I. Guiding Principles

A. The term “financial conflict of interest in research” refers to situations in which financial considerations may compromise, or have the appearance of compromising, a researcher’s professional judgment in designing, conducting or reporting research. The determination that one has a “conflict of interest” does not imply that the actions or character of an individual investigator are compromised.

B. The welfare and safety of research participants is paramount. The fact that an investigator has or appears to have a financial conflict of interest in research does not preclude conduct of that research, but the interest must be disclosed and the conflict managed in a way that ensures that the welfare of subjects and the integrity of the data are not compromised by that interest.

II. The Roles of the Institutional Review Board (IRB) and the Conflict of Interest (COI) Review Board

A. Brown University’s Institutional Review Board (IRB) is responsible for reviewing and approving research protocols to ensure that they protect the rights and welfare of human research participants and abide by University policy and applicable federal and state statutes and regulations.

B. Brown University’s Conflict of Interest Review Board (COI Review Board) is charged with reviewing certain financial disclosures related to Brown research programs, including human subject research. As the outside financial interests of Brown researchers may pose potential or real risks with respect to the rights and welfare of human research participants, Brown has established an integrated process of COI disclosure and institutional review that aims to accomplish the following:
   - Protect the rights and welfare of human research participants.
   - Preserve objectivity and provide transparency in the design, conduct, and reporting of human subject research.
   - Ensure appropriate disclosure of financial conflicts of interest to human research participants via the consent process, and/or manage, reduce or eliminate conflicts that could interfere with the integrity of the research.

C. As part of the application for IRB review, the Brown IRB requires Investigators to:
   - Certify that they have submitted a COI Assurance or COI Reporting Form within the last 12 months and that it is up-to-date.
• Identify if any of their reported **significant financial interests** are **related** to the proposed human subject research protocol conducted at Brown or using Brown resources (i.e. Brown funding, facilities).

### III. When do I Provide this Information to the IRB?

There are COI questions embedded in each of the following forms to facilitate disclosure to the IRB at appropriate time points:

- IRB Form #1: Initial protocol application
- Amendment Request Form
- Progress Report Form

### IV. Who Must Provide this Information?

*As indicated in the forms, all “Brown Investigators” must make the requested disclosures.*

**A.** An **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, postdoctoral fellow, collaborators or consultants.

**B.** A **Brown Investigator** means anyone working on a human subject study protocol that meets the above definition of an **Investigator** and is either appointed by or employed by Brown (and, therefore, must abide by Brown’s **Conflict of Interest** policy for Officers of Instruction and Research).

**C.** A **Brown Investigator** also means anyone working on a human subject study protocol that meets the above definition of an **Investigator** and doesn’t have a compliant COI policy at his/her home institution that he/she must follow. For example, a collaborator at an affiliated hospital or another domestic research institution will have his/her own institutional COI policy and, therefore, does not need to abide by Brown’s policy. However, independent consultants, partners from industry, or collaborators from abroad are unlikely to have compliant (per federal regulations) COI policies, and, therefore, must abide by Brown’s COI policy. Those individuals must also report any significant financial interests related to the human subject research protocol.

### V. How do I Determine if my Significant Financial Interest is “Related” to my Human Subject Research Protocol?

**A.** Related financial interests occur when the researcher, his/her spouse or registered domestic partner, or dependent children, have a disclosable financial interest that 1) would reasonably appear to be affected by the research; or 2) when the entity in which the financial interests are held would reasonably appear to be affected by the research.

**B.** To assist in evaluating whether a financial interest is related, examples may include:

- The project results could be relevant to the development, manufacturing, or improvement of products or services of the entity in which the researcher has a financial interest.
- The project results could validate a treatment approach that is the same or similar or competitive to the approach developed or offered by the entity in which the researcher has a financial interest.
- The researcher has a financial interest in an entity that might manufacture,
commercialize or license a drug, device, procedure or any other product used in the project or that will predictably result from the project.

- The researcher has a financial interest in an entity and the project proposes to subcontract a portion of the work, or lease property, or make referral of participants to, or make purchases from the entity.
- The researcher has a financial interest in an entity that funds or participates in the project.

