IBM Research’s Financial Conflict of Interest on Federal Grants Policy

Covered Institution

International Business Machines (IBM) Corporation through its Thomas J. (T.J.) Watson Research Center and through its Almaden Research Center (hereinafter collectively known as “IBM Research”) is covered under this Financial Conflict of Interest Policy (FCOI Policy) as required by the Public Health Services (PHS), and under all applicable federal and state regulations, to promote transparency as to any Financial Conflicts of Interest (FCOI) in Research, including, without limitation, TITLE 42 CODE OF FEDERAL REGULATIONS (CFR) PART 50 SUBPART F (42 C.F.R., Part 50, Subpart F) pertaining to grants and cooperative agreements and TITLE 45 CFR PART 94 (Title-45/Part-94) pertaining to Research contracts (collectively, “FCOI Regulations”). The required information will be collected pursuant to the FCOI Regulations and recorded on the Attachment A: IBM Research’s FCOI Disclosure Form enclosed.

Purpose:

It is the responsibility of IBM Research to Promote Objectivity in all Research performed by or for IBM Research including all Research for which PHS which includes the NIH, funding is sought or obtained. And, to maintain compliance with the above-named FCOI Regulations governing FCOI funded Research, IBM Research has established the following FCOI Policy.

This FCOI Policy provides the standards that offer a reasonable expectation that the design, conduct, and reporting of Research funded by federal grants or cooperative agreements will be free from bias resulting from Investigator FCOI. It applies to all IBM Research employees prior to undertaking in federally funded Research. An Investigator shall not participate in any PHS-funded Research if he or she has a Significant Financial Interest (SFI) [as defined below] that could directly and significantly influence said design, conduct, or reporting of such Research activity. SFI includes Financial Interests that are related to an Investigator’s IBM Research’s Responsibilities. IBM Research is responsible for determining whether SFI relates to PHS-funded Research and if it is a FCOI. IBM Research will take immediate action, including, but not limited to, corrective counseling and possible corrective action, under this FCOI Policy to manage, reduce, or eliminate any such FCOI that is brought to its attention. This FCOI Policy does not apply to Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Phase 1 applications and grants.

This new process, with new PHS financial disclosure forms, has been designed to reduce and simplify the administrative burden associated with financial disclosure and review at the initial proposal submission stage for new and competing continuation/renewal proposals. Per the PHS, SFI must be re-disclosed on or before the due date of the progress report/non-competing continuation proposal. While this does represent an additional burden, this disclosure process should still minimize that for most Investigators.

Applicability:

IBM Research shall maintain an up-to-date, written, and enforced FCOI Policy that complies with the FCOI Regulations and make available via a publicly accessible website (see “Website Publication” section below). IBM Research and all its employees and researchers shall comply with this FCOI Policy and all applicable FCOI Regulations in all Research. In addition, IBM Research employees and researchers may collaborate with companies, universities, research groups or government institutions to develop scientific
and research breakthroughs or to provide expertise. And to assure professional and commercial integrity in such matters, IBM Research will review these collaborations and, when appropriate, put measures in place to eliminate, minimize, and manage any FCOI that may arise. This FCOI Policy is distinct from, and is in addition to, the general “Business Conduct Guidelines- 7.2 Avoiding Conflicts of Interest” (https://www.ibm.com/investor/att/pdf/IBM_Business_Conduct_Guidelines.pdf) policy that applies to the general duties of all employees of International Business Machines (IBM) Corporation.

**Definition of Terms:**

The following definitions apply to this FCOI Policy unless a specific federal policy uses a different definition, in which case that PHS Awarding Component’s definition will apply.

**Designated Official(s):** means a person designated by IBM Research to determine whether an Investigator’s Significant Financial Interest (SFI) is related to PHS-funded research, and if related, whether the Significant Financial Interest (SFI) is a Financial Conflict of Interest (FCOI).

**Disclosure of Significant Financial Interests (SFI):** means an Investigator's disclosure of Significant Financial Interests (SFI) to IBM Research.

**Electronic Research Administration (eRA) Commons Module:** means the reporting tool for submitting FCOI Reports for grants and/or cooperative agreements.

**Financial Conflict of Interest (FCOI):** means a Significant Financial Interest (SFI), real or perceived, that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.

**Financial Conflict of Interest (FCOI) Committee (FCOIC):** means a team of three (3) or five (5) persons to review all Retrospective Reviews and Mitigation Reports when a potential SFI has been identified, determine if there was FCOI non-compliance, determine whether SFI really exists, help formulate associated Management Plans, accept or suggest modifications to manage or eliminate the potential conflicts, and monitor compliance with Management Plans. The committee will submit Management Plans to the Investigator, Key Personnel, Subrecipient (if applicable), Designated Official(s), and Vice President, IBM Research Business Development for approval signatures. All signed Management Plans from the FCOIC will be provided to the IBM Research Contracts and Negotiations Manager for uploading and/or reporting to the PHS Awarding Component, as needed, along with FCOI Mitigation Reports.

**Financial Conflict of Interest (FCOI) Mitigation Report:** means IBM Research’s written report of a FCOI to a PHS Awarding Component in situations of non-compliance with FCOI Policy and/or when bias has been found after a Retrospective Review to specify the actions that will be taken to manage the FCOI going forward. This report may be submitted via the PHS-funded Research module (e.g., the eRA Commons module). (see “Attachment B: IBM Research’s FCOI Mitigation Report” below)

**Financial Interest:** means any interest of economic or monetary value, whether or not the value is readily ascertainable, in or relationship with an entity or person(s), whether private or public, 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, compensation for serving on boards of directors, scientific and other advisory boards, reimbursed or sponsored travel expenses related to Investigator’s IBM Research’s Responsibilities, or other remuneration.
**HHS**: means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**IBM Research/Institution**: means International Business Machines (IBM) Corporation through its Thomas J. (T.J.) Watson Research Center and through its Almaden Research Center

**IBM Research’s Responsibilities**: means an Investigator’s professional responsibilities on behalf of IBM Research and as defined by IBM Research in its FCOI Policy on FCOI, which may include for example: activities such as, including, but not limited to, research, collaborators, or research consultation.

**Immediate Family or Dependents**: means a (i) spouse; (ii) child; or (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.

**Investigator**: means the Principal Investigator (PI) or Co-Principal Investigator (Co-PI) and any other personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research grants, cooperative agreements, or contracts. This includes, for example, collaborators, consultants, graduate students, and researchers working on the project.

**Key Personnel**: means the PI, PM, and any other personnel considered to be essential to work performance in accordance with HHS Acquisition Regulation (HHSAR) Subpart 352.237-75 and identified as key personnel by IBM Research in the contract proposal submitted to the PHS by IBM Research under the FCOI Regulation and in the award. *(Note: Different definition than the NIH Grants Policy Statement)*

**Management Plan**: means, to the maximum extent possible, taking action to address, via a written plan, the management, reduction, or elimination of a FCOI relating to PHS-funded Research and to ensure that the design, conduct, and reporting of Research will be free from bias.

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

**PHS Awarding Component**: means the organizational unit (federal agency) of the Public Health Service (PHS) that funds the research that is subject to the FCOI Regulations.

**Public Health Service Act or PHS Act**: means the statute codified at 42 U.S.C. 201 et seq [42, chapter 6A](https://www.gpo.gov/fdsys/pkg/USCODE-2015-title42-chapter6a)

**Research**: means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research, product development (e.g., clinical trials, diagnostic test, or drug), and creative activity (e.g., a published article, book, or book chapter). As used in this FCOI Policy, this term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, grant, or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award, whether authorized under the PHS Act or other statutory authority.

**Retrospective Review**: means an evaluation methodology using and applying past and existing data, events, circumstances, or information to reveal facts which have measurable effects on IBM Research’s
performance and to construct ideas for improvement based on these observations to determine if an SFI of an Investigator exists relating to PHS-funded Research.

**Significant Financial Interest (SFI):** means an Investigator’s Financial Interest consisting of one or more of the following interests of the Investigator (and those of his or her Immediate Family or Dependents) that reasonably appears to be related to *IBM Research’s Responsibilities* including:

1. With regard to any **publicly traded entity**, an SFI exists if the value of any remuneration received from a publicly traded entity in the twelve (12) 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;

2. With regard to any **non-publicly traded entity**, an SFI exists if the value of any remuneration received from a non-publicly traded entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds $5,000 or when the Investigator (or the Investigator’s Immediate Family or Dependents) holds any equity interest in such entity (e.g., stock, stock option, or other ownership interest.); or

3. Intellectual Property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests; and

4. Any occurrence of reimbursed or sponsored travel expenses (e.g., 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), must be disclosed by Investigators, related to *IBM Research’s Responsibilities*. Such disclosure will include, at a minimum, the purpose of the trip, the identify of the sponsor/organizer, the destination, and the duration. The FCOIC 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.

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

1. Salary or other remuneration paid by IBM Research to the Investigator if the Investigator currently is employed or otherwise appointed by IBM Research;

2. Any ownership interests in IBM Research held by the Investigator, as IBM Research is a commercial or for-profit organization;

3. 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;

4. As applicable, 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;

5. Reimbursed or sponsored travel expenses provided in FCOI Regulation, e.g., 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.

**Signing Official:** means the person responsible for the procedures under this FCOI Policy but may designate one or more individuals to assist in any or all of these responsibilities and/or may delegate any or all of these responsibilities to one or more individuals.
Small Business Innovation Research (SBIR) Program: means the extramural research program for small businesses that is established by the PHS Awarding Component and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this Policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

Subrecipient: means an individual or entity receiving federal funds that have come from or through IBM Research to conduct a substantive portion of the PHS-funded Research and is accountable to IBM Research for programmatic outcomes and compliance matters. (see “Attachment C: Statement of Intent to Establish Consortium Agreement” below)

Website Publication of FCOI Policy and Conflicts

This FCOI Policy shall be made available in the “About Us” Section of IBM Research’s publicly accessible website (https://resedit.watson.ibm.com/researcher/view_group.php?id=10849). It shall be maintained, enforced, and updated as required when changes are made or as specified in the FCOI Regulation. Additionally, prior to the expenditure of any PHS funds, the Designated Official(s) shall make information concerning FCOIs held by Key Personnel via IBM Research’s website in the “About Us” Section and update such information as specified in the FCOI Regulation. Examples of said information shall include, at a minimum, are:

- the Investigator’s name,
- the Investigator’s title,
- the name of the entity in which the SFI is held, and
- approximate dollar amount 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 reference to public prices or other reasonable measures of fair market value.

If IBM Research does not have any presence on a publicly accessible website or if it has not been updated (and only in those cases), IBM Research shall make this FCOI Policy available to any requestor within five (5) business days of a request. If, however, IBM Research acquires a presence on a publicly accessible website during the time of the PHS award, the requirement to post the information on that website will apply within thirty (30) calendar days.

Information concerning the SFI of an Investigator subject to this section shall remain available, for responses to written requests or for posting via the IBM Research’s publicly accessible website, for at least three (3) years from the date that the information was most recently updated.

In addition to the types of FCOI as defined in this FCOI Policy that must be managed pursuant to this section, IBM Research may require the management of other FCOI in its policy on FCOI, as IBM Research deems appropriate.

IBM Research’s Responsibilities Training Regarding Investigator FCOI. IBM Research shall:

1. Inform each Investigator or consultant engaged by IBM Research, who will be responsible for the design, conduct, or reporting of PHS funded Research of IBM Research’s FCOI Policy on FCOI,
2. Inform them of the Investigator’s responsibilities regarding disclosure of SFI;
3. Inform them of the relevant FCOI Regulations: 45 CFR subtitle A, Subchapter A, Part 94 (Title-45/Part-94); and
4. Require each Investigator and consultant to complete training regarding the same, prior to engaging in research related to any PHS-funded award or project at least every four (4) years, and immediately when any of the following circumstances apply:
   a. IBM Research revises its FCOI Policies or procedures in any manner that affects the requirements of Investigators;
   b. An Investigator is new to IBM Research; or
   c. IBM Research finds that an Investigator is not in compliance with IBM Research’s FCOI Policy or Management Plan.

Designate the Designated Official(s) and the FCOIC to solicit and review disclosures of SFI from each Investigator who is planning to participate in, or is participating in, the PHS-funded Research.

Provide guidelines for the Designated Official(s) and the FCOIC to determine whether an Investigator’s SFI is related to PHS-funded Research and, if so related, whether the SFI is a FCOI. An Investigator’s SFI is related to PHS-funded Research when IBM Research, through its Designated Official(s) and the FCOIC, reasonably determines that the SFI:

1. Could be affected by the PHS-funded Research; or
2. is in an entity whose Financial Interest could be affected by the Research.

If IBM Research carries out the PHS-funded Research through a Subrecipient (e.g., subcontractors, or consortium members), IBM Research (awardee Institution) must take reasonable steps to ensure that any Subrecipient Investigator complies with this part by:

1. Incorporating as part of a written agreement with the Subrecipient terms that establish whether the FCOI Policy of IBM Research (awardee Institution) or that of the Subrecipient will apply to the Subrecipient’s Investigators;
2. If the Subrecipient’s Investigators must comply with the Subrecipient’s financial conflict of interest policy, the Subrecipient shall certify as part of the agreement, as referenced, that its policy complies with this FCOI Policy. If the Subrecipient cannot provide such certification, the agreement shall state that Subrecipient Investigators are subject to IBM Research’s (awardee Institution) FCOI Policy for disclosing SFI that are directly related to the Subrecipient’s work for IBM Research (awardee Institution);
3. Additionally, if the Subrecipient’s Investigators must comply with the Subrecipient’s FCOI Policy, the agreement, as referenced, shall specify time period(s) for the Subrecipient to report all identified FCOI to IBM Research (awardee Institution). Such time period(s) shall be sufficient to enable IBM Research (awardee Institution) to provide timely FCOI Reports, as necessary, to the PHS as required by this FCOI Policy;
4. Alternatively, if the Subrecipient’s Investigators must comply with IBM Research’s (awardee Institution) FCOI Policy, the agreement, as referenced, shall specify time period(s) for the Subrecipient to submit all Investigator disclosures of SFI to IBM Research (awardee Institution). Such time period(s) shall be sufficient to enable IBM Research (awardee Institution) to comply timely with its review, management, and reporting obligations under this FCOI Policy; and
5. Providing FCOI Reports to the PHS Awarding Component regarding all FCOI of all Subrecipient Investigators consistent with this FCOI Policy (e.g., prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

IBM Research may involve the Investigator in the Designated Official’s and FCOIC’s determination of whether an SFI is related to the PHS-funded Research. A FCOI exists when IBM Research, through its Designated Official(s) and the FCOIC, reasonably determine that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

Duties of the Investigator(s):

1. Participate in training and understand this FCOI Policy.
2. Complete required forms in a timely manner.
4. Take necessary actions to eliminate or mitigate FCOIs of the Investigators’ programs.
5. Incorporate language as part of a written agreement with the Subrecipient terms that establish whether the FCOI Policy of IBM Research (awardee Institution) or that of the Subrecipient will apply to the Subrecipient’s Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI Mitigation Reporting requirements to IBM Research (awardee Institution).  
   - Subrecipients who rely on their FCOI Policy must report identified FCOIs to IBM Research (awardee Institution) in sufficient time to allow IBM Research (awardee Institution) to report the FCOI to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module) to meet FCOI Reporting obligations.

Investigator(s) Disclosure of SFI:

The Investigator shall disclose any SFI:

1. **At time of Application:** Require that each Investigator, including Subrecipient Investigators, if applicable, who is planning to participate in PHS-funded Research disclose to IBM Research’s Designated Official(s) the Investigator’s SFI (and those of the Investigator’s Immediate Family and Dependents) no later than the date of submission of IBM Research’s proposal for PHS-funded Research.

2. **Annually:** Require each Investigator, including Subrecipient Investigator, if applicable, who is participating in the PHS-funded Research to submit an updated disclosure of SFI at least annually, in accordance with the specific time prescribed by IBM Research, during the period of the award. Such disclosure shall include any information that was not disclosed initially to IBM Research pursuant to paragraph 1 of this section, or in a subsequent disclosure of SFI (e.g., any FCOI identified on a PHS-funded project that was transferred from another Subrecipient) and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

3. **Within 30 days:** Require each Investigator, including Subrecipient Investigator, if applicable, who is participating in the PHS-funded research to submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a **new** SFI.
**Duties of the Designated Official:**

1. Take expedient actions to manage FCOIs of IBM Research’s Investigators, including any FCOI of Subrecipient Investigators, pursuant to the “IBM Research’s Responsibilities” section above. Management of an identified FCOI requires development and implementation of a Management Plan (see below) and, if necessary, a retrospective review and FCOI Mitigation Report pursuant to §94.5(a) *(Title-45/Section-94.5).*
2. Train Investigators and IBM Research employees in the FCOI Policy.
3. Provide initial and ongoing FCOI Mitigation Reports to the PHS as required pursuant to §94.5(b) *(Title-45/Section-94.5).*
5. Obtain required documents from Investigators including disclosures at time of application, annually, and within thirty (30) days of discovering an SFI.
6. Maintain records relating to all Investigator disclosures of Financial Interests and IBM Research’s review of, and response to, such disclosures (whether or not a disclosure resulted in the IBM Research’s determination of a FCOI), and all actions under IBM Research’s FCOI Policy or retrospective review, if applicable, for at least three (3) years from the date of final payment or, where applicable, for the time periods specified in *(Title-48/Part-4/Subpart-4.7).*
7. Communicate SFIs and FCOIs with the FCOIC.
8. Communicate with the PHS-funded Research entity.
10. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
11. Conduct an audit not less than every two (2) years of awards to Subrecipients for FCOI language. Document the audit findings.
12. If IBM Research identifies an SFI that was *not* disclosed or reviewed in a timely manner, the Designated Official(s) shall within sixty (60) days review of the SFI in coordination with the FCOIC, determine if an FCOI exists and implement an interim Management Plan. (see “Management Plan” section below)
13. In cases of non-compliance, complete a Retrospective Review and submit a FCOI Mitigation Report if bias is found. (see “Retrospective Review and FCOI Mitigation Report” section below)
14. Certify, in each award proposal to which this FCOI Policy applies, that IBM Research:
   - a. Has in effect at IBM Research an up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from the PHS;
   - b. Shall promote and enforce Investigator compliance with this FCOI Policy's requirements including those pertaining to disclosure of SFI;
   - c. Shall manage FCOI and provide initial and ongoing FCOI Mitigation Reports to the PHS Awarding Component consistent with this FCOI Policy;
   - d. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of Financial Interests and IBM Research’s review of, and response to, such disclosure, whether or not the disclosure resulted in IBM Research’s determination of a FCOI; and
   - e. Shall fully comply with the requirements of this FCOI Policy and FCOI Regulation.
**Management Plan for FCOI**

