

Third Party Agreement Guidelines

(adapted from: <http://www.nhlbi.nih.gov/funding/policies/thirdparty.htm#Appropriate>)

ARIC investigators sometimes receive ancillary study support from industry and other third parties. Because ARIC is an NHLBI-supported study, the Institute wants to ensure the primary purpose of ARIC is not compromised as a result of this extra support.

WHAT DOES THIRD PARTY SUPPORT/INVOLVEMENT ENTAIL?

Third party involvement may entail providing financial support; participating directly in a study; supplying study resources; or receiving special access to study results, data, findings, or intellectual property.

EXAMPLES OF TYPES AND MECHANISMS OF THIRD PARTY INVOLVEMENT INCLUDE:

- In kind support of materials, e.g. drugs, devices, reagents
- In-kind support of services, e.g. laboratory services
- Financial support through a conditional gift to the NHLBI Gift Fund
- Financial support through a charitable third party that works in collaboration with the NHLBI and that manages, accounts for, and distributes funds to study investigators in accordance with NHLBI program plans.
- Financial support provided directly to an NHLBI-supported investigator for use in accordance with study plans.

WHAT INFORMATION DOES NHLBI REQUIRE? :

1. To make informed decisions about third party support or involvement, the NHLBI requires information about:

- Third party involvement or influence in study governance and conduct, and in the analysis, interpretation, and reporting of results.
- Third party access to results, and access to and ownership of the dataset, and any other commitments with the third party to intellectual or tangible property.
- The nature and any conditions of third party support.
- The nature of any conflict of interest issues and their proposed resolution.

2. NHLBI also requests that both parties certify that the following conditions will be met:

- The third party will not participate in or has no influence on the governance or conduct of a study, or in the analysis, interpretation, or reporting of its results.
- The third party has no access to study results until after a manuscript has been submitted for publication or a public presentation has been prepared.
- The third party has no access to study data other than those that form the basis for published reports or are available to other qualified members of the scientific community.
- The third party has no commitments with the study investigators as to intellectual or tangible property or other issues of conflict with PHS policy on grants or contracts (particularly as to reporting, distribution of unique research resources, inventions, or commercialization).
- The nature of the third party's support and the conditions under which it is to be provided are clearly stated, and
- The third party's involvement neither raises the appearance of nor creates conflict of interest issues with the study investigators, the NHLBI, or its employees.

NHLBI requires that a third party agreement be drafted by the principal investigator of the ancillary study, the collaborating investigator from the third party/industry, and the Authorized Institutional Representatives from both institutions. All parties should agree to the conditions outlined above (in blue text).

Please send a copy of the draft agreement to the ARIC Study Project Officer who will forward within NHLBI for review and approval.

After NHLBI concurrence, the Authorized Institutional Representatives from both institutions must sign the document to legally commit the institution to the agreement. The principal investigator of the ancillary study and the collaborating investigator from the third party must also sign the agreement.

A copy of this finalized agreement (with the appropriate signatures) should be sent to the ARIC Study Project Officer at NHLBI. *(Please note: The third party agreement should be in place before a Data/Materials Distribution Agreement is completed.)*

See page 4 for an example of a third party agreement.

ADDITIONAL INFORMATION:

NHLBI- THIRD PARTY INVOLVEMENT WEBSITE:

<http://www.nhlbi.nih.gov/funding/policies/thirdparty.htm#Appropriate>

Example of Third Party Agreement:

NIH-NHLBI Third Party Agreement Between
XXX and **YYY**

In accordance with guidelines set forth by the National Heart Lung and Blood Institute (NHLBI), National Institutes of Health (NIH) (<http://www.nhlbi.nih.gov/funding/policies/thirdparty.htm>), this letter serves as an agreement between a third party, **XXX** and **YYY** a contractor for the NHLBI-funded Atherosclerosis Risk in Communities (ARIC) Study.

The third party has agreed to provide in-kind support of materials (i.e., discounted or free reagents) to **YYY** for laboratory work related to the ARIC Study. The measurements to be conducted as part of this research project are not presently widely used in clinical practice in the U.S. Thus, the third party has a vested interest in the results of the research project, which will address the distribution and determinants of the measurements in a population-based setting.

By signing this letter, the third party agrees to the following conditions, which will guide the collaboration between the third party and the study investigators:

- The third party will not participate in and has no influence on the governance or conduct of the study, or in the analysis, interpretation, or reporting of its results,
- The third party will not have access to study results until after a manuscript has been submitted for publication or a public presentation has been prepared,
- The third party will have no access to study data other than those that form the basis for published reports or are available to other qualified members of the scientific community, and
- The third party will have no commitments with the study investigators as to intellectual or tangible property or other issues that conflict with PHS policy on grants or contracts (particularly as to reporting, distribution of unique research resources, inventions, or commercialization).

The study investigators agree to acknowledge the contribution of **XXX** in appropriate publications and presentations.

In meeting these conditions, the involvement of the third party should neither raise the appearance of nor create a conflict of interest with the study investigators, the NHLBI, or its employees.

Third party:

Signature

Date

John Doe, President of XXX
Address for XXX
Contact Information for XXX

For XXX's Authorized Institutional Representative/Administrative Official:

Signature

Date

XXX's Administrative Official
[ADMINSTRATIVE OFFICIAL]

For the ARIC Study:

Signature

Date

YYY
Professor
Address for YYY
Contact Information for YYY

For YYY's Administrative Official:

Signature

Date

YYY's Administrative Official
[ADMINSTRATIVE OFFICIAL]