



Brown University Health

Office of Research

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Research Conflict of Interest
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1.0 Policy Purpose

The purpose of Brown University Health's Policy on Conflict of Interest in Research (Research COI Policy) is to maintain the integrity of Research conducted at or under the auspices of the Institution. This Research COI Policy establishes Brown University Health's conflict of interest (COI) compliance framework for research activities and provides information about regulatory and policy requirements related to conflict of interest in research. The Research COI Policy is compliant with applicable federal COI regulations. The Research COI Policy outlines Brown University Health's approach to identifying, managing, reducing and, when needed, eliminating situations where Financial Interests, including Significant Financial Interests, of its researchers

could interfere with or affect the objectivity of the Research, and to ensure transparency in relationships with Outside Entities as they relate to research activities.

Investigators must also comply with all Brown University Health Policies, including but not limited to [CCPM-46, Vendor Interactions](#); [CCPM-09, Conflict of Interest](#); [CCPM-76, Clinical Conflict of Interest: Physician Disclosure and Patient Consent of Vendor Business Relationships](#); and [CCPM-86, Institutional Conflict of Interest](#), as applicable.

It is the responsibility of an Investigator and their staff to read, understand, and complete appropriate training with regard to these institutional compliance policies.

2.0 To Whom the Policy Applies

This Policy applies to all persons, regardless of title or position, who are *responsible* for the design, conduct or reporting of research that is conducted under the auspices of the individual's affiliation, appointment, or employment at Brown University Health. Principal Investigators/Program Directors of each project are responsible for assisting Brown University Health in determining who meets the definition of "Investigator" (see Section 4.0, Definitions).

3.0 Policy Statement

Conflicts of interest in research may arise in situations where an Investigator's personal, financial, or other interests could affect, or appear to affect, the conduct of their research activities. Having a conflict of interest does not imply improper conduct of research; rather, conflicts of interest must be identified and managed, reduced, or eliminated so that they do not threaten the integrity of scientific investigations and the public's trust in academic research.

3.1 Authority

The Vice President for Research has final authority over this Research COI Policy and serves as the designated Institutional Official responsible for implementation and ensuring compliance with this Research COI Policy and all applicable COI laws, regulations and external policies.

3.2 Conflict of Interest Reporting

Investigators are required to report Financial Interests, Outside Professional Activities, and any other interests or activities, as requested, that could affect or appear to affect their Research, including their Significant Financial Interests that reasonably appear to be related to their professional expertise and Institutional Responsibilities. Conflict of Interest (COI) reporting is completed annually and at various transactional points, as outlined below.

- Annual Reporting: Investigators must submit a COI Reporting Form annually in accordance with the Institution's reporting procedures and time frames.
- Transactional Reporting: In addition to the annual COI reporting requirement, Investigators must also comply with transactional COI reporting requirements throughout the calendar year, and in accordance with the Institution's reporting procedures and time

frames. Transactional COI reporting includes, but is not limited to, submitting a COI Reporting Form or certifying the accuracy of an existing COI Reporting Form when:

- Participating as an Investigator on a new sponsored research proposal submission;
- Participating as an Investigator on a new human subject research study or being added to a study via an amendment; and
- Being added as a new Investigator to an ongoing Research project.

In addition to the initial disclosure, an updated disclosure must be made any time in the course of an on-going research project that a new SFI is discovered or acquired (e.g., through purchase, marriage, or inheritance) by an investigator. Such updated disclosures must be made promptly (or within thirty (30) days for PHS funded Investigators) of discovering or acquiring the new interest.

The Institution may also, within its discretion, request that Investigators submit or update their COI Reporting Forms from time-to-time.

Depending on the source of the funding, additional requirements may apply, including but not limited to the requirements set forth in Section 3.10.

