



Conflicts of Interest Management, Intellectual Property, and Third Party Agreements Policy

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Conflicts of Interest Management, Intellectual Property, and Third-Party Agreements Policy

1. List of Terms

- **RURAL Cohort Study Investigator:** Investigator named in or funded by the RURAL Cohort Study U01 grant application
- **RURAL Cohort Study Affiliated Investigator:** Investigator at a participating institution, but not specifically named within the RURAL Cohort Study U01 grant application
- **Non-RURAL Cohort Study Investigator:** Any Investigator from an institution not named in the RURAL Study Cohort U01 grant application
- **Conflict of Interest:** Conflict of interest is defined by any situation where the interests of RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators are at odds with or appear to be at odds with the interests of the RURAL Cohort Study or participating communities, or may negatively impact the RURAL Cohort Study.
- **Intellectual Property:** “RURAL Cohort Study Intellectual Property” refers to the rights related to the RURAL Cohort Study inventions, ideas, patents, databases, and data resources and their modification, improvement, or enhancement.
- **RURAL Cohort Study Intellectual Property:** Refers to all Intellectual Property created by RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators, regardless of their relationship with/or obligations to other institutions.

2.0 Purpose of the Conflicts of Interest Management, Intellectual Property, and Third Party Agreements Policy

The RURAL Cohort Study will ensure intellectual freedom of its Investigators to conduct research while promoting the disclosure of conflicts of interest, and allowing the commercial development of Intellectual Property, when appropriate. This policy has been created to enable the free communication of ideas and research through publications and collaborations while ensuring the integrity and credibility of the RURAL Cohort Study’s research. The RURAL Cohort Study encourages the use of aggregate data for therapeutic discoveries and patents. It establishes clear guidelines and procedures for the handling of all RURAL Cohort Study generated Intellectual Property.

3.0 Scope of the Policy

3.1 Declaration of Conflicts of Interest

All RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators must declare any existing financial or non-financial conflicts of interest prior to commencing research or work on the RURAL Cohort Study using the Declaration of Conflicts of Interest form in the Appendix.

3.2 Applicability

This policy applies to all Cohort RURAL Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators who participate in research or produce scholarly works using RURAL Cohort Study data or resources. (Under certain circumstances, this policy will apply to community partners and members.)

3.3 Binding Effect of the Policy

This policy is binding for RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators. All parties stated above must sign the Conflicts of Interest Management, Intellectual Property, and Third Party Agreements Policy Agreement stating that they have read and will abide by the conditions set out in this policy (see Appendices). Please send these documents to the RURAL Cohort Study Coordinating Center at: rural@bu.edu

4.0 Conflicts of Interest

- The RURAL Cohort Study will align with the NIH Ethics Program's definition of [conflict of interest](#).
- RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators primary commitment of contributions to data and other materials should be to the RURAL Cohort Study aims and objectives.
- All RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators have a professional stake and obligation to remain in the best interests of the RURAL Cohort Study research. Any actions or situations that may impact the credibility and integrity of the RURAL Cohort Study must be avoided.
- The RURAL Cohort Study key personnel are responsible for ensuring agreements with external parties are not in conflict with the aims and objectives of the RURAL Cohort Study. This may include consultancy and other research service agreements. Any external party agreement must be in parallel with this policy.
- Disclosure of external activities and financial interests is required by all RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators. Key personnel are responsible for reporting financial and non-financial interests to the RURAL Cohort Study Coordinating Center and the National Heart, Lung, and Blood Institute (NHLBI) using the Declaration of Conflicts of Interest Form prior to any projects or research with the RURAL Cohort Study, and also declare any new conflicts of interest that arise while working with the RURAL Cohort Study (see Appendix).

5.0 Management of Conflicts of Interest

- The RURAL Cohort Study takes seriously all potential conflicts, both financial and non-financial, including conflicts of commitment by all RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators. No conflicts of interest will be accepted unless, upon review, the RURAL Cohort Study Steering Committee believes that the risk is manageable by implementing a transparent conflict of interest management plan. The RURAL Cohort Study Steering Committee will assess the risks posed by, and the management of a real and perceived conflict of interests.
- In the event of a conflict of interest, the RURAL Cohort Study Steering Committee will determine whether:
 - The conflict can be eliminated (high risk)
 - The conflict can be managed (medium risk)
 - The conflict is unlikely to impact the RURAL Cohort Study (low risk)

- The RURAL Cohort Study Steering Committee will consider the following factors in assessing the conflict of interest, but not limited to:
 - Can the conflicting financial or non-financial interest affect RURAL Cohort Study aims, objectives, and/or activities?
 - Can the outcome of the RURAL Cohort Study research impact the value of the financial interest causing the conflict (e.g. stock value, consulting income, etc.)?
 - Are there compelling reasons that the RURAL Cohort Study Investigator, the RURAL Cohort Study Affiliated Investigator, or Non-RURAL Cohort Study Investigator should complete the research? Compelling reasons include, but are not limited to:
 - The investigator is uniquely qualified to conduct the research
 - There is a low risk that the conflict of interest would risk the human subjects being studied
- Management techniques include, but are not limited to:
 - Disclosure of the conflict in publications, to other researchers, research sponsors, and research subjects
 - Limit the involvement of the conflicted individual with the approved conflicting research project to the extent possible
 - Change the individual's position at the organization where the conflict lies, such as limitations on memberships in select committees