Prior to IBM Research’s expenditure of any funds under a PHS-funded Research project, IBM Research’s Designated Official(s) and FCOIC, consistent with §94.4(f) (Title-45/Section-94.4), shall:

1. Review all Investigator disclosures of SFI;
2. Determine whether any SFI relates to PHS-funded research;
3. Determine if there was FCOI non-compliance in coordination with the FCOIC;
4. If FCOI exists, develop and implement a Management Plan that shall specify the actions that have been, and shall be, taken to manage such FCOI; and
5. Depending on the nature of the SFI, determine that additional interim measures are necessary regarding the Investigator’s participation in the PHS-funded Research project between the date of disclosure and the completion of the Designated Official’s and the FCOIC’s review.

**Retrospective Review and FCOI Mitigation Report**

Whenever an FCOI is not identified or managed in a timely manner, including:

1. failure by the Investigator to disclose an SFI that is determined by IBM Research to constitute a FCOI;
2. failure by the Designated Official(s) and the FCOIC to review or manage such a FCOI; or
3. failure by the Investigator to comply with a FCOI Management Plan,

Then IBM Research shall within one hundred and twenty (120) days of the determination of non-compliance, complete a Retrospective Review of the Investigator’s activities and the project to determine bias in the design, conduct or reporting of such research.

The Retrospective Review and FCOI Mitigation Report shall include:

1. BGR Number
2. Project Title
3. PD/PI or contact PD/PI if multiple PD/PI mode is used
4. Role and principal duties of the conflicted Investigator in the research project
5. Name of the Investigator with the FCOI
6. Name of entity with which the Investigator has a FCOI (e.g., Subrecipient’s entity)
7. Reason(s) for the Retrospective Review
8. How the conditions of this Management Plan and FCOI Policy were or were not followed
9. How the proposed actions are designed to safeguard objectivity in the research project
10. Confirmation of the Investigator’s agreement to the Management Plan
11. How the Management Plan will be monitored to ensure Investigator compliance,
12. Findings and conclusions of the Review; and
13. Other information as needed.

If results of the Retrospective Review warrant, update previously submitted FCOI Report.

If bias is found through the Retrospective Review, the PHS Awarding Component should be promptly notified (through eRA Commons) and a FCOI Mitigation Report shall be prepared by the Designated Official(s), in coordination with the FCOIC. (see “Reporting of FCOI” section below)
The FCOI Mitigation Report should have:
1. Key elements documented in Retrospective Review
2. Description of the impact of the bias on the research project
3. Plan of action(s) to eliminate or mitigate the effect of the bias
4. Thereafter, submit FCOI Mitigation Reports annually.

FCOI Reporting to PHS Awarding Component via the Electronic Research Administration (eRA) Commons Module:

The reporting tool for submitting FCOI Mitigation Reports for grants and cooperative agreements is the eRA Commons FCOI Module. This reporting tool is currently allows IBM Research to:

1. Initiate and send FCOI Mitigation Reports to PHS through the eRA Commons FCOI Module
2. Revise or update a previously submitted FCOI Mitigation Report
3. Submit a FCOI Mitigation Report when bias is found
4. Search previously created records
5. Edit a previously submitted record
6. Respond to a request for additional information
7. Rescind a previously submitted record
8. View history of actions

To prepare, IBM Research’s Signing Official(s) must assign FCOI roles to users in eRA Commons.

- More information on the FCOI Module can be found at [https://era.nih.gov/erahelp/commons/default.htm#cshid=1048](https://era.nih.gov/erahelp/commons/default.htm#cshid=1048)

FCOI Mitigation Reporting Details:

Prior to IBM Research’s expenditure of any funds under a PHS-funded Research project, IBM Research shall provide to the PHS Awarding Component an FCOI Mitigation Report regarding any Investigator’s SFI found by IBM Research to be conflicting and ensure that IBM Research has implemented a Management Plan in accordance with this FCOI Policy. *In cases in which IBM Research identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, IBM Research shall not submit an FCOI Report to the PHS Awarding Component.*

For any SFI that IBM Research identifies as conflicting after IBM Research’s initial FCOI Mitigation Report during an ongoing PHS-funded Research project (e.g., upon the participation of an Investigator who is new to the research project), IBM Research shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI Mitigation Report regarding the FCOI to ensure that IBM Research has implemented a Management Plan in accordance with this FCOI Policy.