3.3 Conflict of Interest Review

The Institution - acting through its designated Institutional Officials and their designees, the Brown University Health Research COI Committee, and the Office of Research - has the authority to and is responsible for:

- Administering the COI Reporting Form submission and review process for Investigators;
- Reviewing reported Financial Interests and Outside Activities, including Significant Financial Interests, that reasonably appear to be related to the Investigator's Institutional Responsibilities;
- Conducting COI reviews in accordance with standards set forth in the federal PHS COI regulations, 42 CFR 50 Subpart F and the NSF COI Policy including:
 - Determining whether any reported Significant Financial Interest is related to any of the Investigator's Research, and
 - Determining whether any reported related Significant Financial Interest constitutes a Financial Conflict of Interest.
- Evaluating and resolving identified Financial Conflicts of Interest, including how identified Financial Conflicts of Interest must be managed, reduced, or eliminated;
- Providing appropriate oversight of identified Financial Conflicts of Interest and any related management plans with Institutional officials and offices as circumstances require; and
- Evaluating Financial Interests, Outside Activities, and any other reported interests that do not constitute Significant Financial Interests and do not constitute Financial Conflicts of Interest, but where it is determined that there are other conflict of interest concerns and/or action is needed to preserve the integrity of the research.

- Reviewing regularly and revising periodically as necessary research conflict of interest policies and procedures.
- Reviewing and considering the impact of institutional conflict of interest on the proposed research.

3.4 Conflict of Interest Management

When a Financial Conflict of Interest is determined to exist, the Institution must develop and implement a management plan that specifies actions that have been taken and/or will be taken to manage the Financial Conflict of Interest.

As FCOIs are evaluated on a case-specific process, there is no one formula that dictates which management actions best resolve an identified FCOI. The Committee will keep the following in mind as it develops its management plans:

- Relationship of the investigator(s) to the entity that is the source of the SFI;
- Magnitude of the financial interest;
- Nature of the research project and role of the investigator(s);
- Relative value of the technology to the entity that is the source of the SFI; and
- Risks to the research subjects (i.e., invasive, non-invasive; multi-center, single center trial).

A Financial Conflict of Interest may be managed through full and open disclosure of the Significant Financial Interest:

- To all students and trainees and other personnel who are directly supervised by the Investigator or who work in the Investigator's lab;
- In all publications and presentations of Research related to the Significant Financial Interest; and
- To human subjects participating in a study, the results of which could affect the Investigator's Significant Financial Interest, via a written statement in the informed consent or provided orally, as approved by the Institutional Review Board (IRB).

In addition, other actions that may be taken to manage an identified Financial Conflict of Interest include, but are not limited to, the following:

- Periodic review of the Research, the Significant Financial Interest, and related activities in the lab by a neutral party or committee;
- Disclosure of the Significant Financial Interest to the relevant research team and provision of measures to protect members of the research team (e.g., where a power differential may exist);
- Modification of the research plan to ensure the integrity of the Research;
- Independent oversight of the Research, including appointment of an independent monitor;
- Involvement of an independent statistician to review research results, data analysis and interpretation;

- Change of personnel responsibilities;
- Prohibition to participate in the Research;
- Divestiture of the Significant Financial Interest that creates the Financial Conflict of Interest; and
- Severance of the relationship(s) that creates a Financial Conflict of Interest.

The Institution may also develop a management plan in situations that do not constitute Financial Conflicts of Interest, but where it is determined that there are other Conflict of Interest concerns and/or action is needed to preserve the integrity of the Research.

3.5 Presumptively Prohibited Activities

3.5.1 Conflict of Interest in Research Involving Human Subjects

Conflicts of interest in Research involving human subjects require enhanced considerations beyond preserving the integrity of the Research, to include risks to the rights and welfare of participants.

To protect research participants and preserve the integrity of the research study and data, the Institution has a presumptive prohibition against participation in human subject research by an Investigator in the following situations:

- The human subject research is funded by an Outside Entity in which the Investigator has a Significant Financial Interest;
- The human subject research involves a product or intellectual property from an Outside Entity in which the Investigator has a Significant Financial Interest; and
- The human subject research is funded by an Outside Entity for which the Investigator serves in a Fiduciary Role (e.g., Board of Directors, Chief Executive Officer).