6.0 Third-Party Agreements

- Third-Party Agreements are facilitated and handled by the RURAL Cohort Study Coordinating Center at Boston University.
- The RURAL Cohort Study Steering Committee determines if a Third-Party Agreement is needed and/or is appropriate for an approved project. Third-Party Agreements are generally encouraged if they support the RURAL Cohort Study aims, and do not compromise the RURAL Cohort Study.
- The RURAL Cohort Study Investigator, RURAL Cohort Study Affiliated Investigator, and Non-RURAL Cohort Study Investigator will be notified of the necessary Third-Party Agreement in the RURAL Cohort Study Steering Committee Approval Letter.
- RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators are advised to read the NHLBI policy on [Third Party Involvement](#) for further details.
- Third Party Agreements Process:
 - If the RURAL Cohort Study Steering Committee determines that a Third-Party Agreement is necessary, the RURAL Cohort Study Steering Committee will send the relevant RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Cohort Study Investigator a Third Party Agreement draft. The RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Cohort Study Investigator will then create a Third-Party Agreement with their institution's contracts office and the third party.
 - After the Third Party Agreement language has been agreed upon between the RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Cohort Study Investigator's institution and the third party, an unsigned copy is sent to the RURAL Cohort Study Coordinating Center for review. The RURAL Cohort Study Coordinating Center will also send the unsigned copy to NHLBI for their review.
 - NHLBI edits and comments will be relayed to the RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Cohort Study Investigator by the RURAL Cohort Study Coordinating Center.

- There will be no direct communication between the RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Study Investigator and the NHLBI during review of the Third Party Agreement.
- The RURAL Cohort Study Coordinating Center's Research Project Manager will coordinate the negotiations of the language in the Third Party Agreement between the RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Cohort Study Investigator, the third party, and the NHLBI, until an agreement is made.
- After all parties are in agreement with the language in the Third-Party Agreement, the RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Cohort Study Investigator, their institution, and the third party will all sign the agreement and a fully executed copy will be given to the RURAL Cohort Study Investigator/Affiliated Investigator/Non-RURAL Cohort Study Investigator and the NHLBI.
- The RURAL Cohort Study Coordinating Center will keep a copy of the agreement on file.

7.0 Ownership of RURAL Cohort Study Related Intellectual Property

Ownership of RURAL Cohort Study Related Intellectual Property may include works or inventions created by RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators.

8.0 Patents and Commercial Licenses

RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators may apply for commercial licenses or patents using RURAL Cohort Study Related Intellectual Property, if necessary. The RURAL Cohort Study Steering Committee will review and approve commercial licenses or patent applications prior to the individual requesting them. If the RURAL Cohort Study Steering Committee approves the request, the relevant RURAL Cohort Study Investigator, RURAL Cohort Study Affiliated Investigator, or Non-RURAL Cohort Study Investigator must apply for relevant licenses and/or patents, and copy the RURAL Cohort Study Coordinating Center on all communications. The inventor will grant the RURAL Cohort Study a royalty-free non-transferable license, including the use of such Intellectual Property for research at the RURAL Cohort Study.

9.0 Modification of the Intellectual Property and Conflict of Interests Policy

This policy may be reviewed and revised by the RURAL Cohort Study Steering Committee. All RURAL Cohort Study Investigators, RURAL Cohort Study Affiliated Investigators, and Non-RURAL Cohort Study Investigators will be notified of any changes to the policy and will be in effect immediately upon notification.

10.0 RURAL Cohort Study Contact Information

RURAL Study Coordinating Center, Boston University
Email: rural@bu.edu

11.0 Appendices

A. Intellectual Property and Conflicts of Interest Policy Agreement

I confirm that I have received and read the RURAL Cohort Study Intellectual Property and Conflicts of Interest Policy. I hereby accept, and will follow, and fully comply with this policy, including any modifications to the policy that are approved by the RURAL Cohort Study in the future, as determinative of my rights and obligations in regards to any intellectual property or conflicts of interest. I agree to assign to the RURAL Cohort Study my right, title, and interest in intellectual property subject to this policy. I also agree to declare any conflicts of interest using the Declaration of Conflicts of Interest Form both prior to employment or beginning any projects or research with the RURAL Cohort Study, and also will declare any new conflicts of interest that arise during my work with the RURAL Cohort Study. All RURAL Cohort Study collaborators and investigators must complete this form, even if they are not disclosing conflicts of interest. I agree to deliver all documents and do all things needed to abide by this policy.

Signature

Date (DD/MM/YYYY)

Name (please type or print)

Affiliation with the RURAL Study

Institution

B. Declaration of Conflicts of Interest

All RURAL Cohort Study collaborators and investigators must complete this form, even if they are not disclosing conflicts of interest.

Conflicts of Interest Definition: A potential or actual conflict of interest is when commitments and obligations may be compromised by the individual's other material interests, or relationships (both financial and non-financial), especially if those interests or commitments are not disclosed.

This Conflict of Interest Form should indicate whether the individual/family member has a financial or non-financial interest in any outside entity whose financial interests would be affected by their involvement with the RURAL Cohort Study. This includes personal, business, or volunteer affiliations.

Please disclose your interests and affiliations in **one** of the following boxes:

- I/family members **do not** have any conflicts of interest with the RURAL Cohort Study
- I/family members **do** have a conflict of interest/ with the RURAL Cohort Study
(describe below)
- I/family members **may** have any conflict of interest with the RURAL Cohort Study **(describe below)**

Please describe any conflicts of interest, including the approximate monetary value:

Organization(s)	Your Role/Title	Details

Please turn overleaf to provide more details if necessary.

I hereby certify that the information set forth above is true and complete to the best of my knowledge.

Signature

Date (DD/MM/YYYY)

Name (please type or print)

Affiliation with the RURAL Cohort Study

Institution