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INTRODUCTION

This policy governing financial conflict of interest applies to all Public Health Service (PHS)-sponsored Investigators working with Third Pole, Inc. (the Institution). The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest (FCOI) is resolved or other action deemed appropriate by the Institutional official is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to this policy.

DEFINITIONS

Clinical Trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

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

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, member interests, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration paid by Third Pole to the Investigator if the Investigator is currently employed or otherwise appointed by Third Pole, including intellectual property rights assigned to Third Pole and agreements to share in royalties related to such rights; any ownership interest in Third Pole held by the Investigator, if Third Pole is a commercial or for-profit organization;
- b) 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;
- c) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- d) income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by 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.

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

- a) (1) financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
- b) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- c) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- d) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this FCOI policy, the Institutional Official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by Third Pole to the Investigator if the Investigator is currently employed or otherwise appointed by Third Pole, including intellectual property rights assigned to Third Pole and agreements to share in royalties related to such rights; any ownership interest in Third Pole held by the Investigator, if Third Pole is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education."

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Financial Conflict of Interest exists when Third Pole, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

Institutional Official means the individual within Third Pole 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 the individual designated by Third Pole as the Institutional Official for Compliance. The Institutional Official must review all financial disclosures by Investigators and determine whether any Significant Financial Interest is related to a NIH-funded research and a Financial Conflict of Interests exists by making a reasonable determination that the Significant Financial Interest: could be affected by the NIH-funded research or is in an entity whose financial interest could be affected by the research.

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 the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

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.

PHS-Sponsored Research means Research funded by the PHS or proposed for such funding.

Research means a systematic investigation, study, or experiment designed to 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).

Subrecipient means a non-Federal entity that receives a sub-award from Third Pole to carry out part of a federally funded research, but does not include an individual that is a beneficiary of such program.

CONFLICT OF INTEREST:

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

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mechanisms for Investigators and Third Pole 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) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to Third Pole 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) Initial Disclosure

Third Pole is responsible for ensuring that the financial disclosure is up-to-date at the time Third Pole submits to the NIH for funding. A new financial disclosure is not required unless an Investigator needs to report a change to the SFI data from what was previously disclosed to Third Pole.

b) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the Investigator's Institutional responsibilities to Third Pole, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional Official or designee by March 1 for the previous calendar year.

c) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests and those of the investigator's spouse and independent children to Third Pole, through the Institutional Official, within 30 days of their initial appointment or employment.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest and those of the investigator's spouse and independent children they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

d) Travel

Investigators must also disclose reimbursed or sponsored travel related to their Institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. 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 Financial Conflict of Interest with the Investigator's Research.

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2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

The Institutional Official will solicit and review disclosures of SFIs of the Investigator (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI.

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the Financial Conflict of Interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Official determines that there is a Financial Conflict of Interest 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.

The Investigator may be involved in making the determination of whether the SFI is related to the PHS/NIH-funded research. An FCOI exists when Third Pole, through its designated official(s), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the Research results, and to otherwise oversee compliance with Third Pole's management plan.

The Institutional Official will require when an Investigator who is new to participating in the research project or when an existing Investigator discloses a new SFI, Third Pole's designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/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.

The Institutional Official will require whenever an SFI was identified that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Third Pole during an ongoing PHS/NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall within sixty (60) days review disclosures of SFIs, determine whether the SFI is related to PHS/NIH-funded research; determine whether an FCOI exists; and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage such FCOI going forward.

The Institutional Official will take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

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3) CLINICAL TRIALS

Review of Significant Financial Interests Related to Clinical Trials

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial.

4) PUBLIC PRESENTATIONS

The Institutional Official will ensure that in any case in which the Department of Health and Human Services determines that a PHS/NIH-funded research project of clinical research 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 an FCOI that was not managed or reported by Third Pole as required by the regulation, Third Pole shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research, and to request an addendum to previously published presentations.

