



FINANCIAL CONFLICT OF INTEREST PLAN

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1.0 POLICY STATEMENT

Atlas Research (Atlas) and each member of its staff are committed to complying fully with the requirements set forth by 42 Code of Federal Regulations (CFR), Part 50, Subpart F as well as 45 CFR Part 94 regarding financial conflicts of interest (FCOI) for all U.S. Public Health Services (PHS)-sponsored research performed by Atlas. Atlas is committed to protecting the integrity and objectivity of its work by ensuring that the work will not be biased or appear to be biased by a personal FCOI. This plan has been developed to identify, manage, mitigate, neutralize, and/or eliminate actual, apparent, and potential FCOI in work performed for both the federal government and other clients.

2.0 DEFINITIONS

For the purposes of this plan, the following definitions shall apply:

1. *Designated Official* is the individual designated by Atlas to oversee the FCOI process, including solicitation and review of disclosures of significant financial interests.
2. *Equity interest* includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.
3. *Financial conflict of interest* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research as determined by Atlas through the Designated Official.
4. *Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.
5. *Immediate family* refers to an Investigator's spouse and dependent children.
6. *Investigator* means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
7. *PHS* means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the following agencies:
 - Agency for Healthcare Research and Quality (AHRQ);
 - Agency for Toxic Substances and Disease Registry (ATSDR);
 - Centers for Disease Control and Prevention (CDC);
 - Food and Drug Administration (FDA);
 - Health Resources and Services Administration (HRSA);
 - Indian Health Service (IHS);
 - National Institutes of Health (NIH);
 - Office of the Assistant Secretary for Health (OASH);
 - Office of the Assistant Secretary for Preparedness and Response (ASPR);
 - Office of Global Affairs (OGA); and

- Substance Abuse and Mental Health Services Administration (SAMHSA).
8. *PHS Awarding Component* means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F and 45 CFR Part 94.
 9. *PHS-funded Research* means research funded under PHS grants, cooperative agreements, or contracts.
 10. *Public Health Service (PHS) Act* means the statute codified at 42 U.S.C. 201 *et seq.*
 11. *Remuneration* includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, and paid authorship).
 12. *Research* means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research as well as product development. For PHS-funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
 13. *Significant financial interest* means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's Atlas project responsibilities:
 - With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the twelve (12) months preceding the disclosure and any equity interest in the entity as of the date of disclosure, in which the value when aggregated exceeds five thousand dollars (\$5,000.00);
 - With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the twelve (12) months preceding the disclosure, in which the value when aggregated exceeds five thousand dollars (\$5,000.00), or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents and copyrights), upon receipt of income related to such rights and interests.

Significant financial interests also include any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's Atlas project responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government; an institution of higher education as defined at 20 U.S.C. § 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Atlas (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Atlas, including

that paid for intellectual property rights assigned to Atlas Research and agreements to share in royalties related to such rights;

- Any ownership interest in Atlas (or a subrecipient as applicable) held by the Investigator;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. § 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state, or local government agency; an institution of higher education as defined at 20 U.S.C. § 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.

3.0 PROCEDURES

The following are procedures followed by Atlas to identify, manage, mitigate, neutralize, and/or eliminate actual, apparent, and potential FCOI.

3.1 RESPONSIBILITIES OF DESIGNATED OFFICIAL

The Designated Official or his/her designee shall be responsible for the following:

- Informing Atlas Investigators of their obligations under this plan and any related regulations;
- Reviewing disclosures of significant financial interest with the appropriate Atlas manager(s) to determine whether they are related to the subject research and, if so, whether they constitute FCOI;
- Screening and managing potential FCOI;
- Maintaining all records related to disclosures of financial interests, Atlas's review of and response to such disclosures, and any related actions under this plan;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this plan and applicable regulations.

For PHS-funded research, the Designated Official shall also take reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this plan or provide Atlas with sufficient assurances to enable Atlas's compliance with all applicable laws and regulations. To this end, any written agreement between Atlas and a subrecipient will specify whether Atlas's or the subrecipient's FCOI plan will apply to the subrecipient's Investigators and, if the subrecipient's plan will apply, the Designated Official will:

- Obtain certification from the subrecipient that its plan complies with Atlas's plan and the applicable regulations (absent such certification, Atlas's plan will apply to the subrecipient's Investigators); and

- Establish time periods for subrecipient reporting of FCOI to Atlas that will enable Atlas to report such conflicts in a timely manner, as required under its plan and the applicable regulations.

If Atlas's plan will apply to the subrecipient Investigators, Atlas will be responsible for meeting the requirements of this plan and the reporting obligations reflected in the applicable regulations.

3.2 INTERNAL REPORTING REQUIREMENTS

For PHS-funded research in particular, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to the Designated Official. This requirement also applies to Investigators who work for subgrantees, subcontractors, or collaborators on PHS-funded research. SFID Forms will be provided to Investigators in conjunction with annual training and will be otherwise made available.

The Atlas manager for the anticipated PHS contract will review SFID submissions with the Designated Official. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests, and the significant financial interests of his/her immediate family, that reasonably appear to be related to entities whose financial interests could be affected by the research. Atlas Investigators in non-PHS-funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete a SFID Form and submit it to the Designated Official as part of the funding application or proposal and prior to performing any work on the research.