Exceptions to the presumptively prohibited activities may be made in compelling circumstances on a study-by-study basis. Compelling circumstances could include the nature of the Research, the risk level of the study (minimal risk vs. more than minimal risk, as defined at 45CFR 46.102(j)), the nature of the Significant Financial Interest, how closely the Significant Financial Interest is related to the proposed Research, and the degree to which the interest may be affected by the proposed Research.

Investigators wishing to participate in a presumptively prohibited human subject research activity must present a written request for an exception to the Research COI Committee and the Institutional Review Board (IRB). This request must include a list of compelling circumstances, and a proposal on how the conflict of interest could be effectively managed.

3.5.2 Conflict of Interest in Research Involving Sponsorship, and/or Products from a Privately-held Entity

An Investigator wishing to conduct Research activities that involve sponsorship, including but not limited to funding or in-kind support, or products/intellectual property from a privately held

Outside Entity, including a start-up, in which the Investigator has a Significant Financial Interest, should be aware that these situations may create conflicts of interest that can impact the scientific integrity of the Research.

The following activities/situations are presumptively prohibited as they create, in almost all circumstances, conflicts of interest that cannot be effectively managed.

- An Investigator's Research at Brown University Health is sponsored by a privately held Outside Entity, including a start-up, in which the Investigator has a Significant Financial Interest or otherwise holds a Fiduciary Role or executive-level position.
- An Investigator's Research at Brown University Health is sponsored by a privately held Outside Entity, including a start-up, in which the Investigator's current research assistants, trainees, students, or others over which the Investigator has supervisory authority have a Significant Financial Interest or otherwise hold a Fiduciary Role or executive-level position.

The Research COI Committee (RCOIC) may make exceptions in compelling circumstances, which will depend in each case upon the nature of the Research, the status of the Outside Entity, the nature of the Significant Financial Interest, how closely the Significant Financial Interest is related to the proposed Research, and the degree to which the interest may be affected by the proposed Research. The RCOIC may, within its discretion, consult other offices as necessary and appropriate in its evaluation of the compelling circumstances or it may refer a case to Institutional leadership for adjudication.

Investigators wishing to engage in a presumptively prohibited activity must present a written request for exception to the Review COI Committee. This request must include a list of compelling circumstances, and a proposal on how the conflict of interest could be effectively managed.

Phase I of the Small Business Innovation Research (SBIRs) and Small Business Technology Transfer (STTRs) programs are exceptions to this presumption and the compelling circumstance requirement; in such cases, however, the Research COI Committee will normally recommend management of the Financial Conflict of Interest that may arise with the Research conducted under Phase I SBIRs and STTRs.

3.5.3 Self-Funded Research

Investigators are presumptively prohibited from using their own personal funds or receiving funding from a Family Member or a Family Trust to support research efforts they are directing or conducting under the auspices of the Institution, including efforts that involve research personnel such as, but not limited to, graduate students.

Self-funded research can blur the boundary between funder and researcher, and may give rise to concerns regarding appropriate oversight, accountability, and conflict of interest.

As an exception to this presumptive prohibition, an Investigator may, in the normal course of conducting research, use personal funds to purchase low-cost, routine research-related items or to supplement travel. Review and prior approval by the Vice President for Research is required if an Investigator wishes to use personal funds to purchase major or capital research items or equipment.

Investigators and their Family Members wishing to support research projects at the Institution may donate in accordance with the Institution's donation guidelines and policies. However, Investigators cannot donate to a research account over which they or someone they directly supervise has spending authority.

3.6 SBIR and STTR Awards

The purpose of the federally funded Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs is to promote research by U.S. companies engaged in innovation and commercialization of technology.

Only small for-profit businesses are eligible to apply for these Federal awards. Many small businesses that receive SBIRs or STTRs collaborate with universities and other research institutions. For many faculty-owned start-up companies, SBIRs and STTRs, in particular, provide critical funding opportunities. When applying for SBIRs and STTRs, it is important to be aware that the Federal Government places certain restrictions and limits on subcontracting under SBIR and STTR awards.

