



PREVENTION OF FINANCIAL CONFLICTS OF INTEREST

RELATED TO NIH FUNDED RESEARCH

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1. PURPOSE

The purpose of this policy is to establish guidelines for implementation of federal Public Health Service (PHS) agency requirements related to financial disclosures by a Principal Investigator (PI) or any employee, regardless of title or position, participating in National Institutes of Health (NIH) grant-funded research and to promote objectivity in grant-funded research.

2. SCOPE

This policy applies to any 23andMe employee who is responsible for the design, conduct or reporting of NIH grant-funded research or proposed for such funding, which may include collaborators or consultants. This policy does not apply to NIH Small Business Innovation Research (SBIR) Program Phase I applications.

3. REFERENCES

- 3.1. 42 CFR Part 50, Subpart F (2011) – “Promoting Objectivity in Research”

4. RESPONSIBILITIES

- 4.1. A **grant-funded investigator** is any 23andMe employee responsible for the conduct, design, or reporting of NIH grant-funded research. Investigators are responsible for disclosing any SFIs related to their research responsibilities to the DO before participating in NIH grant-funded research.
- 4.2. **The Designated Official (DO)** is 23andMe’s Chief Legal Officer, or if that position is not filled, the President or the Controller. The DO is responsible for reviewing disclosures of SFIs, identifying and managing FCOIs, and maintaining records related to SFI disclosures.

5. DEFINITIONS



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- 5.1. National Institutes of Health (NIH)** – The U.S. National Institutes of Health, an operating component of the Department of Health and Human Services.
- 5.2. Public Health Service (PHS)** – The U.S. Public Health Service, an operating component of the Department of Health and Human Services.
- 5.3. Significant Financial Interest (SFI)** – A SFI is a financial interest consisting of one or more of the following interests of the investigator (and those of the investigator’s spouse/domestic partner or dependent children) that reasonably appears to be related to the investigator’s research responsibilities:

- With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceed \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interests include 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 value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator’s spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term SFI does not include the following types of financial interests:

- Salary, royalties, equity or other remuneration paid by 23andMe (the Company) to the investigator, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights
- Any ownership interest in the Company 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



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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

5.4. Sponsored Travel – Travel expenses paid by a third party. Sponsored travel does not include travel expenses paid by the Company or 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.

5.5. Financial Conflict of Interest (FCOI) – a SFI that could directly and significantly affect the design, conduct, or reporting of NIH grant-funded research.

6. PROCEDURE

6.1. Investigator disclosures

- 6.1.1. Each investigator is required to certify that he or she has appropriately disclosed any SFIs or sponsored travel that occurred in the previously twelve-month period and reasonably appears to be related to his or her research responsibilities to the DO before participating in grant-funded research. Additionally, the investigator must disclose any sponsored travel within 30 days of occurrence to the DO to determine if a financial conflict exists.

6.2. Review of SFIs

- 6.2.1. Before an investigator may participate in grant-funded research, the DO must review all disclosed SFIs and determine if the SFI is related to the investigator's research responsibilities. An SFI could be considered related if the SFI could be affected by grant-funded research or the SFI is in an entity whose financial interest could be affected by the research. The DO may involve the investigator in the determination of whether a SFI is related to grant-funded research.
- 6.2.2. The DO will determine if a SFI related to research creates a FCOI. If a FCOI is determined to exist, then the DO will develop and implement a Management Plan that will specify actions that have been and shall be taken to manage such a FCOI.

6.3. Management of FCOIs



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- 6.3.1. If the DO has identified a FCOI, the DO and the Company will take appropriate steps to address and manage the FCOI, which might include, but are not limited to, the following actions:
- 6.3.2. Public disclosure of FCOI (e.g., when presenting or publishing the research; to the Company's Institutional Review Board);
 - Disclosure of FCOI directly to human research participants;
 - Monitoring of research by independent reviewer(s);
 - Modification of research plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - Reduction or elimination of SFI (e.g., sale of an equity interest); and/or
 - Severance of relationships that create financial conflicts.

