



Financial Conflict of Interest Policy

Version: 1 RAD-P-002

Effective Date: 05/18/2021

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1. Purpose and Scope

1.1. General Policy

This document establishes Allele Diagnostics' ("Allele's") policies on financial conflicts of interest regarding Public Health Service (PHS) funded research. It is Allele's policy to ensure that personnel avoid situations in which a personal financial interest may affect, or have the appearance of affecting, their professional judgement in exercising their duties or responsibilities, or in conducting or reporting research. This policy is intended to guide personnel in managing their personal affairs and financial activities that may appear to conflict with their responsibilities and to ensure that Allele and its employees comply with applicable federal laws when participating in research funded by the PHS. Personnel should promptly disclose the circumstances of any situation that might be covered by this policy.

1.2. Scope

This statement of policy and procedures is designed to comply with PHS regulations (42 CFR Part 50 Subpart F, Promoting Objectivity in Research, 45 CFR Part 94, Responsible Prospective Contractors). These standards and procedures are intended to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator FCOIs.

The policy applies to Research projects Allele applies for, or has received, research funding from PHS, except for Phase I SBIR or STTR research projects and to all Investigators, as defined in this Policy, who will participate, or are participating in the Research. Each Investigator must complete the required training. Subcontractors and consultants who perform services within the definition of an Investigator must also comply with this policy.

2. Definitions

Company Official means the individual within Allele that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's family related to the Investigator's Company Responsibilities.

Company Responsibilities means the Investigator's responsibilities associated with their position with Allele, such as research, administration, and internal and external professional committee service.

Family means an Investigator's spouse, domestic partner, or dependent children.

Financial Conflict of Interest (FCOI) is a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct or reporting of PHS funded Research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable, including remuneration, salary, other payments for services (e.g., consulting fees, paid authorship or honoraria), equity interests (e.g., stocks, stock options, or other ownership



Financial Conflict of Interest Policy

Version: 1 RAD-P-002

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interest), intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and reimbursed or sponsored travel unless the sponsored travel is paid for by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Investigator means any 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. Generally, this includes all individuals listed on a grant budget, regardless of title or position, who may be responsible for the designing, conducting, or reporting of Research. It always includes the Principal Investigator (PI), Co-Investigators, and Key Scientific Personnel.

Public Health Service (PHS) is the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Senior/Key personnel mean the PI and any other person identified as senior/key personnel by Allele in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Sub-recipient means any party that has entered into an Agreement with Allele as a sub-grantee, subcontractor, collaborator, contractor, or consultant.

Significant Financial Interest (SFI) means a Financial Interest of one or more of the following interests of the Investigator (and the Investigator's family) that reasonably appears to be related to the Investigator's Company Responsibilities:

- With regard to any publicly traded entity, a SFI exists if the aggregate value of any remuneration received for services during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting income, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- With regard to any non-publicly traded entity, a SFI exists if the aggregate value of any remuneration received for services during the 12-month period preceding the disclosure exceeds \$5,000 or when the Investigator (or the Investigator's family) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Income related to intellectual property rights and interests not reimbursed through Allele.

The term Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by Allele to the Investigator if the Investigator is currently employed or otherwise appointed by Allele, including intellectual property rights assigned to Allele and agreements to share in royalties related to such rights.



Financial Conflict of Interest Policy

Version: 1 RAD-P-002

Effective Date: 05/18/2021

- Any ownership interest in Allele held by the Investigator.
- Income from investment vehicles, such as mutual funds and retirement accounts, if 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.
- 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. Training Requirements

Prior to engaging in any research project as defined in the policy, all Investigators must complete training on the Investigator's obligations under this policy and repeat the training at least every four years. Training must be completed immediately (1) if this policy is revised to the extent that it affects requirements to the Investigators; (2) a new Investigator joins Allele; or (3) when an Investigator has not complied with the policy or applicable management plan.

4. Disclosure Requirements

Investigators who are planning to participate in PHS funded Research must submit a Financial Interest Disclosure Form to the CO no later than at the time of application for PHS funded Research. On the form, Investigators must disclose any known SFIs (and those of their family) in entities whose financial interests would reasonably appear to be affected by the research for which PHS funding is sought. If an Investigator does not have any SFIs to report, the Investigator must still complete the Financial Interest Disclosure Form. Financial disclosures must be updated by all investigators on an annual basis during the award period and within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new SFI during the term of the grant.

