

# Eko Devices' Financial Conflict of Interest (FCOI) Policy for NIH-Funded Research

Eko Devices is dedicated to maintaining public trust in the integrity of our research-related activities. The management of financial conflicts of interest (FCOI) is crucial for safeguarding research objectivity and for compliance with federal regulations.

Eko Devices seeks to ensure the integrity of its research and to comply with the Public Health Service (PHS) requirements for institutions that seek research funding. The PHS has implemented regulations (42 CFR 50, "FCOI Regulations") to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants will be free from bias resulting from investigator FCOIs.

This policy includes any research performed at Eko that is funded from NIH monies (PHS grants).

- Eko may be the primary research institution.
- Eko may be a sub-investigating/contracted research institution.

This policy includes any investigators that are participating in NIH-funded research at Eko or any subcontracting organization. The policy provides mandatory training, policy documentation and essential details on processes that investigators must follow to comply with FOCI Regulations.

## Definitions

An "[investigator](#)" is defined for this policy as

- Any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by NIH, or proposed for such funding.
- Examples include but are not limited to: program director, principal investigator, co-principal investigator, collaborator, and consultant.

A "[significant financial interest](#)" (SFI) is defined as:

1. 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 appears to be related to the Investigator's responsibilities at Eko:
  - a. 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, 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

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- determined through reference to public prices or other reasonable measures of fair market value;
- b. 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
  - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of 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 their responsibilities at Eko; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. Eko' requires that disclosure to include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this policy, Eko's designated official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
  3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by Eko to the Investigator if the Investigator is currently employed or otherwise appointed by Eko, including intellectual property rights assigned to Eko and agreements to share in royalties related to such rights; any ownership interest in Eko 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.

A "[financial conflict of interest](#)" (FCOI) exists when Eko's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

## Mandatory Training requirements

- Each investigator shall be informed of Eko's FCOI policy.

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- Each investigator shall be informed of his or her responsibility to disclose to Eko any FCOI.
- Each investigator shall be informed of the Federal regulation(s) pertaining to FCOI disclosure requirements per 42 CFR 50.604(c).
- Each investigator shall be required to complete FCOI training
  - Prior to engaging in research related to any PHS-funded grant,
  - At least every 4 years. or
  - Immediately, if
    - Eko revises this policy in a manner that affects the requirements of investigators,
    - An investigator is new to Eko, or
    - An investigator is not in compliance with this policy or management plan.

## Disclosure, Review and Monitoring Requirements

- Each investigator shall disclose to Eko his or her own SFIs, and those of his or her spouse and dependent children, related to the investigator's responsibilities that meet or exceed the regulatory definition of an SFI:
  - No later than at the time of application for PHS-funded research
  - At least annually during the period of the award
  - Within 30 days of discovering or acquiring a new SFI
- Eko assigns to its Administrative Signing Official (ASO) the responsibility of soliciting and reviewing investigator SFI disclosures (and SFI disclosures for the investigator's spouse and dependent children) that are related to the investigator's responsibilities at Eko.
- Eko will provide adequate guidelines to its ASO that are consistent with 42 CFR 50.604(f) so that the ASO is able to determine whether an investigator's SFI is related to NIH-funded research and, if so related, whether the SFI is an FCOI.
- Prior to Eko's expenditure of NIH-related research funds, OR upon the participation of a new investigator, OR upon Eko becoming aware of an existing investigator disclosing a new SFI, OR within 60 days of Eko identifying an SFI that was not disclosed in a timely manner by an investigator, Eko's ASO will
  - Review all investigators' SFI disclosures
  - Determine if any SFIs relate to PHS-funded research
  - Determine if an FCOI exists (*i.e.*, whether that SFI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)
  - Develop and implement management plans, as needed, to manage FCOIs
- The above disclosure, review, and monitoring requirements also apply to any FCOIs brought to Eko's attention regarding any subrecipient investigator.

