Financial Conflict of Interest (FCOI) Policy

Effective Date: August 20, 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 an Investigator financial conflict of interest (**FCOI**).

The governing regulation for this policy is the 2011 revised regulation at 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought," commonly referred to as "Promoting Objectivity in Research." This regulation applies to PHS/NIH grants and cooperative agreements. This policy is written to implement the regulatory requirements for PHS/NIH grants and cooperative agreements, including Phase Il SBIR or STTR, FastTrack, and direct-to-Phase Il applications and awards. This policy does not apply to Phase I SBIR or STTR applications or awards.

Halcyon Biomedical Incorporated ("**Halcyon**") maintains this policy for all **Investigators** (as defined below) who plan to participate in, or are participating in, PHS/NlH-funded research. It establishes processes to identify, disclose, and manage Investigator FCOIs to protect research integrity, ensure the safety of any human and animal subjects, and maintain public trust in PHS/NlH-supported research.

For each NIH application, Halcyon will certify that it has an up-to-date, written, and enforced administrative process to identify and manage FCOIs; will promote and enforce Investigator compliance; will manage identified FCOIs and submit required initial and ongoing reports through the eRA Commons FCOI Module; will make FCOI and Significant Financial Interest (**SFI**) information, including related institutional reviews and determinations, available to NIH promptly upon request; and will comply fully with 42 CFR Part 50 Subpart F.

Halcyon will make this policy publicly accessible at https://www.halcyonbiomedical.com/fcoi-policy and will submit a copy through the eRA Commons Institution Profile (**IPF**) Module.

2. Applicability

This policy applies to individuals who meet the definition of "Investigator" (as defined below) who are planning to participate in, or participate in, PHS/NlH-funded research.

This policy applies only to Investigators who plan to participate in or participate in PHS/NIH-funded research under a grant or cooperative agreement. It does not apply solely because an individual is employed by or affiliated with Halcyon, and it does not apply to individuals who are not involved in PHS/NlH-funded research under a grant or cooperative agreement.

3. Definitions

For purposes of this policy, the following definitions apply:

Financial Conflict of Interest (FCOI): A significant financial interest (SFI) that is related to the PHS/NlH-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: An Investigator's professional responsibilities on behalf of Halcyon, and as defined by Halcyon 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.

For Halcyon, Institutional Responsibilities may include responsibility for research design and protocol development; participant recruitment, enrollment, consent, interaction, intervention delivery, or follow-up; data collection, management, analysis, interpretation, or reporting; product, software, or artificial-intelligence development, testing, or validation; research operations and project management; engagement with clinical, community, commercial, or other stakeholders; regulatory strategy or communications, including FDA-related activities; human-subjects protection, safety, quality, or compliance activities; preparation of publications, presentations, progress reports, or other research communications; and supervision or independent oversight of these activities.

Designated Official (DO): The individual appointed by Halcyon 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 FCOIs.

Jamie L. Caird, CPA, will serve as the Designated Official. The DO may not review or determine their own disclosure. If the DO has a conflict of interest or is otherwise unable to act impartially, Halcyon will appoint another qualified, impartial official, or independent reviewer to perform the review and determination.

Institution: Any public or private organization, domestic or foreign (excluding a federal agency) that is applying for or receiving 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. Halcyon 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.

At Halcyon, the PD/PI is always an Investigator. Other individuals are Investigators whenever their role gives them responsibility for, and sufficient independence in, the design, conduct, or reporting of the NIH-funded research. Relevant functions may include the activities listed under Institutional Responsibilities above. Routine administrative, clerical, technical, or support work does not by itself make a person an Investigator when the individual has no responsibility for the design, conduct, or reporting of the associated 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 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.

For purposes of this Halcyon policy, PHS/NIH-Funded Research means research supported through an NIH grant or cooperative agreement.

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: The biomedical research agency within the Public Health Service 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 any other report submitted 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): A domestic or foreign financial interest consisting of one or more of the following interests of the Investigator, and/or those of the Investigator's spouse, domestic partner, and/or dependent children, that also reasonably appears to be related to the Investigator's Institutional responsibilities performed on behalf of Halcyon:

- 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 $5000. 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.

