

InstaRecon, Inc.
Financial Conflict of Interest Policy
Applicable to Funding Under a Public Health Services

1. INTRODUCTION

The National Institutes of Health and other Public Health Service (PHS) funding agencies require all institutions applying for or receiving research funding from PHS to maintain a financial conflict of interest (FCOI) policy, with the objective of *Promoting Objectivity in Research*. The purpose of this policy is to ensure compliance with these important regulations referred to in this document as the “FCOI Regulations”. The regulations apply to all PHS funded grants, cooperative agreements, research contracts (but not Phase 1 SBIR or STTR grants), and subawards where the originating sponsor is PHS.

All Investigators defined below, are obligated to comply with the requirements of the FCOI Regulations and this policy. This policy has been drafted in accordance with the requirements of grantee institutions as put forth in the National Institutes of Health’s guidelines (see <http://grants.nih.gov/grants/policy/coi>) and the code of federal regulations 45 CFR § 50.F 2011 revisions.

2. DEFINITIONS

The following definitions apply to this policy:

Financial Conflict of Interest or ***FCOI*** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. The regulations set forth herein and in 45 CFR § 50.F are used as guidance to determine whether an SFI is considered a FCOI.

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

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, or proposed for such funding, which may include, for example, collaborators or consultants. InstaRecon’s Principal Investigator/Project Director, upon consideration of the individual’s role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

Investigator’s InstaRecon Responsibilities means an Investigator’s professional activities on behalf of InstaRecon, which may include research, development, teaching, or administration. Specifically, these include:

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results)
- Research (includes effort on non-sponsored research)
- Mentoring students and trainees

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of key personnel and Investigator.

PHS – 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 NIH.

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by InstaRecon in the grant application, progress report, or any other report submitted to the PHS by InstaRecon.

Significant Financial Interest means (subject to the exclusions listed below) a 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 appear to be related to the Investigator’s InstaRecon Responsibilities:

- i. **Publicly Traded-Entities** - 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 for the investigator, investigator's spouse and dependent children, 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.

- ii. Privately Held Entities - 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).
- iii. Intellectual Property – With regard to Intellectual property rights and interests (e.g., patents, copyrights), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests in the twelve months preceding the disclosure.
- iv. Travel Reimbursements - Investigators also must disclose the occurrence of any external reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator) related the Investigator's InstaRecon Responsibilities in the twelve months preceding the disclosure. 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.

Exclusions: the term *significant financial interest* does not include the following types of financial interests:

- i. Salary, stock options, royalties, or other remuneration paid by InstaRecon to the Investigator if the Investigator is currently employed or otherwise appointed by InstaRecon, including intellectual property rights assigned to InstaRecon and agreements to share in royalties related to such rights;
- ii. Any ownership interests in InstaRecon;
- iii. 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;
- iv. Income from seminars, lectures, or teaching engagements sponsored by a U.S. 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
- v. Income from service on advisory committees or review panels for a U.S. 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.
- vi. Travel reimbursed or sponsored by InstaRecon or by a U.S. federal, state, or local government agency, a U.S. 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.

Subrecipient - means an individual or entity receiving federal funds that have come from or through InstaRecon to conduct a substantive portion of the PHS-funded research and is accountable to InstaRecon for programmatic outcomes and compliance matters.

3. INVESTIGATOR OBLIGATIONS

To comply with federal law, federal regulations, and InstaRecon's FCOI Policy, all Investigators must perform the following tasks:

- 1) Training
 - a. Complete FCOI training specified in Section 4 within 30 days of employment commencement.
 - b. Repeat FCOI training at least every four years.
 - c. Training must be completed immediately, if:

- i. InstaRecon revises its FCOI policy in a manner that affects Investigator obligations;
 - ii. Investigator is not in compliance with the FCOI policy or Management Plan.
- 2) Disclosure
 - a. Disclose any SFI(s) using the SFI Disclosure Form provided to you at the end of training
 - b. Update your SFI Disclosure Form at the following time points:
 - i. prior to the submission of a research proposal to any federal agency;
 - ii. at least every year from the date of last disclosure;
 - iii. within 30 days of discovering or acquiring a new SFI.