3.6.1 SBIR Awards (R43/R44)

Under SBIR awards, the principal investigator for the small business must be a full-time employee (at least 51%) of the small business. Small businesses receiving SBIR grants are not required to collaborate with universities or research institutions. However, the SBIR program permits and encourages research partnerships. For Phase I SBIR awards, no more than thirty-three percent (33%) of the SBIR award can be performed by any collaborating research institution. For Phase II awards, no more than fifty percent (50%) can be performed by any collaborating research institution.

3.6.2 STTR Awards (R41/R42)

The principal investigator for an STTR award needs to be (1) a full-time employee (at least 51%) of the small business or (2) a full-time employee of the collaborating research institution and have a formal relationship with the small business.

Small businesses receiving STTR awards must collaborate with a non-profit research institution, like a university. STTR awards require that the collaborating research institution perform at least thirty percent (30%) of the award. At least forty percent (40%) must be performed by the small business. The remaining thirty percent (30%) of an STTR award may be performed by the small business, the research institution, or third parties.

While small business-related research is encouraged at the Institution, it can give rise to specific conflict of interest and conflict of commitment concerns. The following general principles have been adopted by the Institution to address these concerns.

3.6.3 General Principles Pertaining to SBIR/STTR Awards

- All work performed for, or in connection with, SBIR- or STTR-funded Research that makes use of Brown University Health facilities, equipment, materials, employees, or students, must be performed under a fully negotiated agreement (*e.g.*, sponsored research agreement or facilities use agreement) executed by the appropriate Institutional Official, in compliance with all applicable Institutional policies related to the use of facilities and resources.
- The principal investigator for a small business and the principal investigator for a Brown University Health sub-award must be separate individuals, and neither may be a Family Member of the other.
- The principal investigator of the sub-award for the performance site must be independent from the principal investigator of the small business grantee, and cannot report directly to the individual who serves as principal investigator for the business
- A full-time (at least 51%) employee of Brown University Health may not serve as the principal investigator for a small business's SBIR prime award due to likely Conflict of Commitment issues.
- No student, staff member, visiting researcher, or visiting scientist may perform Research under the Institution's portion of a small business's SBIR or STTR award, and concurrently perform Research under the small business's portion of the award at or on behalf of the small business.
- An interinstitutional agreement (IIA) may be required for IRB or IACUC review of the work that will be done under the sub-contract.
- All SBIR or STTR subcontracts that Brown University Health receives from a small business, and that involve an Investigator who has a Significant Financial Interest or a Fiduciary Role in the small business, must be reviewed by the Research COI Committee.

3.7 Disclosure and other Obligations

3.7.1 Disclosure

Disclosure is a method for ensuring open and transparent communication regarding financial and other interests that could affect or appear to affect research activities, and for informing collaborators, trainees, and the scientific community more generally of interests that may have interfered with objectivity and could create a potential for bias. Investigators should disclose any

relevant financial and other interests, but must disclose relevant Significant Financial Interests and Fiduciary Roles:

- to students and trainees who are under active mentorship and who work on projects and Research related to the Significant Financial Interest or Fiduciary Role; and
- in publications and presentations presenting results or data that are related to the Significant Financial Interest or Fiduciary Role.

3.7.2 Other Disclosure Obligations

Investigators are also required to comply with any reporting requirements set forth in their funding instruments or established by external sponsors and agencies.

3.7.3 Gifts

Gifts, including equipment, given to an Investigator or the Investigator's lab for research purposes must be reported on the Investigator's COI Reporting Form. Investigators must also comply with the Institution's policy on the solicitation and acceptance of Gifts, as outlined in [Vendor Interactions, CCPM-46](#) and [Gift Acceptance, CCPM-30](#).

3.7.4 Office/Laboratory Space and other Resources

Investigators may only use the facilities and resources of the Institution for Brown University Health business.

