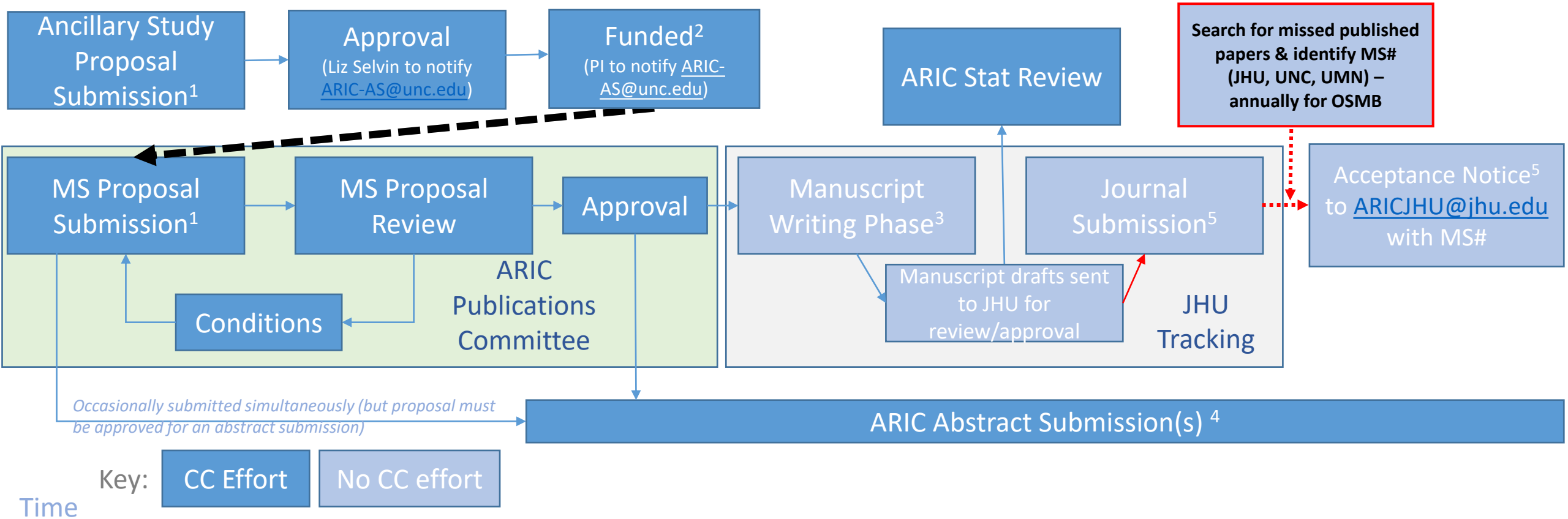
When preparing a manuscript for submission to a journal such as PLOS One that requires data to be made available without restriction, use only data from those participants who provided full consent (that is, not “ARIC Only” or “Not for Profit”) and coordinating center approval must be obtained prior to sharing data since ARIC no longer has any control over how it is used. For other journals we expect that we will be able to require a DMDA and so restrict use of the data to reproduce results in the manuscript.

(The CC’s current contract from NHLBI does not cover this work. If the number of requests for materials for reproducing results becomes substantial, the above policy may need to be re-visited.)

7.3. Documenting and archiving datasets and analytic methods

Even if a journal does not require datasets to be made available on request, it is good scientific practice that investigators working on a manuscript document their analyses, preferably including preparation of a statistical analysis plan before undertaking the analyses and details of exclusions applied to get to the subset of ARIC participants actually used in the analyses. Further, once the work is complete the relevant analytic data sets and documentation should be archived securely. ARIC centers maintain network drives that allow for secure archiving

ARIC Ancillary and Manuscript Proposal Life Cycles



For more information on the ARIC Publications Committee review process (green box), see the P&P Process Flowchart.

[1]*Ancillary study proposal submission could happen prior to MS Proposal submission but it is not required*

[2]*Progressing from AS proposal approval requires an ARIC DMDA*

[3]*Requires an approved ARIC manuscript proposal AND one member of writing group to have ARIC DMDA* or *some other agreement (outside of UNC) where they can obtain data from an ARIC investigator that does have a DMDA*

[4]*Requires an approved ARIC manuscript proposal number or Ancillary Study proposal number to be shared with submission AND one member of writing group to have ARIC DMDA* or *some other agreement (outside of UNC) where they can obtain data from an ARIC investigator that does have a DMDA*

[5] *Journal submission & review can take months to years and authors should still let aricjhu@jhu.edu know about acceptance (with MS proposal #).*

ARIC PROPOSAL and MANUSCRIPT REVIEW PROCESS: