# Numiera Therapeutics Corporate Financial Conflict of Interest (FCOI) Policy

Effective: July 31, 2026

## 1) Introduction

The purpose of this policy is to ensure that research funded by the National Institutes of Health (NIH) is designed, conducted, and reported objectively and without bias resulting from Investigator financial conflicts of interest (FCOI).

The 2011 revised regulations are 42 CFR Part 50 Subpart F, "Promoting Objectivity in Research" and 45 CFR Part 94, "Responsible Prospective Contractors", which set requirements for promoting objectivity in Public Health Service (PHS)–funded research for grants, cooperative agreement, and research contracts, respectively. The regulations and this policy do not apply to SBIR or STTR Phase I applications or awards.

This policy is intended to implement the regulatory requirements for PHS/NIH grants and cooperative agreements per the regulation at 42 CFR Part 50 Subpart F and NIH's guidance.

Numiera Therapeutics ("NUMIERA" or "The Company") adopts this policy for all Investigators (as defined below) engaged in PHS/NIH-funded research. It establishes processes to identify, disclose, and manage Investigator financial conflicts of interest to protect research integrity, ensure the safety of human and animal subjects, and maintain public trust in PHS/NIH-supported research.

## 2) Applicability

This policy implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH. This policy applies to individuals who meet the regulatory definition of "Investigator" (as defined below) who are planning to participate in or who participate in PHS/NIH-funded research.

## 3) Definitions

For the purpose of these policies and procedures, the following definitions apply:

**Financial Conflict Of Interest (FCOI):** A significant financial interest that the Institution's designated official(s) determines is related to the PHS/NIH-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**Financial Interest:** Anything of monetary value, whether or not its value is readily ascertainable.

**Institutional Responsibilities:** The professional responsibilities of an Investigator on behalf of NUMIERA, which may include activities such as research, research consultation and collaboration, product development, product testing and validation, development of datasets, models, or systems, publication and communication of research results, and other professional services performed on behalf of NUMIERA. These responsibilities also extend to institutional committee memberships and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Designated Official (DO):** The individual appointed by NUMIERA to solicit and review disclosures of significant financial interests, determine FCOIs in accordance with 42 CFR 50.604(f) and this policy, and develop management plans for identified FCOI.

**Institution:** Any public or private organization, domestic or foreign (excluding a federal agency) that is applying for or receives PHS/NIH research funding.

**Investigator:** The Project Director (PD) or Principal Investigator (PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS/NIH or proposed for such funding, which may include, for example, collaborators or consultants. The institution determines who is responsible for the design, conduct, or reporting of PHS/NIH-funded research. The Institution will consider the individual's role, rather than the title (e.g., senior/key personnel, faculty, MD, PHD, etc.), of those individuals involved in the research and the degree of independence in carrying out the work when determining who is responsible for the design, conduct, or reporting of the PHS/NIH-funded research.

**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.

**Research:** means 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 the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, 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.

**PHS-Funded Research:** Any activity supported by a Public Health Service (PHS) Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

**PHS:** 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).

**NIH:** The biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

**Senior/Key Personnel:** The PD/PI and any other individual identified as senior/key personnel by the Institution in a grant application, progress report, or other submission to PHS/NIH. For this policy, the term applies specifically to the public accessibility requirement, which mandates disclosure only of financial conflicts of interest held by these senior/key personnel, as described in Section 9.

## Significant Financial Interest (SFI):

1) A **domestic or foreign** financial interest consisting of one or more of the following interests of the Investigator, and those of the Investigator's spouse, domestic partner, and dependent children, that reasonably appears to be related to the Investigator's *Institutional Responsibilities* (see definition) performed on behalf of NUMIERA, and that consists of one or more of the following:

    (i) **Publicly traded entity:** An 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, 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;

(ii) **Non-publicly traded entity:** An 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) **Intellectual property rights and interests:** An SFI exists if receipt of income related to intellectual property rights or interests (e.g., patents, copyrights), exceeds $5,000 during the 12 months preceding the disclosure, related to such rights and interests.

2) Investigators must disclose any **reimbursed or sponsored travel** related to their institutional responsibilities in excess of $5000. Such travel includes trips paid on behalf of the Investigator rather than reimbursed directly, where the exact cost may not be known. The disclosure must cover the previous 12 months and include, at minimum, the purpose, sponsor or organizer, destination, and duration of each trip.

