



Publications and Presentations Policy

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Publications and Presentations Policy

1.0 List of Terms

Below is a list of commonly used terms throughout the policy and their definitions:

- **RURAL Cohort Study Investigator**: Principal Investigator and Co-PIs named in the RURAL Cohort Study U01 grant application
- **RURAL Cohort Study-affiliated Investigator**: Investigator, including consultants at a participatory institution, but not specifically named within the grant application
- **Non-RURAL Cohort Study Investigator**: Any Investigator from an institution not named in the RURAL Cohort Study U01 grant application

2.0 Principles and Objectives of RURAL Cohort Study Publications

The RURAL Cohort Study is committed to sharing its findings through scientific publications and presentations. The purpose of this policy is to ensure RURAL Cohort Study data is used appropriately and to describe the procedures for proposing a manuscript or presentation.

The goals of the RURAL Cohort Study Publications and Presentations Policy are listed below:

- Disseminate major RURAL Cohort Study findings to the scientific community in a timely manner.
- Create accurate and rigorous scientific publications using RURAL Cohort Study findings.
- Enable RURAL Cohort Study Investigators, especially junior fellows and early stage Investigators to collaborate and be recognized in RURAL Cohort Study manuscript proposals and published papers.
- Create procedures for the RURAL Cohort Study Steering Committee (SC) and National Heart, Lung and Blood Institute (NHLBI) to review manuscript proposals and publications before they are submitted for peer-review.
- Prevent duplication of published material and/or analyses.
- Ensure that abstracts, publications, and presentations using the RURAL Cohort Study data are accurate, objective, and do not compromise the scientific integrity of the overall study.

3.0 Publications and Presentations Subcommittee

The RURAL Cohort Study Publications and Presentations (P&P) Subcommittee oversees all RURAL Cohort Study P&P activities, with final decisions being made by the RURAL Cohort Study Steering Committee. The RURAL Cohort Study P&P Subcommittee approves the proposal of publications, submission of abstracts, and completed manuscripts prior to them being submitted for publication, as well as presentations before they are made available to the public. The RURAL Cohort Study P&P Subcommittee will submit its decisions to the RURAL Cohort Study Steering Committee for final approval at the RURAL Cohort Study Steering Committee meeting. The RURAL Cohort Study Steering Committee can appeal decisions made by the RURAL Cohort Study P&P Subcommittee.

3.1 Potential Overlap

- The first and senior authors of a proposed manuscript will be responsible for ensuring there is no overlap with manuscripts in progress or published. Prior to submitting a proposal, the first and senior authors must review the manuscript proposals and published papers, which will be listed on the RURAL Cohort Study website.
- In the manuscript proposal, first and senior authors will not only need to verify, but also state that they have checked previous manuscripts for potential overlaps.

- If the authors find any potential overlap with previous manuscript proposals or published papers, please disclose this in your manuscript proposal and describe how your proposal will be different from those it may potentially overlap with.

3.2 Priority Manuscript Proposals

- The RURAL Cohort Study Coordinating Center can commission manuscripts (e.g. design papers). This will be reviewed by the RURAL Cohort Study P&P Subcommittee.
- The RURAL Cohort Study P&P Subcommittee and the RURAL Cohort Study Steering Committee may review all the submitted manuscript proposals and create a list of priority manuscripts.
- Criteria for high-priority manuscripts will include: Scientific importance of potential findings; impact of publication on future RURAL Cohort Study activities, possibility for high visibility in prestigious scientific journals, and the need to make findings available to the scientific community and public.
- Determining authorship of high-priority manuscripts will be established by the RURAL Cohort Study P&P Subcommittee. One option to determine authorship will be to rotate the first or senior authors among the multiple Cores or groups. Shared first and senior authorship will be strongly encouraged.
- The RURAL Cohort Study Coordinating Center will prioritize high priority manuscripts in preparing RURAL Cohort Study analytic datasets.

4.0 Multi-Core vs One-Core Manuscripts

Most manuscripts will be study-wide and include multiple RURAL Cohort Study Cores to make maximum use of the RURAL Cohort Study findings. However, a manuscript that only includes data from one RURAL Cohort Study Core or county/parish will be considered and approved on a case-by-case basis by the RURAL Cohort Study P&P Subcommittee and RURAL Cohort Study Steering Committee.

5.0 Types of Studies

5.1 Main Study Manuscript

A main study manuscript will analyze data collected from the RURAL Cohort Study data set and can be analyzed either centrally at the RURAL Cohort Study Coordinating Center, the Statistical Data Coordinating Core (SDCC), or locally at one of the RURAL Cohort Study Cores. Main study manuscripts can be proposed by RURAL Cohort Study Investigator(s), RURAL Cohort Study-affiliated Investigators and/or Non-Rural Investigators. At least one of the authors of the manuscript must be a RURAL Investigator or RURAL-affiliated Investigator.

5.2 Ancillary Study Manuscript

An ancillary study manuscript will analyze additional data collected as part of an ancillary study of the RURAL Cohort Study. These manuscripts may include analysis of data for hypotheses related or unrelated to the RURAL Cohort Study. Ancillary study manuscript proposals will follow the same policies and procedures as the main study manuscript.

For manuscript proposals that use ancillary study data from the RURAL Cohort Study, it will be recommended that the first and senior authors invite at least one or more RURAL Cohort Study Investigator(s) to join the writing group. Please refer to the RURAL Cohort Study Ancillary Studies Policy for further details.

6.0 Manuscript and Abstract Proposal Process

6.1 Proposal Submission Guidelines

- Main study and ancillary study manuscript proposals can be submitted by any RURAL Cohort Study Investigator(s), RURAL Cohort Study-affiliated Investigators and/or Non-Rural Cohort Study Investigators. Non-Rural Cohort Study Investigators must first obtain approval from the lead PI from the relevant Core or Center before submitting a manuscript proposal.
- A proposed manuscript timeline for completion of the RURAL Cohort Study manuscript proposal will be part of the Manuscript Proposal Form and Instructions. The completed form will be submitted to the RURAL Cohort Study P&P Subcommittee. The approval of the proposal will be contingent on adherence to the timeline. It will be the responsibility of the first and senior authors to ensure adherence to the timeline. The RURAL Cohort Study P&P subcommittee will review non-adherence to the timeline and act accordingly.
- All manuscripts proposals will be submitted to the RURAL Cohort Study P&P Subcommittee at least one week prior to the regular RURAL Cohort Study P&P Subcommittee conference call.

6.2 Manuscript and Abstract Proposal Components

To submit a proposal for a manuscript, the first and senior authors must submit a full proposal using the template in the appendix. The manuscript proposal includes two parts: 1) general information; and 2) study details

The application template includes:

Part I: General Information

- Proposal Title
- Abbreviated Title (Up to 60 characters)
- Authors (Include order of authors and roles e.g., data collection, data analysis, writing the manuscript)
- Sponsors
- Abstract (Under 250 words)
- Type of Study (Main or Ancillary Study)
- Type of Manuscript (e.g., Cross-Sectional, Events, Longitudinal)
- Location of Data Analysis (e.g., Local or centrally at the RURAL Cohort Study Statistical Data Coordinating Center, or the Study Coordinating Core)
- RURAL Cohort Study data set to be requested
- Sample size/power
- Genetic Information (e.g., Use of genetic information)
- Keywords
- Additional Comments
- Timeline of manuscript completion
- Verification statement of potential manuscript overlaps

Part II: Manuscript Details (2-4 pages maximum. Proposals more than 4 pages will not be accepted)

- Introduction: Study reasoning and appropriate background (Brief)
- Hypothesis: Clearly stated and specific scientific questions to be addressed
- Type(s) of data: State variables, sample inclusions/exclusions, description of sample
- Analysis plan and methods (Description of statistical analysis)
- References

6.3 Authors on RURAL Cohort Study Manuscript Proposals

- At least one RURAL Cohort Study Investigator must participate and contribute to the proposed manuscript and will be listed as an author.
- Designated RURAL Cohort Study Investigator can be the PI, Co-PI or PI from the relevant RURAL Cohort Study Core or Coordinating Center, and Investigators who may be on the study manuscripts, abstracts, and main or ancillary studies.
- The RURAL Cohort Study NHLBI Program Officer cannot be an author on a manuscript proposal; however, the RURAL NHLBI Project Scientists may participate in the manuscript process, including serving as a co-author.

6.4 Genetic RURAL Cohort Study Manuscript Proposals

- The RURAL Cohort Study Steering Committee will receive proposals and manuscripts that involve the analysis of genetic data from RURAL Cohort Study participants.
- The RURAL Cohort Study P&P Subcommittee will have at least one member of the RURAL Cohort Study Genomics Core, who will review the proposals and manuscripts and then submit their recommendations to the RURAL Cohort Study P&P Subcommittee for their consideration.
- Following discussions and voting procedures, there will be three potential outcomes:
 - The RURAL Cohort Study Genomics Core member reviewer and the RURAL Cohort Study P&P Subcommittee will approve the proposal or manuscript.
 - The RURAL Cohort Study Genomics Core member reviewer will approve the proposal or manuscript, while the RURAL Cohort Study P&P Subcommittee either will disapprove or approve the proposal or manuscript with major revisions. While the final decision will be voted upon by the RURAL Cohort Study P&P subcommittee, the RURAL Cohort Study Steering Committee may review some of these cases and provide its recommendations.
 - The RURAL Cohort Study Genomics Core member reviewer will disapprove the proposal or manuscript based upon their concerns, but the RURAL Cohort Study P&P Subcommittee will approve the proposal or manuscript, and will have the final decision. To address any questions or concerns with the content, design and analysis of the proposal or manuscript, the proposer can request for additional feedback and comments from the RURAL Cohort Study Genomics Core member reviewer.

6.5 Abstract Proposals for Conferences

- Abstract proposals are restricted to the analyses with approved manuscripts.
- Requests for a new abstract proposal will be submitted to the RURAL Cohort Study P&P Subcommittee. The abstract proposal document will be limited to 200-250 words and will include the following sections: Background, objectives, data analysis methods, and conclusions.
- Authors on abstracts should include at least one RURAL Cohort Study Investigator, PI, Co-PI and PI from the relevant RURAL Cohort Study Core or Coordinating Center, or Project Scientists at NHLBI.

7.0 Authorship and Writing Groups

7.1 Formation of the Writing Groups

- PIs or Co-PIs of the RURAL Cohort Study, affiliated Investigators of RURAL Cohort Study and/or Non-Rural Cohort Study Investigators as well as individuals in the Cores can contribute as a co-author and participate as a member of the writing group. However,

authorship and membership will be contingent on the topic of the manuscript, levels of contribution, and qualifications according to the [ICJME](#) guidelines.

- The proposer of the manuscript will be the first and/or senior author; and will be chosen to lead the writing group. However, the proposer can designate another member of the writing group to be the lead author and to chair the writing group.
- Writing groups should contain at least one participating RURAL Cohort Study Steering Committee Investigator as a co-author. Non-Rural Cohort Study Investigators must first obtain approval from the lead PI from the relevant RURAL Cohort Study Core or Coordinating Center before being considered as a co-author.
- The RURAL Cohort Study Program Officer at NHLBI will not be able to participate as a co-author. However, the RURAL Cohort Study Project Scientist can serve as a co-author. He or she will provide NHLBI's guidance on the RURAL Cohort Study and input into the overall design of the manuscript.

7.2 Writing Group Responsibilities

The writing group lead chair will be accountable for the development and production of a written manuscript, approval processes, and manuscript submission. Responsibilities will include the following (but are not limited to):

- Defining tentative authorship (e.g., membership and order), preparation of outlines, assessment of data, analyses required, review of written materials, and creating timelines.
- Assignment of responsibilities to writing group members, with explicit deadlines for completion of tasks and clarification of co-authors' expectations.
- Regular discussions with study group members regarding sections of the manuscript, plans to analyze data, and adherence to timelines.
- Obtaining co-authors signatures on the Statement of Authors Form prior to the submission of the proposal to RURAL Cohort Study P&P subcommittee.
- Preparation and distribution of drafts for review, comments, and approval by each writing group member before submission of a draft to the RURAL Cohort Study P&P Subcommittee and to the journal.
- Regular communications (e.g. progress reports) with the RURAL Cohort Study P&P Subcommittee and the RURAL Cohort Study Steering Committee.
- Responses to NHLBI, as well as comments and correspondences with journal editors.

The writing group members will be involved in all or some of the phases of the manuscript preparations. Responsibilities will include the following (but are not limited to):

- Contributions to the writing of the manuscript, statistical analyses, and review of manuscript sections.
- Timely responses to communications with the writing group chair.
- Completion of tasks according to deadlines set by the writing group chair.
- Review of final manuscript draft prior to submission to RURAL Cohort Study P&P Subcommittee and Steering Committee.

7.3 Authorship

- Any writing group member who actively and substantially contributes to the manuscript will be considered as a co-author.
- The RURAL Cohort Study P&P Subcommittee recommends that for each RURAL Cohort Study manuscript proposal or abstract participating co-authors should be from more than one Institution, Core or Center.

- The writing group chair will follow guidelines set by [ICJME](#) in determining who should qualify for authorship. Criteria will include significant contribution to design of the article, procurement of data, review and/or assessment of data, drafting or revising article sections, and approval of final manuscript draft.
- The writing group members will determine the order of authorship based upon the effort level and contributions made by the members, by mutual consensus.
- For manuscripts in progress simultaneously, there may be a manuscript limit per year for first or senior authorship for an individual. This will be determined by the RURAL Cohort Study P&P Subcommittee.
- While the P&P Subcommittee can restrict the number of authors on a manuscript, the journal can also limit the number of participating authors on a given manuscript. (e.g., the Journal of American Medical Association and The National Library of Medicine's online reference service both list only six names.)
- Since the RURAL Cohort Study is a multi-centered and multi-investigator project, the RURAL Cohort Study P&P Subcommittee and the RURAL Cohort Study Steering Committee acknowledge that there will be occasions for several authors on a manuscript. The RURAL Cohort Study P&P Subcommittee will recommend the maximum number of authors on any RURAL Cohort Study manuscript. The RURAL Cohort Study P&P Subcommittee and RURAL Cohort Study Steering Committee will review authorship at their discretion.
- Some co-authors may fail to provide substantial contributions to the manuscript or fail to commit to the work group. In these instances, he or she may lose their authorship rights and may be left off the final manuscript. This will be reviewed by the RURAL Cohort Study P&P Subcommittee and the RURAL Cohort Study Steering Committee as necessary.
- A Statement of Authors will be required along with a statement stating that the authors acknowledge that this work was either a main or ancillary study of the RURAL Cohort Study and received NHLBI support (Grant No. U01HL146382).

8.0 Authorship for Ancillary Studies

- Authorship for ancillary study manuscripts using RURAL Cohort Study findings will be reviewed and approved by RURAL Cohort Study P&P Subcommittee and the RURAL Cohort Study Steering Committee.
- While the proposing ancillary study Investigators will be the lead members of the writing group, the writing group should also include individuals from the RURAL Cohort Study Steering Committee, RURAL Cohort Study Coordinating Center and other RURAL Cohort Study Cores as relevant.
- The criteria for authorship on ancillary manuscripts will follow authorship for main study manuscripts as indicated above.
- A Statement of Authors will be required along with a statement stating that the authors acknowledge that this work was an ancillary study of the RURAL Cohort Study and received NHLBI support (Grant No. U01HL146382).

9.0 Data to be obtained from RURAL Cohort Study

Data request for the development of a grant proposal, hypothesis generation and power calculations should be sent to the RURAL Cohort Study Coordinating Center and the RURAL Cohort Study Statistical Data Coordinating Center. These data requests should be associated with an approved manuscript proposal or an approved ancillary study manuscript proposal. Investigators should be instructed that NHLBI policies for data distribution will be applied and

compliance will be ensured through signed data distribution agreements and forms. Depending on the type of request, authors will be required to complete and submit these agreements and forms to the Steering Committee, as well as the NHLBI RURAL Cohort Study Program Officer and Project Scientists for approval.

9.1 Data and Materials Distribution Agreement (DMDA)

- A DMDA will be required if an ancillary study Investigator requests genetic material, and/or includes statistical analyses, laboratory, examination, questionnaire results, and primary results.
- The requesting Investigators should review and sign the DMDA based upon their data needs for the proposed manuscript. The completed form will then be submitted to the NHLBI RURAL Cohort Study Program Officer and Project Scientist, with a copy sent to the RURAL Cohort Study Coordinating Center.
- If the RURAL Cohort Study Coordinating Center does not have on file the DMDA, the Center will not permit the release of RURAL Cohort Study data set nor will allow the requester access to the RURAL Cohort Study data set.
- The DMDA form can be found in the Appendix.

9.2 Data Set Request (DSR) and Notice to Analyze Form

- Requesting Investigators will be required to complete a Data Set Request (DSR), which describes the nature of the request; and Notice of Intent Analyze form.
- The DSR form should be linked with an approved manuscript proposal or an approved ancillary study manuscript proposal. For grant applications, the DSR may be linked to an ancillary proposal that is under Committee review.
- The signed form must be submitted to the RURAL Cohort Study Coordinating Center, the RURAL Cohort Study Statistical Data Coordinating Center and to the RURAL Cohort Study Program Officer and Project Scientists at NHLBI.
- Once approved, the RURAL Cohort Study Statistical Data Coordinating Center will prepare and disseminate the RURAL Cohort Study analytic data set to the requesting Investigator. The RURAL Cohort Study Coordinating Center will not permit nor will allow the requester access to the RURAL Cohort Study data set if this form is not on file at the Center.
- The DSR and Notice to Analyze form which can be found in the Appendix.

9.3 Analytic Data Set Requests

- **Communications with Collaborating RURAL Cohort Study Investigators**
 - In preparing the manuscript, the first author, senior author, and co-authors will review all of the RURAL Cohort Study findings and data sets that may be of relevance to the topic of the manuscript.
 - The first author, senior author and co-authors will communicate with their RURAL Cohort Study co-authors or representatives when preparing the original data request and data needs for the proposed manuscript.
- **Original request for data**
 - Once the DMDA and DSR forms are approved and are archived at the RURAL Cohort Study Coordinating Center, the Center will fulfill the request for the RURAL Cohort Study data set. Data set will be sent to the requesting Investigator(s) or Center(s).
- **Additional requests for data approved in manuscript proposal**
 - If the first and senior authors determine that additional RURAL Cohort Study data sets will be needed for the production of the manuscript, those additional requests can be made by completing the DSR form.

- The request will be processed by the RURAL Cohort Study Statistical Data Coordinating Center and submitted to the RURAL Cohort Study Program Officer and Scientists at NHLBI for their review.
- Once approved, the RURAL Cohort Study Statistical Data Coordinating Center will send the requested RURAL Cohort Study data sets to the Investigator(s) or Center(s).
- **Additional requests for data “NOT” in approved manuscript proposal**
 - If the first and senior authors request other RURAL Cohort Study data sets that were not requested in the original and approved RURAL Cohort Study data set request, requests for additional RURAL Cohort Study data sets will be obtained by completing a new and second DSR form.
 - This request will be submitted to the RURAL Cohort Study Coordinating Center, the RURAL Cohort Study Statistical Data Coordinating Center, and the RURAL Cohort Study P&P Subcommittee.
 - The RURAL Cohort Study P&P Subcommittee will have seven days to review and approve this request. If there is no response, the request will be submitted to the RURAL Cohort Study Coordinating Center for their review. Upon approval, the Center will submit the request to the RURAL Statistical Data Coordinating Center for their release of the RURAL Cohort Study data set.
 - Following the review of RURAL Cohort Study data requests, the RURAL Cohort Study P&P Subcommittee will have the right to deny data requests. The first and/or senior author(s) as well as their representative will be able to discuss this decision further with the RURAL Cohort Study P&P Subcommittee on a conference call.
- **Secondary Data Analysis**
 - Review of current RURAL Cohort Study data sets will be considered as secondary RURAL Cohort Study data analysis. Regarding the study or manuscript, no additional data will be collected from participants.
 - In the preparation of grant applications, investigators can choose to carry out secondary data analysis on RURAL Cohort Study data sets. A manuscript proposal, grant summary and intent for analyses plan will need to be submitted to the RURAL Cohort Study P&P Subcommittee for their review and approval.

10.0 Manuscript Initiation and Completion Process

- Once the study manuscript proposal has been approved by RURAL Cohort Study P&P Subcommittee, the first and senior authors will arrange for a conference call with all co-authors. The goals of the call will include (but are not limited to): Finalizing the timeline, discussing proposal sections, defining and assigning responsibilities and clarifying expectations.
- Based upon the proposal, the first and senior author will discuss with the RURAL Cohort Study representative and co-authors tasks for research, data analysis and writing as well as gather general feedback on the manuscript process.
- Since manuscripts are multi-authored and multi-centered, the P&P Subcommittee will require a proposed timeline for manuscript completion as part of the proposal process.
- The first and senior authors will be responsible for co-authors’ adherence to the timeline. To ensure that the manuscript will be written and completed in a timely manner, it will be essential that co-authors acknowledge and respond to any communications from the first and senior authors regarding manuscript preparation within one week. When contacted, individuals should be able to provide an update on tasks or provide feedback as soon as possible.

- The RURAL Cohort Study P&P Subcommittee and the RURAL Cohort Study Steering Committee will periodically assess the preparation of the manuscript and requires the first and senior authors to inform the Committees of the manuscript's progress.
- To request a status update of manuscripts in progress, the RURAL Cohort Study Coordinating Center will contact the first and senior authors at least twice a year. If there are no communications from the first and senior authors, the Center will reach out to the first and senior author again and request a response within a month. If there is still no response, the Center will consider the manuscript as dormant. At this time the RURAL Cohort Study P&P Subcommittee will re-assign first and/or senior authorship(s) to another member within the writing group. The RURAL Cohort Study P&P Subcommittee can also state the manuscript as withdrawn. A withdrawn manuscript can then be written by other RURAL Cohort Study Investigator(s) outside the writing group.
- Once the manuscript is ready for submission to the RURAL Cohort Study P&P Subcommittee for their approval, the first, senior, and all co-authors should ensure that they have met the scientific requirement for authorship as listed above. Co-authors will be required to complete and sign the Statement of Authors form. To acknowledge support, authors are required to provide the U01 grant number (U01HL146382). The RURAL Cohort Study P&P Subcommittee will review and approve the final version of the manuscript.
- While the manuscript is being reviewed by the P&P Subcommittee, the first or senior authors will be required to submit to the RURAL Cohort Study Coordinating Center a copy of the submitted final manuscript and a copy of the cover letter. This will allow the Center to track RURAL Cohort Study manuscript status and journal responses.
- At NHLBI, the NHLBI staff person, who is listed as a co-author on the manuscript will forward the manuscript for review and to the appropriate Division within NIH. NIH clearance of manuscripts will be needed.

11.0 Review of Abstracts and Manuscripts by the RURAL Cohort Study P&P Subcommittee

To assess the importance of the scientific content, precision of writing and the similarities to other RURAL Cohort Study findings, main and ancillary study manuscripts will be review by the RURAL Cohort Study P&P Subcommittee.

11.1 Assignment of Lead RURAL Cohort Study P&P Subcommittee Member Reviewer

- The RURAL Cohort Study P&P Subcommittee member will choose a member to lead communications with the first and senior authors and the RURAL Cohort Study Steering Committee, and to coordinate a timely review process. The options for the selection of the Lead RURAL Cohort Study P&P Subcommittee member reviewer will include, rotation among members, subject expertise, nominations or number of present manuscripts to be reviewed.
- The first and senior authors will be required to submit the final manuscript to the RURAL Cohort Study Coordinating Center by the Wednesday, three weeks before the scheduled RURAL Cohort Study P&P Subcommittee is scheduled to review manuscript proposals. The Center will deliver the manuscript to the RURAL Cohort Study P&P Subcommittee and review members immediately upon their receipt. Any feedback and comments will be sent to the first and senior authors, and RURAL Cohort Study P&P Subcommittee.
- Following review, the Lead RURAL Cohort Study P&P Subcommittee member reviewer will make one of three recommendations:
 - 1) Approve with no changes;
 - 2) Approve with minor revisions and final approval from the Lead RURAL Cohort Study P&P Subcommittee member; or

- 3) Reject with major revisions and re-review by the RURAL Cohort Study P&P Subcommittee. It is recommended that the Lead RURAL Cohort Study P&P Subcommittee member reviewer communicate his/her proposed recommendations prior to the RURAL Cohort Study P&P Subcommittee conference call.
- Before manuscript submission to the journal, the Lead RURAL Cohort Study P&P Subcommittee member reviewer will ensure the resolution of all questions and concerns with the first and senior authors.

11.2 Assignment of Statistical Reviewer

- The role of the Statistical Reviewer will be to assess the accuracy of data analysis, verify the data conclusions, and precision of writing in the manuscript.
- The RURAL Cohort Study Coordinating Center will assign a Statistical Reviewer to the final manuscript. He or she will have two weeks to finish their review and provide comments to the first and senior authors, Lead RURAL Cohort Study P&P Subcommittee member reviewer, P&P Subcommittee chair and RURAL Cohort Study Coordinating Center. This review may be discussed during the RURAL Cohort Study P&P Subcommittee conference call.

11.3 Abstracts

- Abstracts will be reviewed by two or more RURAL Cohort Study P&P subcommittee members with simultaneous review by the RURAL Cohort Study Coordinating Center and the RURAL Cohort Study Program Officer and Project Scientists at NHLBI. Reviewers will respond in a timely manner, with the recommendations to approve, approve with modifications, or disapprove the abstract.
- Only approved abstracts can be allowed to move forward for the approved manuscript. This will prevent abstracts from never becoming incorporated into a published manuscript.
- For archival purposes, authors should send a copy of the approved presentation or publication to the RURAL Cohort Study Coordinating Center and the RURAL Cohort Study Program Officer and Scientists at NHLBI.
- Individuals will be able to submit a previously approved abstract to the P&P Subcommittee. These accepted abstracts should also be sent to the RURAL Cohort Study Coordinating Center for listing of RURAL Cohort Study Publications and Presentations.

12.0 Review of Abstracts and Manuscripts by NHLBI

- The NHLBI may require review and receipt of manuscripts that do not include NHLBI RURAL Cohort Study Staff as co-authors.
- The NHLBI will approve and review manuscripts that have NHLBI Project Staff as co-authors.
- Reviews will occur accordingly: Abstracts will occur within five business days, non-high priority manuscripts will occur within ten business days, and high-priority manuscripts will occur within five working days. The review of RURAL Cohort Study manuscripts will be done with the RURAL Cohort Study P&P Subcommittee reviews.
- Those manuscripts and abstracts that need NHLBI's review and approval will be electronically submitted to NHLBI Project Officer.
- RURAL Cohort Study manuscripts will not be submitted to a journal if NHLBI approval has not been obtained.

Individuals' Role in Manuscript Preparation and Completion

	Manuscript Proposal	Abstract	Presentation	Manuscript
First author or Senior author	1,2	1,2	1,2	1,2
Co-authors	3,4,5	3,4,5	3,4,5	3,4,5
Lead P&P Subcommittee member reviewer	N/A	N/A	N/A	6,7
P&P Subcommittee	8,9	8,9	8,9	8,9
NHLBI	N/A	14	N/A	14
Study Coordinating Center	12	12	12	11,12
PI of originating center	4	4	4	4
Study Data Coordinating Center Analysts	N/A	N/A	N/A	13

N/A =Not Applicable

1. Prepares manuscript draft, reviews data analyses, assesses writing efforts, and communications with co-authors.
2. Obtains required approvals and forms.
3. Contributes actively and substantially in all scientific endeavors.
4. Approves document before submission to P&P Subcommittee.
5. Informed of P&P Subcommittee decision, and approves minor or major revisions.
6. Approves final manuscript prior journal submission.
7. Communicates feedback and written comments to first and senior author and provides recommendations to P&P Subcommittee.
8. Approves manuscript proposal. Approves manuscript prior to journal submission or delegates this authority to Lead P&P Subcommittee member reviewer. Approves abstract prior to submission or presentation prior to meeting or delegate responsibility to an appointed committee member.
9. Provides feedback to first author, senior author, and Lead P&P Subcommittee member reviewer prior to P&P Subcommittee discussion.
10. Assigns Lead P&P Subcommittee member reviewer.
11. Confirms that all co-authors have approved manuscript in writing prior to Steering Committee submission.
12. Maintains tracking system and communicates with first and senior author regarding publication status.
13. Validates or approves results presented in manuscript prior to submission to journal.
14. Approves only if NHLBI co-author.

13.0 Acknowledgement of NHLBI

The recognition of funding and support of all main and ancillary study manuscripts that utilize RURAL Cohort Study data sets is mandatory.

The inclusion of the following text within the manuscript is recommended: The Risk Underlying Rural Area Longitudinal Study (RURAL) is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI). The content of the manuscript has been reviewed by RURAL Cohort Study.

If the first or senior author(s) do not obtain RURAL Cohort Study's approval, the following disclaimer statement is required within the manuscript: This manuscript has not been approved by RURAL Cohort Study. The ideas, opinions, and conclusions reported in this manuscript do not reflect the views and opinions of RURAL Cohort Study Investigators or NHLBI. Some journals will request the role of the sponsor to be designated and acknowledged in the manuscript. During the course of the RURAL Cohort Study, the Program Officer and Project Scientists at NHLBI will provide direction in this regard. He or she may also provide additional information to assist in the preparation of the manuscript and may have authorship rights.

14.0 Use of Data for Thesis or Other Academic Project by Graduate Students

Graduate students will be allowed to use RURAL Cohort Study data sets for doctoral or masters' level thesis; however, the P&P Subcommittee will review and approve their work. Publications and presentations stemming from these studies will conform to the above publication policies. This will include obtaining the P&P Subcommittee approval of manuscript proposals and presentations, preparing and completing the manuscript, and submitting to the journal as well as with the review of seminars and thesis defenses that the public may attend. The RURAL Cohort Study P&P Subcommittee request to use RURAL Cohort Study data sets in a graduate work should include (but is not limited to):

- The name of at least one RURAL Cohort Study PI or Co-PI, RURAL-affiliated Investigator or Non-affiliated Investigator who will agree to serve on the student's dissertation committee and as a co-author of the publication;
- A brief summary for the thesis, including reasoning, scientific background, main hypothesis and data analysis plan;
- A proposed timeline for thesis and for completion of proposed RURAL Cohort Study manuscript;
- A completed and signed DMDA from the student and advisor that will allow the use of RURAL Cohort Study data set to be used for the thesis work;
- A proposal of one RURAL Cohort Study manuscript to result from the thesis work;
- Acknowledgment of the student having read the publication policies and commitment to adhere to them;
- A formal email or letter from the student's thesis Investigator that will state their commitment to the project, supports the manuscript proposal, availability to discuss work with the student, and their commitment to adhere to RURAL Cohort Study publication policies.

15.0 Use of Data for Grant Application or Contract Proposal

- The RURAL Cohort Study Steering Committee, the RURAL Cohort Study Program Officer and Project Scientist from NHLBI will be required to review and approve any RURAL Cohort Study data sets that have not been previously published but may be needed for grant applications or contract proposals. Requesters will be able to submit notification of intent to the Steering Committee. Following discussions, the RURAL Cohort Study Steering Committee will have the right to disapprove the use of any RURAL Cohort Study data sets in new grant applications or contract proposals.

16.0 Invited RURAL Manuscripts and Presentations

- RURAL Cohort Study PIs or Co-PIs, Affiliated Investigator or Non-affiliated Investigator may receive personal invitations to prepare manuscripts regarding RURAL Cohort Study findings or other aspects related to the RURAL Cohort Study.

- Acceptance of these invitations will be dependent on approval from the P&P Subcommittee. The Subcommittee will determine if the invitee should be the lead author in writing the manuscript. If the inviter has selected the particular invitee for a certain reason (i.e. expertise in the topic or participation within the institution) that the invitee should inform the RURAL Cohort Study P&P Subcommittee to aid in their decision.
- When an invitation is sent directly to the Chair of the Steering Committee or the Chair of the RURAL Cohort Study Coordinating Center, the members of the Steering Committee will determine who may represent the RURAL Cohort Study on the invited manuscript or presentation.
- Only published RURAL Cohort Study reports or manuscripts will be used in presentations, unless prior approval is obtained from the RURAL Cohort Study P&P Subcommittee and RURAL Cohort Study Steering Committee.
- Acceptance of invitations for a presentation to present at their institution using any previously published RURAL Cohort study findings will be strongly supported by RURAL. The RURAL Cohort Study P&P Subcommittee should be aware of local talks and grand rounds; but no formal approval will be necessary.

17.0 RURAL Cohort Study Contact Information

RURAL Cohort Study Coordinating Center

Boston University

Email: rural@bu.edu

17.0 Appendices

A. Manuscript Form

The RURAL Cohort Study Coordinating Center recommends reading the RURAL Cohort Publications and Presentations Policy before completing this form. This Policy can be found on the RURAL Cohort Study website (<https://www.theruralstudy.org/>) and is available via email request from The RURAL Cohort Study Coordinating Center Administrator at: rural@bu.edu.

Date of Submission:

WRITING CHAIR NAME:

Contact Information:

Institution:

Email Address:

Phone Number:

(If this is your first RURAL Cohort Study manuscript proposal, please include a letter of introduction from a RURAL Cohort Study Investigator.)

RURAL Cohort Study Investigator/Sponsor:

Name:

Institution:

Email Address:

Phone Number:

Proposal Title:

Abbreviated Title (Up to 60 characters):

Proposed co-authors names, institution, email addresses, and co-author contributions:

(The RURAL Cohort Study Executive Committee and/or the Publications and Presentation Subcommittee may nominate additional authors if special expertise for interpreting RURAL Cohort Study data is needed. For all locally analyzed papers, please justify the

use of each co-author; if the paper is from a multisite ancillary study, co-authors from contributing Cores of the RURAL Cohort Study should be involved.)

Have all co-authors reviewed and approved this document? Yes No

Has the lead author checked for overlap of manuscripts with the RURAL Cohort Study Administrator? Yes No

Please confirm that this manuscript has been checked for overlap with the RURAL Cohort Study Coordinating Center Administrator at rural@bu.edu. If possible overlap exists, please describe your resolutions here:

PART 1: General Information

1. Type of study (Select only one):

Main Study Ancillary Study

If Ancillary Study, please list

Study Title:

PI:

2. Type of data (select one):

- Methodological Paper (Focus on approaches to assemble and evaluate the Cohort or new statistical methods)
- Cross-sectional Paper (Focus on reporting data collected as part of the baseline evaluations, including description of the distribution of risk factors, differences between groups (including races) in the distribution of risk factors, and the association between risk factors)
- Longitudinal Paper (Focus on the association of baseline characteristics with data collected during the follow-up of the RURAL Cohort Study)
- Event data Paper (Focus on adjudicated stroke events, MI events, other vascular events, all-cause mortality and adjudicated causes of death [For the use of this data, please contact the RURAL Cohort Study Coordinating Center Administrator at rural@bu.edu])

2a. If cross-sectional paper (This is dependent on the hypothesis and variable(s) being assessed):

“Complete participants”: Yes No

(Participants who complete the baseline (gave verbal consent over the telephone) as well as the in-person exam)

“Partial participants”: Yes No

(Partial participants are those who only completed baseline but did not have in-person exam component.)

3. Type of Data Set or Samples requested from the RURAL Cohort Study:

4. Location of analysis:

Central (By the RURAL Cohort Study Data Coordinating Center staff)

Local (Site): Please see the RURAL Cohort Study Publications and Presentation Policy as additional details are required.

5. Genetic Information:

Do you propose the use of data from participants' DNA? Yes No

If yes, is the paper addressing vascular-related conditions? Yes No

<p>If no, the RURAL Cohort Study participants did not provide consent for uses of DNA for diseases unrelated to vascular problems. Please refer to the RURAL Cohort Study Coordinating Center for guidance.</p>
<p>6. Conflict of Interest:</p> <p>a. Are these analyses to involve a for-profit corporation? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>b. Do you or any member of your Writing Group intend to patent any process, aspect, or outcome of these analyses? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>c. If the answer to a or b is yes, the involvement includes (check one):</p> <p><input type="checkbox"/> An unrestricted educational or research grant</p> <p><input type="checkbox"/> Hypothesis development and/or data analysis (results require verification by the RURAL Cohort Study Coordinating Center)</p>
<p>7. Timeline for Manuscript Completion:</p> <p>Projected date for first draft (MM/YYYY):</p> <p>Projected date for initial submission to a journal (MM/YYYY):</p>
<p>8. Name of Potential Journal for Manuscript Submission:</p>

PART II: Manuscript Details

The following information should be provided in this document with a page length of approximately 2-4 pages. Proposals over 4 pages will not be accepted.

<p>Abstract: Under 250 words</p>
<p>Keywords: 4-5 keywords</p>
<p>Introduction: Provide the Study reasoning and appropriate background</p>
<p>Hypothesis: Clearly stated and specific scientific questions to be addressed</p>
<p>Data: Description of the sample: type, size, inclusion/exclusion criteria, and stated variables</p>
<p>Analysis plan and methods: Description of statistical analysis (i.e. sample power) and other methods</p>
<p>Summary: Any preliminary conclusions</p>
<p>References: Provide formatted references</p>

Part III: Submission of Manuscript Form

Please let the RURAL Cohort Study Coordinating Center Administrator know if you should have any additional comments or questions. For the first manuscript proposal submitted by a non-RURAL investigator, a brief letter of introduction must be provided, including their background and credentials, and the name of the RURAL Cohort Study Investigator who is the sponsor.

Following the completion of Part I and II, please send this document and if needed the letter of authorship support to the RURAL Cohort Study Coordinating Center Administrator at rural@bu.edu

B. Statement of Authorship Form

The first author and each co-author listed on the manuscript must complete the following Statement of Authorship form prior to submission of their manuscript to the RURAL Cohort Study Publications & Presentations Subcommittee. In addition, the RURAL Cohort Study Publications and Presentations Subcommittee will review the completed form prior to the manuscript being submitted to the journal.

Digital Signatures are accepted. If for any reason, an author cannot complete and sign the form, he or she may send an email with their respective contributions to the first author. This is an exception and not the rule.

The RURAL Cohort Study Publications & Presentations Subcommittee recommends for the first author to review the co-author's contributions. All authors should review authorship criteria as defined by the [ICMJE](#).

If the first author or any of the co-authors should have any questions, please contact the RURAL Cohort Study Coordinating Center's Administrator at rural@bu.edu.

RURAL Cohort Study Publication Policy – Statement of Authorship		
TITLE:		
I agree that each of the co-authors has made contributions as stated below and that these contributions are sufficiently substantive to merit authorship.		
1. FIRST AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
** Each co-author must briefly state their contribution to the manuscript and sign **		
2. CO-AUTHOR	SIGNATURE	DATE(MM/DD/YYYY)
CONTRIBUTION		
3. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
4. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
5. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		

6. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
7. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
8. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
9. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
*** For each additional co-author, the first author or senior author must justify inclusion of more than nine authors and attach justification statements. ***		
10. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
11. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
12. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
13. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
14. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)

CONTRIBUTION		
15. CO-AUTHOR	SIGNATURE	DATE (MM/DD/YYYY)
CONTRIBUTION		
JUSTIFICATION FOR MORE THAN NINE AUTHORS:		

C. Data and Materials Distribution Agreement

The undersigned parties hereby enter into this Data and Materials Distribution Agreement (DMDA) as of the date specified on the final page hereof.

INTRODUCTION

The **Risk Underlying Rural Areas Longitudinal (RURAL) Cohort Study** is a multicenter prospective epidemiology cohort study that seeks to address gaps in our knowledge of heart and lung disorders as well as to understand the health concerns of rural communities in the southeastern regions of the United States. Focusing on ten counties in Alabama, Kentucky, Louisiana, and Mississippi, the multi-investigator team will examine 4,600 rural residents to study their heart, lung, and overall health. The RURAL Cohort Study will have a mobile examination vehicle (MEU) that will be staffed with trained technicians and will travel to the target counties to perform the RURAL Cohort Study. The RURAL Cohort Study will collect biological specimens and clinical data from participants, which will serve as valuable scientific resources for the population and scientific community. This repository will be maintained under the joint stewardship of Boston University and the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). As part of the RURAL Cohort Study, participants will receive their results and general Study information will be shared with the communities.

To ensure the confidentiality and privacy of RURAL Cohort Study participants and their families, the approved investigator requesting access to RURAL Cohort Study Data and Materials must follow the requirements detailed in this DMDA. The failure to adhere with this DMDA could result in its termination, denial of further access to the RURAL Cohort Study and other NHLBI resources, and may leave violators liable to legal action on the part of the RURAL Cohort Study participants, their families, Boston University, or the U.S. Government.

The undersigned parties entering into this DMDA include: the Recipient and Recipient's Principal Investigator (defined in the next section), the NHLBI, and Boston University, on behalf of the RURAL Cohort Study and under the direction of the RURAL Cohort Study Steering Committee.

DEFINITIONS

For purposes of this agreement,

“Genetic Analysis Data” refers to any and all information derived from genetic materials, and any and all data derived from statistical analyses linking data from genetic materials with other study data.

“Data” refers to any and all study data, including laboratory, examination, and questionnaire results, and Analysis Data, images (e.g., computed tomography scans), or primary signal data (e.g., ECG, spirometry tracings, or pulse wave velocity forms) and associated records either obtained directly from RURAL Cohort Study participants or obtained from third parties as authorized by the participants pursuant to the contracts with the NHLBI, as well as data provided to the RURAL Cohort Study by ancillary studies.

“Resultant Data” refers to data derived in whole or in part by Recipient from Data and/or Materials provided under this DMDA.

“Materials” refers to bio-samples, including but not limited to, urine and blood samples and products thereof, including but not limited to, immortalized lymphocytes and extracted DNA from said bio-samples pursuant to the contracts with the NHLBI, as well as Materials provided to the RURAL Cohort Study by ancillary studies.

“RURAL Study Investigator” is a research investigator who works with the RURAL Cohort Study either as an employee of Boston University, as an employee of a RURAL Cohort Study associated institution, or the NHLBI or through a current and active contract or consulting agreement with Boston University, the NHLBI, or one of their contractors.

“Research Project” refers to the project described in the attached research application.

“**Recipient**” refers to the institution or other entity receiving access to the RURAL Cohort Study Data and/or Materials requested for the Research Project identified in Section 3 below as described in the attached research application.

“**Principal Investigator (PI)**” refers to the Research Project Director for the Recipient.

TERMS and CONDITIONS

It is mutually agreed as follows:

1. Materials. Boston University and NHLBI agree to transfer to Recipient the Materials described below, including the types of samples, amount per sample, the number of individuals from whom samples are to be provided, and whether samples are nonrenewable or from a renewable resource (e.g., DNA from immortalized cell lines) for use by the Recipient's PI to conduct the Research Project as summarized in Section 3 below.

2. Data. Boston University agrees to provide Recipient with Data described as follows:

The RURAL Cohort Study will provide Recipient with the name and contact information of Study Investigators and all other investigator(s) who generated such Data.

3. Research Project.

3.1 These Materials and Data will be used by Recipient's PI solely in connection with the Research Project, as named and described in the attached research application (insert Research Project name below):

3.2 If any aspect of the Research Project, e.g., biological assays and/or genetic analyses, is to be performed by an entity other than Recipient as permitted by Section 4.2, such entity is to be named below:

3.3 This DMDA covers only the Research Project cited in Section 3.1 of this DMDA. Recipient must submit a separate DMDA for each Research Project for which Data and/or Materials are requested.

4. Non-transferability. This DMDA is not transferable.

4.1 Recipient and Recipient's PI agree that substantive changes made to the Research Project, and/or appointment by Recipient of another Principal Investigator and/or transfer of Recipient's PI to another institution or other entity to complete the Research Project, require execution of a separate DMDA. Except as provided in Section 4.2 below, Recipient may not distribute Data or Materials to any other individual or entity, regardless of the intended use of such Data or Materials. However, nothing in this section precludes Recipient from publishing results of the Research Project through the usual channels of scientific publication.

4.2 Recipient and Recipient's PI may transfer or cause to be transferred Materials to an institution or institutions or other entities not affiliated with Recipient but with which Recipient either has a fee-for or subcontract agreement or specific authorization from the NHLBI for the performance of assays and/or genetic analyses for the Research Project as identified in Section 3.2. A separate DMDA is not required if the derived data are either returned to the Recipient and Recipient's PI or are deposited for Recipient and Recipient's PI in a publicly accessible database authorized by the NHLBI upon completion of the

assays. No Data are to be provided to such institutions or other entities unless a separate DMDA has been approved by Boston University and NHLBI.

5. Conduct of Research Project. Recipient's PI is responsible for the conduct of the Research Project and shall be responsible for assuring that any Co-Investigator(s) comply with the terms of this DMDA.

6. Publication. Prompt publication of the results of the Research Project is encouraged. Boston University and NHLBI request that the Recipient's PI provides to the contact representative for the RURAL Cohort Study (named below) a copy of any abstract ten (10) days in advance of submission for publication and any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to permit review and comment and ensure compliance with the confidentiality requirements of this DMDA.

7. Acknowledgments. Recipient and Recipient's PI agree to acknowledge the contribution of the RURAL Cohort Study staff in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data or Materials.

7.1 Collaborations. If a manuscript resulting from the Research Project has Study Investigators as co-authors, then the manuscript will be reviewed by the RURAL Cohort Study Publications and Policy Committee.

7.1.a If the manuscript is approved by the RURAL Cohort Study Publications and Policy Committee, the Recipient and Recipient's PI agree to include the following language in an acknowledgment:

"The RURAL Cohort Study is supported by Contract No. U01HL146382 from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from other sources."

"This manuscript has been reviewed by the RURAL Cohort Study for scientific content and consistency of data interpretation with previous RURAL Cohort Study publications."

7.1.b If the manuscript is not approved by the RURAL Cohort Study Publications and Policy Committee, and the Recipient and Recipient's PI wish to proceed to publish without the inclusion of Study Investigators as co-authors, the Recipient and Recipient's PI agree to include the following language in an acknowledgment:

"The RURAL Cohort Study is supported by Contract No. U01HL146382 from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from other sources."

"This manuscript was not approved by the RURAL Cohort Study. The opinions and conclusions contained in this publication are solely those of the authors, and are not endorsed by the RURAL Cohort Study or the NHLBI and should not be assumed to reflect the opinions or conclusions of either."

7.2 Other Studies. If the Research Project does not involve collaboration with Study Investigators, then the Recipient and Recipient's PI agree to include the following language in an acknowledgment.

"The RURAL Cohort Study is supported by Contract No. U01HL146382 from the National Heart, Lung, and Blood Institute (NHLBI) with additional support from other sources."

"This manuscript was not prepared in collaboration with investigators of the RURAL Cohort Study and does not necessarily reflect the opinions or conclusions of the RURAL Cohort Study or the NHLBI."

7.3 Ancillary Study Investigator Acknowledgments. If Data include data provided to the RURAL Cohort Study by ancillary study investigators, Recipient and Recipient's PI also agree to acknowledge their contribution in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of such Data.

8. Non-Identification. Recipient and Recipient's PI agree that Materials and/or Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data and/or Materials were obtained or derived.

9. Use Limited to Research Project. Recipient and Recipient's PI agree that Data, Materials, their progeny, or derivatives thereof will not be used in any experiments or procedures unless said experiments or procedures are disclosed and approved as part of the Research Project.

10. Use in Human Experimentation Prohibited. Recipient and Recipient's PI agree that Materials, their progeny, and derivatives thereof will not be used in human experimentation of any kind.

11. Compliance with Participants' Informed Consent. Recipient and Recipient's PI agree that Data and/or Materials, their progeny, and derivatives thereof will not be used for any purpose contrary to a participant's applicable signed informed consent document(s). Recipient and Recipient's PI agree to consult with Study Investigators and ascertain, specifically and in detail, the terms and conditions of applicable RURAL Cohort Study informed consent documents.

12. No Distribution; Avoidance of Waste. Recipient and Recipient's PI agree to retain control over Data, Materials and their progeny, and derivatives thereof. Recipient and Recipient's PI further agree not to transfer Data, Materials and their progeny, and derivatives thereof, with or without charge, to any other entity or individual, except for Data and/or Materials as provided for in Section 4.2 above. Recipient and Recipient's PI agree to make reasonable efforts to avoid contamination or waste of Materials.

13. Resultant Data to be Provided to Boston University and NHLBI. Recipient and Recipient's PI agree to provide the RURAL Cohort Study with a report every twelve (12) months during the term of this DMDA. The report shall include a description of the activities performed and Resultant Data obtained during the twelve (12) months before the reporting date. Recipient and Recipient's PI agree that Boston University and NHLBI, in accordance with the [NIH Data Sharing Policy](#) and [NHLBI Policy for Data Sharing from Clinical Trials and Epidemiologic Studies](#), may distribute all such Resultant Data through established NHLBI procedures to all institutions requesting access for their identified qualified scientific investigators to such Resultant Data, and that submit to NHLBI and Boston University a signed DMDA comparable to this DMDA. Recipient and Recipient's PI will provide all Resultant Data in the precise electronic format specified by NHLBI or Boston University. If errors in family structure, especially paternity, are identified, Recipient and Recipient's PI agree to contact the RURAL Cohort Study contact representative (named below), at the time such errors are identified, to receive detailed instructions as to how to provide such information and to whom. Recipient and Recipient's PI further agree to refrain from any disclosure of such identified errors to anyone other than the individual(s) specifically identified and authorized by Boston University and NHLBI.

14. Costs/No Warranties. Cost for Materials distribution will be determined on a case by case basis. Costs are subject to change following written notification from Boston University with the approval of NHLBI. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS AND/OR DATA PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE MATERIALS AND/OR DATA MAY BE EXPLOITED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.

15. Recipient's Responsibility for Handling Materials. Recipient and Recipient's PI acknowledge that Materials may carry viruses, latent viral genomes, and other infectious agents. Recipient and Recipient's PI agree to treat Materials as if they were not free of contamination, and affirm that Materials will be handled by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting Materials, Recipient assumes full responsibility for their safe and appropriate handling.

16. Non-Endorsement, Indemnification. Recipient and Recipient's PI agree not to claim, infer, or imply United States Government endorsement of the Research Project, the entity, or personnel conducting the Research Project, or any resulting commercial product(s) except as described in Section 7.

Recipient and Recipient's PI agree to release the United States Government, Boston University, and all investigator(s) who generated Data and Materials, and the agents and employees of each of them from all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose.

Except where prohibited by law, Recipient agrees to defend and indemnify the United States Government, Boston University, and all investigator(s) who generated Data and Materials, and the agents and employees of each of them for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose.

17. Accuracy of Data. Recipient agrees that the United States Government and Boston University are not responsible for the accuracy of Data or the provenance or integrity of Materials provided.

18. Recipient's Compliance with Recipient IRB's Requirements. Recipient certifies that the conditions for use of the Data and/or Materials in conjunction with the Research Project have been reviewed by the Recipient's Institutional Review Board (IRB) or similar human subjects oversight body in accordance with the Department of Health and Human Services (HHS) regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions and with the participants' informed consent documents, and any additional conditions that may be imposed by the University of Alabama Birmingham's IRB, which serves as the single IRB governing the RURAL Cohort Study. Recipient agrees to report promptly to Boston University and the NHLBI any unanticipated problems or proposed changes in the Research Project. Recipient also agrees to report to Recipient's IRB any unanticipated problems or changes in the Research Project that involve additional risks to participants or others. Recipient remains subject to applicable state and local laws and regulations and institutional policies that provide additional protections for human subjects.

19. Recipient's Responsibility to follow Data Security Best Practices. Recipient is aware of computer and data security best practices and will follow them for receipt, storage, and use of Data and Resultant Data. An example of best practice guidelines can be found in

https://osp.od.nih.gov/wp-content/uploads/NIH_Best_Practices_for_Controlled-Access_Data_Subject_to_the_NIH_GDS_Policy.pdf

20. Amendments. Amendments to this DMDA must be made in writing and signed by authorized representatives of all parties.

21. Termination. This DMDA shall terminate at the earliest of: the completion of the Research Project; five (5) years after the effective date of this DMDA; abandonment of the Research Project; or violation by Recipient of any provisions of this DMDA not remedied within 30 days after the date of written notice by NHLBI or Boston University of such violation.

Upon termination of this DMDA:

(a) If Data provided to Recipient include Center for Medicare and Medicaid Services (CMS) data, Recipient agrees to destroy all copies of all Data received from the RURAL Cohort Study and consult with the Boston University and the NHLBI regarding the disposition of all remaining Materials. Recipient will verify that the RURAL Cohort Study data have been destroyed in a written or electronic communication to the RURAL Cohort Study contact representative (named below).

(b) If Data provided to Recipient do not include Center for Medicare and Medicaid Services (CMS) data, Recipient agrees to consult with Boston University and the NHLBI regarding the disposition of all remaining Data and/or Materials.

22. Disqualification, Enforcement. Failure to comply with any of the terms of this DMDA may result in the disqualification of Recipient from receiving additional Data and/or Materials. The United States Government and/or Boston University may have the right to institute and prosecute appropriate proceedings at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this DMDA, the limitations on the use of the Data or Materials provided, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding at law or in equity, including obtaining the proceeds from

any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient and Recipient's PI acknowledges that a breach or threatened breach of the confidentiality requirements or use limitations of this DMDA may subject Recipient and Recipient's PI to legal action on the part of RURAL Cohort Study participants, their families, or both.

23. Representations. Recipient and Recipient's PI expressly certify that the contents of any statements made or reflected in this document are truthful and accurate.

24. Prior Distribution Agreements. By execution of this DMDA, Recipient certifies its good faith belief that it is in compliance with the terms and conditions of all its existing DMDAs with Boston University and/or the NHLBI.

25. RURAL Cohort Study Contact Representative:

RURAL Cohort Study Coordinating Center

Boston University

Email: rural@bu.edu

AUTHORIZED SIGNATURES

Required signatures begin on the next page.

RECIPIENT'S PRINCIPAL INVESTIGATOR AND RECIPIENT'S AUTHORIZED REPRESENTATIVE:

Name and Title of Recipient's Principal Investigator

Surface Mail Address of Recipient's Principal Investigator

Email Address of Recipient's Principal Investigator

Telephone and Fax Number of Recipient's Principal Investigator

Signature of Recipient's Principal Investigator and Date

_____ (a [non-profit] OR [for-profit] corporation/institution)
Name of Recipient (Corporation/Institution)

organized under the laws of (State/Country): _____

with a principal address at: _____

and Title of Recipient's Authorized Representative

Signature and Date of Recipient's Authorized Representative

COORDINATING CENTER FOR THE RISK UNDERLYING RURAL AREAS LONGITUDINAL (RURAL) COHORT STUDY

Name and Title of RURAL Coordinating Center Authorized Representative

Signature and Date of RURAL Coordinating Center Authorized Representative

NHLBI (for Materials only):

Name and Title of NHLBI's Authorized Representative

Signature and Date of NHLBI Authorized Representative

This Distribution Agreement is entered into as of: _____ (effective date)

D. Dataset Request and Notice of Intent to Analyze Instructions and Form

Prior to obtaining any RURAL Cohort Study datasets, an approved Manuscript Proposal is required. The Dataset Request and Notice to Analyze Form should be submitted to the RURAL Cohort Study Coordinating Center at Boston University in order to receive the dataset. This form will also be used by the RURAL Cohort Study Coordinating Center to track and monitor the use of RURAL Cohort Study datasets.

The RURAL Cohort Study Publications and Presentations Policy states that first or senior authors who are requesting RURAL Cohort Study datasets to have an approved manuscript proposal archived at the RURAL Cohort Study Coordinating Center. In addition, a Data and Materials Distribution Agreement (DMDA) is required for each manuscript proposal, for which data is being requested for. A single Data and Materials Distribution Agreement can be used to request multiple datasets for a single manuscript. However, the Dataset Request and Notice of Intent to Analyze Form is required for all dataset that will be requested.

The first author or senior author will be responsible for the usage of all datasets and return when analyses are completed. The RURAL Cohort Study Coordinating Center will only approve requests submitted by the first or senior author.

The following documents can be found within the Publications and Presentations Policy

- Dataset Request and Notice of Intent to Analyze Form (DSR)
- Data and Materials Distribution Agreement (DMDA)
- Manuscript Proposal Form

Collate completed forms into ONE document, scan, save as a PDF file and email to the RURAL Cohort Study Coordinating Center Administrator at: rural@bu.edu

Original Data Request Requirements	
This page only – below are check boxes; single click box to select “checked when completed”	
1. Complete the Data and Materials Distribution Agreement	YES <input type="checkbox"/>
2. Complete the Dataset Request and Notice of Intent to Analyze Form	YES <input type="checkbox"/>
3. Email the dataset packet to the RURAL Cohort Study Coordinating Center	YES <input type="checkbox"/>
Additional Data Request Requirements	
This page only – below are check boxes; single click box to select “checked”	
1. Provide a statement describing in detail, additional analyses and years data, addressed to RURAL Cohort Study Publications and Presentations Subcommittee.	YES <input type="checkbox"/>
2. Complete the Dataset Request and Notice of Intent to Analyze Form	YES <input type="checkbox"/>
3. Include the original Manuscript Proposal approved by the Publications and Presentations Subcommittee	YES <input type="checkbox"/>
4. Email the dataset packet to the RURAL Cohort Study Coordinating Center	YES <input type="checkbox"/>
Questions – Contact the RURAL Study Coordinating Center – rural@bu.edu	
Submit this page with your request	

Dataset Request and Notice of Intent to Analyze Form

General Document Instructions: Required font: Arial: 11pt. The document must be named as follows: First author's last name, first initial, manuscript #, data req, and current date

(e.g., Rural_S_001_data req_01-01-2019.)

Date of Request (MM/DD/YYYY)	
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Original Date Request	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Additional Data Request	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Title	
Abbreviated Title	

Approved Manuscript Proposal Number	
This number is assigned upon approval of the manuscript. If you have not received this number, contact the RURAL Cohort Study Coordinating Center Administrator at: rural@bu.edu	

DMDA Included with Request	Yes <input type="checkbox"/>	No <input type="checkbox"/>
DMDA Previously Submitted	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Purpose	Manuscript <input type="checkbox"/>	Other <input type="checkbox"/>
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For Main and Ancillary Study Manuscript Proposals: Include ALL authors in the area below.

For Genetic Manuscript Proposals: Include authors accordingly in the area below: 1) first three authors, 2) RURAL Cohort Study Representative, and 3) last author.

First Author:	
First Author's Institution:	
First Author's Email:	
First Author's Phone:	
Co-authors names:	
Statistical Analyst Name:	
RURAL Cohort Study Representative:	