Use of Brown University Health space for Research by an Outside Entity is permissible only under special conditions and with a formal agreement executed in accordance with Brown University Health Policy and approved in advance by the Research COI Committee.

3.7.5 Use of Students/Trainees

To limit potential conflicts of interests and to protect the relationship of educator/mentor and students or subordinates, investigators may not solicit for personal benefit gratuities, favors or anything of monetary value from subordinate staff, matriculating graduate students, undergraduate students, medical students, or post-doctoral fellows. Students should only be involved in Brown University Health research that positively benefits the students and their academic requirements.

Any students, trainees, or other personnel whom an Investigator actively or directly supervises or advises cannot be involved in work at a privately owned Outside Entity in which that Investigator has a Significant Financial Interest or a Fiduciary Role. In exceptional circumstances, approval may be granted by the Vice President for Research, in coordination with the Investigator's Department Chair.

3.7.6 Required Financial Conflict of Interest Training

Each investigator is required to complete conflict of interest training prior to engaging in any research and at least every four (4) years. The training will cover the Brown University Health Research Conflict of Interest Policy, the PHS regulations applicable to conflicts of interest, and the specific disclosure obligations on Brown University Health investigators. Additional training will be required on an immediate basis (or no later than 60 days if PHS funded), if Brown University Health revises its Research Conflict of Interest Policy in a way that affects the requirements applicable to investigators, when an investigator is new to Brown University Health, or when an investigator fails to comply with this policy or an imposed FCOI management plan.

Financial conflict of interest training is administered by the Office of Research.

3.8 Appeals

Should an Investigator wish to appeal a decision made by the Research COI Committee, the Investigator may present the appeal within 90 days of the Committee's decision in writing to the Vice President for Research (VPR). The VPR at their discretion will consider the case with input from the Research COI Committee and/or other offices as necessary. The Investigator may be asked to present the appeal in person to the VPR and/or the Committee. The VPR will convey their decision in writing to the Investigator. The decision of the VPR shall be final.

3.9 Confidentiality

Access to COI Reporting Forms submitted to the Office of Research is limited to authorized individuals in the conduct of their official Institutional responsibilities. Information will not be shared with any individual, organization, or entity outside of the Institution except where required contractually or by law, such as in cases of federal audits or investigations, or when Financial Conflict of Interest notifications are sent to outside research sponsors. Investigators whose records will be shared with an individual, organization, or entity outside the Institution will be notified by the Office of Research.

3.10 Specific Requirements for Research Awards Funded by the Public Health Service (PHS)

The 2011 Public Health Service (PHS) regulations on "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought," 42 C.F.R. Part 50, Subpart F, ("the PHS COI regulations") overseen by the U.S. Department of Health and Human Services (HHS), and the Department of Energy (DoE) interim Conflict of Interest Policy Requirements for Financial Assistance as outlined in FAL2022-02 ("the DoE interim COI policy"), impose special requirements on Investigators on research awards funded by PHS or the DoE as well as on the institution administering such funded research.

These special requirements apply to researchers who are Investigators participating in PHS-Funded Research or research funded by a foundation that follows the PHS COI requirements.

3.10.1 Report Sponsored or Reimbursed Travel

Investigators participating in PHS-Funded Research are required to report on their annual COI Reporting Form the occurrence of any Reportable Travel.

The internal threshold for reporting and reviewing travel is \$5,000 for any 12-month period. Exceptions to this reporting requirement are set forth in PHS COI regulations and include when travel is reimbursed or sponsored by (1) a federal, state, or local government agency; (2) an institution of higher education as defined at 20 U.S.C. 1001 (a); (3) an academic teaching hospital; (4) a medical center; or (5) a research institution that is affiliated with an institution of higher education.

Investigators must provide information on the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

3.10.2 Institutional Reporting Requirements for PHS- Funded Research

For any Financial Conflict of Interest that the Institution identifies, prior to the expenditure of any funds under PHS-Funded Research, the Institution, acting through its designated Institutional Officials and Research COI Committee shall:

- Ensure that any Financial Conflict of Interest is managed, mitigated, or eliminated;
- Develop and ensure the implementation of a management plan that specifies how an identified Financial Conflict of Interest will be managed; and
- Notify the PHS awarding agency of the existence of any Financial Conflict of Interest in accordance with PHS requirements.

For any Financial Conflict of Interest that the Brown University Health identifies after PHS funding for the research at the Institution has commenced, the Brown University Health shall, within sixty (60) days of identification:

- Ensure that any impermissible Financial Conflicts of Interest are eliminated;
- Ensure that any other identified Financial Conflicts of Interest are managed and a management plan has been implemented, at least on an interim basis, and take any interim measures deemed necessary; and
- Notify the PHS awarding agency of the Financial Conflict of Interest in accordance with PHS requirements.

3.10.3 Public Accessibility

Under PHS COI regulations, the Institution is required to make available to the public, upon request, specific information regarding Financial Conflicts of Interest identified for senior and

key personnel on PHS-Funded Research. The Institution is required to provide specific information relative to such public requests within five business days of the request.

3.10.4 Subrecipients

When proposed PHS- Funded Research is to be carried out through a subrecipient, Brown University Health will:

- Establish, at the time of proposal submission whether the subrecipient on PHS-funded Research has a COI policy that is compliant with 42 CFR 50 Subpart F;
- Establish, in cases where the subrecipient does not have a COI policy that is compliant with 42 CFR 50 Subpart F, whether the subrecipient will implement a compliant policy prior to accepting funding or follow the Institution's Research COI Policy for the duration of the PHS-Funded Research activity (if the latter, subrecipient's Investigators must adhere to procedures and time frames outlined in the Institution's internal COI procedures document); and
- In cases where the subrecipient has a compliant COI policy, incorporate terms into the subrecipient agreement that establish obligations of the subrecipient relative to conflict of interest, including specific time periods for providing Financial Conflict of Interest reports.

3.10.5 Non-Compliance with the Special Requirements under 42 CFR 50 Subpart F

In the event of non-compliance with special requirements under 42 CFR 50 subpart F, the Institution must conduct a retrospective review of the Investigator's activities on the PHS-Funded Research project to determine whether any PHS-funded research, or portion thereof, conducted during the time of non-compliance, was biased in the design, conduct, or reporting. Furthermore, the Institution must, to the extent required by federal regulations or policy, submit a mitigation report to the PHS.

Non-compliance with special requirements includes the following:

- An Investigator failed to report a new Significant Financial Interest within the required time frame or the Institution failed to review a new Significant Financial Interest within the required time frame, and that Significant Financial Interest, upon review by the Institution, is then determined to create a Financial Conflict of Interest with a PHS-funded research project;
- A Financial Conflict of Interest is not identified or managed in a timely manner; and
- An Investigator fails to comply with a Financial Conflict of Interest management plan.

4.0 Definitions

For purposes of this policy, the terms below have the following definitions:

COI Reporting Form:

The COI Reporting Form is the Institution's conflict of interest reporting form that is collected electronically annually and at various transaction points from Investigators who are subject to this Policy. It requires Investigators to report Financial Interests, Outside Professional Activities, and any other interests that could affect or appear to affect their research, including reporting their Significant Financial Interests that reasonably appear to be related to their professional expertise and Institutional Responsibilities. The Significant Financial Interests and Outside Professional Activities of an Investigator's spouse and dependent children must also be reported if they are related to the Investigator's institutional responsibilities.

Conflict of Interest Review Board (Research COI Committee):

The Research COI Committee is a subcommittee of the Brown University Health System Compliance Committee (SCC), reporting annually or more frequently if necessary. The SCC reports to the Brown University Health President and CEO. The members of the Committee are appointed by the Chair of the SCC. The Committee is comprised of senior members of Brown University Health's research community and Brown University Health executives and is responsible for reviewing submitted research COI Reporting Forms and for conducting research COI reviews in accordance with standards set forth in the federal PHS COI regulations: 42 CFR 50 Subpart F. For all identified Financial Conflicts of Interest, the Research COI Committee determines whether the Financial Conflict of Interest needs to be managed, reduced, or eliminated.

Family Member:

Family Member means an individual's spouse, domestic partner, parent, child, sibling, grandparent, grandchild, parents-in-law, brothers- and sisters-in-law, and step parent, step child, step sibling, step grandchild, guardian, ward, or member of one's household.

Family Trust:

A Family Trust is a trust created to benefit persons who are related to one another by blood, affinity, or law.

Fiduciary Role:

A Fiduciary Role is a position in which one has a legal responsibility of care for the assets or rights of another entity or person. Fiduciary roles include serving as a member of a company's board of directors, or a position such as an officer or executive of a company (*e.g.*, Chief Executive Officer, Chief Operating Officer) that requires high-level responsibility for the day-to-day management of the business.

Financial Conflict of Interest (FCOI):

Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

Financial Interest:

Financial Interest means anything of monetary value whether or not the value is readily ascertainable and generally refers to any pecuniary interests in and from Outside Entities. The term includes salary, honoraria, or other payments for services, equity and ownership interests like stocks and stock options, as well as intellectual property rights and royalty payments.

Gifts:

Gifts are contributions received for either restricted or unrestricted purposes in support of Brown University Health's mission for which the institution has made no commitment of resources or services other than, possibly, committing to use the gifts as the donor specifies.

Institutional Official:

The Institutional Official (IO) is an individual who is legally authorized by Brown University Health to act for the Institution or, on behalf of the Institution, obligates the Institution to the Terms of the Assurance.

Institutional Responsibilities:

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Brown University Health, including research, education, clinical care, administrative, and other Institutional activities and services.

Investigator:

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research, which may include, for example, collaborators and consultants. "Design, conduct, or reporting" includes, but is not limited to, the following:

- Designing, conducting, and/or directing Research;
- Analyzing, reporting, presenting, or publishing research data.

Outside Entity:

Outside Entity means any for-profit or non-profit corporation, foundation, or other organization, including any governmental entity that is not a Brown University Health-affiliated institution. The term includes the entity itself and entities that own or control, are owned or controlled by, or are under common ownership or control with the entity, with ownership and control defined as a 50% or greater direct or indirect interest.

Outside Professional Activity:

An Outside Professional Activity is generally an engagement in specific work or services for an entity that is not part of, or affiliated with, the Institution. Outside Professional Activities can be compensated or uncompensated, and are generally related to the professional expertise of the individual. Outside Professional Activities may include private consulting activities, service on non-Brown University Health advisory boards, and engaging in entrepreneurial activity. Activities for which an authorized Institutional official has signed a contract or agreement are not considered Outside Professional Activities.

PHS-Funded Research:

PHS-Funded Research means Research funded by the Public Health Service.

Professional Staff:

Professional Staff refers to staff members who are licensed to provide patient care and are credentialed by medical staff.

Reportable Travel:

Reportable Travel means travel that is either reimbursed or sponsored by a non-Brown University Health entity, and that is related to the investigator's institutional responsibilities. Reimbursed travel is travel for which the investigator is directly reimbursed by the sponsoring entity. Sponsored travel is travel that is paid directly by the sponsoring entity and is not reimbursed to the investigator.

Research:

Research means any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test, drug or device), and non-research projects such as training, clinical services, educational

conferences, exhibitions, performances, archives, workshops, and library projects for which external funding is received.

Research also includes any such activity for which a proposal is submitted for funding from external sources through a grant, contract or agreement, including, but not limited to, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects and research resources awards. Research also includes projects that are internally funded (*i.e.*, funded by the Institution), as well as research for which approval of an IRB (or IRB exemption) or Institutional Animal Care and Use Committee (IACUC) is required.

