


Potentiometric Probes



Financial Conflict of Interest (FCOI) Policy

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PURPOSE

Potentiometric Probes LLC conducts basic biomedical research and technology development for human health-related applications. Potentiometric Probes is committed to the integrity of this research by maintaining objectivity and eliminating bias. Financial conflicts of interest are one instance where bias may arise and, for this reason, Potentiometric Probes has developed the following Financial Conflict of Interest (FCOI) policy to ensure that the design, conduct, and reporting of research is free from bias resulting from an investigator's conflicting financial interest.

Potentiometric Probes is a recipient of NIH (National Institutes of Health) grants and its FCOI policy shall conform to regulations adopted by NIH promoting objectivity in research ([42 CFR Part 50 Subpart F](#) and [45 CFR Part 94](#)). These regulations describe the actions an individual and an organization must take to identify, disclose, and manage financial conflicts of interest, along with measures and procedures to follow when conflicts are not properly identified or managed.

SUMMARY OF PROCESS

Significant Financial Interests (SFI) (as defined below) with a potential for conflict of interest shall be disclosed in writing by specified investigators to the designated company FCOI official. Current disclosures must be filed at least annually, even when there are no SFIs to disclose or no new SFIs have been discovered or created. SFI disclosures must be current before investigators start work on NIH-sponsored research projects. Newly created or discovered SFIs arising during the course of research must be disclosed in a timely manner (defined below). Training for investigators on FCOIs likewise must be maintained and updated.

The SFI disclosure form and supporting materials are forwarded to the FCOI officer for review who will investigate the "relatedness" to research with the help of the investigator and decide whether a real conflicts exist, in which case a management plan will be implemented, including possibly the elimination of the conflict. The FCOI officer and the CEO will be responsible for evaluating and instituting a plan for managing any financial interests including actual conflicts of interest, for producing institutional reports and other required reports to external sponsors and governmental agencies, and for the general administration and enforcement of this policy.

For government-sponsored research, advance approval by the FCOI officer is required prior to engaging in research. An SFI review must be completed before any expenses are incurred under an award.

Annual updates are required of all Investigators and key personnel participating in research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the FCOI officer. Annual updates and newly acquired interests are reported using the Significant Financial Interest Disclosure Form.

DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at [42 CFR 50.603](#) and more details can be found in relevant sections below.

Investigators include the Principal Investigator/Project Director and any other individuals, regardless of title or position, who are responsible for the design, conduct, or reporting of NIH/NIH-funded research, or proposed for such funding, and which may include, for example, collaborators or consultants.

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial interest means anything of monetary value, whether the value is readily ascertainable.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Financial Conflicts of Interest in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research.

Significant Financial Interest (SFI) is a financial interest, typically with total, aggregate value greater than \$5000, consisting of one or more assets or interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities on behalf of Potentiometric Probes LLC.

FCOI TRAINING

In compliance with federal regulations, all Potentiometric Probes investigators who are planning to participate in or are participating in NIH-funded research are required to review the Potentiometric Probes FCOI policy and complete the [NIH FCOI Training module](#):

- Prior to engaging in research related to any NIH-funded grant
- At least every four (4) years
- Immediately, if:
 - Institution revises its FCOI policy that affects requirements of Investigators
 - An Investigator is new to an Institution
 - An Investigator is not in compliance with the policy or management plan

Upon completion of the training, a certificate of completion must be sent to the designated FCOI Official. Investigators should also retain a copy for their records.

SIGNIFICANT FINANCIAL INTEREST (SFI) DETAILS

- ❖ A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to

be related to the Investigator's institutional responsibilities on behalf of Potentiometric Probes.