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- a federal, state, or local government agency located in the United States,
- a United States Institution of Higher Education,
- an academic teaching hospital,
- a medical center, or
- a research institute affiliated with a United States Institution of Higher Education

3) The term "significant financial interest" does not include, and therefore investigators are not required to disclose, the following types of financial interests:

- Salary, royalties, or other remuneration paid by NUMIERA to the Investigator if the Investigator is currently employed or otherwise appointed by NUMIERA, including intellectual property rights assigned to NUMIERA and any agreements to share royalties related to those rights.
- Any ownership interest in the Institution (i.e., NUMIERA) held by the Investigator, since the Institution (i.e., NUMIERA) is a commercial or for-profit organization
- Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not directly control the investment decisions for those vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.
- Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

**Exclusions Related to Foreign (non-U.S.) Financial Interests:** Investigators must disclose all financial interests originating outside the United States, including income from seminars, lectures, teaching engagements, service on advisory committees or review panels, and reimbursed or sponsored travel, received from any foreign entity. This includes foreign institutions of higher education and foreign governments (including local or provincial governments). Disclosure is required when the aggregated amount of such income meets the threshold for disclosure (e.g., income in excess of $5,000).

## 4) Significant Financial Interest (SFI) Disclosure Requirements

Investigators will disclose their SFIs that are related to their "*institutional responsibilities*" as defined in the policy.

The disclosure will not be limited to an Investigator's research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation.

The Investigator SFI Disclosures will be retained by the Institution as part of the record maintenance requirements.

Investigators are required to disclose SFIs at the following times:

A. **At the time of application:** The PI and all other individuals who meet the definition of "Investigator" must disclose their SFIs to the DO(s). Any new Investigator who joins the project after the NIH application has been submitted or during the course of the research must also disclose their SFI(s) to the DO(s) promptly and before participating in the project, using the SFI Disclosure Form.

B. **Annual disclosure during the award:** Each Investigator participating in research under an NIH award must submit an updated SFI disclosure at least annually as prescribed by NUMIERA (on or before October 1) during the award period. The annual disclosure must include: (1) any new information that was not previously disclosed to the DO under this policy, including SFIs associated with NIH-funded projects transferred from another institution; and (2) updated details for any previously disclosed SFI, such as changes in the value of an equity interest.

C. **Ad-hoc basis during the award:** Each Investigator participating in PHS/NIH-funded research must submit an updated SFI disclosure within 30 days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Updated disclosure of reimbursed or sponsored travel must also be submitted within 30 days of each occurrence.

## 5) Review of SFI Disclosures

The NUMIERA Executive Team, which consists of its Chief Executive Officer, Chief Program Officer, and Chief Operations Officer, will serve as the Designated Officials (DOs) responsible for reviewing all SFI disclosures and making determinations of FCOI. In cases where it is determined that one of the members of the Executive Team has a disclosed SFI related to the research under review, or where additional independence is warranted, the DO team member will recuse themselves from the review and determination. In such cases, the remaining members of the Executive Team will serve as the DOs. In situations where an Executive Team member must recuse themselves, the situation will be documented.

Each SFI will be evaluated in relation to every PHS/NIH research application or award on which the Investigator is responsible for the design, conduct, or reporting of research, to determine whether the SFI is related to the funded research and, if so, whether it constitutes a Financial Conflict of Interest (FCOI).

## The SFI disclosures will be reviewed as described below:

A. **Prior to the issuance of a new award or before any expenditure of any awarded funds (e.g., during Just-in-Time stage):** The DO will review the Investigator's SFIs before NIH issues a new award. If an FCOI is identified, an FCOI report will be submitted to NIH via the eRA Commons FCOI Module prior to any expenditure of funds.

B. **Annual SFI disclosure:** As part of the annual disclosure process, Investigators must provide updated information on any previously disclosed SFIs (e.g., revised value of an equity interest). The DO will review these updates to determine whether changes to an existing management plan are needed. Any modifications will be reflected in the next Annual FCOI report submitted to NIH, if applicable.

C. **Ad hoc basis during award period**: If a new Investigator joins a project or an existing Investigator acquires or discovers a new SFI during the project, the DO will, **within 60 days**:
   (1) review the disclosure;
   (2) determine whether the SFI is related to the PHS/NIH-funded research;
   (3) determine whether an FCOI exists; and, if so,
   (4) implement, on at least an interim basis, a management plan.

An FCOI report will be submitted to NIH within 60 days of identifying the FCOI.

