HRPP SOP #208: IRB Member Conflict of Interest

Responsible Office(s): Office of Research Administration
Responsible Official(s): Associate Provost for Research Administration
Effective Date: March 26, 2018
Revision Date:

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I. Purpose of this SOP

The purpose of this SOP is to set forth the procedures to identify and manage conflicts of interest when they arise for members of the Brandeis University IRB when reviewing IRB applications.

II. Scope of this SOP

This SOP applies to Brandeis University IRB members and the review of human subjects research projects conducted under the auspices of Brandeis University.

III. Key Definitions

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 in those instances where an IRB member has a conflict of interest, s/he must recuse him/herself from the review of that human subjects research.

V. Procedures

An IRB member will disclose to the IRB chair any conflicts of interest s/he may have with a particular research application under review by the IRB.

An IRB member may not review any application under expedited review in which s/he has a conflict of interest. If the IRB member finds an application in which s/he has a conflict of interest is assigned for his/her review, s/he will inform the IRB chair and IRB office of the conflict and recuse him/herself from its review. The application will then be assigned to another IRB member for review.

An IRB member will not be present for full-committee review of any application in which s/he has a conflict of interest. If the IRB member finds an application in which s/he has a conflict of interest comes before the committee for review, s/he will inform the IRB chair and IRB office of the conflict and remove him/herself
from the room prior to the committee's review of the application.

After review, the principal investigator (and student researcher, if applicable) will be informed by the IRB administrator of the committee's decision according to usual procedures. If revisions to the application are required, the principal investigator (and student researcher, if applicable) must re-submit his/her revised application for re-review. At the meeting in which the revised application is reviewed, the IRB member with the conflict of interest may be invited to provide information regarding the revised application prior to leaving the room while the committee deliberates the revisions and comes to a decision regarding the application.

If an IRB member recuses him/herself from review, s/he will not be counted to reach the necessary quorum. If a quorum is no longer reached, the application will be tabled and reviewed at the next convened meeting in which quorum is reached without the inclusion of the IRB member with the conflict of interest.

The IRB member's recusal will be listed in the meeting minutes.

Situations in which an IRB member will recuse him/herself:

- The IRB member is listed in the application as a member of the research team, including as PI on a student's research project
- The IRB member has a significant financial interest in the research
- The principal investigator is a member of the IRB member's family
- The IRB member feels s/he has personal biases which may interfere with his/her ability to conduct an impartial review

In addition, the IRB may determine if any of the following reach the level of a conflict of interest:

- The IRB member has a fiduciary relationship with the sponsor of the research
- The IRB member is in competition with the principal investigator for funding, sponsorship, or research subjects
- The IRB member has a relationship with the principal investigator which could influence the judgment of the IRB member in reviewing the research

VI. Applicable Regulations and Guidance

The US government code of federal regulations for the protection of human subjects (45 CFR 46) contains the following requirements involving an IRB member's conflicts of interest:

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. [§46.107(e)]