5) REPORTING TO PHS

Third Pole will send to the PHI:

All required information defined in the regulation and/or NIH's to the NIH via the eRA Commons FCOI Module for Third Pole and its subrecipients at the following timepoints:

- Initial, annual (i.e., ongoing) and revised FCOI reports
- Prior to the expenditure of funds
- Within sixty (60) days of identification for an Investigator who is newly participating in the project
- Within sixty (60) days for new, or newly identified, FCOIs for existing Investigators
- At least annually (at the same time as when Third Pole is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- After a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.

Third Pole will notify NIH promptly if bias is found with the design, conduct or reporting of PHS/NIH-funded research and include the requirement to submit a Mitigation Report to explain what action(s) have been or will be taken to mitigate the effects of the bias in accordance with the regulation.

Third Pole will notify NIH promptly if an Investigator fails to comply with this FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

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Third Pole will notify NIH promptly and take corrective action for noncompliance with this policy or the management plan.

6) SUBRECIPEINTS

Third Pole is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. Third Pole will establish a written agreement with a subrecipient that the Financial Conflict of Interest policy will be adhered to and ensure compliance of the subrecipient within 30 days to meet disclosure and/or Financial Conflict of Interest reporting requirements.

Subrecipient of Third Pole who rely on this Financial Conflict of Interest policy must report identified financial conflicts of interests to Third Pole in sufficient time to allow Third Pole to report the Financial Conflict of Interest to the NIH to meet its reporting obligations.

Subrecipient of Third Pole that must comply with this policy must submit all Investigator disclosures of Significant Financial Interests to Third Pole in sufficient time to allow Third Pole to review, manage and report identified FCOIs to the NIH.

Third Pole is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

Third Pole will obtain a certification from the subrecipient that its FCOI policy complies with the regulation.

7) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

The Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision.

The Institutional Official will establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds).

Third Pole will promptly notify the PHS-awarding component of the action taken or to be taken. If the funding for the Research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

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b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official may appoint a committee to complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the PHS-sponsored research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research.

The Institutional Official will complete a retrospective review within 120 days of Third Pole determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a significant financial interest that is determined by the Third Pole to constitute a financial conflict of interest;
- Failure by the Third Pole to review or manage such a financial conflict of interest;
- Failure by the Investigator to comply with the financial conflict of interest management plan;

The Institutional Official will document the retrospective review which shall include at a minimum the following key elements:

- Project Number
- Project Title
- PD/PI or contact PD/PI if multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Reasons for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
- Findings of the review; and
- Conclusions of the review

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, Third Pole will promptly notify the PHS-awarding component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

8) TRAINING

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Each Investigator must complete training on this Policy, the Investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS/NIH funded grant, and at least every four years thereafter. They must also complete training immediately in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the Investigator is new to working with Third Pole, or if it is determined that the Investigator has not complied with this policy or with a management plan related to his/her activities.

9) RECORD RETENTION

The Institutional Official will retain all disclosure forms, and Third Pole's review of, and response, to such disclosures, (whether or not a disclosure resulted in the Third Pole's determination of a financial conflict of interest) and all actions under the Third Pole's policy or retrospective review, if applicable, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless 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.

Records will need to be maintained from other dates specified in 45 CFR 75.361 for different situations including from the date of submission of the final expenditure report or, for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a subrecipient.

10) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Third Pole may be required to make such information available to the PHS-awarding component and/or HHS, 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 Third Pole, if requested or required. If Third Pole is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

11) PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Third Pole will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-sponsored research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

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The information to be made available shall be consistent with the requirements of the PHS regulation. The publicly accessible information will also be updated as follows:

- Be updated, at least annually (Web site only but any response to a written request should include the updated information)
- Be updated, within sixty (60) days of a newly identified FCOI (Web site only but any response to a written request should include the updated information)
- Remain available for three (3) years from the date the information was most recently updated.

12) REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.