ISGlobal Barcelona Institute for Global Health

Regulations on Objectivity in Research

ISGlobal

Issuing Officer: *General Manager*
Responsible Dept: *Steering Committe*
Effective Date: *15th September 2014*
Supersedes: *1st August 2013*

I. PURPOSE & SCOPE

This Policy implements the National Institutes of Health (NIH) regulations on Promoting Objectivity in Research. This policy is applicable to all NIH funded Research Activities. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the design, conduct or reporting of a NIH funded Research Activity.

The Policy is applicable to all research activities supported by NIH and by other sponsors and programs that specifically request review consistent with the NIH regulations on objectivity in research.

II. DEFINITIONS

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

Conflict of Interest Review Committee (CIRC): A ISGLOBAL committee charged with determining if Significant Financial Interests that are related to the proposed research constitute Financial Conflicts of Interest and developing plans to eliminate, reduce or manage Financial Conflicts of Interest. The CIRC acts as Designated Official under NIH regulations. It is formed by the Technical Director, Econonic Director and General Director.

Designated Official(s): ISGLOBAL official(s) designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator to determine whether an Investigator's Significant Financial Interest is related to the Investigator's NIH funded Research Activity and if related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest.

Financial Conflict(s) of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of NIH funded Research Activity.

Institutional Responsibilities: Teaching/education, research, outreach, clinical service, and University and public service, on behalf of ISGLOBAL which are in the course and scope of the Investigator's appointment/employment.

Investigator: The Principal Investigator or project director and any other person regardless of title or position who is responsible for the design, conduct or reporting of research proposed for funding or funded by NIH. This includes, but is not limited to Key Personnel named on a proposal budget

Key Personnel: The Principal Investigator or project director and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

NIH Research Activity(ies): Any award for which research funding is available from NIH, including research contracts, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards and conference grants. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.

Principal Investigator (PI): An Investigator (normally an academic appointee) who has primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project.

Significant Financial Interest (SFI): Anything of monetary value that:

- meets the NIH thresholds (see Section III.C below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse or registered domestic partner and dependent children for the following categories; and
- reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities.

Examples of SFIs include:

- Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a for-profit or non-profit organization; or salary received outside ISGLOBAL.

- Any equity interest in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.

- Receipt of income from any organization other than ISGLOBAL for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from previous employers or other universities.

- The occurrence of travel by the Investigator which is reimbursed or sponsored by a for-profit or non-profit entity, *excluding* a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute.

III. STATEMENT

The NIH regulations on Objectivity in Research (revised in August 2011) are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of NIH Research Activities will be free from bias resulting from any Investigator's Financial Conflicts of Interest.

Each institution applying for or receiving research support from NIH must comply with the regulations by putting in place a policy to ensure that:

A. Investigators complete a training/education program:

1. Before engaging in NIH Research Activities and at least every four years thereafter while receiving NIH research funding, and
2. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest.

B. Investigators disclose SFIs at the following times:

1. Initial disclosures must be made by all Investigators planning to participate on a proposed NIH Research Activity before the application for funding is submitted.

2. ISGLOBAL Investigators who are engaged in NIH Research Activities have an ongoing responsibility to update their disclosures throughout the period of NIH support:

- Within 30 days of acquiring or discovering any new SFI; and
- At least annually

3. New Investigators must complete an initial disclosure of SFIs before joining an ongoing NIH Research Activity.

C. Investigators disclose to ISGLOBAL SFIs that meet the following thresholds:

1. For a *publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months *and* the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of
the date of disclosure, which when aggregated, exceeds $5,000.

[Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles]

2. For a *non-publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months that exceeds $5,000, *or* equity interest of any amount, including, but not limited to stock, stock options, or ownership interest in the entity.
[Investigators are not required to disclose (a) payments made by ISGLOBAL, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from ISGLOBAL; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education]

3. *Intellectual property rights and interests:* Income received during the previous 12 months that exceeds $5,000 for such rights and interests.

[SFIs do not include royalties received from ISGLOBAL related to patents or copyrights]

4. *Travel:* The occurrence of any sponsored or reimbursed travel must be disclosed whether payment is made to the Investigator directly or expenses are paid on behalf of the Investigator by a for-profit or non-profit organization:

   a. Either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or
   b. Within 30 days of the occurrence if the trip wasn't reported prospectively.

With respect to any such reimbursed or sponsored travel, Investigators must disclose, at a minimum, the (i) purpose of the trip, (ii) identity of the sponsor/organizer, (iii) destination and (iv) duration of the trip. The Designated Official(s) will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a FCOI with the Investigator's research.

The initial disclosure include reimburses or sponsored travel that is received in the preceding 12 months.

[Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education]

Should the Designated Official(s) 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 presentations.

IV. DISCLOSURES BY COLLABORATORS

ISGLOBAL will take reasonable steps to ensure that any subawardee's Investigator complies with PHS FCOI regulations by:

1. Incorporating terms as part of a written agreement with the subawardee that establish whether ISGLOBAL's FCOI policy or the subawardee's policy will apply to the subawardee's Investigators.

2. If the subawardee's Investigators are to comply with the subawardee's FCOI policy, the subawardee must certify that its policy complies with the PHS FCOI regulations and the agreement will specify the time period(s) for the subawardee to report all identified FCOIs to ISGLOBAL. If the

subawardee cannot provide such certification, its Investigators must comply with ISGLOBAL's FCOI policy.

Subawards issued by ISGLOBAL will indicate that the subawardee organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending ISGLOBAL notification of their ability to manage the identified conflicts, in accordance with NIH reporting requirements.

Collaborators who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by ISGLOBAL should be identified as Investigators by the ISGLOBAL PI and must complete the ISGLOBAL disclosure forms. If, upon review, ISGLOBAL determines that an SFI could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to manage the identified conflicts of interest.

V. REVIEWS AND REPORTING

A. Disclosed SFIs will be reviewed prior to acceptance of new and renewal awards, and before submission of progress reports, proposals for supplemental funding, or requests for no-cost time extensions. Investigators may be asked to provide additional information about the SFIs that they previously disclosed. This information will be used by ISGLOBAL to conduct a preliminary review in order to reasonably determine whether any of an Investigator's SFIs:

- Could be affected by the NIH funded Research Activity; or
- Are in an entity whose financial interest could be affected by the research.

If after review it is determined that an SFI is related to the proposed NIH Research Activity, a second review will be conducted by the CIRC or a Designated Official to determine whether the SFI(s) reasonably appears to directly and significantly affect the design, conduct or reporting of the NIH Research Activity and thereby constitute an FCOI that may need to be managed.

In accordance with the NIH regulations, plans put into place to manage identified FCOI will be monitored for compliance until the completion of the NIH funded Research Activity. Each management plan will specify the way in which that will be accomplished.

B. Initial reports of FCOI must be made to NIH prior to ISGLOBAL's expenditure of any funds provided under a NIH Research Activity. ISGLOBAL is not required to submit a report to NIH if conflicts of interest are eliminated before research funds are expended.

Additional FCOI reports must be submitted to NIH under the following circumstances:

1. Throughout the lifetime of an award when progress reports are submitted, or when an award is extended (either through extension notification or an NIH prior approval request). When during the course of an ongoing NIH funded Research Activity an FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.

2. Within 60 days of determining that an FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing NIH funded Research Activity.

3. Within 60 days of determining that an FCOI exists for an Investigator who joins an ongoing NIH Research Activity.

C. When during the course of an ongoing NIH funded Research Activity, ISGLOBAL identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Designated Official will review the SFI within 60 days to determine whether it is related to NIH Research Activities and whether an FCOI exists. If an FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever an FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be an FCOI, or ISGLOBAL did not review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, ISGLOBAL must, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the NIH Research Activities.

Such retrospective review will be documented including all the following as applicable: the project number, project title, project director, name of the investigator with the SFI/FCOI, name of entity with which the SFI/FCOI exists, reason for the retrospective review, detailed methodology used for the review process, compositions of the review panel, and findings and conclusion of the review.

The purpose of this retrospective review is to determine if the ongoing NIH Research Activity was biased in its design, conduct or reporting.

- Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that ISGLOBAL will take to manage the identified FCOI.

- If bias was found during the retrospective review, ISGLOBAL will promptly notify NIH and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines ISGLOBAL's plans to eliminate or mitigate the effect of the bias.

VI. RECORDS ACCESS AND RETENTION

A. NIH regulations require that ISGLOBAL respond within 5 business days to any request for information about SFIs held by Key Personnel when ISGLOBAL has determined that the disclosed SFIs are related to NIH Research Activities and constitute FCOIs.

B. The information provided in the disclosure forms may be released or transmitted to NIH upon request. Completed disclosure forms also may be released in response to a public records request.

C. Information concerning FCOI will remain available for responses to written requests for at least 3 years from the date that the information was most recently updated.

D. Records of financial disclosures, Designated Official's determinations, CIRC recommendations, and institutional actions regarding management of an FCOI will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by NIH involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

VII. SANCTIONS

Failure by an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline measures. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. Similarly, an agreement with a subrecipient organization may be terminated for cause if that organization fails to comply with its obligations under the NIH regulations.

Barcelona, 15th September 2014

Questions concerning this policy or procedure should be referred to The Responsible Department listed at the top of this document.