Investigators are expected to complete and submit an updated SFID Form during the period of the award as necessary, and at least annually for PHS-funded research. This annual update will typically be done in conjunction with completion of annual training. Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within thirty (30) days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

3.3 DETERMINATION AND MANAGEMENT OF FCOI

Upon receipt of a completed SFID Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a FCOI under this plan and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is an entity whose financial interest could be affected by the research. A FCOI exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If Atlas determines that an actual or potential FCOI exists, a FCOI mitigation plan will be implemented and monitored on an ongoing basis. The mitigation plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;

- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.
- In addition to the conditions or restrictions described above, Atlas may require the management of conflicting financial interests in other ways as it deems appropriate.

3.4 EXTERNAL REPORTING REQUIREMENTS

Atlas will disclose FCOI as required by applicable laws or regulations. Before expending any funds under a PHS award, Atlas will ensure public accessibility by posting FCOI information on a publicly available website or by responding in a timely manner to written requests as required under the regulations. The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any FCOI that has not been eliminated and will ensure that Atlas has implemented a plan to mitigate the conflict.

If a FCOI is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Atlas will provide the PHS Awarding Component with an update within sixty (60) days and ensure that it has implemented a plan to mitigate the conflict. If the FCOI report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Atlas (e.g., not reviewed or reported by a subrecipient in a timely manner), Atlas will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Atlas will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Atlas will provide HHS with information relating to any Investigator disclosure of significant financial interest; Atlas's review of, and response to, such disclosure; and whether the disclosure resulted in Atlas's determination of a FCOI.

4.0 CONFIDENTIALITY

Atlas will, to the extent possible, protect the confidentiality of Investigator disclosures. In every instance, Atlas will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and mitigate conflicts of interest. Disclosures will be available to Atlas staff only on a need-to-know basis and will not be disclosed outside of Atlas unless necessary to comply with contractual, legal, or regulatory requirements.

5.0 INVESTIGATOR NONCOMPLIANCE

If an Investigator knowingly fails to comply with this plan (e.g., fails to identify an actual or potential FCOI), Atlas may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this plan or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this plan or a FCOI mitigation plan has biased the design, conduct, or reporting of the PHS-funded research, Atlas shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;

- Atlas will make available to HHS all records pertinent to FCOI and the mitigation of those conflicts; and
- If HHS determines that a clinical PHS-funded research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was neither disclosed nor managed, Atlas shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

6.0 TRAINING

Atlas provides all staff with training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. This training occurs annually as well as when (a) Atlas revises its FCOI plan in any manner that affects the staff's obligations; (b) an employee is newly hired by Atlas; and (c) Atlas finds that an Investigator is not in compliance with this plan or a specific FCOI mitigation plan.

7.0 RETENTION OF RECORDS

The Designated Official will retain FCOI disclosure forms and other supporting information consistent with Atlas's document retention policy. For PHS-funded research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by Atlas with respect to each FCOI will be retained for at least three (3) years from the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 CFR 74.53(b) or 48 CFR Part 4, Subpart 4.7.

SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM

Prior to completing this form, please review the *Atlas Research Financial Conflict of Interest Plan*. Upon completion, sign and return a hard copy of this form to Atlas Research's Designated Official.¹ Your completed form must be received and approved by the Designated Official prior to commencing any work on the applicable project.

Name: _____

Position: _____

Project: _____

1. Do you or your immediate family² have a Significant Financial Interest³ that (a) would reasonably appear to be affected by your research and/or (b) is in an entity or entities whose financial interests would reasonably appear to be affected by your research?

Yes No

2. If you answered "Yes" to above-question, please elaborate on whether your Significant Financial Interest is comprised of the following elements:

- a. Salary or other payment for services (e.g. consulting fees, honoraria, or paid authorship)

Yes No

If "Yes," please describe each instance of salary or payment for services and the applicable dollar amounts:

- b. Equity interests (e.g. stock, stock options, or other ownership interests)

Yes No

If "Yes," please describe each equity interest, including the value of all applicable stock or ownership interest:

c. Intellectual property rights (e.g. patents, copyrights, and royalties from such rights)

Yes No

If “Yes,” please describe each instance of intellectual property rights:

d. Sponsored or reimbursed travel (i.e. travel paid on your behalf)

Yes No

If “Yes,” please describe each instance of sponsored or reimbursed travel and the applicable dollar amount:

e. Other Significant Financial Interest(s) that could possible affect or be perceived to affect the results of the research in question

Yes No

If “Yes,” please describe each Significant Financial Interest and the applicable dollar amounts:

By signing below, I confirm that I have reviewed and fully understand the *Atlas Research LLC Financial Conflict of Interest Plan*. The information stated above is complete and accurate to the best of my knowledge. I hereby agree to update this disclosure during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

Signature

Date

Designated Official Signature

Date

¹ Unless otherwise instructed when given this form to complete, the Designated Official is the President of Atlas Research.

² "Immediate family" means an Investigator's spouse and dependent children.

³ "Significant Financial Interest" means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's project responsibilities:

- With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the twelve (12) months preceding the disclosure and any equity interest in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
- With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the twelve (12) months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g. stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g. patents and copyrights), upon receipt of income related to such rights and interests.

Significant Financial Interests also include any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's Atlas Research project responsibilities, provided, however, that this does not apply to travel that is reimbursed or sponsored by a federal, state, or local government; an institution of higher education as defined at 20 U.S.C. 1001(a); an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education. See the full Atlas Research LLC Financial Conflict of Interest Plan for examples of what does not constitute a Significant Financial Interest.