## 6) Relatedness of SFIs to PHS/NIH-Funded Research and FCOI

The Dos are responsible for assessing the relatedness of SFIs to NIH-funded research and determining when they constitute a FCOI.

**Relatedness Test:** The DOs determine whether an Investigator's SFI is related to research under an NIH award. An SFI is considered "related" when the DOs reasonably determine that:

- The SFI could be affected by the PHS/NIH-funded research, **or**
- The SFI is in an entity whose financial interests could be affected by the PHS/NIH- funded research.

**Designated Officials FCOI Determination:** An FCOI exists when the DOs reasonably determine that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH- funded research ("significantly" meaning that the financial interest would have a material effect on the research). The DOs may consult with the Investigator when assessing whether an SFI is related to the research.

## 7) Management of SFIs that Pose an FCOI

When an FCOI is identified, the DO will determine and implement management strategies to ensure the research is conducted objectively. Examples of management conditions include, but are not limited to:

1. Public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the IRB, IACUC, or Data Safety Monitoring Board).
2. For human subjects research, disclosure of the FCOI to participants in the informed consent document.
3. Appointment of an independent monitor to protect against bias in the design, conduct, and reporting of the research.
4. Modification of the research plan.
5. Change of personnel roles or removal from portions of the research.
6. Reduction or elimination of the financial interest (e.g., divesting equity).
7. Severance of relationships that create financial conflicts.

The DOs will communicate the determination and the management plan in writing to the Investigator and will require the Investigator to certify compliance with the management plan.

No expenditures on an NIH award may occur until the Investigator has met all disclosure requirements and agreed in writing to comply with the management plan. The DOs will submit an FCOI report to NIH via the eRA Commons FCOI Module.

## 8) Monitoring Investigator Compliance

NUMIERA will monitor Investigator compliance with the management plan for the duration of the NIH award. When the Institution's FCOI policy applies to subrecipient Investigators, the Institution will monitor subrecipient Investigator compliance with the management plan.

As part of this monitoring process, the DO may request and review documentation demonstrating compliance with required FCOI disclosures, including publications, presentation materials, abstracts, posters, and written communications to study personnel. Investigators must provide copies of such materials, including relevant emails or other written disclosures, to the DO for recordkeeping. These records will be maintained to document compliance with the management plan and to support institutional review and audit activities.

## 9) Public Accessibility of the FCOI Policy and FCOIs Held by Senior/Key Personnel

**FCOI Policy:** A copy of this FCOI policy is available on NUMIERA's public website at https://numiera.com/ as required by Section 4.1.10 Financial Conflict of Interest of the NIH Grants Policy Statement.

**Identified FCOIs held by Senior/Key Personnel:** Before any funds are spent under an NIH award, NUMIERA will ensure public accessibility, by providing a written response within **five business days** to requests for information about any SFI that meets all three of the following criteria:

- The SFI was disclosed, is still held by Senior/Key Personnel (the PD/PI and any other individual identified by NUMIERA as senior/key personnel in the application, progress report, or other NIH submission).
- NUMIERA has determined that the SFI is related to the NIH-funded research.
- NUMIERA has determined that the SFI constitutes an FCOI.

When applicable, NUMIERA will make available at least the following information:

- Investigator's name
- Investigator's title and role with respect to the research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI in the following ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined by public prices or reasonable fair market value measures.

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the institution's identification of a new FCOI, which should be requested subsequently by the requestor.

If NUMIERA uses a publicly accessible website to meet this requirement, the information will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key Personnel related to the NIH-funded research that was not previously disclosed, or
- A new SFI being disclosed by Senior/Key Personnel joining the project and determined by the DO to be related and an FCOI. Information on SFIs subject to public accessibility will remain available for at least three years from the most recent update.

## 10) Reporting Identified Financial Conflicts of Interest

Prior to spending any funds under an NIH-funded award, NUMIERA will submit an identified FCOI report to NIH, in accordance with the FCOI regulations, for any Investigator's SFI determined to be an FCOI. NUMIERA will also ensure that the Investigator has agreed to and begun implementing the associated management plan.

NUMIERA will designate an institutional official to act as the FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module. The FCOI SO is authorized to submit FCOI reports to NIH. FCOI reports are submitted only when an award is active and an FCOI has been identified (i.e., no award means no FCOI report, and no FCOI means no FCOI report).