## Management of FCOI Requirements

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- Prior to expenditure of any funds, the ASO (consistent with 42 CFR 50.604(f)) review all investigator disclosures of significant financial interests to:
  - Determine whether any significant financial interests relate to PHS-funded research
  - Determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.
- Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI to Eko, the ASO shall within 60 days:
  - Review the disclosure of the SFI
  - Determine whether it is related to PHS-funded research
  - Determine where an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.
- If a FCOI that was not disclosed timely by an Investigator or was not previously reviewed by Eko during the PHS-funded research project, the ASO shall within 60 days:
  - review the SFI
  - determine whether it is related to PHS-funded research
  - determine whether a financial conflict of interest exists; and, if so:
    - Implement a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
    - Eko shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. Eko shall document the retrospective review and include the following elements:
      - Project number
      - Project title
      - PD/PI or contact PD/PI if a multiple PD/PI model is used
      - Name of the Investigator with the FCOI
      - Name of the entity with which the Investigator has a financial conflict of interest
      - Reason(s) for the retrospective review
      - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
      - Findings of the review; and
      - Conclusions of the review
    - Based on the results of the retrospective review, if appropriate, Eko shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Eko is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include,

at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

- Thereafter, Eko will submit FCOI reports annually

## Reporting FCOI Requirements

- Prior to Eko's expenditure of any funds under a PHS-funded research project, Eko shall provide to the PHS an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with 42 CFR 50 Subpart F.
- Within 60 days, Eko shall send an FCOI report if any significant financial interest that Eko identifies as conflicting subsequent to the Institution's initial FCOI report during the PHS-funded research project.
- The FCOI report shall include (but not be limited to) the following:
  - Project Number
  - PD/PI or Contact PD/PI if a multiple PD/PI model is used
  - Name of the Investigator with the financial conflict of interest
  - Name of the entity with which the Investigator has a financial conflict of interest
  - Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
  - Value of the financial interest (42 CFR 50.605(b)(3)(vi)).
  - A description of how the financial interest relates to the PHS-funded research and the basis for Eko's determination that the financial interest conflicts with such research; and
  - A description of the key elements of the Institution's management plan, including:
    - Role and principal duties of the conflicted Investigator in the research project
    - Conditions of the management plan
    - How the management plan is designed to safeguard objectivity in the research project
    - Confirmation of the Investigator's agreement to the management plan
    - How the management plan will be monitored to ensure Investigator compliance; and
    - Other information as needed.
- For any FCOI previously reported, Eko shall provide PHS an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists.

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## Maintenance of Records

- Eko will maintain all FCOI-related records for at least 3 years from the date the final expenditures report is submitted to the NIH, and from other dates as specified in 45 CFR 75.361, where applicable.

## Enforcement Mechanisms and Remedies and Noncompliance

- Eko is responsible to create enforcement mechanisms and provide for employee sanctions to ensure Investigator compliance.
- All retrospective reviews will be completed and documented within 120 days of Eko's determination of noncompliance for SFIs not disclosed in a timely manner or previously reviewed.
- If the Department of Health and Human Services determines that a NIH-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of one of Eko's medical devices has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by Eko as required by the regulation, Eko shall require that the investigator involved
  - Disclose the FCOI in each public presentation of the results of the research, and
  - Request an addendum to previously published presentations.

## Subrecipient Requirements

- Eko will obtain from each award subrecipient, via a written agreement, that the subrecipient will follow Eko's FCOI policy.
- Eko will obtain a certification from each award subrecipient that its FCOI policy complies with the regulation.
  - Eko will include in the written subrecipient agreement a requirement for the subrecipient report identified FCOIs for its Investigators to Eko in a time frame that allows the Eko to report identified FCOIs to the NIH as required by the regulation.
  - Alternatively, Eko may, upon its judgment, include in the written subrecipient agreement a requirement to solicit and review subrecipient Investigator disclosures that will enable Eko to identify, manage and report identified FCOIs to the NIH.

## Public Accessibility Requirements

- Eko will make its FCOI policy publicly accessible by posting the FCOI policy on its public website.
- Eko will make available information concerning identified FCOIs held by senior/key personnel prior to the expenditure of funds. This information will
  - Include the minimum elements as provided in the regulation

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- Be posted on Eko's public website or made available within 5 calendar days of a written request
- Be updated on Eko's website at least annually
- Be updated on Eko's website within 60 days of a newly identified FCOI
- Remain available for 3 years from the date the information was most recently updated.