

SUBJECT: Policy on Financial Conflicts of Interest in Research

I. PURPOSE

- A. The purpose of this policy is to ensure research objectivity to preserve the credibility of research activities conducted by Nimbic Systems (“Nimbic”) employees and research partners through a transparent process for financial conflict of interest (“FCOI”) disclosure and resolution.

II. SCOPE

- A. This policy is guided by federal regulatory requirements for the disclosure, review, management, and reporting of financial conflicts of interest as defined in 42 CFR 50 Subpart f.
- B. This policy applies to Nimbic employees and other Investigators involved in PHS-funded research.

III. DEFINITIONS

- A. **Disclosure of Significant Financial Interests (“Disclosure”)**: an Investigator’s disclosure of significant financial interests.
- B. **Financial Conflict of Interest (“FCOI”)**: Significant financial interest that could directly and significantly affect the design, conduct, or reporting of Public Health Service (“PHS”)-funded research.
- C. **Financial Interest**: Anything of monetary value, whether or not the value is readily ascertainable.
- D. **Institution**: any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
- E. **Investigator**: The project director, principal investigator (“PI”), or 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 collaborators and consultants.
- F. **Institutional Responsibilities**: an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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.
- G. **Research**: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, 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.
- H. **Significant Financial Interest (“SFI”)**:
1. A Financial Interest held by the Investigator (or his/her Immediate Family or Household Member) consisting of one or more of the following that reasonably appears to be related to the Investigator’s Institutional Responsibilities:
 - a) Publicly traded entity – The value of any remuneration received by the entity in the twelve months preceding the disclosure and the value of any equity interest (as of date of disclosure) in the entity that, 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 determined through reference to public prices or other reasonable measures of fair market value;
 - b) 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); **Nimbic Systems is a non-publicly traded entity**; or
 - c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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2. Investigators must disclose the occurrence of any reimbursed or sponsored travel, related to their institutional responsibilities except if they are for a federal, state or local government agency, a U.S. institution of higher education, an academic teaching hospital, or a medical center. Investigator must disclose the purpose of the trip, identity of the sponsor, destination, and duration.
3. Significant financial interest **does not** include:
 - a) salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - b) any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; or
 - c) 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;

IV. PROCEDURE

- A. This policy will be made publicly available on the Nimbic website. FCOIs made public via the website shall contain the reporting requirements and be updated annually and as specified in 42 CFR 50.605.
- B. Training – All Investigators must be trained on this policy prior to engagement in Research, upon hire of a new Investigator, immediately if noncompliance is discovered or if significant revisions to this policy are made, and every four years thereafter.
- C. Disclosure, Review and Monitoring
 1. Upon hire or commencement of other relationship with Nimbic, and annually thereafter, Investigators must disclose FCOIs meeting the definition of Significant Financial Interest relating to the Research.
 2. Investigators must update their disclosures within 30 days of receiving new SFI related to the Research.
 3. Particular emphasis is placed on disclosure of FCOIs when the Research involves clinical research whose purpose is to evaluate the safety or effectiveness of a medical device. Failure to comply with this policy may require the Investigator to disclose the FCOI in each public presentation of the Research.
 4. FCOI disclosures will be submitted to the President of Nimbic who is responsible for reviewing FCOIs to determine whether an Investigator's SFI is related to the Research and, if so, whether the SFI is a financial conflict of interest.
 5. If the President determines that a FCOI exists with an Investigator and the Research, a Management Plan may be implemented to mitigate the conflict of interest, or the Investigator may be required to sever ties to the Research. Sanctions on the Investigator may be imposed, up to and including termination, if compliance is not adhered.
 6. Records relating to all Investigator disclosures of SFI; Nimbic's review of and response to such disclosures; and all actions under this policy, including retrospective reviews, will be maintained for at least three years from the date the final expenditures report is submitted to PHS or other dates specified in 45 CFR 74.53(b) and 92.42(b).
- D. Sub-recipient Investigators (e.g. consortium members)
 1. A written agreement will be established between Nimbic and any sub-recipient Institution or Investigator that provides for maintaining compliance with the requirements of 42 CFR 50(F).
 2. If the sub-recipient's policy regarding management of SFI and FCOI applies, the agreement will certify that the sub-recipient complies with 42 CFR 50 and 45 CFR 94. Alternatively, if applicable, a requirement for the sub-recipient to solicit and review sub-recipient Investigator disclosures that enable Nimbic to identify, manage and report FCOIs to NIH.
 3. The sub-recipient Institution or Investigator must provide FCOI reports to Nimbic prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

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E. Reporting

1. Initial FCOI (PHS) Report

- a) New PHS-funded Research – If a FCOI exists, an initial FCOI report will be sent to PHS prior to the expenditure of funds. However, if a FCOI is eliminated prior to the expenditure of funds, a report is not required.
- b) Ongoing PHS-funded Research – Within 60 days of making a FCOI determination, a report will be sent to PHS for any FCOI identified subsequent to the initial DCOI report.

2. PHS Retrospective Review and Mitigation Reports

- a) If a SFI was not disclosed or reviewed in a timely manner in an ongoing PHS-funded research project, the President will, within 60 days, determine if the SFI relates to Research and if a FCOI exists.
- b) If a FCOI exists, the President will implement an interim Management Plan, report to PHS and, within 120 days of discovery of noncompliance, conduct and document a retrospective review of the Investigators activities and the Research to determine if there is any bias in Research design, conduct, or reporting. The retrospective review will document, at a minimum, the requirements of 42 CFR 50.605.
- c) If appropriate, an update to the previously submitted FCOI report will be sent to PHS.
- d) If bias is found, a mitigation report will be developed and PHS will be notified promptly.

3. Annual FCOI Report

- a) For any previously reported FCOI, an annual FCOI report will be submitted to PHS for the duration of the PHS-funded Research.

F. Confidentiality

1. All Disclosure forms and their contents will be treated as confidential and will only be revealed as necessary to implement and enforce this policy or as required by law.