- Non-publicly traded entity: An SFI exists if the aggregated value of remuneration received from the entity in the 12 months preceding the disclosure exceeds $5000, or if the Investigator (or their spouse or dependent children) holds any equity interest in the entity (e.g. stock, stock options, or other ownership interest).

- Intellectual property: An SFI exists if receipt of income related to intellectual property rights or interests (e.g. patents, copyrights), exceeds $5000 during the 12 months preceding the disclosure, related to such rights and interests.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel that is related to the Investigator's institutional responsibilities received in excess of $5000 (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). The initial disclosure must cover the previous 12 months and include, at minimum, the purpose of the trip, 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.

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 Halcyon to the Investigator if the Investigator is currently employed or otherwise appointed by Halcyon, including intellectual property rights assigned to Halcyon and any agreements to share royalties related to those rights.

- Any ownership interest in Halcyon held by the Investigator, since Halcyon is a commercial or for-profit organization. Accordingly, an Investigator is not required to disclose salary, other remuneration, or ownership interests received from or held in Halcyon itself.
- 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.

Foreign 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 (i.e. income in excess of $5000).

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.

This means the Investigator discloses qualifying interests that reasonably appear related to their broader Halcyon responsibilities, even when the interest is not obviously connected to the specific NIH-funded project. The DO—not the Investigator—makes the final relatedness and FCOI determinations.

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:

At the time of application: The PD/PI and all other individuals who meet the definition of "Investigator" must disclose their SFIs to the DO. 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 promptly and before participating in the project.

Annual disclosure: Each Investigator participating in research under an NIH award must submit an updated SFI disclosure at least annually during the award period. The annual disclosure must include:

- 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.
- updated details for any previously disclosed SFI, such as changes in the value of an equity interest.

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

Jamie L. Caird, CPA, will serve as the FCOI Designated Official (**DO**). The DO is responsible for soliciting and reviewing SFI disclosures and for making the institutional determinations required by this policy. 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:

Before any expenditure of funds under a new NIH award (e.g. during the Just-in-Time stage): The DO will review all Investigator SFI disclosures and determine whether any SFI is related to the NIH-funded research and whether an FCOI exists before Halcyon expends award funds. If an FCOI is identified, an FCOI report will be submitted to NIH through the eRA Commons FCOI Module before any expenditure of funds.

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 FCOI report submitted to NIH, if applicable.

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:

- review the disclosure; determine whether the SFI is related to the PHS/NIH-funded research, determine whether an FCOI exists; and, if so, 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 DO is responsible for assessing the relatedness of SFIs to NIH-funded research and determining when they constitute a FCOI.

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

Investigator Involvement: The DO may consult with the Investigator when assessing whether an SFI is related to the research.

Designated Official FCOI Determination: An FCOI exists when the DO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research ("significantly" means that the financial interest could have a material effect on 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:

- Public disclosure of the FCOI (e.g. disclosure in publications or presentations, to study personnel, to the IRB, IACUC, or Data Safety Monitoring Board).
- For human subjects research, disclosure of the FCOI to participants in the informed consent document.
- Appointment of an independent monitor to protect against bias in the design, conduct, and reporting of the research.

- Modification of the research plan.
- Change of personnel roles or removal from portions of the research.
- Reduction or elimination of the financial interest (e.g. divesting equity).
- Severance of relationships that create financial conflicts.

The DO will communicate the determination and the management plan in writing to the Investigator, the PD/PI, and the appropriate supervisor, as appropriate.

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 DO will submit an FCOI report to NIH via the eRA Commons FCOI Module.

8. Monitoring Investigator Compliance

Halcyon and its DO will monitor Investigator compliance with any implemented management plan for the duration of the NIH award.

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 will be publicly accessible at https://www.halcyonbiomedical.com/fcoi-policy, as required by Section 4.1.10, Financial Conflict of Interest, of the NIH Grants Policy Statement.

Halcyon will submit a copy of this policy through the eRA Commons Institution Profile (IPF) Module.