Any FCOI Mitigation Report required under this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of IBM Research’s Management Plan. Elements of the FCOI Mitigation Report shall include, but are not necessarily limited to the following:

1. BGR Number
2. Project Title
3. PM/PD/PI or Contact PM/PD/PI if a multiple PM/PD/PI model is used
4. Role and principal duties of the conflicted Investigator in the research project
5. Name of the Investigator or Subrecipient Investigator with the FCOI
6. Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
7. Value of the Financial Interest (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 reference to public prices or other reasonable measures of fair market value
8. A description of how the Financial Interest relates to the PHS-funded research and the basis for IBM Research’s determination that the Financial Interest conflicts with such Research; and
9. A description of the key elements of IBM Research’s Management Plan
10. How the conditions of this Management Plan and FCOI Policy were or were not followed
11. How the proposed actions are designed to safeguard objectivity in the research project
12. Confirmation of the Investigator’s agreement to the Management Plan
13. How the Management Plan will be monitored to ensure Investigator compliance; and
14. Other information as needed.

For any FCOI previously reported by IBM Research about an ongoing PHS-funded Research project, IBM Research shall provide to the PHS Awarding Component an annual FCOI Mitigation Report that addresses the status of FCOI and any changes to the Management Plan for the duration of the PHS-funded Research project. The annual FCOI Mitigation Report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. IBM Research shall provide annual FCOI Mitigation Reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component as requested.

In addition to the types of FCOI as defined herein this FCOI Policy that must be reported pursuant to this section, IBM Research may require the reporting of other FCOI in its FCOI Policy, as IBM Research deems appropriate.

**HHS Authority**

The HHS may at any time inquire into IBM Research’s procedures and actions regarding conflicting Financial Interests in PHS-funded Research. The HHS authority applies before, during, or after an award regarding any Investigator disclosure of Financial Interests, regardless of whether the disclosure resulted in IBM Research’s determination of an FCOI. IBM Research is required to submit, or permit on-site review of, all records pertinent to compliance with this FCOI Policy to HHS. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests.

Based on its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded Research to such an extent that further corrective action is needed or that IBM Research has not managed the FCOI in accordance with this part. The PHS Awarding Component may determine that issuance of a Stop Work Order by the Contracting Officer or other enforcement action is necessary until the matter is resolved.

In any case in which the HHS determines that a PHS-funded Research project has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by IBM Research
as required by this FCOI Policy, IBM Research 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 any previously published presentations.

**Enforcement**

The Vice President, IBM Research Business Development, with the advice and consult of the Designated Official(s) and the FCOIC, shall have the authority to enforce this FCOI Policy. Sanctions, administrative actions, and other actions up to and including termination may be taken to enforce this FCOI Policy and ensure Investigator compliance.

The Vice President, IBM Research Business Development may require that one or more of the following actions, conditions, or restrictions be imposed to manage, reduce, or eliminate a potential FCOI:

1. Public disclosure of FCOI and SFI (e.g., when presenting or publishing the research),
2. Disqualification of Investigator or change of Investigator or Investigator responsibilities from participating in all or a portion of the PHS-funded Research, including a Subrecipient’s Investigator.
3. For research projects involving human subjects research, disclosure of FCOI and SFI directly to participants and publishers;
4. Monitoring of PHS-funded Research by appointed independent researchers and/or reviewers, disinterested individuals, or committees capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the FCOI;
5. Requiring that SFI be divested, restructured, or placed in blind trust;
6. Changing terms of agreement relating to the PHS-funded Research;
7. Requiring that Investigator participation in the recruitment or consent of subjects in human subjects PHS-funded Research be prohibited or restricted;
8. Requiring additional disclosures or actions with respect to matters to be reviewed by the Research Management Team;
9. Modification of the Management Plan; or
10. Severance or modification of relationships that create a potential financial conflict.

**Revision of Policies**

This FCOI Policy shall be reviewed upon changes to the Federal Regulation and revised as appropriate.
Attachment A:

IBM Research’s Financial Conflicts of Interests” (FCOI) Disclosure Form

It is the responsibility of IBM Research to Promote Objectivity in all Research performed by or for IBM Research including all Research for which Public Health Service (PHS), which includes the NIH, funding is sought or obtained. And to maintain compliance with federal laws and FCOI Regulations (42 C.F.R., Part 50, Subpart F) (Title-45/Part-94) governing FCOI funded Research, IBM Research has established a required FCOI Policy.

