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I. Purpose of this SOP

The purpose of this SOP is to set forth the procedures to be followed by investigators in the identification of actual, potential, or apparent conflicts of interest in their human subjects research. IRB members remain subject to HRPP SOP #208: IRB Member Conflict of Interest.

II. Scope of this SOP

This SOP applies to all human subjects research conducted under the auspices of Brandeis University.

III. Key Definitions

Ad Hoc Disclosures are disclosures of actual, potential, or apparent conflicts of interest made via modification request after the initial application has been submitted and within 30 days of acquiring the interest

Conflict Management Plan is an agreement that sets out limits and restrictions on the investigator for the purpose of reducing or eliminating a conflict of interest that could directly and significantly affect the design, conduct, or reporting of institutional research

Conflict of Interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity

IV. Statement of SOP

It is the standard operating procedure of Brandeis University that all investigators are required to disclose all actual, potential, or apparent conflicts of interest prior to initiating human subjects research conducted under its auspices and within 30 days of the development of a new conflict.

V. Procedures
All investigators and collaborators are required to outline, in the initial protocol (or through a modification request for ad hoc disclosures), all interests that could be construed as being a conflict of interest with the human subjects research they plan to conduct.

Conflicts of interest may necessitate otherwise exempt research to be reviewed as expedited or by the full board, as well as research which otherwise qualifies for expedited review to be reviewed by the full board. During their administrative review of the application or modification, HRPP staff will determine the level of review necessary for the reported interests.

If a conflict of interest is believed by the IRB to exist, the IRB may request additional information from the principal investigator in order to determine whether a conflict does exist, as well as the significance of the conflict and possible strategies for its mitigation.

If a conflict of interest is determined to exist, the investigator may be required to abide by a conflict management plan to mitigate the conflict of interest. If required, the conflict management plan must be in place prior to the initiation (for new applications) or continuation (for ad hoc disclosures) of the human subjects research. Some common strategies required by a conflict management plan include but are not limited to:

- Disclosure on the informed consent form of the conflict
- Re-consenting subjects with an updated informed consent form disclosing the conflict
- Public disclosure of the conflict
- Independent monitoring and oversight of the research
- Removing the conflicted investigator from participation in all or a portion of the research
- Divestiture of interests

VI. Applicable Regulations and Guidance

The Department of Health and Human Services, Office for Human Research Protections offers the following guidance with regards to managing financial conflicts of interest in human subjects research:

1. The regulations protecting human research subjects are based on the ethical principles described in the Belmont report: Respect for persons, beneficence, and justice. The Belmont principles should not be compromised by financial relationships. Openness and honesty are indicators of respect for persons, characteristics that promote ethical research and can only strengthen the research process.

2. Financial interests are not prohibited, and not all financial interests cause conflicts of interest or affect the rights and welfare of human subjects. HHS recognizes the complexity of the relationships between government, academia, industry and others, and recognizes that these relationships often legitimately include financial relationships. However, to the extent financial interests may affect the rights and welfare of human subjects in research, IRBs, institutions, and investigators need to consider what actions regarding financial interests may be necessary to protect those subjects.

3. The Department recommends that in particular, IRBs, institutions, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects.

4. Financial interests determined to create a conflict of interest may be managed by eliminating them or mitigating their impact. A variety of methods or combinations of methods may be effective. Some methods may be implemented by institutions engaged in the conduct of research, and some methods may be implemented by IRBs or investigators. Some of those may apply before research begins, and some may apply during the conduct of the research.