Significant Financial Interest (SFI):

A Significant Financial Interest (SFI) means the receipt by an Investigator or an Investigator's spouse and dependent children of any of the following, provided that they appear to be reasonably related to the Investigator's Institutional Responsibilities:

- Income that exceeds \$5,000 from any Outside Entity, measured on a 12-month basis. This may be one payment from a particular company of more than \$5,000, or multiple payments from the same company that, in the aggregate, exceed \$5,000;
- Acquisition of equity in a public company that exceeds \$5,000 in value;
- Aggregated income and equity/ownership interest from a public company that exceeds \$5,000, as measured on a 12-month basis;
- Any equity/ownership interest in a privately-held company;
- Any income received from rights in intellectual property, as measured on a 12-month basis, and

Excluded from this definition are payments (including travel) received from or through Brown University Health and income from investment vehicles over which the Investigator or Investigator's spouse and dependent children do not exercise control, such as mutual funds and retirement accounts. Also excluded from this definition are payments received from any of the following entities, provided these payments are received for teaching engagements, lectures, seminars, or service on advisory committees or review panels:

- Government agencies;
- U.S. institutions of higher education and research institutes affiliated with them;
- Academic teaching hospitals; and
- Medical centers

Venture or Capital Financing

Venture or capital financing is a type of funding that is provided by investors to private early-stage companies and businesses. This type of funding can be provided by individual investors as well as venture capital funds.

5.0 Responsibilities

All individuals to whom this policy applies are responsible for becoming familiar with and following this policy. Supervisors are responsible for promoting the understanding of this policy and for taking appropriate steps to help ensure compliance with it.

- Compliance with the Policy: All Investigators are responsible for becoming familiar with and adhering to this policy.
- External Reporting Obligations: In accordance with applicable regulations and research sponsors' policies and guidelines, Brown University Health may be obligated to report identified Financial Conflicts of Interest to the sponsor of research that could be affected by the presence of the Financial Conflict of Interest. Additional special reporting and accessibility requirements apply to PHS-Funded Research (see Section 3.10).
- Report Violations: All Investigators have a responsibility to report violations of this policy to the institution.

6.0 Consequences for Violating this Policy

The protection of research subjects and the viability of the peer-reviewed conflict of interest program at Brown University Health depend on complete and accurate disclosure(s) of information by the investigators required by the disclosure reporting forms. Failure to disclose this information and to comply with all aspects of this policy breaks the first link of public trust and will result in sanctions by Brown University Health and/or the investigator's academic/service departments. Failure by investigators to adhere faithfully to the terms of a management plan imposed by the Research COI Committee undermines the system that permits research in which an FCOI has been identified to proceed responsibly and safely, and such failure will also result in sanctions by Brown University Health and/or the investigator's academic/service departments. Such sanctions may include, but are not limited to, termination of employment, suspension or termination of research privileges, termination of the research project, suspension, reprimand, or other such remedial actions.

7.0 Related Information

Brown University Health is a community in which employees are encouraged to share workplace concerns with Institutional leadership. Additionally, Brown University Health's Corporate Compliance reporting system allows anonymous and confidential reporting on matters of concern [online](#) or by phone (888-678-5111)

The following information complements and supplements this document. The information is intended to help explain this policy and is not an all-inclusive list of policies, procedures, laws and requirements.

7.1 Related Policies

- [CCPM-46, Vendor Interactions](#)
- [CCPM-09, Conflict of Interest](#)

- [CCPM-76, Clinical Conflict of Interest: Physician Disclosure and Patient Consent of Vendor Business Relationships](#)
- [CCPM-86, Institutional Conflict of Interest](#)

7.2 Related Procedures:

- COI Training- to be completed on-line through www.CITIProgram.org
- [Instructions for Accessing COI training course through CITI Program](#)

7.3 Related Forms:

7.4 Frequently Asked Questions (FAQs)

7.5 Related Information

- [42 CFR Part 50 Subpart F \(“Promoting Objectivity in Research”\)](#)