Identified FCOIs held by Senior/Key Personnel: The public-accessibility requirement in this section applies only to identified FCOIs held by Senior/Key Personnel. It does not require Halcyon to publicly disclose every SFI or every FCOI held by an Investigator who is not Senior/Key Personnel.

Before any funds are spent under an NIH award, Halcyon will ensure public accessibility, by providing a written response within five (5) 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 (i.e., the PD/PI and any other individual identified by Halcyon as senior/key personnel in the application, progress report, or other NIH submission);
- Halcyon has determined that the SFI is related to the NIH-funded research; and
- Halcyon has determined that the SFI is an FCOI.

When applicable, Halcyon 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; and
- 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 Halcyon 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, Halcyon will submit an identified FCOI report to NIH, in accordance with NIH regulations, for any Investigator's SFI determined to be an FCOI. Halcyon will also ensure that the Investigator has agreed to and begun implementing the associated management plan.

Halcyon 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 FCO! report, and no FCOI means no FCOI report).

The NIH eRA Commons FCOI Module User Guide provides instructions for preparing and submitting FCOI reports: https://www.era.nih.gov/files/fcoi user_guide.pdf

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

Initial (Original) FCOI Reports: The report will include all information required under 42 CFR 50.605(b)

(3) or as outlined in NIH FAQ H.5. The Original Report will be submitted at the following times:

- 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 through the eRA Commons FCOI Module before any funds are spent.
- Within 60 days 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 who has an associated FCOI), the Institution will submit an Original FCOI report within 60 days of identifying the FCOI.

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 when the Research Performance Progress Report (**RPPR**) or multi-year progress report is due, and at the time of any grant extension, if applicable, following the NIH guidance (see NIH's FAQ H.2). 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 email when an annual report is due.

Annual FCOI reports are not required at grant closeout.

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 NIH FCOI Reports – Summary Chart:

Report type	Content	When required
Initial (Original) FCOI Report	Grant number; PD/PI or Contact PD/PI; name of the Investigator with the FCOI; name of the entity; nature and value of the financial interest; description of how the financial interest relates to the NIH-funded research and why it was determined to conflict with the research; and key elements of the management Ian.	Before expenditure of funds and within 60 days of identifying any 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.	At the same time as the annual progress report or multi-year progress report, and at the time of any extension, until completion of the project.
Revised FCOI Report	Updates to a previously submitted FCOI report, including actions that have been or will be taken to manage the FCOI going forward and any corrected or newly discovered information.	Following a retrospective review when a revision is needed.
Mitigation Report	Project number; project title; PD/PI or Contact PD/PI; name of the Investigator with the FCOI; name of the entity; reason for the review; detailed methodology; findings and conclusions; impact of the bias on the research; and the plan of action or actions taken to eliminate or mitigate the effect of the bias.	Promptly when bias is found as a result of a retrospective review.

11.Training Requirements for Investigators

Each Investigator will be informed of Halcyon'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:

- Halcyon revises this policy or related procedures in a way that affects an Investigator;
- Halcyon 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 meet Halcyon's training requirement for NIH FCOI, each Investigator must complete one of the following:

- The NIH FCOI Training Tutorial available at https://grants.nih.gov/policy-and-compliance/policytopics/fcoi/fcoi-training. The Investigator must retain the completion certificate and provide a copy to the DO for Halcyon's records; or
- The NIH Virtual Seminar presentation on FCOI compliance available at https://www.youtube.com/watch?v=D292YZ6BX24. The Investigator must email the DO at jlcaird@halcyonbiomedical.com to certify completion of the presentation.

Regardless of the NIH training option selected, each Investigator must also complete Halcyon-specific instruction regarding this FCOI Policy, the Investigator's disclosure responsibilities, and Halcyon's disclosure procedures. Each Investigator must acknowledge in writing that they have reviewed and agree to comply with the current policy and must complete and sign the applicable SFI Disclosure Form at the times required under Section 4 of this policy.

12. Noncompliance With FCOI Policy and Corrective Actions

Whenever Halcyon identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS/NlH-funded research project (e.g. was not timely reviewed or reported by a subrecipient), the DO will, within 60 days: review the SFI; determine whether the SFI is related to the NIH-funded research; determine whether 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 FCOI going forward. The institution will also submit an FCOI report to the 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; or
- Failure by the Investigator to comply with an established management plan;

Halcyon will, within 60 days of determining noncompliance:

- 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 of the research.
- Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B) and NIH's FAQ 1.2. The documentation will include, at a minimum:
    - 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 the FCOI;
    - Reason or reasons for the retrospective review;
    - Detailed methodology used for the retrospective review, including the review process, composition of the review panel or reviewers, and documentation reviewed;
    - Findings of the review; and
    - Conclusions of the review.
- If bias is found, Halcyon 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 1.3 to NIH via the FCOI Module.

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.

Thereafter, Halcyon will submit FCOI reports annually to NIH in accordance with the NIH guidance as provided in the summary chart above in Section 10. Depending on the nature of the FCOI, Halcyon may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the FCOI is identified or the Investigator's noncompliance is determined and the completion of the Halcyon's retrospective review.

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, Halcyon 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 Halcyon's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research, Halcyon 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 Halcyon on how to maintain appropriate objectivity in the PHS/NIH-funded research project. The Awarding Component may, for example, require Halcyon 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 PHS/NIH 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, Halcyon 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 Halcyon to another individual or entity that will carry out a substantive portion of a PHS-funded research project and is accountable to Halcyon for programmatic outcomes and compliance.

Subrecipients (e.g. subcontractors or consortium members) are subject to Halcyon's terms and conditions. Halcyon will take reasonable steps to ensure that all subrecipient Investigators comply with the federal FCOI regulations at 42 CFR Part 50 Subpart F. Halcyon will include in each written agreement with a subrecipient terms specifying whether Halcyon's FCOI Policy or the subrecipient's own FCOI policy will apply to subrecipient Investigators (see NIH Grants Policy Statement Section on Written Agreements at https://grants.nih.gov/policy-and-compliance/nihgps).

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 Halcyon in time for Halcyon 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 Halcyon within 50—55 days of identification. The 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 Halcyon's FCOI Policy applies. In this case, subrecipient Investigators must disclose their SFIs to Halcyon. The SFI disclosure must include SFIs that are directly related to the subrecipient's work for Halcyon. The agreement will allow sufficient time for Halcyon to review, manage, and report any resulting FCOIs. When an FCOI is identified, Halcyon 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

Halcyon will maintain records of all Investigator financial interest disclosures, Halcyon's review and response to those disclosures (whether or not they resulted in 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 for specific situations. Copies of Investigator management plans will be retained as part of the Institution's records per NIH's FAQ guidance.

16. Enforcement Actions and Remedies for Investigator Noncompliance

Compliance with this policy is a condition of employment and/or participation for all applicable Investigators. Investigators who fail to comply may be subject to disciplinary action, which can include termination of employment or contract, formal warning letter or official notice of disciplinary action, restrictions on the use of research funds, and/or disqualification from further participation in any PHS/NIH-funded research, as deemed appropriate.

In addition, the PHS/NIH Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator's 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 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, the 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 Awarding Component may determine that imposition of specific award conditions under 2 CFR 200.208, or suspension of funding or other enforcement action under 2 CFR 200.339 is necessary until the matter is resolved.

17. Useful FCOI and NIH Resources

- NIH's email address for FCOI-related inquiries: FCOICompliance@mail.nih.gov
- FCOI Regulation 42 CFR Part 50 Subpart F—Promoting Objectivity in Research: https://www.ecfr.gov/current/titIe-42/chapter-I/subchapter-D/part-50/subpart-F
- NIH Financial Conflict of Interest website: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi
- NIH FCOI Training: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training
- NIH FCOI Frequently Asked Questions (FAQs): https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm
- NIH Grants Policy Statement Section 4.1.10, Financial Conflict of Interest: https://qrants.nih.qov/qrants/policv/nihqps/HTML5/section 4/4.1.10 financial conflict of interest.htm

18. Point of Contact

If you have a question related to the FCOI Policy of Halcyon, or would like to disclose or address a potential financial interest, please contact us using the information below:

Jamie L. Caird, CPA
FCOI Designated Official – Halcyon Biomedical Incorporated
jlcaird@halcyonbiomedical.com