- With regard to any publicly traded entity, a significant financial interest 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 for the investigator, investigator's spouse and dependent children, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, 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 significant financial interest 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - With regard to intellectual property rights and interests (e.g., patents, copyrights), a significant financial interest exists upon receipt of income of greater than \$5,000 related to such rights and interests.
 - Third party reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, or research activities) must be disclosed to Potentiometric Probes. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement excludes travel paid for by Potentiometric Probes and does not apply to travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, a U.S. 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.
- ❖ The term significant financial interest does not include the following types of financial interests:
- Salary, royalties, or other remuneration paid by Potentiometric Probes to the Investigator if the Investigator is currently employed or otherwise appointed by Potentiometric Probes, including intellectual property rights assigned to Potentiometric Probes and agreements to share in royalties related to such rights;
 - 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 U.S. 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 U.S. 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.

IDENTIFICATION OF PERSONS REQUIRED TO DISCLOSE AN SFI

The designated FCOI Official will be responsible for identifying investigators (see definition) required to disclose SFIs. The FCOI Official will coordinate with the CEO and any Principal Investigator of a Research Project to identify these investigators and will be responsible for ensuring that annual updates and disclosures of new or modified financial interests are completed.

SUBMISSION OF SIGNIFICANT FINANCIAL INTEREST (SFI) DISCLOSURE FORM

Each Investigator identified by the FCOI Official will be required to complete and submit the SFI Disclosure Form:

- At the start of employment,
- Annually,
- Before participating in any NIH-funded research activities,
- Within 30 days of discovering or acquiring a new SFI. The discovery or acquirement may be due to marriage, purchase, or inheritance.

REVIEW OF FINANCIAL INTEREST DISCLOSURE FORM

A review of the SFI Disclosure Form will be conducted by FCOI Official, and the PI for grant-funded research, with input from the Investigator to determine whether a conflict of interest exists. The requirement that an Investigator discloses a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential Financial Conflict of Interest.

A Financial Conflict of Interest exists when Investigator's Significant Financial Interest is:

- For NIH-funded research, is related to and could be affected by the research or is in an entity whose financial interest could be affected by the research, and
- An SFI is considered a FCOI when the SFI could directly and significantly (i.e., have a material effect) affect the design, conduct, or reporting of the research.

If it is determined that there is a conflict of interest, then steps will be taken to determine what measures are needed to manage, reduce or eliminate specific SFI to prevent the potential to compromise or bias professional judgment or objectivity regarding the design, conduct, or reporting of research.

A management plan may be required to outline the terms, conditions, and restrictions, if any, to ensure compliance with this policy. The management plan may require one or more of the following actions (but not limited to) to be taken:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to staff members working on the project, etc.)
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest.
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research.

- Reduction or elimination of the financial interest (e.g., sale of an equity interest), or
- Severance of relationships that create financial conflicts

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the designated official will determine by what means – such as the individual’s recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the designated official will be guided by the principles discussed in this Policy the designated official will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- A. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- B. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- C. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- D. Modification of the research plan;
- E. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- F. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- G. Severance of relationships that create financial conflicts;
- H. For research projects involving human subjects research, use of a data and safety monitoring board;
- I. Double-blind conditions;
- J. Provisions to conduct the work simultaneously at multiple sites;
- K. Written disclosure of the conflict to all individuals working on the research project;
- L. Annual reports on the research progress to the designated official.
- M. Disclosure at any presentation of information related to the FCOI.

If the designated FCOI official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The designated official will keep a record of the disclosure and other relevant information for at least three years. If the designated official prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a NIH award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the designated official necessary to manage the Conflict of Interest. The designated official will communicate, in writing, with the NIH Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the NIH Grantee has reported the FCOI to NIH.

The designated official will keep a record of Investigator disclosures of financial interests and the designated official's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the award and relevant NIH Regulations.

Compliance and Failure to Comply with Potentiometric Probes's Conflict of Interest Policy

Investigators are expected to comply fully and promptly with this policy. Whenever an investigator has violated this policy, steps will be taken to mitigate bias, and disciplinary proceedings may be taken against the violating individual. The company will follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy as described above. The federal agency may take its own action as it deems appropriate, including the suspension of the funding for the Investigator until the matter is resolved.

