

Ibis Reproductive Health

Financial Conflict of Interest Policy for Public Health Service (PHS) supported Projects

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Overview

Ibis Reproductive Health (Ibis) is a nonprofit organization which drives change through bold, rigorous research and principled partnerships that advance sexual and reproductive autonomy, choices, and health worldwide. In addition to its Conflict of Interest policy and policies on ethics in research, Ibis has instituted this financial conflict of interest (FCOI) Policy for Project Directors (PD) and Principal Investigators (PI) supported by US Public Health Services (PHS) funding. This policy is posted publicly to satisfy the requirements of the U.S. Department of Health and Human Services FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94). It aims to reflect a commitment to maintaining a research culture that promotes the prevention, detection, and resolution of instances of fraudulent, dishonest, or other wrongful conduct, and to safeguard the work and reputations of Ibis, its staff and partner organizations.

Scope of Policy

This FCOI Policy for PHS-supported projects specifies guidance for PHS-Investigators only.

All employees of Ibis Reproductive Health (including consultants, temporary employees, interns, and others working on behalf of the organization) must comply with and abide by appropriate standards of ethical conduct in carrying out their duties and responsibilities for and on behalf of Ibis. Ibis's Conflict of Interest policy and policies on ethics in research specify the expectations for all staff. Any Ibis PHS-supported Project Director/Principal Investigator is expected to also be familiar with and remain in compliance with all Ibis policies. Any questions about research ethics policies can be directed to the Vice President for Research.

Ibis has established this specific FCOI policy to satisfy the requirements of the U.S. Department of Health and Human Services FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94). Consistent with these regulations, this policy aims:

- To promote objectivity and integrity in the work of Ibis Reproductive Health and its individual staff members;
- To ensure that Ibis staff identify, disclose, and appropriately manage or eliminate situations in which their personal or familial interests might otherwise compromise or appear to compromise their objectivity as researchers or administrators.
- To establish reasonable standards of expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (FCOI).

Should Ibis Reproductive Health engage in PHS-funded research that evaluates the safety or effectiveness of drugs, medical devices or treatments, or includes work with pharmaceutical, biotechnology or other business on the development of drugs, medical devices or other products or innovations, reporting of FCOI will follow all federal regulations including any requirements additional to those outlined in this policy.

Oversight

The Director of Finance and Administration has overall responsibility for this policy and serves as the Institute's Conflict of Interest Officer. It is the obligation of any PHS-supported Investigator or staff with concerns or questions about this policy to seek guidance. Questions or concerns relating to this policy should be directed to:

Martha Williams
(mwilliams@ibisreproductivehealth.org)
617-349-0040 x1043

What is a Financial Conflict of Interest (FCOI)?

Financial conflict of interest (FCOI) means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.

What is a financial interest?

In general, a financial interest is anything of monetary value, related to a PHS-Investigator's employment responsibilities, whether or not the value is readily ascertainable, in any of these categories:

- Remuneration or compensation (e.g., salary, consulting fees, honoraria, etc.) from a public or private company;
- Equity (e.g., stock, stock options or other ownership interest) in a public or private company;
- Intellectual property rights (e.g., patents, copyrights), and any royalties and licensing income from such rights;
- A position in an outside entity that gives rise to a fiduciary duty, such as director, officer, partner, trustee, employee or any position of management;
- For Investigators with PHS funding, also any reimbursed or sponsored travel.

What is a significant financial interest?

As per 42 CFR 50.603, the following definitions for a financial interest and significant financial interest are operational:

1. A financial interest consists 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:
 - i. 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:
 - a. salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
 - b. 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. With regard to any **non-publicly traded entity**, a *significant financial interest* exists if:

- a. the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or
 - b. 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
 - iii. **Intellectual property** rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 2. 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:
 - a. travel that is reimbursed or sponsored by a Federal, state, or local government agency,
 - b. an institution of higher education as defined at 20 U.S.C. 1001(a),
 - c. an academic teaching hospital, a medical center, or
 - d. a research institute that is affiliated with an institution of higher education.

This disclosure of reimbursed or sponsored travel will include, at a minimum:

- the purpose of the trip,
- the identity of the sponsor/organizer,
- the destination, and
- the duration.

Ibis's Conflict of Interest Officer, or those acting in that role, 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.

What does not count as a financial interest?

As per 42 CFR 50.605(a)(1), a financial interest **DOES NOT** include:

- Salary, royalties or other remuneration paid by Ibis Reproductive Health to the PHS-Investigator if the Investigator is currently employed or otherwise appointed to Ibis, including intellectual property rights assigned to Ibis and agreements to share in royalties related to such rights;
- 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 (e.g. 403b plan or target date retirement fund);
- 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

Requirements for PHS-Investigators

As per 42 CFR 50.604(b) and 42 CFR 50.604(b), all PHS-Investigators have additional FCOI requirements including:

- Will review this policy before engaging in any PHS-funded grant or contract
- Must undergo conflict of interest training before engaging in any PHS-funded grant or contract;
- Must undergo financial **conflict of interest (FCOI) training** every 4 years;
- Must have filed **an annual disclosure form** within the past 12 months;
- Must update their conflict of interest form within 30 (thirty) days of discovering or acquiring a new financial interest related to their Institute responsibilities;
- All Investigators of sponsored research to report financial interests before filing applications or proposals for funding;
- Must complete FCOI training immediately under the following circumstances:
 - o If Ibis revises its FCOI policy resulting in a change that affects Investigator requirements;
 - o An Investigator is new to Ibis;
 - o An Investigator is found to be noncompliant with the FCOI policy or management plan;
- Investigators with financial conflicts of interest must enter into a management plan before expenditures can begin.

Who is an Investigator?

A PHS-Investigator is any person who is responsible for the design, conduct, or reporting of research funded by or proposed to the PHS, regardless of title or position, and may include, for example, collaborators, consultants, or staff of partners receiving subawards. Among Ibis employees, this includes (but may not be limited to):

- Project leads
- Project managers
- Principal Investigators
- Co-Investigators
- Key study personnel
- Essential study staff, which may include research assistants/coordinators, collaborators or consultants.

If an Ibis staff member with any doubts about whether they could be classified as a “PHS- Investigator,” should contact the Vice President for Research. Questions or concerns regarding who is classified as an Investigator should be directed to:

Caitlin Gerdtz
cgerdts@ibisreproductivehealth.org
 510-822-2686

FCOI Training

As per 42 CFR 50.604(b), Investigators who receive Public Health Service (PHS) funding:

- Will review this policy before engaging in any PHS-funded grant or contract
- Must undergo financial conflict of interest training before engaging in any PHS-funded grant or contract;
- Must undergo financial conflict of interest training every 4 years;
- Must update their FCOI form within 30 (thirty) days of discovering or acquiring a new financial interest related to their Ibis responsibilities;
- Must complete FCOI training immediately under the following circumstances:
 - o If Ibis revises its FCOI policy resulting in a change that affects Investigator requirements;
 - o An Investigator is new to Ibis;
 - o An Investigator is found to be noncompliant with the FCOI policy or management plan;
- If a financial conflict of interest exists, must enter into a management plan before expenditures can begin on a PHS-supported grant or contract.

Investigators' Disclosure and Training Requirements

As per 42 CFR 50.603 and 42 CFR 50.604(e)(1)-(3), Investigators are required to disclose to Ibis all of their significant financial interests (including those of the Investigator's spouse and dependent children) that reasonably appear to be related to their Institutional responsibilities that meet or exceed the regulatory definition of a significant financial interest:

- No later than at the time of application for PHS-funded research;
- at least annually during the period of award;
- Within 30 days of discovering or acquiring a new significant financial interest (e.g., through purchase, marriage, or inheritance).

The conflicts of interest disclosure form and instructions including details on where the forms need to be submitted, is located on Ibis Sharepoint and available from the Director of Finance and Administration.

To ensure compliance with this policy and pursuant to 42 CFR 50.604(b) and 42 CFR 50.604(b), Ibis requires that all PHS-Investigators:

- Must undergo financial **conflict of interest (FCOI) training** every 4 years;
- Must file an **annual FCOI disclosure form**
- Prior to submitting any proposal to a PHS source:
 - o All Investigators of sponsored research to report financial interests **before** filing applications or proposals for funding;
- Prior to initiating activities on any new PHS-funded grant:
 - o Will review and acknowledge (sign) this policy before engaging in any PHS-funded grant or contract

- Will complete the financial conflict of interest training before engaging in any PHS-funded grant or contract;
- With any new FCOI Ibis staff must:
 - Update their conflict of interest form within 30 (thirty) days of discovering or acquiring a new financial interest related to their university responsibilities;
- Staff must complete FCOI training immediately under the following circumstances:
 - If Ibis revises its FCOI policy resulting in a change that affects Investigator requirements;
 - An Investigator is new to Ibis;
 - An Investigator is found to be noncompliant with the FCOI policy or management plan;

Review of PHS-Investigator Disclosures

As per 42 CFR 50.604(d), PHS-Investigator disclosure forms will be reviewed by the appropriate Conflict of Interest Officer, who will determine whether or not it identifies an actual or potential conflict of interest of the Investigator (including those of the Investigator's spouse and dependent children) that is related to PHS-funded research and, if so, what action is required to appropriately manage the situation.

In most instances, the appropriate Conflict of Interest Officer will be the Director of Finance and Administration, but this function may also be performed by or in collaboration with the Vice President for Research or President.

The Conflict of Interest Officer may request additional information from an employee to make these determinations. When a conflict is identified, the Conflict of Interest Officer may work with the staff member to put in place and to document an appropriate conflict management plan. An employee who disagrees with the decision of the Conflict of Interest Officer may seek review with the President.

Considerations when determining whether a conflict of interest exists

Ibis recognizes that no guidelines can anticipate all situations in which a conflict of interest may exist. Guidelines have been established to aid with making these determinations and are listed below.

When reviewing a financial conflict of interest disclosure submitted by a staff member (including, on behalf of their spouse or dependent children):

- The determination of the existence of a significant financial interest will be based on the aggregation of all Financial Interests by the staff member (or the spouse or dependent children);
- The Conflict of Interest Officer may utilize several forms of review to reasonably determine whether an FCOI exists;
- The following financial interests are generally considered to represent a conflict at Ibis:
 - a. Any activities or business endeavors, whether paid or unpaid, that could pose a conflict with a staff member's responsibilities to Ibis;
 - b. Any outside activities for which staff earn compensation;

- c. PHS-Investigator or their immediate family members (spouse or dependent children) gives or accepts commissions, gifts, payments, entertainment, services, loans or promises of benefits from suppliers, government agencies or third parties that might influence the Investigator or the third party's decision-making or actions affecting Ibis. However, gifts of nominal value (e.g., cookies for a holiday that can be shared) may be acceptable.
- d. Occasional meals or social invitations that are in keeping with the highest standards of business ethics may be acceptable, as long as they do not obligate the PHS-Investigator in any way.
- e. Receipt of remuneration from any **publicly traded entity**, received from the entity in the 12 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:
 - i. Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
 - ii. Equity interest that includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- f. Receipt of remuneration from any **non-publicly traded entity** if:
 - i. The value of any remuneration received from the entity in the 12 (twelve) months preceding the disclosure, when aggregated, exceeds \$5,000, or
 - ii. 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
- g. Receipt of income related to **intellectual property** rights and interests (e.g., patents, copyrights);
- h. 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 an Investigator's institutional responsibilities provided, however, that this disclosure requirement does not apply to:
 - i. travel that is reimbursed or sponsored by a Federal, state, or local government agency,
 - ii. an Institution of higher education as defined at 20 U.S.C. 1001(a),
 - iii. an academic teaching hospital, a medical center, or
 - iv. a research institute that is affiliated with an Institution of higher education.
- i. A Fiduciary role on behalf of an Outside Organization and/or equity in a privately held Outside Organization;
- j. Equity with a value > \$50,000 or > 5% ownership in a publicly traded Outside Organization, if such entity is actively conducting or seeking to conduct business related to the research;
- k. Payments > \$25,000 in the preceding 12 months from an Outside Organization;

- I. Intellectual property interests (not assigned to Ibis or other Excluded Payers) if any income has been received from such Intellectual Property interest in the preceding 12 months;

Management of Conflict of Interest

As per 42 CFR 50.604(f) and 42 CFR 50.605(a)(1), if the Institutional Official determines that a financial conflict of interest exists relating to PHS research then:

- Submission of a conflict of interest disclosure by a PHS-Investigator shall not constitute approval for the purposes of this policy, nor be deemed to constitute compliance with any applicable provisions of this policy, or the Ibis Conflict of Interest policy.
- A *Conflict Management Plan* shall be developed and implemented by the Conflict of Interest Officer;
- No PHS -Investigator having a financial conflict of interest may participate in research without prior written approval from the Conflict of Interest Officer;
- All financial conflict of interest reviews, including any required *Conflict Management Plan*, must be completed before any research activity begins or research expenses are incurred under an award;
- In the event the Conflict of Interest Officer concludes that a financial conflict of interest cannot be reduced, eliminated or managed, the research project may not be allowed to proceed, unless (or until) a satisfactory *Conflict Management Plan* can be implemented;
- The financial conflict of interest review and *Conflict Management Plan* shall be completed prior to a conflicted Investigator participating in the research;
- The Conflict of Interest Officer shall confirm with the PHS-Investigator as part of the review process that the Disclosure on file is current as of the date of the conflict of interest review.

All Conflict Management Plans shall:

- Consist of measures that in the reasonable judgment of the Conflict of Interest Officer will reduce, eliminate, or manage the effects of the financial conflict of interest;
- As part of their development, the Conflict of Interest Officer may conduct factual inquiries and consult with and receive recommendations from such persons as the officer deems necessary and appropriate.
- Include terms that are consistent with all legal and regulatory requirements, the requirements of this policy
- May include one or more of the following:
 - a. Disclosure of financial conflict of interest, including to the public, human subjects, researchers and other participants, publishers, and conference organizers, either *a priori* or as required (e.g., by conference organizers);
 - b. Monitoring or oversight of the research by independent co-researchers, reviewers, disinterested individuals, or committees;
 - c. Maintaining copies of research data with a neutral party;
 - d. Restricting participation in any activity affecting or affected by a research project;
 - e. Requiring that the significant financial conflict of interest creating the financial conflict of interest be divested, restructured, or placed in a blind trust;

- f. Modification or severance of relationships that create or are likely to create financial conflict of interest(s);
- g. Modifying the terms of written agreements relating to the research;
- h. Reduction (or cessation) of the Ibis appointment;
- i. Requiring compliance with other relevant Ibis Institute policies, including those referenced in the section below titled “*Other Relevant Ibis Policies and Procedures*”;
- j. Requiring that participation in the recruitment or consent of subjects in human subjects’ research by a conflicted PHS-Investigator be prohibited, restricted, or otherwise limited;
- k. Requiring additional disclosures or actions with respect to matters before a human subject review committee;
- l. Requiring that the PHS-Investigator not participate in any business transactions between Ibis and parties to agreements involving the research.

