

Contents

Financial Conflict of Interest Policy	2
DEFINITIONS	2
TRAINING.....	3
DISCLOSURE.....	4
Reporting Prior to Research Submission and Pursuant to a Management Plan.....	4
Reporting an After-Acquired Financial Interest	4
Reporting Annually	4
Reporting Instructions.....	4
REVIEW.....	4
Research Management Team Review.....	4
Standards for Approval.....	4
Management Plan	4
Retrospective Review	5
Summary Disposition Procedures.....	5
PUBLIC ACCESSIBILITY	5
SANCTIONS AND REMEDIES FOR VIOLATION OF POLICY	6
SUBRECIPIENT REQUIREMENTS	6
REPORTING TO PHS FUNDING AGENCY	6
RECORD RETENTION.....	7

Financial Conflict of Interest Policy

INFOTECH Soft, Inc. (INFOTECH) is committed to the design, conduct, and reporting of Research in an objective manner, free from bias or under the influence of financial conflicts of interest (FCOI). The purpose of this policy is to promote, in compliance with federal law and regulations, objectivity in research for all grants, contracts or cooperative agreements funded by any PHS agency or from any other NON-PHS organization that has adopted the FCOI Regulations.

An INFOTECH Investigator shall not participate in any PHS-funded Research if he or she has a Financial Interest that could influence the design, conduct or reporting of such Research activity. INFOTECH will take immediate action under this policy to manage, reduce or eliminate any such Conflict of Interest. As set forth herein, all PHS-funded Research undertaken at INFOTECH shall be conducted in full compliance with this policy and with all applicable federal and state laws *pertaining* to financial conflicts of interest, including, without limitation, Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants and cooperative agreements and Title 45 CFR Part 94 for contracts (collectively, FCOI Regulations). Investigators failing to comply with all FCOI Regulations shall be subject to sanctions, up to and including termination of employment. All capitalized terms shall have the meanings as set forth herein.

DEFINITIONS

Conflict of Interest: means an interest that INFOTECH's Research Management Team reasonably determines is a Significant Financial Interest related to PHS-funded Research and could directly and significantly affect the design, reporting, or conduct of such Research.

Financial Interest: means any interest of economic value in or relationship with an entity, including, but not limited to, ownership of stocks, bonds, stock options, partnership or other equity interests, rights to patent or royalty payments, receipt of consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific and other advisory boards, reimbursed or sponsored travel expenses related to Investigator's Institutional Responsibilities, or other remuneration.

Immediate Family and Dependents: means a (i) spouse; (ii) child; and (iii) any other person residing in the same household as the Investigator who is a dependent of the Investigator or of whom the Investigator is a dependent.

Institutional Responsibilities: means an Investigator's professional responsibilities on behalf of INFOTECH, including, but not limited to, activities such as research, research consultation, teaching, professional practice, committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

Investigator: means any person who is responsible for the design, conduct or reporting of INFOTECH's Research under PHS contracts, grants or cooperative agreements, including Investigators working for Sub-recipients.

Management Plan: means a written plan for the management, reduction or elimination of a Conflict of Interest relating to PHS-funded Research.

PHS Awarding Component: means the organizational unit of the PHS that funds the Research that is subject to the FCOI Regulations.

Research: means any systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development. This term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, grant, or cooperative agreement, excluding Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) Phase I Programs.

Research Management Team: means (1) Patrick Shironoshita and (2) Mansur R. Kabuka.

Public Health Service: means an operating division of the U.S. Department of Health and Human Services, which includes, without limitation, the National Institutes of Health and the Centers for Disease Control.

Financial Conflict of Interest Policy

Senior or Key Personnel: means the Project Director, Principal Investigator, Co-Principal Investigator, and any other persons identified as senior or key personnel in INFOTECH's grant or contract application or proposal, progress report, or other report submitted to the PHS funding agency.

Significant Financial Interest: ("SFI") means a Financial Interest consisting of one or more of the following interests of the Investigator (and those of its Immediate Family and Dependents) that reasonably appears to be related to Investigator's Institutional Responsibilities:

- Remuneration received from a publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure that, when aggregated, exceeds \$5,000. For the 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 a fair market value
- Remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000 or any equity interest in such entity
- Intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests
- Non-INFOTECH reimbursed or sponsored travel expenses (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children) of greater than \$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, research, or clinical activities). The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

A Significant Financial Interest does **not** include any of the following:

- Salary or other remuneration from INFOTECH
- Any ownership interests in INFOTECH
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as Investigator does not directly control the investment decisions made in such 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
- Reimbursed or sponsored travel expenses paid for by INFOTECH or 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

Sub-recipient: means an individual or entity receiving federal funds flowed down from or through INFOTECH (including sub-grantees, contractors or collaborators) to conduct a significant portion of the PHS-funded Research and is accountable to INFOTECH for programmatic outcomes and compliance matters.