5. Responsibilities

5.1. PHS-Funded Investigators/Senior/Key Personnel:

- Complete FCOI training prior to engaging in a PHS research project and thereafter, every four years.
- Complete and submit to the CO a Financial Interest Disclosure Form prior to working on PHS-funded projects.
- Update the Financial Interest Disclosure Form annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.
- Follow management plan as prescribed by the CO for FCOIs.

5.2. Sub-Recipient

- Complete and submit to the CO a Financial Interest Disclosure Form prior to working on PHS funded projects.
- Sub-recipient organization will certify that it has a PHS FCOI compliant policy in place or that it intends to have one in place at the time of the award or that it will abide by Allele's policy.



Financial Conflict of Interest Policy

Version: 1 RAD-P-002

Effective Date: 05/18/2021

- Sub-recipient organization will certify that the investigators, senior and/or key personnel will complete required training.

5.3. Company Official (CO)

- Solicit, record, and review all Financial Interest Disclosure forms from PHS-funded researchers to determine whether a FCOI exists.
- Provide required information concerning FCOIs to the expenditure of PHS funds and must update such information at least annually and within 60 days of changes to Financial Interest Disclosure forms, whichever occurs first.
- Prepare the Public Financial Conflict of Interest Disclosure form, including the following information, for reported FCOIs such that it can be made publicly available upon request:
 1. Project number
 2. Investigator's name
 3. Investigator's title and role with respect to the research project
 4. Name of the entity in which the relevant significant financial interest (SFI) is held
 5. Nature of the relevant SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.)
 6. Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.)
- For reported FCOIs, must develop a FCOI management plan to include: role and principal duties of the Investigator with the FCOI; how the FCOI Management Plan is designed to safeguard objectivity in the PHS research project; confirm that Investigator agrees with the FCOI Management Plan; and how the FCOI Management Plan will be monitored.
- Maintain for three years records of all Financial Interest Disclosure form records and FCOI Management Plans.
- Provide the FCOI Policy and Procedure and all revised versions to Allele's IT department to be posted on Allele's external website.
- Ensure compliance with FCOI policy and procedures.

6. SFI Review Process

- 6.1. The CO reviews each SFI received from personnel. If necessary, the CO collects additional information from the disclosing individual and/or from other individuals who possess relevant information. The CO determines whether the disclosed financial interests are significant, whether they are related to the individuals research responsibilities at Allele, and whether a management plan is required. In conducting this review, the CO considers factors such as the value of the individual's financial interest and how it could affect their ability to objectively complete their research with Allele.
- 6.2. If a significant financial interest is deemed to be a financial conflict of interest, the CO will develop a management plan in consultation with the Investigator. The goal of the management plan is to reduce or eliminate the financial conflict of interest, which can include reducing or eliminating the financial conflict of interest and to ensure that the design, conduct and reporting of research will be free from bias. The management plan may include, but is not limited to: (1) requiring the individual to recuse him/herself from particular decisions or activities related to the research, (2) requiring the individual to inform certain persons or institutions about the conflict of interest and the management plan (e.g. relevant review bodies, research sponsors, co-investigators, journals to which manuscripts about the research



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are submitted, media, etc.), (3) requiring others to review decisions in which the individual participates, (4) requiring the individual to reduce, modify or eliminate a financial interest (e.g. divesting ownership, restricting the sale or exercise of stock and stock options, and deferring or waiving royalties or milestone payments), or (5) requiring the individual to vacate a position.

7. Enforcement

If the failure of an Investigator to comply with this Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, Allele is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken by Allele. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Allele for further action, which may include directions to Allele on how to maintain appropriate objectivity in the PHS funded Research project.

Failure of Allele staff to comply with this Policy may result in disciplinary action up to and including termination. Additional sanctions may also be applied per research funding agency (such as requiring investigator financial conflict of interest training), up to and including sponsor suspension of function per application federal regulations.

8. Records Retention

In accordance with federal regulations, Allele will maintain records relating to all disclosures of financial interests and Allele’s review of, and response to, such disclosures by retaining FCOI records for at least three years beyond date of the final expenditure report is submitted to PHS for an award.

9. Public Accessibility

This policy will be posted to Allele’s publicly accessible website. Allele will inform covered individuals of the policy and of their responsibilities regarding disclosure and if the policy is revised and updated.

10. Confidentiality

All disclosures or information obtained in reviewing a potential FCOI is kept confidential, except where disclosure is required by federal regulations.

REFERENCE DOCUMENTS

Public Health Service (PHS) Regulations (42 CFR Part 50 Subpart F, Promoting Objectivity in Research, 45 CFR Part 94, Responsible Prospective Contractors)

Document Revision History

Version	Description of Changes	Approver	Date Approved
1	New policy	Beth Torchia	05/18/2021