The above process for determining and managing FCOIs will apply to all of the following:

- Investigators who are new to participating in the research projects, as per 42 CFR 50.605(a)(2)
- An existing Investigator who discloses a new significant financial disclosure, as per 42 CFR 50.605(a)(2)
- A situation in which Ibis identifies a significant financial conflict of interest that was not disclosed in a timely manner by an Investigator, or was not previously reviewed by Ibis, in which case the process as described above will occur and a Conflict Management Plan developed within **60 (sixty) days**, as per 42 CFR 50.605(a)(3) and (i) – (iii)
- To complete and document a retrospective review within 120 days of Ibis’s determination of noncompliance for significant financial conflicts of interest not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation, pursuant to 42 CFR 50.605(a)(3).

When Ibis implements a Conflict Management Plan, the Conflict of Interest Officer will monitor [Investigator](#) compliance with the management plan on an ongoing basis until the completion of the [PHS](#)-funded [research](#) project.

Management of Conflict of Interest for partners (subrecipients)

As per 42 CFR 50.604 (g), 42 CFR 50.605(a)(4), if Ibis conducts PHS-supported research or other activities through a subrecipient (e.g., subgrantees, contractors, or collaborators), Ibis will take reasonable steps to ensure compliance with 42 CFR 50.604(c), 42 CFR 42.50.604(c)(1)(1)-(iii), and NIH Grants Policy Statement 15.2.1, which may include:

- a. Confirming that the subrecipient (or their institution of employment) has its own policies in place that meet all conflict of interest requirements of the PHS sponsor;
- b. Require via a written agreement, acknowledging whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient, where applicable;
- c. Obtaining a written certification from the subrecipient that stipulates:
 - a. Its FCOI policy complies with the PHS and all applicable federal regulations;
 - b. A requirement for the subrecipient to report identified FCOIs for its PHS-Investigators to Ibis (as the awardee Institution) in a timeframe that allows Ibis to report identified FCOIs to the NIH, as required by the regulation; or

- c. Alternatively, if applicable, a requirement to solicit and review subrecipient Investigator disclosures that enable Ibis (as the awardee Institution) to identify, manage and report identified FCOIs to the NIH

Notification to Awarding Entity

Ibis will make reports to the PHS Awarding Component to the extent required by and in accordance with its funding agreement with the sponsor and applicable law and regulation. As stipulated in 42 CFR 50.604(h) and 42 CFR 50.605(b), such reports will be sent when financial conflicts of interest are present,

- Prior to the expenditure of funds;
- Within 60 days of identification for a PHS-Investigator who is newly participating in a research project;
- At least annually (at the same time as when Ibis is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to an applicable conflict management plan(s), if applicable, until the completion of the project;
- Following a retrospective review to update a previously submitted report, if appropriate, pursuant to 42 CFR 50.605(a)3(iii);
- If bias is found, is found with the design, conduct or reporting of NIH-funded research and will include a *Mitigation Report* in accordance with the regulation, pursuant to 42 CFR 50.605(a)3(iii).
- If an Investigator fails to comply with this financial conflict of interest policy or if a *Conflict Management Plan* appears to have biased the design, conduct, or reporting of the NIH-funded research, pursuant to 42 CFR 50.606(a).

Maintenance of Records

Records relating to all PHS-Investigator disclosures of financial conflicts of interests and external activities, including Ibis's review of and response to such disclosures, will be maintained for at least 3 (three) years from the date the final expenditures report is submitted to the PHS or for such longer periods as prescribed in the external agreement or applicable regulations, pursuant to 42 CFR 50.604(i) and 45 CFR 75.361.

Upon authorized request of a sponsoring agency, disclosure documents and related records pertaining to the specific sponsored project will be made available to appropriate officials.

Enforcement mechanisms, remedies, noncompliance and retroactive review

Staff violations of this policy may result in discipline up to and including termination of employment, pursuant to 42 CFR 50.604(j).

The processes for determining and managing FCOIs (described in "*Management of Conflict of Interest*") will apply to the completion and documentation of a retrospective review within 120 days of Ibis's determination of noncompliance with the policy, in cases of r significant financial conflicts of interest not disclosed in a timely manner or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation, pursuant to

42 CFR 50.605(a)(3).

Whenever Ibis identifies a [significant financial interest](#) that was not disclosed timely by an [Investigator](#) or, for whatever reason, was not previously reviewed by Ibis an ongoing [PHS-funded research](#) project (e.g., was not timely reviewed or reported by a subrecipient), the Conflict of Interest Officer shall, within sixty days: review the [significant financial interest](#); determine whether it is related to [PHS-funded research](#); determine whether a [financial conflict of interest](#) exists; and, if so:

(i) 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 [financial conflict of interest](#) going forward;

(ii)

(A) In addition, whenever a [financial conflict of interest](#) 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 [Institution](#) to constitute a [financial conflict of interest](#); failure by the [Institution](#) to review or [manage](#) such a [financial conflict of interest](#); or failure by the [Investigator](#) to comply with a [financial conflict of interest](#) management plan, Ibis shall, within 120 days of the dermination of noncompliance, complete a retrospective review of the [Investigator's](#) activities and the [PHS-funded research](#) project to determine whether any [PHS-funded research](#), or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such [research](#).

(B) Ibis will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key 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 (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, Ibis shall update the previously submitted [FCOI report](#), specifying the actions that will be taken to [manage](#) the [financial conflict of interest](#) going forward. If bias is found, Ibis will notify the [PHS Awarding Component](#) promptly and submit a mitigation report to the [PHS Awarding Component](#). The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the [research](#) project and the [Institution's](#) plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the [research](#) project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the [research](#) project is salvageable).

If Ibis conducts PHS-funded research to evaluate the safety or effectiveness of a drug, medical device or treatment, and if during the course of that research a situation arises in which the Department of Health and Human Services determines that a PHS-funded project of such clinical research has been designed, conducted, or reported by an *Investigator* with a Financial Conflict of Interest that was not managed or reported by the Institute as required by this Policy, the Institute will require that the *Investigator* disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations, pursuant to 42 CFR 50.606(c).

To ensure that in any case in which the Department of Health and Human Services determines 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, Ibis 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

Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated.

Agreements with partner/subrecipient organizations may be terminated if that organization fails to comply with its obligations under the PHS regulations.

Public Disclosure of Information

Ibis shall make this financial conflict of interest policy available on its publicly accessible website, pursuant to 42 CFR 50.604(a) and NPH GPS 4.1.10.

Prior to the expenditure of any funds under a PHS-funded research project, Ibis will make available, either via a publicly accessible website or by responding within five (5) days to any written request, information concerning any significant financial interest determined by Ibis to be a financial conflict of interest held by a senior Investigator (project lead, project principal, project manager, principal Investigators, co-Investigator) or any other individual who has been identified by Ibis as key personnel on the PHS-funded project.

As per 42 CFR 50.605(a)(5)(i)-(iv), the information provided on the publicly accessible site will:

- Contain at least the minimum elements as provided in the regulation, and include:
 - a. The name of the Investigator;
 - b. The Investigator's title and role with respect to the research project;
 - c. The name of the entity in which the SFI is held;
 - d. The nature of the SFI;
 - e. 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 process or other reasonable measures of fair market value;
- Be posted on a public website or made available within 5 (five) calendar days of a written request;
- Be updated, at least annually (website only but any response to a written request should include the updated information);

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

Other Relevant Ibis Policies and Procedures

- Conflict of Interest
- Whistleblower Policy
- Research ethics and scientific misconduct

Definitions Applicable to PHS-Funded Research

Definitions applicable to PHS-funded research are provided by the PHS and can be accessed here:
<https://ecfr.io/Title-42/Section-50.603>