Every Investigator, Key Personnel, and any other individual who is responsible for the design, conduct, or reporting of Research funded by PHS or any agency or organization that follows PHS disclosure requirements, must disclose their personal Significant Financial Interests (SFI) (and those of their “Immediate Family or Dependents”) related to “IBM Research’s Responsibilities”.

Instructions: You are to complete this required form with grant applications, at time of proposal, prior to award, and annually with any renewal of award.

<table>
<thead>
<tr>
<th>Project Information</th>
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<tbody>
<tr>
<td>Investigator:</td>
</tr>
<tr>
<td>Research Division:</td>
</tr>
<tr>
<td>BGR#:</td>
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<tr>
<td>Grant Number (if applicable):</td>
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<tr>
<td>Project Begin Date:</td>
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<td>Project End Date:</td>
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<tr>
<td>Project Title:</td>
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<tr>
<td>Sponsor: PHS</td>
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<tr>
<td>Other</td>
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<tr>
<td>Subcontract of PHS Funds from ____________________________</td>
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<tr>
<th>Type of Proposal/Disclosure:</th>
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<tr>
<td>New Proposal</td>
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<tr>
<td>Supplemental Funding Including Time Extension</td>
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<td>Annual Reporting, PHS Award#</td>
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<td>No-Cost Extension</td>
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<td>Renewal/Competing Continuation</td>
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<tr>
<td>New Investigator Added to Project</td>
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<thead>
<tr>
<th>Investigator Disclosure</th>
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<tbody>
<tr>
<td>For the purpose of this Disclosure Form, IBM Research’s Responsibilities means an Investigator’s teaching/education, research outreach, clinical service, and public service on behalf of IBM Research which are in the course and scope of the Investigator’s IBM Research employment.</td>
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<tr>
<th>FCOI Questions</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1. Publicly Traded Entity (Income and Equity Interests)</td>
<td></td>
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<tr>
<td>Have you, your spouse, and/or dependent children (Immediate Family or Dependents) received income consulting fees, honoraria, paid authorship, or payment for services in the past twelve (12) months or own individual stock or equity interest in any publicly traded entity related to your IBM Research Responsibilities exceeding $5,000 when aggregated? This does not include interests in mutual funds, retirement funds, or stock in own company in which you do not directly control investment decisions.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If yes, is this entity related to healthcare, drug discovery, IT or any field related to the Research you are proposing? If you answered ‘yes’ please explain below.</td>
<td>☐</td>
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</table>
### 2. Non-Publicly Traded Entity (Income)

Have you, your spouse, and/or dependent children *(Immediate Family or Dependents)* received income or other payment for services, in the past twelve (12) months, exceeding $5,000, when aggregated, from any *non-publicly traded entity*? This does *not* include payments from IBM Research or income from seminars, lectures, or teaching engagements sponsored by a federal, state, local government agency, a US institution of higher education, an affiliated research institute, an academic teaching hospital, or a medical center.

If yes, is this entity related to healthcare, drug discovery, IT or any field related to the Research you are proposing? If you answered ‘yes’ please explain below.

### Explanation:

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### Equity Interests

Do you, your spouse, and/or dependent children *(Immediate Family or Dependents)* currently own, or have acquired in the past twelve (12) months, any equity interest in any non-publicly traded entity (other than IBM Research) related to your IBM Research Responsibilities? This can include any stock, stock option or other ownership interest.

If yes, is this entity related to healthcare, drug discovery, IT or any field related to the Research you are proposing? If you answered ‘yes’ please explain below.

### Explanation:

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### 3. Intellectual Property Rights and Interests

Have you, your spouse, and/or dependent children *(Immediate Family or Dependents)* received any payments, in the past twelve (12) months, for any Intellectual Property rights and interests (e.g., patents, copyrights, assigned or licensed to a party other than IBM Research) exceeding $5,000 related to your IBM Research’s Responsibilities?

Is this patent or copyright related to your proposal, to healthcare, or to IT? If you answered ‘yes’ please explain below.

### Explanation:

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### 4. Travel Reimbursement/Sponsorship

Have you received any travel reimbursement or been sponsored for travel (e.g., travel expenses paid on behalf of Investigator and not reimbursed to Investigator), in the past 12 months, by any entity related to your IBM Research responsibilities? This does **not** include travel sponsored or reimbursed by a federal, state, or local government agency, a US institution of higher education or an affiliated research institute, an academic teaching hospital, or a medical center.

If yes, is this entity related to healthcare, drug discovery, IT or any field related to the Research you are proposing? If you answered ‘yes’ please explain below.