6.4. Reporting requirements

- 6.4.1. Prior to the expenditure of grant-related funds, as well as within 60 days for an interest that the DO identifies as conflicting subsequent to the Company's initial FCOI report to the PHS, the Company is obligated to notify the PHS of any FCOI associated with grant-funded research. The Company will provide annual FCOI reports on any previously identified FCOI for the duration of the grant-funded research project or until the FCOI ceases to exist. The annual FCOI report will address the status of the FCOI and any changes to the management plan.
- 6.4.2. If a FCOI is identified, either before grant-funded research begins or during the course of grant-funded research, the Company must notify the PHS through the eRA Commons FCOI Module.
- 6.4.3. In the event that the DO identifies a SFI that was not disclosed in a timely fashion by the investigator or previously reviewed by the DO during ongoing grant-funded research, the Company will, within 60 days, determine whether a FCOI exists, and if so, implement a management plan that will specify the actions that have been, or will be, taken to manage the FCOI. If a FCOI exists, the Company must submit a FCOI notification to the PHS within this same 60-day period.



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- 6.4.4. If a FCOI is not identified or managed in a timely manner, the DO will, within 120 days of determination of non-compliance, complete a retrospective review of the investigator's activities and the grant-funded research project to determine whether any grant-funded research conducted during the period of non-compliance was biased in its design, conduct or reporting. Based on the retrospective review, the Company will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI.
- 6.4.5. If bias is found within grant-funded research design, conduct, or reporting, the Company will notify and submit a mitigation report to the PHS Awarding Component. The mitigation report will include key elements documented in the retrospective review, the impact of the bias on the research project, and the Company's plan of action or actions to eliminate or mitigate the effect of the bias.
- 6.4.6. The DO will maintain records relating to all investigator disclosures of financial interests and the Company's review of and actions taken related to such disclosures for at least three years from the date the final expenditures report is submitted to the PHS, or, where applicable, from other dates specified in PHS regulations.
- 6.4.7. If requested, the Company will promptly make information available to the NIH/HHS relating to any investigator disclosure of financial interests, as well as the Company's review of, and response to, such a disclosure, including whether the disclosure resulted in the DO's determination of a FCOI.

6.5. Public accessibility

- 6.5.1. Prior to the expenditure of grant funds, the Company will make certain information concerning FCOIs held by senior/key personnel publicly accessible via a Web site or by written response to any requestor within five business days of a request or as required by law. This information will remain publicly accessible for at least three years from the date that it was most recently updated.
- 6.5.2. If the Company identifies additional FCOIs that were not previously disclosed, it will make them publicly available within 60 days. If the Company responds to written requests, the Company will note in its response that the information provided is current as of the date of correspondence and is subject to updates, on at least an annual basis, which should be requested subsequently by the requestor, and within 60 days of the company's identification of a new FCOI.

6.6. Investigator Training



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6.6.1. Investigators are responsible for complying with the Company's FCOI policy. Investigators must review the Company's FCOI policy and disclose SFIs before engaging in grant-funded research. The DO will notify investigators when a review of the Company's FCOI is required, which will occur no less than every four years. In the event that the Company's FCOI policy changes or should the Company find an investigator to be noncompliant with the FCOI policy or management plan, all investigators will be required to review the FCOI policy promptly.

6.7. Subrecipients

6.7.1. In the event that grant-funded research includes a subrecipient of federal funds, such as a collaborator or consultant, the Company will incorporate terms that establish whether the FCOI policy of the Company or that of the subrecipient will apply to subrecipient investigators as part of the Company's written agreement with the subrecipient. This written agreement must include time periods to meet disclosure and/or FCOI reporting requirements, which will allow the PI sufficient time to report the FCOI to the PHS. If the Company's FCOI policy applies to the subrecipient, then the subrecipient will be considered an investigator and will be subject to the responsibilities and requirements of Investigators as set forth in this document.