The NIH eRA Commons FCOI Module User Guide, available at the following location, provides instructions for preparing and submitting FCOI reports.

https://www.era.nih.gov/files/fcoi_user_guide.pdf

**Schedule for Reporting Identified FCOIs to PHS/NIH:**

The institution will submit the following types of reports as explained below:

A. **Initial (Original) FCOI Reports:** The report must include all information required under 42 CFR 50.605(b)(3) or as outlined in NIH's FAQ currently numbered H.5. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888.

   When an FCOI is identified, the Original Report will be submitted as described below:

   - **Prior to the expenditure of funds:** If an FCOI is identified at the time a new NIH award is issued, the FCOI SO will submit an "Original" FCOI report (2011 FCOI) through the eRA Commons FCOI Module before any funds are spent.
   - **Within 60 days of Identifying a New FCOI during the award:** If an FCOI is identified during the award period (e.g., a new SFI is disclosed or a new Investigator joins the project), the Institution must submit an Original FCOI report within 60 days of identifying the FCOI.

B. **Annual FCOI Reports:** For the duration of an award, including any extensions with or without funds, the Institution must submit an annual FCOI report to NIH. This report will indicate whether each previously reported FCOI is still being managed or no longer exists and describe any changes to the management plan, if applicable.

- The annual report must be submitted at the same time as the Research Performance Progress Report (RPPR) or multi-year progress report, and at the time of any grant extension, following NIH guidance (see https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi#elements-of-an-fcoi-report) NIH creates the opportunity for the FCOI SO to submit the Annual report 75 days prior to the next budget period start date for continuation awards. NIH will notify the Institution by an email when an annual report is due.
- Annual FCOI reports are not required at grant closeout.

C. **Revision (or Mitigation) FCOI Reports:** After completing a retrospective review, the Institution will submit a Revision report to NIH if new information about the FCOI is discovered, or a Mitigation report if the review finds that bias has occurred.

## Types of FCOI Reports Summary Chart for NIH:

| **Required FCOI Reports to NIH via eRA Commons FCOI Module** | | |
|---|---|---|
| **REPORT** | **CONTENT** | **REQUIRED WHEN** |
| New FCOI Report (Initial Submission) | Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan | 1) Prior to the expenditure of funds on a new award; or<br>2) Within 60 days of identifying any new FCOI during the award period |
| Annual FCOI Report | Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable. | Submitted annually at the same time as the annual progress report, multi-year progress report, or at the time of a grant extension. |
| Revised FCOI Report | If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report. | Following a retrospective review when noncompliance with the regulation is identified, if applicable. |
| Mitigation Report | Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, findings, and conclusions. | After a retrospective review when bias is found. |

## 11) Training Requirements for Investigators

Each Investigator will be informed of NUMIERA's FCOI Policy and trained on their responsibility to disclose foreign and domestic SFIs under this policy and the FCOI regulation at 42 CFR Part 50 Subpart F. Training must be completed before an Investigator engages in PHS/NIH-funded research, at least once every four years, and promptly (as described below) when any of the following occur:

- NUMIERA revises this policy or related procedures in a way that affects Investigator requirements.
- An Investigator is new to NUMIERA research under an NIH award (training must be completed before participating in the research).
- NUMIERA determines that an Investigator has not complied with this policy or with a management plan issued under it (training must be completed within 30 days as directed by the DO).

To supplement the regulatory training requirements, NUMIERA will utilize NIH's training programs to train Investigators on the FCOI regulation. NUMIERA requires Investigators to complete either:

- The NIH Training module at https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training and print and retain the Completion Certificate for audit purposes. Certificate should be shared with the DO.
- Review the NIH Virtual Seminar presentation on FCOI compliance from the following location: https://www.youtube.com/watch?v=D292YZ6BX24.

## 12) Noncompliance With FCOI Policy and Corrective Actions

If NUMIERA identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the DO will, within 60 days: review the SFI; determine whether it is related to NIH-funded research; determine whether it constitutes an FCOI; and, if so, implement an interim management plan describing actions that have been and will be taken to manage the FCOI going forward. NUMIERA will also submit an FCOI report to NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose an SFI that is later determined to constitute an FCOI
- Failure by the institution to review or manage an FCOI
- Failure by the Investigator to comply with an established management plan

NUMIERA will, within 120 days of identifying noncompliance:

1. Complete a retrospective review of the Investigator's activities and the NIH-funded research to determine whether the research, or any part of it, was biased in the design, conduct, or reporting.
2. Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52895. Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found, NUMIERA will promptly notify NIH and submit a mitigation report as required by 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52896

The report will include:

- The impact of the bias on the research project, and
- The plan of action or corrective steps taken to eliminate or mitigate the effect of the bias.