#### Explanation:

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### 5. Acknowledgement and Certification

I certify under penalty of perjury that this is a complete disclosure of all my Significant Financial Interests (SFI) related to my IBM Research Responsibilities and I have used all reasonable diligence in preparing this Financial Interest Disclosure, and to the best of my knowledge it is true and complete. I also acknowledge that by signing my name below that it is my responsibility to disclose, within thirty (30) days, any **new** Significant Financial Interests obtained during the term of the above proposed project. And also by signing my name below, I certify that I and all Investigators responsible for the design, conduct, or reporting of Research, as defined in IBM Research’s FCOI Policy, have completed the PHS- training.

____________________________  ____________________
Signature of Investigator        Date

____________________________  ____________________
Printed Name                    Title

**Attach additional sheets as required to identify and include financial disclosure information for all project Investigators**

Please complete the information below for **all** project personnel responsible for the design, conduct, or reporting of Research.
No other project personnel responsible for the design, conduct, or reporting of Research.

<table>
<thead>
<tr>
<th>First Name</th>
<th>M.I.</th>
<th>Last Name</th>
<th>Email Address</th>
<th>Work Number</th>
<th>For FCOIC Use Only</th>
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</table>
Attachment B:

IBM Research’s Financial Conflicts of Interests” (FCOI) Mitigation Report

It is the responsibility of IBM Research to Promote Objectivity in all Research performed by or for IBM Research including all Research for which Public Health Service (PHS), which includes the NIH, funding is sought or obtained. And to maintain compliance with federal laws and FCOI Regulations (42 C.F.R., Part 50, Subpart F) (Title-45/Part-94) governing FCOI funded Research, IBM Research has established a required FCOI Policy.

And per the FCOI Policy, if bias is found through the Retrospective Review, the PHS Awarding Component should be promptly notified (through eRA Commons) and a FCOI Mitigation Report shall be prepared by the Designated Official(s), in coordination with the FCOIC.

Instructions: To be completed with grant applications, at time of proposal, prior to award, and annually with any annual renewal of award if a FCOI is determined via the IBM Research FCOI Disclosure Form.

<table>
<thead>
<tr>
<th>Project Information</th>
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<td>Investigator/Subrecipient:</td>
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<td>BGR#:</td>
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<tr>
<td>Project Begin Date:</td>
</tr>
<tr>
<td>Project Title:</td>
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<tr>
<td>Sponsor:</td>
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</table>

| Role and duties of conflicted Investigator |

| Nature of the Financial Interest |

| Value of the Financial Interest |

| Description of FCOI to PHS-funded Research |

<p>| Description of key elements in Management Plan |</p>
<table>
<thead>
<tr>
<th>How the conditions were/were not followed</th>
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<tbody>
<tr>
<td>Confirmation of Investigator’s agreement to Management Plan</td>
</tr>
<tr>
<td>How Management Plan will be monitored to ensure Investigator compliance</td>
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</tbody>
</table>
Attachment C

Statement of Intent to Establish a Consortium Agreement

IBM RESEARCH
Institution Name and Address:

PD/PI Names:
Funding Agency:

Application Title:

Project Period:

SUBRECIPIENT INSTITUTION
Institution Name and Address:

DUNS Number:

Subaward PD/PI Name:

Is Subaward PD/PI a Multiple PD/PI? [ ] Yes [ ] No

TOTAL PROPOSED AMOUNT

Direct Costs: $
Indirect Costs: $
Total Costs: $

The appropriate Subrecipient programmatic and administrative personnel involved in this sponsored grant application have reviewed and approved this application. By signing this letter, the authorized institutional official for the proposed Subrecipient acknowledges and is aware of all applicable Public Health Service (PHS), Federal, regulations and policies and will establish the necessary inter-institutional agreement(s) consistent with those policies should the referenced proposal be funded. In addition, Subrecipient institution has in place a Conflict of Interest (COI) policy that is compliant with the PHS COI policy.

Certification of Compliance with HHS Financial Conflict of Interest (FCOI) Requirements 42 CFR Part 50, Subpart F, entitled “Responsibility of Applicants for Promoting Objectivity in Research” Effective 8/24/12
___________ (SUBRECIPIENT INSTITUTION) is compliant with the above FCOI regulations and is included on the FDP website “List of Compliant Institutions and Entities,” The website is located at: http://thefdp.org/default/fcoi-clearinghouse/compliant-entities/

___________ (SUBRECIPIENT INSTITUTION) is compliant with the above FCOI regulations and is not included in the FDP website. Its FCOI policy can be found here ______________________________

___________ (SUBRECIPIENT INSTITUTION) does not have its own FCOI policy and will use IBM Research’s FCOI Policy

AUTHORIZING ORGANIZATION REPRESENTATIVE (AOR) OF SUBRECIPIENT INSTITUTION

____________________________________________________________________________
Name: Title:

____________________________________________________________________________
Telephone Number: Email:

____________________________________________________________________________
Signature: Date: