

## Kephera Diagnostics, LLC Financial Conflict of Interest Policy

### Policy Statement

Kephera Diagnostics, LLC (“Kephera”) is committed to ensuring the integrity and objectivity of its research activities by preventing real or apparent bias in the design, conduct, and reporting of research due to a personal financial conflict of interest. Kephera has implemented this policy to identify, resolve and eliminate financial conflicts of interest.

The procedures described in this policy are intended primarily to comply with the specific regulatory requirements for U.S. Public Health Service (PHS)-sponsored research, but are also intended to apply to potential financial conflicts of interest relating to Kephera’s other research activities. For non-PHS research, the specific application of this policy may be tailored as appropriate but will maintaining Kephera’s high standards for research integrity and effectively eliminating or managing actual or potential financial conflicts of interest.

### Purpose

This policy and related procedures have been developed to identify, manage, mitigate, neutralize, or eliminate actual, apparent, and potential financial conflicts of interest. This policy requires that each investigator, subrecipient, subgrantee and collaborator affiliated with Kephera on a Funding Agency project be in compliance with the Code of Federal Regulations (CFR) 42, Part 50, Subpart F, for grants and cooperative agreements, and 45 CFR Part 94, for contracts. A copy of the Federal Regulation is at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>. Details of the final rule are at: [fcoi\\_final\\_rule.pdf \(nih.gov\)](#)

With respect to subrecipients, Kephera shall establish, via a written agreement, whether a subrecipient will follow the FCOI policy of Kephera or the FCOI policy of the subrecipient. If applicable, Kephera shall obtain a certification from a subrecipient that its FCOI policy complies with the applicable regulation. If applicable, Kephera shall include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows Kephera to report identified FCOIs to the applicable Funding Agencies as required by the regulation. Alternatively, if applicable, Kephera shall include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable Kephera to identify, manage and report identified FCOIs to the Funding Agency.

These regulations do not cover Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase 1 applications or awards but do apply to applicants and recipients under the SBIR/STTR Program Phase II. SBIR is the extramural research program for small business that was established by the Awarding Components of PHS and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the STTR Program, which was established by Pub. L. 102-564.

### Definitions

For purposes of this policy, the following definitions shall apply:

**Designated Official** is the individual designated by Kephera to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests.

**Equity interest** includes any stock, stock option, or other ownership interest, and its value may be determined through reference to public prices or other reasonable measures of fair market value.

**Financial conflict of interest** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research as determined by Kephera through the Designated Official.

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

**Immediate family** refers to an Investigator’s spouse and dependent children.

**Investigator** means the project director/principal investigator and any other person who is responsible for the design, conduct, or reporting of the research or proposed research.

**PHS** means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

**PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

**PHS-funded Research** means research funded under PHS grants, cooperative agreements, or contracts.

**Public Health Service Act, or PHS Act** means the statute codified at 42 U.S.C. 201 et seq.

**Remuneration** includes, for example, salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

**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). For PHS-Funded Research, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.

**Significant financial interest** means a financial interest consisting of one or more of the following interests of the Investigator and his/her immediate family that reasonably appear to be related to the Investigator's Kephera project responsibilities, including:

1. With regard to interests in any publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure and any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, in which the value when aggregated exceeds \$5,000;
2. With regard to interests in any non-publicly traded entity, a financial interest consisting of any remuneration received from the entity in the 12 months preceding the disclosure, in which the value when aggregated exceeds \$5,000, or when the Investigator or his/her immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant financial interests also include 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 the Investigator's Kephera project 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.

Significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Kephera (or a subrecipient as applicable) to the Investigator if the Investigator is currently employed or otherwise appointed by Kephera, including that paid for intellectual property rights assigned or licensed to Kephera and agreements to share in royalties related to such rights;
- Any ownership interest in Kephera (or a subrecipient as applicable) held by the Investigator (e.g., Employee Stock Ownership Plan or other stock or option plan);
- 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.

## Procedures

### *Responsibilities of Kephera's Designated Official*

The Designated Official or his/her designee shall be responsible for the following:

- Informing Kephera Investigators of their obligations under this policy and any related regulations;
- Reviewing disclosures of significant financial interest with Kephera's Administrator to determine whether they are related to the subject research and, if so, whether they constitute financial conflicts of interest;
- Screening and managing potential financial conflicts of interest;
- Maintaining all records relating to disclosures of financial interests, Kephera's review of and response to such disclosures, and any related actions under this policy;
- Ensuring inclusion of any required certifications in applications for funding or contract proposals; and
- Reporting and disclosure as required under this policy and applicable regulations.

For PHS-funded research, the Designated Official shall also have the following responsibility:

- Taking reasonable steps to ensure that Investigators for subrecipients (e.g., subgrantees, subcontractors, or collaborators) fully comply with this policy or provide Kephera with sufficient assurances to enable Kephera's compliance with all applicable laws or regulations. To this end, the written agreement between Kephera and the subrecipient will specify whether Kephera's or the subrecipient's financial conflicts of interest policy will apply to the subrecipient's Investigators and, if the subrecipient's policy will apply, the Designated Official will:
  - Obtain certification from the subrecipient that its policy complies with Kephera's policy and the applicable regulations (absent such certification, Kephera's policy will apply to the subrecipient's Investigators, and
  - Establish time periods for subrecipient reporting of financial conflicts of interest to Kephera that enable Kephera to report such conflicts in a timely manner, as required under its policy and the applicable regulations.

If Kephera's policy will apply to the subrecipient Investigators, Kephera will be responsible for meeting the requirements of this policy and the reporting obligations reflected in the applicable regulations.

### *Internal Reporting Requirements*

For PHS-funded research in particular, as part of the funding application or proposal and prior to performing any work on the research, each Investigator who is planning to participate in the research is required by regulation to complete a Significant Financial Interest Disclosure (SFID) Form and submit the SFID Form to Kephera's Administrator. This requirement also applies to Investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research. SFID Forms will be provided to Investigators in conjunction with the annual training and will be otherwise made available. Kephera's Administrator will review SFID submissions with the Designated Official. The information reported on the SFID Form includes a listing of the Investigator's known significant financial interests and those of his/her immediate family that reasonably appear to be related to the research or that are in entities whose financial interests could be affected by the research.

Kephera Investigators in non-PHS-funded research who have any significant financial interest that may reasonably appear to be affected by the research are also expected to complete the SFID Form and submit it to Kephera's Administrator.

Investigators are expected to submit an updated SFID Form during the period of the award as necessary (at least annually for PHS-funded research). The annual update will typically be done in conjunction with completion of the annual training. Such disclosures shall include any information that was not previously disclosed; any change in information regarding any previously disclosed significant financial interest; or, within 30 days of discovery or acquisition, any new significant financial interest (e.g., an interest acquired through purchase, marriage, or inheritance).

### *Determination and Management of Financial Conflicts of Interest*

Upon receipt of a completed SFID Form, the Designated Official shall determine whether an Investigator's significant financial interest is related to the subject research and, if so, whether the interest constitutes a financial conflict of interest under this policy and any applicable regulations. The Investigator may be required to submit additional information as part of the process. A disclosed interest may be related to the subject research either because the interest could be affected by the research or because it is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists if the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If Kephera determines that a financial conflict of interest exists, a financial conflicts of interest management plan will be implemented and monitored on an ongoing basis. The management plan will include appropriate steps to manage, reduce, or eliminate the conflict. The following are examples of conditions or restrictions that might be imposed:

- Disclosure to research participants or the public of significant financial interests (e.g., when presenting or publishing the research);
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification of staff from participation in all or a portion of the research;
- Reduction or divestiture of a financial interest; or
- Severance of relationships that create actual or potential conflicts.

In addition to the conditions or restrictions described above, Kephera may require the management of conflicting financial interests in other ways as it deems appropriate.

#### *External Reporting Requirements*

Kephera will disclose financial conflicts of interest as required by applicable laws or regulations. Before expending any funds under a PHS award, Kephera will ensure public accessibility by posting financial conflicts of interest information on a publicly available web site or by responding in a timely manner to written requests as required under the regulations. The Designated Official will also report to the PHS Awarding Component, as detailed in the regulations, the existence of any financial conflict of interest that has not been eliminated and will ensure that Kephera has implemented a plan to manage the conflict.

If a financial conflict of interest is identified after its initial reporting and during ongoing research (e.g., through participation of a new Investigator) and has not been eliminated, Kephera will provide the PHS Awarding Component with an update within 60 days and ensure that it has implemented a plan to manage the conflict. If the financial conflicts of interest report involves a significant financial interest that was not disclosed by an Investigator or not previously reviewed or managed by Kephera (e.g., not reviewed or reported by a subrecipient in a timely manner), Kephera will undertake a retrospective review. Such retrospective review will determine whether there was bias in the design, conduct, or reporting of the PHS-funded research, or portion thereof, conducted prior to the identification and management of the conflict. If bias is found, Kephera will promptly notify the PHS Awarding Component and submit a mitigation report. Upon request, Kephera will provide HHS with information relating to any Investigator disclosure of significant financial interests; Kephera's review of, and response to, such disclosure; and whether the disclosure resulted in Kephera's determination of a financial conflict of interest.

#### *Confidentiality*

Kephera will, to the extent possible, protect the confidentiality of disclosures. In every instance, Kephera will endeavor to balance the privacy interests of individuals with its responsibility and obligation to identify and manage conflicts of interest. Disclosures will be available to Kephera staff only on a need-to-know basis and will not be disclosed outside of Kephera unless necessary to comply with contractual, legal, or regulatory requirements.

#### *Investigator Noncompliance*

If an Investigator knowingly fails to comply with this policy (e.g., fails to identify an actual or potential financial conflict of interest), Kephera may take appropriate disciplinary action, which may include, without limitation, termination of the Investigator's participation in the research. In addition, for PHS-funded research, failure to comply with this policy or the applicable regulations shall result in the following:

- If the Investigator's failure to comply with this policy or a financial conflicts of interest management plan has biased the design, conduct, or reporting of the PHS-funded research, Kephera shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
- Kephera will make available to HHS all records pertinent to financial conflicts of interest and the management of those conflicts; and
- If HHS determines that a clinical PHS-funded 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 financial conflict of interest that was neither disclosed nor managed, Kephera shall require disclosure of the conflicting interest in each public presentation of the results of the research and shall request an addendum to previously published presentations, if necessary.

### *Training and Education*

Investigators will receive training to promote objectivity in research and to ensure Investigator compliance with regard to the applicable regulations and significant financial interest disclosure obligations. The training module and other resources developed by NIH will be updated as appropriate and can be accessed through the [NIH Web site](#).

Kephera requires Investigators to complete such training annually, and when any of the following occurs:

- Kephera revises its financial conflicts of interest policy or procedures in any manner that affects the Investigator's obligations;
- An Investigator is new to Kephera; or
- Kephera finds that an Investigator is not in compliance with this policy or a financial conflicts of interest management plan.

### *Retention of Records*

The Designated Official will retain financial conflicts of interest disclosure forms and other supporting information consistent with Kephera's Record Retention policy. For PHS-funded research, records of all financial disclosures, whether or not they result in a reporting obligation, and all actions taken by Kephera with respect to each financial conflict of interest will be retained for at least 3 years from the date of submission of the final expenditures report or final payment on the contract or, where applicable, from other dates specified in 45 CFR 74.53(b) or 48 CFR Part 4, Subpart 4.7.

### **Point of Contact**

If you have a conflict of interest or if you have a question to discuss, contact the Kephera Administrator at [FCOI@kephera.com](mailto:FCOI@kephera.com).

[Download Kephera SIF Disclosure Form](#)