All training certificates and disclosure forms should be submitted to InstaRecon's Designated Official (DO) (listed at end of this document). If there is any uncertainty about what classifies as an SFI or if you have questions about InstaRecon's FCOI policy, please contact the DO. The DO will review and determine if there appears to be a potential conflict of interest. Then the designated FCOI committee will review the potential conflict of interest and initiate steps to manage or eliminate the conflict(s) if appropriate.

All Investigators must comply with InstaRecon's FCOI policy to reduce, manage, and eliminate all potential financial conflicts of interest. In the event an FCOI is present or there has been noncompliance of the FCOI policy, the Investigator must cooperate with the management plan set forth to remedy the FCOI or noncompliance.

Except to the extent required by law and federal regulations, the information disclosed by Investigators will be kept confidential. You should know, however, that InstaRecon is required to report the existence of real or potential conflicts of interest to PHS. Specifically, the PHS requires institutions to report to the PHS the existence of any conflicting interests and to assure that the interest has been managed, reduced or eliminated.

4. INSTITUTION'S OBLIGATIONS

Policy Creation

Federal Regulations require that InstaRecon develop, maintain, and enforce a financial conflicts of interest policy in order to discover and eliminate any conflicts of interest in ongoing research programs. InstaRecon is required to inform all Investigators of this policy and appropriately train and enforce this foregoing FCOI policy for all Investigators.

Training

Every new Investigator must be provided a copy of this policy and training materials within 5 business days of start date. The Investigator must complete training and submit the training certificate to the designated institutional official within 30 days. This certificate must be filed in the Investigator's record until an updated certificate is received. Training must be completed and a new training certificate must be filed at the following times:

- 1) If the Institution revises its FCOI policy that affects requirements of Investigators;
- 2) If the Investigator is not in compliance with the policy or management plan;
- 3) At least every four years.

The training presentation can be found at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

Disclosures, Review, and Monitoring SFI

InstaRecon must collect SFI Disclosure Form(s) from every Investigator after completion of training and within 30 days of employment commencement. A separate disclosure form is required for each entity in/with which the Investigator holds an SFI. It is the responsibility of the DO to ensure he/she receives the disclosure forms from each Investigator upon the respective due dates as designated above.

The SFI Disclosure Form will conform to the requirements of the FCOI regulations and include a link to the FCOI regulations and the PHS Conflict of Interest Websites. The SFI Disclosure Form asks Investigators to identify any of the Investigator's SFIs (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator's InstaRecon Responsibilities (as defined above).

The SFI disclosure must include, at a minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one whose value cannot readily be determined. For disclosures relating to travel, at a minimum, they must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In addition, the Investigator must cooperate with all requests from the applicable PHS awarding Contracting Officer (CO) for additional information. All such internal disclosures will be treated as confidential personnel information with all necessary precautions to protect any sensitive proprietary company or sponsor information, except to the extent that they may be required to be released to PHS per the FCOI Regulations.

The disclosure forms should be collected by the DO and reviewed for potential conflict of interest within fifteen (15) business days of receipt. In the case of an SFI disclosure submitted by the person that is the Designated Official at the time, acting in the role of an Investigator, then the review of the SFI will be handled by the PD/PI, acting in the role of a DO. The DO must complete the SFI review form and attach it to the original SFI disclosure form. If the DO suspects a potential FCOI, he or she will select a review committee to consist of at least 2 unbiased personnel to review the SFI. The review committee will meet to discuss and determine whether or not the SFI is related to PHS- funded research and, if so related, whether the SFI is an FCOI. An SFI is related to PHS-funded research when the review committee reasonably determines that the SFI: could be affected by the PHS- funded research; or is in an entity whose financial interest could be affected by the research. InstaRecon may involve the Investigator in the review committee's determination of whether an SFI is related to the PHS-funded research. An FCOI exists when the review committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

If it is determined that an FCOI exists, a management plan must be developed by the review committee to report, manage and eliminate the conflict of interest within sixty (60) days. This management plan must be shared with the Investigator along with a list of tasks and/or sanctions to resolve the conflict of interest. The review committee must meet at least monthly to ensure the management plan has been appropriately executed until the conflict has been sufficiently resolved.

InstaRecon will comply with PHS requests to make information available about any FCOIs and how they have been managed, reduced, or eliminated.

Reporting

InstaRecon is required to certify in each application for research funding from PHS the existence of this policy and to identify any existing FCOIs and assure that they have been managed, reduced or eliminated. InstaRecon also must report any FCOIs to PHS at the following time points:

- 1) prior to expenditure of any grant funds;
- 2) within sixty (60) days of any new conflicts of interest that become apparent after the initial report to the relevant federal agency;
- 3) within sixty (60) days of the identification of a new Investigator or investigator participating in the research project;
- 4) at least annually based on the requirements for the annual progress report, multi-year report, if applicable, or at time of extension to provide status of the FCOI and updates to the management plan, if applicable, until end of the project;
- 5) following a retrospective review to make appropriate changes to the previously submitted report. If applicable, a mitigation report must be filed when bias is found as a result of a retrospective review.

InstaRecon is required to submit all FCOI reports to the NIH through the eRA Commons FCOI Module.

Maintenance of Records

InstaRecon is required to keep all FCOI-related documents including the review and response to each SFI disclosure on file for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53 (b) and 92.42 (b) for different situations.

Enforcement Mechanisms and Remedies and Noncompliance

FCOI regulations require InstaRecon to impose sanctions where appropriate. InstaRecon maintains the right to impose sanctions on Investigators for failure to disclose SFIs and for failure to abide by this policy. Sanctions may include restrictions on future submission of research proposals and other disciplinary actions up to and including dismissal.

If it has been determined that an Investigator or InstaRecon is in noncompliance with this policy (e.g. SFIs not disclosed, reviewed or managed in a timely or appropriate manner), then InstaRecon must complete and document a retrospective review within 120 days. The retrospective review should be conducted by the SFI disclosure review committee as designated by DO. The results of the retrospective review shall be documented and attached to the disclosure documents. If bias is found, InstaRecon must immediately notify the NIH by submitting a mitigation report.

InstaRecon must enforce any sanctions or actions required by the Department of Health and Human Services pertaining to a PHS-funded research project involving clinical research. If an FCOI was not reported or managed according to regulations for a project whose purpose is to evaluate safety or effectiveness of a drug, medical device, or treatment, then InstaRecon must require the Investigator or Investigator to disclose the FCOI in each public presentation of the results or research and request an addendum to previously published results or presentations.

Subrecipient Requirements

If a subrecipient is not employed by InstaRecon, then they may comply with their institution's FCOI policy provided that their institution has a suitable policy in place and that they supply InstaRecon with the necessary disclosure information to meet all reporting obligations and deadlines. Prior to the subrecipient's participation in the research project, they must submit details demonstrating that their institutional FCOI policy complies with regulations. If the subrecipient's institution does not have a suitable FCOI policy in place, then they shall adhere to this policy set forth for Investigators of InstaRecon. The subrecipient must agree in writing to comply with the FCOI policy and to provide the required information to InstaRecon.

Public Accessibility

This FCOI policy is publicly available on our website at www.instarecon.com/Papers/InstaRecon_FCOI_Policy.pdf. Information regarding FCOIs held by senior/key personnel must be accessible via the website prior to expenditure of any research funds received. The website must be updated annually and within sixty (60) days of a new FCOI being identified. The FCOI information shall remain publicly available for three (3) years. The required FCOI information that shall be publicly available includes: (i) Investigator's name; (ii) Investigator's title and role with respect to the research project; (iii) Name of the entity in which the SFI is held; (iv) Nature of the SFI; and (v) Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

InstaRecon is required to submit to NIH, or permit on site review of, all records pertinent to compliance with the regulation.

RESOURCES

<http://grants.nih.gov/grants/policy/coi>
<mailto:FCOICompliance@mail.nih.gov>

Designated Institutional Official: Yoram Bresler
info@InstaRecon.com

Policy Last Update: 12/30/2014