TRAINING

Each Investigator who is an INFOTECH employee will be trained prior to engaging in any PHS-funded Research and then periodically, but no less than once every four years. Each such Investigator must complete training on INFOTECH's Financial Conflict of Interest Policy to ensure the Investigator understands and is compliant with this policy. Additional training may be necessary in the following circumstances:

- INFOTECH's financial conflict of interest policies change in a manner that affects Investigator requirements.
- An Investigator is found to be noncompliant with INFOTECH's Financial Conflict of Interest Policy or Management Plan.

DISCLOSURE

It is each Investigator's responsibility to disclose all of his or her (including Immediate Family and Dependents) Financial Interests as set forth herein.

Reporting Prior to Research Submission and Pursuant to a Management Plan

Prior to the submission of an application or proposal for PHS-funded Research and as required pursuant to a Management Plan, each Investigator shall submit the "INFOTECH Investigator Report of Financial Interests in Research" form (INFOTECH Disclosure Form) to INFOTECH's FCOI Compliance Official in accordance with the reporting instructions set forth below. Investigators who are planning to participate in PHS-funded research must disclose their reimbursed or sponsored travel related to their institutional responsibilities over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research. Investigators who are joining ongoing funded PHS research must disclose SFI(s) to INFOTECH's FCOI Compliance Official no later than at the time of starting participation in the research.

Reporting an After-Acquired Financial Interest

Each Investigator shall submit an INFOTECH Disclosure Form identifying any new or increased Significant Financial Interest within thirty (30) days of acquiring such Financial Interest. These reports shall be submitted to INFOTECH's FCOI Compliance Official in accordance with the reporting instructions set forth below.

Reporting Annually

All Investigators shall submit an INFOTECH Disclosure Form annually during the period of the applicable PHS-funded Research program. Annual reporting shall include submission of any new Significant Financial Interest. These reports shall be submitted to INFOTECH's FCOI Compliance Official in accordance with the reporting instructions set forth below.

Reporting Instructions

The INFOTECH Disclosure Form should be sent to the INFOTECH designated FCOI Compliance Official via mail or email to the following addresses:

Shabbir Songerwala C.P.A., FCOI Compliance Official SRS & Company, LLC. 8410 NW 53 Terrace, Ste 209 Doral, FL 33166 Email: shabbir@srscca.com

REVIEW

Research Management Team Review

If any Financial Interests are disclosed on an INFOTECH Disclosure Form, INFOTECH's FCOI Compliance Official will forward each such form and any supporting materials to the appropriate members of the Research Management Team. A member of the Research Management Team will then contact the Investigator for any additional information and documentation necessary to complete the review. Reviews will be completed by the Research Management Team within forty-five (45) days of receipt of the Investigator's disclosure form and any necessary supporting documentation. The review must be completed before any expenses are incurred under an award and before any Research can begin. An Investigator shall not conduct Research activity for any PHS-funded project if he or she receives notification from INFOTECH's FCOI Compliance Official that the Research Management Team has not approved such participation.

Standards for Approval

Proposed Research activities will only be approved if the Research Management Team determines that (1) no Conflict of Interest exists or that (2) an adequate Management Plan can be implemented to manage or eliminate a Conflict of Interest.

Management Plan

The Research Management Team shall determine the terms, conditions and restrictions, if any, that are required as part of a Management Plan. The Research Management Team may convey the Management Plan either verbally or in writing to the persons deemed appropriate.

Financial Conflict of Interest Policy

The Management Plan may require that one or more of the following actions be taken in order to manage, reduce, or eliminate a potential Conflict of Interest:

- a. Disclosure of Significant Financial Interests, including to the public, human subjects, researchers and other participants and publishers;
- b. Monitoring of PHS-funded Research by independent researchers and/or reviewers, disinterested individuals or committees;
- c. Disqualification from participation in all or a portion of the PHS-funded Research;
- d. Requiring that Significant Financial Interests be divested, restructured, or placed in blind trust;
- e. Modification or severance of relationships that create a potential Conflict of Interest;
- f. Changing terms of agreement relating to the PHS-funded Research;
- g. Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted;
- h. Requiring additional disclosures or actions with respect to matters before the Research Management Team; or
- i. Requiring non-participation in any business transactions between INFOTECH and parties to agreements involving sponsored PHS-funded Research.

INFOTECH shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Retrospective Review

The Research Management Team will conduct and document a retrospective review in the case of non-compliance with this policy. This review will be conducted within one hundred and twenty days (120) days of the Research Management Team's determination of such non-compliance. INFOTECH will document the retrospective review, which will include the following elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review;
- (8) Findings of the review; and
- (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, INFOTECH shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, INFOTECH shall notify the PHS Awarding Component and submit a mitigation report including the above retrospective review elements and a description of the impact of the bias on the research project and INFOTECH's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Summary Disposition Procedures

The Research Management Team may implement procedures for the disposition of matters involving compliance with this policy that it deems reasonable and appropriate. These procedures may include written approvals for annual reports, renewals, and no-cost extensions where the Research Management Team reasonably determines that the facts and circumstances pertaining to the matter being approved have not materially changed since the date of the original review and approval. All such summary approvals shall be in writing.

PUBLIC ACCESSIBILITY

The nature and monetary value of any Significant Financial Interest of Senior or Key Personnel that is determined to be a FCOI will be posted on INFOTECH's website prior to spending any funds for any related PHS-funded Research or provided by written response to any requestor within five (5) business days of receipt

Financial Conflict of Interest Policy

of a request for such information. The information will include the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI 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. The information will note that the information provided is current as of the date listed, or as of the date of the correspondence, and is subject to updates on at least an annual basis and within 60 days of INFOTECH's identification of a new FCOI, which should be requested subsequently by the requestor. INFOTECH will update such publicly accessible information on its website at least annually or within sixty (60) days of any of the following: (a) INFOTECH's receipt of information concerning any Significant Financial Interest that is related to PHS-funded research and is determined to be a FCOI that was not previously disclosed, or (b) disclosure of any SFI of new Senior or Key Personnel to a PHS-funded Research program that is determined to be a FCOI.

SANCTIONS AND REMEDIES FOR VIOLATION OF POLICY

Whenever an Investigator has violated this policy, including failure to make a required disclosure of Financial Interests or failure to comply with the requirements of any Management Plan, the Research Management Team shall be responsible for enforcing this policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to: (1) suspending expenditures on applicable Research account, (2) administratively suspending approval and (3) instituting disciplinary measures to include suspension or termination of such employee.

Should INFOTECH determine that a PHS 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 the Institution as required by the regulation, the Institution 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

SUBRECIPIENT REQUIREMENTS

Subrecipient requirements shall be established via a written agreement between the Institution and the subrecipient and where applicable shall address whether subrecipient will follow the Financial Conflict of Interest policy of the awardee institution or the Financial Conflict of Interest policy of the subrecipient. If the latter, the subrecipient will certify that the subrecipient's Financial Conflict of Interest policy complies with the regulation, and will provide any additional information that may be necessary to allow the prime awardee to fulfill their reporting obligations to the PHS. Subrecipients must report any Significant Financial Interest to INFOTECH prior to submission of a proposal or an application for PHS-funded Research and within thirty (30) days of acquiring a Significant Financial Interest.

REPORTING TO PHS FUNDING AGENCY

Prior to INFOTECH's expenditure of any funds under a PHS-funded research project, INFOTECH shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that INFOTECH has implemented a management plan in accordance with this subpart. In cases in which INFOTECH identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component. For any FCOI previously reported by INFOTECH with regard to an ongoing PHS-funded research project, INFOTECH shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project or until the FCOI ceases to exist. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. INFOTECH shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period in the time and manner specified by the PHS Awarding Component.

For any SFI that INFOTECH identifies as conflicting subsequent to the INFOTECH's initial FCOI report during an ongoing PHS-funded research project, INFOTECH shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the FCOI and ensure that INFOTECH has implemented a management plan in accordance with 42 CFR 50.605(b). Where such FCOI report involves a SFI that was not disclosed

Financial Conflict of Interest Policy

timely by an Investigator or, for whatever reason, was not previously reviewed or managed by INFOTECH, INFOTECH shall complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. If bias is found, INFOTECH shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

RECORD RETENTION

INFOTECH will maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.52(b) and 92.42(b) for different situations.