VI. What Happens when I Submit an IRB Protocol Document and Indicate that I (or another Investigator) have a Significant Financial Interest to my Human Subject Research Protocol?

A. The Office of Research Integrity team coordinates COI review behind the scenes. Related financial interests disclosed through the IRB process will either have already been reviewed by the COI Review Board, or will be referred to the COI team for assessment. Similarly, if the COI Review Board is prompted to review a human subject Investigator’s significant financial interest(s) reported either through the Annual COI Assurance process or via a transactional COI Reporting Form, the COI Review Board will provide relevant information to the IRB for its consideration.

B. The IRB will then evaluate whether a disclosure in the informed consent form (or other actions) are necessary. If disclosure is required and the Investigator has not already included recommended disclosure language in the informed consent, then the IRB will specify acceptable language for the informed consent.

In section of the informed consent titled “Researcher Financial Interests in this Study:”

“You are being given this information so that you can decide if this interest/relationship [these relationships] affect(s) whether you want to participate in this study. If you have any questions, please contact [the study coordinator/other study party]. He/she will answer any questions you may have.”

<table>
<thead>
<tr>
<th>Situation</th>
<th>Recommended Consent Language</th>
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<tbody>
<tr>
<td>Researcher received compensation for consulting work</td>
<td>Dr. _______ is [the lead researcher] [a researcher] on this study and receives consulting payments from [name of company], the company that is funding this research.</td>
</tr>
<tr>
<td></td>
<td>Dr. _______ is [the lead researcher] [a researcher] on this study and receives consulting payments from [name of company], a company that has similar interests to the company that is funding this research.</td>
</tr>
<tr>
<td>Researcher is a Scientific Advisory Board member</td>
<td>Dr. _______ is [the lead researcher] [a researcher] on this study and is also a Scientific Advisory Board member of the company/foundation that is funding this research. Dr. _______ does not [does] receive money for serving on the Scientific Advisory Board.</td>
</tr>
<tr>
<td></td>
<td>Dr. _______ is [the lead researcher] [a researcher] on this study and</td>
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</table>
is also a Scientific Advisory Board member of a company/foundation that does research in the same area as this study. Dr. ______ does not [does] receive money for serving on the Scientific Advisory Board.

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<tr>
<th>Researcher has stock/equity in the company</th>
<th>Dr. ______ is [the lead researcher] [a researcher] on this study and has stock/equity in [the company/foundation funding the research], the company that is funding this research.</th>
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<tr>
<td>Researcher is on Board of Directors</td>
<td>Dr. ______ is [the lead researcher] [a researcher] on this study and is a member of the Board of Directors of the company that is funding this research [or a company or foundation that is performing research in the same area as this study].</td>
</tr>
<tr>
<td>Researcher is an inventor on a patent or an author on the copyright</td>
<td>Dr. ______ is [the lead researcher] [a researcher] on this study and is an inventor of the [drug, compound, device, etc.] being studied. He/she may benefit financially if the [drug, compound, device, etc.] is found to be helpful and is made available for sale.</td>
</tr>
<tr>
<td>Researcher received honoraria or travel reimbursement</td>
<td>[Brown University may also be involved in the patent and marketing process and, therefore, also has a financial interest in the drug, compound, device, etc.].</td>
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**C. IMPORTANT NOTE:** When a financial interest may affect the protection of human subjects, disclosure to potential human subjects and/or the public may not be a sufficient method of management of the conflict of interest. In such an instance, the COI Review Board and/or the IRB might recommend or require a limited role of certain researchers with financial interests to recruit or consent subjects or to analyze data.

**VII. What if I Disagree with the IRB’s Assessment that a Significant Financial Interest is Related to my Human Subject Research or the Language Requested to be Included in the Informed Consent?**

Ultimately, it is the institution’s responsibility to determine whether a significant financial interest is related to your research and, when it involves human subjects, to decide whether it is necessary to disclose such information to research participants. Any appeal to the institution’s determination must be requested in writing and include a detailed rationale as to why the significant financial interest does not create a financial conflict of interest.