

## **CONFLICT OF INTEREST POLICY**

### **Glympse Bio**

#### **PURPOSE**

With this policy, Glympse Bio Inc. (Glympse) aims to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of funded research or grants will be free from bias resulting from an Investigator's financial conflicts of interest. This policy complies with the following federal regulations:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought

Where there are substantive differences between this policy and the regulations, the regulations shall take precedence.

This policy governing financial conflicts of interest (FCOI) applies to all investigators participating in, or planning to participate in the design, conduct, reporting or proposing of research funded by the Public Health Service (PHS), including the National Institutes of Health (NIH). The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the FCOI is resolved or other action deemed appropriate is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Glympse's policy.

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a FCOI in research policy is in effect at that institution and compliant with all applicable federal regulations. Should PHS or NIH funds be subcontracted by Glympse to a subrecipient institution without a FCOI in research policy, a written agreement must state that this policy shall apply to the subrecipient.

#### **KEY DEFINITIONS**

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

*Conflict of Interest Committee (COI Committee)* means Glympse's committee or individual that advises the Glympse Institutional Official on conflict-of-interest matters. The committee consists of Glympse's Chief Executive Officer, Chief Financial Officer, and Head of Human Resources.

*Family* means any member of the Investigator's immediate family, specifically, any dependent children and spouse.

*Financial Conflict of Interest* means a Significant Financial Interest (see below) related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.

*Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.

*Institutional Official* means the individual within Glympse that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as Glympse's Chief Financial Officer.

*Institutional responsibilities* means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

*Investigator* means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

*Public Health Service* or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

*Research* means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to science and health. 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).

*Significant Financial Interest* or *SFI* means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments (e.g., consulting fees, honoraria, paid authorship) for services received during the 12-month period preceding the disclosure, and the value of any equity interest (e.g., any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value) during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly traded company, is an equity interest of any value (e.g., stock, stock option, or other ownership interest) during the 12-month period preceding or as of the date of disclosure; or
- d) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

*Significant Financial Interest* does NOT include:

- a) salary, royalties, or other remuneration from Glympse;
- b) income from seminars, lectures, or teaching engagements sponsored by or from: advisory committees or review panels for U.S. Federal, state, or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- c) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

## **POLICY**

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and Glympse to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

### **1) RESPONSIBILITIES**

Investigators are responsible for:

- Disclosing all significant financial interests

- Providing updates to disclosed information as needed
- If acting as the PI/PD, providing a list of individuals who meet the definition of “Investigator” within the required disclosure timeline
- Completing all required training and education
- Completing the annual disclosure form even if they have no significant financial interests to report.
- Ensuring that an updated FCOI in Research Disclosure is on file at the time of Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) approval for any new research proposals.

## **2) DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**

All Investigators are required to disclose their Significant Financial Interests (SFIs) as defined above to Glympse on an annual and on an ad hoc basis, as described below. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

### **a) Annual Disclosures**

All Investigators must disclose their SFIs that are related to the Investigator’s institutional responsibilities to Glympse, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official or designee by September 1<sup>st</sup> of each year.

### **b) Ad hoc Disclosures**

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their SFIs to Glympse, through the Institutional Official, within thirty (30) calendar days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a SFI, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her SFI with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any SFIs they acquire or discover during the course of the year within thirty (30) calendar days of discovering or acquiring the SFI.

### **c) Travel**

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a FCOI with the Investigator's research.

### **3) REVIEW AND DECISION OF SIGNIFICANT FINANCIAL INTERESTS**

If the disclosure form reveals a SFI, it will be reviewed promptly by the Institutional Official or designee within sixty (60) calendar days for a determination of whether it constitutes a FCOI.

A FCOI will exist when the Institutional Official or designee determines that a SFI could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If a FCOI exists, the Institutional Official will take action to manage the FCOI including the reduction or elimination of the conflict, as appropriate. If the Institutional Official determines that there is a FCOI that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

Such a plan will include some or all of the following as deemed appropriate:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate;
- Disclosure of significant financial interests directly to subjects involved in human research;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- Modification of research plan;
- Change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create the actual or potential conflict of interest;

If it proves impossible to reach an acceptable plan of action, funds will be returned to the sponsor.

#### **4) MONITORING**

The Institutional Official will periodically review and monitor the Investigator's compliance with the management plan, to ensure open and timely dissemination of research results, and to otherwise oversee compliance with the management plan.

#### **5) INVESTIGATOR NON-COMPLIANCE**

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities until the matter is resolved or take disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action.

If a SFI is not disclosed or reviewed in a timely manner, Glympse will review, within sixty (60) calendar days of learning of the SFI, the Investigator's SFI, determine if it is related to PHS-funded research, and determine whether a FCOI exists, and if so:

- Implement an action plan for ongoing research, at a minimum implement an interim action plan;
- Complete a retrospective review of Investigator's activities and the PHS-funded research project within one hundred twenty (120) calendar days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
- If bias/non-compliance is found, Glympse will promptly inform the PHS Awarding Component by submitting a mitigation report

If the retrospective review finds that the Investigator knew or should have known about the FCOI related to his/her institutional responsibilities, but failed to disclose in compliance with this policy, the costs associated with the retrospective review and mitigation report may be pulled from the Investigator's salary or other relevant remuneration or the subrecipient's Indirect Cost Allocation portion.

If the Department of Health and Human Services determines that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported to Glympse, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.

#### **6) REPORTING TO PHS/NIH**

Glympse will report FCOIs or non-compliance to PHS in accordance with PHS regulations.

Prior to expenditure of any funds under the PHS-funded research project, Glympse will provide a FCOI report regarding any SFI found to be a FCOI. Glympse will also provide a FCOI report within sixty (60) calendar days: 1) of identification for an Investigator who is newly participating in the relevant project; or 2) from the date of a new or a newly identified FCOI for existing Investigators. Last, Glympse will provide a FCOI report after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review. The FCOI report will include the following information:

- Grant/Contract Number
- PD/PI
- Name of Investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
- Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Key elements of the FCOI action plan

Annual updates to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI
- Changes to the action plan
- Justification that an FCOI no longer exists

## **7) TRAINING**

Glympse's FCOI Training Program will inform Investigators of:

- This FCOI Policy;
- Investigator's disclosure responsibilities; and
- Relevant provisions of 42 CFR 50 Subpart F

PHS-funded Investigators must complete Conflict of Interest training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed *as soon as reasonably possible* under the following circumstances:

- This policy changes in a manner that affects Investigator requirements;
- An Investigator is new to Glympse and will be working on PHS-funded research; or
- An Investigator is found to be noncompliant with this policy or their approved management plan

## **8) RECORD RETENTION**

Glympse will retain all disclosure forms, conflict management plans, and related documents for at least 3 years after:

- The date of creation;
- The date of termination or completion of a research award or contract;
- The final expenditure report is submitted to the PHS or to the prime PHS awardee. In the event any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.
- The date of final resolution of any investigation, audit, or similar action involving the records.

## **9) CONFIDENTIALITY**

Financial and other information disclosed in compliance with this policy will be kept confidential. However, the Institution may be required to make such information available to the PHS Awarding Component, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

## **10) PUBLIC ACCESSIBILITY**

- This policy will be posted on Glympse's public website. In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via an email response within five (5) business days from receipt of the request. This information may be requested by emailing [info@glympsebio.com](mailto:info@glympsebio.com).

This information will be updated at least annually and within sixty (60) calendar days of a newly identified FCOI, and will remain available for three (3) years from the date the information was most recently updated.

## **11) POLICY REVISION**

Glympse may modify this policy to conform to organizational changes and circumstances including revisions to federal or state laws or regulations. Glympse's COI Committee is responsible for granting final approval for these policy revisions. It will review all proposed revisions in collaboration with management and will consider any relevant feedback during the review process. When necessary, procedures will be developed or modified to implement this policy.