NUMIERA will thereafter submit FCOI reports annually to NIH as required by the regulations and the terms and conditions of the award. Depending on the circumstances, NUMIERA may implement additional interim measures regarding the Investigator's participation in the research until the retrospective review is complete.

If bias is not found following completion of the retrospective review, no further action will be taken unless new information is discovered that needs to be reported to the NIH. If applicable, the Institution will update an existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update the previously-submitted report information (e.g., increase in value of the SFI or add any newly identified SFIs) following the completion of the retrospective review.

If the failure of an Investigator to comply with an Institution's FCOI or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, the Institution shall promptly notify the PHS/NIH Awarding Component of the corrective action taken or to be taken. The PHS/NIH Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS/NIH-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS/NIH award or when the transfer of a PHS/NIH grant(s) involves such an Investigator.

## 13) Clinical Research Requirements

If HHS determines that a PHS-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, NUMIERA will require the Investigator to disclose the conflict in every public presentation of the research results and to request an addendum to previously published presentations.

## 14) Subrecipient Requirements

A subrecipient relationship exists when federal funds flow from or through NUMIERA to another individual or entity that will carry out a substantive portion of a PHS-funded research project and is accountable to NUMIERA for programmatic outcomes and compliance.

Subrecipients (e.g. collaborators or consortium members) are subject to NUMIERA's terms and conditions. NUMIERA will take reasonable steps to ensure that all subrecipient Investigators comply with the federal FCOI regulations at 42 CFR Part 50 Subpart F. NUMIERA will include in each written agreement with a subrecipient terms specifying whether NUMIERA's FCOI Policy or the subrecipient's own FCOI policy will apply to subrecipient Investigators (in accordance with NIH Grants Policy Statement Section15.2.1 at https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm).

- If the subrecipient's FCOI policy applies:

  The subrecipient institution must certify in the agreement that its policy complies with federal FCOI regulations. The agreement will specify the timeframe for the subrecipient to report identified FCOIs to NUMIERA in time for NUMIERA to meet NIH reporting deadlines (i.e., before funds are spent and within 60 days of the subrecipient identifying an FCOI). Typically, this means requiring subrecipients to report FCOIs to NUMIERA within 50–55 days of identification. NUMIERA's DO will then submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

- If the subrecipient cannot certify compliance:

  The agreement will specify that NUMIERA's FCOI Policy applies. In this case, subrecipient Investigators must disclose their SFIs to NUMIERA. The SFI disclosure must include SFIs that are **directly related to the subrecipient's work for NUMIERA**. The agreement will allow sufficient time for NUMIERA to review, manage, and report any resulting FCOIs. When an FCOI is identified, NUMIERA will implement a management plan, monitor compliance by the subrecipient Investigator, and submit the required FCOI report to NIH via the eRA Commons FCOI Module.

## 15) Maintenance of Records

NUMIERA will maintain records of all Investigator financial interest disclosures, NUMIERA's review and response to those disclosures (whether or not they resulted in a determination of an FCOI), and any actions taken under this policy or through retrospective review. These records will be retained for at least three years from the date of submission of the final expenditures report, or for longer periods as specified in 2 CFR 200.334 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR4acc10e7e3b676f/section-200.334) for different situations. NUMIERA will retain these records for each competitive segment as required by regulation.

Copies of management plans will be retained as part of the record maintenance requirements and not submitted to the NIH per NIH's FAQ guidance.

## 16) Enforcement Actions for Investigator Noncompliance and Remedies for Noncompliance

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Failure to comply with this policy, including failure to disclose Significant Financial Interests, failure to comply with a Conflict Management Plan, or failure to complete required training, may result in appropriate corrective or disciplinary actions.

Such actions may include, but are not limited to, formal notification or disciplinary measures, restrictions on participation in research activities or use of research funds, suspension or termination of employment or contractual relationship, and/or disqualification from participation in Government Award–funded research, as appropriate.

In addition, NUMIERA will take all actions required under applicable federal regulations and sponsor requirements, including conducting retrospective review, implementing mitigation measures where necessary, and notifying the sponsor when required.

In addition, the PHS/NIH Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of an FCOI. The Institution will submit, or permit on site review of, all records pertinent to compliance with the regulation and this policy. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS/NIH Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS/NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the FCOI in accordance with the regulation or this policy. The PHS/NIH Awarding Component may determine that imposition of specific award conditions under 2 CFR 200.208 (https://www.ecfr.gov/current/title-2/section-200.208), or suspension of funding or other enforcement action under 2 CFR 200.339 (https://www.ecfr.gov/current/title-2/section-200.339) is necessary until the matter is resolved.

## 17) Useful FCOI and NIH Resources

- NIH e-mail address for FCOI-related inquiries: fcoicompliance@mail.nih.gov
- FCOI Regulation 42 CFR Part 50 Subpart F - Promoting Objectivity in Research at https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F
- Financial Conflict of Interest Information at https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi
- Financial Conflict of Interest Training at https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training
- Exhibit A: Guidance for Identifying and Managing a Financial Conflict of Interest
- Exhibit B: Process for Identifying and Managing a Financial Conflict of Interest

## 18) Point Of Contact

If you have a question related to the FCOI Policy of NUMIERA, or would like to disclose a financial interest, contact leadership using the information below:

Izi Stoll, Ph.D.
Chief Executive Officer
Numiera Therapeutics, Inc.
225 S Broadway Unit 9533
Denver CO 80209

**Exhibit A: Guidance for Identifying and Managing a Financial Conflict of Interest (FCOI)**

- The rules that govern grants and cooperative agreements are detailed at 2 CFR Part 200, and in certain cases further codified through HHS regulation, provide the framework for the terms and conditions of NIH awards, as specified in Part II: Terms and Conditions of NIH Grant Awards. These terms include adhering to a FCOI Policy.

- An Investigator's foreign and domestic SFI is considered an FCOI based on the following circumstances and criteria explained below for the institution's determination of an FCOI:

- First, the Investigator (see FAQ D.5) must determine their professional responsibilities they perform on behalf of the applicant and/or recipient institution (e.g., activities such as research, research consultation, fund raising, product development, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data Safety and Monitoring Boards).

- Secondly, after determining their institutional responsibilities, the Investigator must disclose all domestic and foreign SFIs (including those of their spouse and dependent children) per the institution's SFI definition *that are related to their institutional responsibilities*.

- SFIs (see FAQ D.8.) include remuneration (e.g., salary, payment for services, consulting fees, honoraria, paid authorship), royalties, or reimbursed or sponsored travel received from an entity (not the applicant or recipient) or equity interest held in a publicly or non-publicly traded entity (not the applicant or recipient) again, that are related to the Investigator's *institutional responsibilities*. Disclosure is based on the dollar thresholds indicated in the institution's SFI definition for each category of disclosure.

- Disclosure of SFIs is ***not*** based on whether the Investigator determines if their SFI is related to the NIH-funded or to-be-funded research. The determination of relatedness to the NIH-funded research is an institutional responsibility. Putting the onus on the Investigator to determine if their SFI is related to the research runs the risk of nondisclosure or under disclosure of SFIs and is not in compliance with the 2011 revised FCOI regulation.

- SFIs for consultants and collaborators who meet the definition of "Investigator" are subject to the regulation. If the consultant or subrecipient institution does not have an FCOI policy that implements the regulation, the consultant or subrecipient institution must follow the applicant and/or recipient's institutional FCOI policy. When a policy does not exist, Investigator disclosure of SFIs is made to your institution for review and determination of an FCOI per the regulatory criteria provided below.

- For subrecipient Investigators who are following the prime's FCOI policy, disclose SFIs that are related to the consultant's or subrecipient's work performed for the recipient institution. See the regulation at https://www.ecfr.gov/current/title-42/part-50/subpart-F#p-50.604(c) or NIH's FAQ K.1. at Frequently Asked Questions (FAQs) | Grants & Funding.

- Institutions must appoint a designated official(s) to solicit and review the SFI(s) to determine if an SFI is "related to the NIH-funded research" and whether the SFI constitutes an FCOI based on the following criterion as provided in the regulation at 42 CFR 50.604(f):

- **Test to Determine if SFI is Related to the NIH-funded Research**: An SFI is related to the research if a "yes" response is provided to either of these questions: Could the SFI be affected by the NIH-funded research? Or is the SFI in an entity whose financial interest could be affected by the NIH-funded research?

- **Test to Determine if Related SFI is an FCOI:** A related SFI is an FCOI when the institution's designated official(s) determines that the SFI could directly and significantly affect the design, conduct or reporting of the NIH-funded research. "Significantly" in this statement means that the financial interest would have a material effect on the research.

- When an FCOI is identified, the institution must develop a management plan, obtain the Investigator's agreement to the plan, report the identified FCOI to the NIH via the eRA Commons FCOI Module, and monitor the Investigator's compliance with the plan. See NIH's FAQ F.1. for information on how to manage an FCOI as well as Numiera Therapeutics Corporate Financial Conflict of Interest (FCOI) Policy.

### Exhibit B: Process for Identifying and Managing a Financial Conflict of Interest (FCOI)

**First Step: Investigator Must Determine their *Institutional Responsibilities*:**

The Investigator must determine the professional activities they perform on behalf of the Institution (e.g., the a*pplicant and/or recipient institution*). The professional responsibilities of an Investigator on behalf of NUMIERA, which may include activities such as research, research consultation and collaboration, product development, product testing and validation, development of datasets, models, or systems, publication and communication of research results, and other professional services performed on behalf of NUMIERA. These responsibilities also extend to institutional committee memberships and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

**Second Step: Investigator must determine and disclose all domestic and foreign (non-United States) Significant Financial Interests (SFIs) (including those of their spouse, domestic partner, and dependent children) that reasonably appear to be related to the Investigator's *Institutional Responsibilities* received from or held in entities *outside* the applicant and/or recipient institution:**

**NOTE**: Do **not** limit SFI disclosure to the Investigator's "research" activities nor the NIH-funded research. The 2011 regulation results in the disclosure by Investigators to Institutions of a wider array of interests. The Institution is responsible for determining whether a disclosed SFI relates to PHS-funded research and whether it constitutes an FCOI as described below.

**Subrecipient Investigator Disclosure –** Subrecipient Investigators who utilize the recipient's policy, are required to disclose their SFI related to the subrecipient's work for the recipient.

**Investigators are <u>not</u> required to disclose the following financial interests**:

- Salary, royalties, or other remuneration paid by the Institution (i.e., grant recipient) 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;
- Any ownership interest in the Institution held by the Investigator, if the Institution (i.e., grant recipient) is a commercial or for-profit organization (This exclusion applies only if the applicant or recipient (including a sub-recipient) is a for-profit or commercial institution);
- 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 located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.
- Reimbursed or sponsored travel received from a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

**Third Step**: **The institution's designated official(s) (DO) will review each SFI to determine if the SFI is related to the NIH-funded research and is an FCOI. The review should be documented to show that the Institution fulfilled its responsibility to review the SFI disclosure. The documentation of whether an FCOI is determined or not will be part of the Institution's internal records.**

The SFI is related to the research when the DO determines the SFI*: 1) could be affected by the NIH-funded research or 2) is in an entity whose financial interest could be affected by the NIH-funded research*. If the SFI is related to the research, an FCOI exists when the DO determines *the SFI could directly and significantly affect the design, conduct or reporting of the NIH-funded research* (note: "significantly" means the financial interest would have a material effect on the research).

If an FCOI is identified, a management plan will be implemented to protect the design, conduct and reporting of NIH-funded research from bias resulting from an Investigator's FCOI. Copies of management plan should be retained in the Institution's records. Only identified FCOIs are reported to the NIH. If an FCOI is not identified, no reporting is required.

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**Disclosing Investigator's Name:** ______________________________________________

**Principal Investigator's Name (if different from Investigator):**__________________________

**Grant Application or Funded NIH Grant Number(s):**________________________________

**Role on the Project(s):**______________________________________________________

**Project Dates:**____________________________________________________________

**Project Title(s)**: __________________________________________________________

**Name of funder (e.g., National Institutes of Health):** _______________________________

**INITIAL DISCLOSURE:** ☐

**ANNUAL DISCLOSURE:** ☐

**NEW SFI DISCLOSURE:** ☐

| **Definitions** | |
|---|---|
| **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 options, or other ownership interest as determined through reference to public prices or other reasonable measures of market value. |
| **Intellectual property rights and interests** (e.g., patents, copyrights) | upon receipt of income related to rights and interests (e.g., royalties) not from the awarded company. |
| **Institutional Responsibilities** | INCLUDE THE DEFINITION PER YOUR INSTITUION'S FCOI POLICY - |

**To promote objectivity of Public Health Service (e.g., NIH) funded research and preserve the public's trust that the research supported by the PHS/NIH is conducted without bias and with the highest scientific and ethical standards, Investigators are required to disclose their "Significant Financial Interests" as described below.**

Disclose all domestic and foreign Significant Financial Interests (SFI) (including those of your spouse and dependent children) *that reasonably appear to be related to your* ***institutional responsibilities*** *(i.e., SFI disclosure is* <u>*not*</u> *limited to your research responsibilities nor your NIH-funded research)* per the categories and dollar thresholds provided below:

1. **SFIs RELATED TO A PUBLICLY TRADED ENTITY** – Have you, your spouse and dependent children received any *remuneration* over the preceding 12 months and hold any *equity interest* in a publicly traded entity as of the date of disclosure, that when the values are aggregated, exceeds $5,000?

   **If "yes," provide the following information for each entity in which an SFI is identified or indicate that No SFI(s) exists:**

   - The Value of SFI or indication that value cannot be readily determined:_____________
   - Entity Name as it appears on the entity's public website:__________________
   - Nature of the SFI (e.g., salary, consulting fees, honorarium, paid authorship, payment for services, equity interest, etc.):______________________________________
   - OR: No SFI(s) exist under this category _______________

2. **SFI RELATED TO A NON-PUBLICLY TRADED ENTITY** – Have you, your spouse and dependent children received any *remuneration* over the preceding 12 months that *exceeds $5,000* and hold <u>*any*</u> *equity interest* in a non-publicly traded entity as of the date of disclosure?

   **If "yes," provide the following information for each entity in which an SFI is identified or indicate that No SFI(s) exists:**

   - The Value of SFI or indication that value cannot be readily determined :_____________
   - Entity Name as it appears on the entity's public website:______________
   - Nature of the SFI (e.g., salary, consulting fees, honorarium, paid authorship, payment for services, equity interest, etc.):________________________________________
   - OR: No SFI(s) exist under this category_______________

3. **SFI RELATED TO INTELLECTUAL PROPERTY (IP) RIGHTS AND INTERESTS** – Have you, your spouse and dependent children received any income *greater than $5,000* over the preceding 12 months that is related to **intellectual property rights and interests** (e.g., patents, copyrights) from an entity other than the applicant and/or recipient institution?

   **If "yes," provide the following information for each entity in which an SFI is identified or indicate that No SFI(s) exists:**

   - The Value of SFI or indication that value cannot be readily determined __________
   - Entity Name as it appears on the entity's public website:______________
   - Nature of the SFI (e.g. royalties, licensing fees):_____________________
   - OR: No SFI(s) exist under this category _______________

4. **SFI RELATED TO REIMBURSED OR SPONSORED TRAVEL** – Have you, your spouse, and dependent children received any reimbursed or sponsored travel that exceeds $5,000 over the preceding 12 months from an entity that is related to your ***institutional responsibilities*** performed on behalf of the applicant and/or recipient Institution?

   As part of the travel disclosure, provide the following information for each entity in which reimbursed or sponsored travel is identified unless travel is received from a federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education:

   - Value of the reimbursed or sponsored travel______________________
   - Purpose of the trip:___________________________________________
   - Identity of the sponsor/organizer:_______________________________
   - Destination:_______________________________ _________________
   - Duration:___________________________________________________
   - OR: No SFI(s) exist under this category _______________

*Although this is an institutional determination, in your opinion are any disclosed "Significant Financial Interests" identified above related to an NIH application that is expected to be awarded or an already funded NIH research project per the criteria below:*

- *Could the SFI be affected by the NIH-funded research? YES_____ No_____*
- *Is the SFI in an entity whose financial interest could be affected by the NIH-funded research? Yes____ No____*

If yes, provide which SFI(s) you believe meets the criteria for relatedness to the NIH-funded research from what is disclosed above. The institution's designated official(s) will consider this information when making determinations of FCOI.

__________________________________________________

**Certification:** I certify under penalty of perjury that this is a complete disclosure of all my domestic and foreign significant financial interests that are related to my **institutional responsibilities** (e.g., research, research consultation and collaboration, product development, product testing and validation, development of datasets, models, or systems, publication and communication of research results, and other professional services performed on behalf of NUMIERA, which also extend to institutional committee memberships and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards) and are not limited to my PHS/NIH research. In addition, I have used all reasonable diligence in preparing this Financial Interest Disclosure, and to the best of my knowledge it is true and complete. I also acknowledge that by signing my name below it is my responsibility to disclose my significant financial interests on an annual basis and within 30 days of discovering or acquiring a new significant financial interest or within 30 days of each travel occurrence that may arise during the period of performance of a NIH-funded project. I also certify that I have received FCOI training prior to engaging in PHS/NIH-funded research and/or within the past four years.

Investigator's Signature ____________________________________________

Investigator's Name ____________________________________________

Date ____________________________________________