Clinical Research. In any case in which the sponsor determines that an NIH-funded project of clinical research 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 financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

When a FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by Potentiometric Probes; or because an investigator failed to comply with a management plan; then Potentiometric Probes will within 120 days:

- A. Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct, or reporting of research;
- B. Document the retrospective review consistent with the regulation;
- C. Document Potentiometric Probes' determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research;

If bias is found, Potentiometric Probes shall notify NIH promptly and submit a mitigation report to NIH that shall address the following:

- Impact of the bias on the research project and
- Potentiometric Probes' plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Potentiometric Probes shall submit FCOI reports annually to NIH, in accordance with the regulation and terms and conditions of the award agreement. Depending on the nature of the Financial Conflict of Interest, Potentiometric Probes may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project

between the date that the Financial Conflict of Interest is identified and the completion of Potentiometric Probes's independent retrospective review.

Subrecipient FCOI Compliance

A subrecipient relationship is established when federal funds flow down from or through the Potentiometric Probes to another individual or entity and the subrecipient will be conducting a substantive portion of a NIH-funded research project and is accountable to the Potentiometric Probes for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees, are subject to the Potentiometric Probes's terms and conditions, and as such, the Potentiometric Probes will take reasonable steps to ensure that any subrecipient Investigator is in compliance with the federal FCOI regulation. The Potentiometric Probes will incorporate, as part of a written agreement with the subrecipient, terms that establish whether the Potentiometric Probes's Investigator FCOI Policy or that of the subrecipient's institution will apply to the subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with the Potentiometric Probes that it is in compliance with the federal FCOI regulation and that the institution's portion of the project is in compliance with the federal conflict of interest policy. If the subrecipient cannot provide the certification, the agreement shall state that the subrecipient Investigator is subject to the Potentiometric Probes's Investigator FCOI Policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the Potentiometric Probes. The Potentiometric Probes will, if applicable, submit a FCOI report to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

If the subrecipient's conflict of interest policy applies to the subrecipient Investigator, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to the Potentiometric Probes. Such time period must be sufficient to enable the Potentiometric Probes to provide timely FCOI reports to the NIH as necessary, through the eRA Commons FCOI Module.

If the subrecipient Investigator is subject to the Potentiometric Probes's Investigator FCOI Policy, the agreement shall specify the time period for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the Potentiometric Probes. Such time period shall be sufficient to enable the Potentiometric Probes to comply with its review, management, and reporting obligations under the regulation. The Potentiometric Probes will submit any NIH FCOI reports for a subrecipient Investigator through the eRA Commons FCOI Module.

PUBLIC DISCLOSURE AND RECORDS MANAGEMENT

Potentiometric Probes will publish the institution's policy on its public website. The posted policy will be updated at least annually. Potentiometric Probes will also maintain public accessibility to Significant Financial Interests of senior/key personnel (as defined by the regulation) that were identified as FCOIs and reported to the sponsor. As such, Potentiometric Probes will respond to all requests for information within five business days and then release the following information about such Significant Financial Interest using the most up-to-date information available.

- The name of the Investigator.
- The title and role of the Investigator with respect to the research project.
- Name of the entity with which the Significant Financial Interest is held.

- The nature of the Significant Financial Interest.
- Approximate value of the Significant Financial Interest as determined by:
 - dollar range \$0-\$4,999, \$5,000-\$9,999, \$10,000-\$19,999
 - amounts between \$20,000-\$100,000 by increments of \$20,000
 - amounts above \$100,000 by increments of \$50,000
 - or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value.

Records of Investigator SFI Disclosure forms, and of actions taken to manage actual or potential conflicts of interest, will be retained for a minimum of three years from the date the final expenditure report is submitted to the sponsor as required by [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#). Upon the NIH request, Potentiometric Probes will also make information relating to any investigator's SFI disclosure and the institutional review available, whether or not the disclosure resulted in the institution's determination of an FCOI.

CURRENT FCOI OFFICER

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