



SOP: IRB Review of Conflict of Interest

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1 PURPOSE

- 1.1 This procedure establishes the IRB process to review Investigator financial Conflict of Interest (COI) or institutional financial interest related to the research. The IRB is charged with reviewing the executed management plan to ensure that the rights and welfare of participants are protected and that research objectivity is maintained.
- 1.2 The process begins when Northwestern University's COI Office determines that an Investigator or research staff has reported a financial interest Related to the Research or an institution financial interest Related to the Research has been identified.
- 1.3 The process ends when the IRB makes the final decision as to whether the financial interest and its management, if any sufficiently protects the rights and welfare of participants, and allows the research to be approved.

2 PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The Northwestern University Policy on Conflict of Interest and Conflict of Commitment establishes the University's compliance framework to promote objectivity in research.
- 3.2 The Northwestern Conflict of Interest Committee has been established by the University to consider matters in accordance with the University's Conflict of Interest policies.
- 3.3 The IRB ensures that COI Office review is complete and documented in eIRB+. If a conflict exists, a management plan must be uploaded to the COI Management Plan section in eIRB+.
- 3.4 The IRB will consider the COI Management Plan during review to determine whether the investigator's relationship to the research creates a bias that might affect the rights and welfare of the human subject or the reliability of the data.
- 3.5 University policies, "Conflict of Interest in Research (HRP-055)" and "Institutional Conflict of Interest in Research (HRP-054)" and "Institutional Conflict of Interest in Research (HRP-054)", outlines Investigator roles and responsibilities, and requirements for training, disclosure and COI management.

4 RESPONSIBILITIES

- 4.1 The COI Office, IRB Office staff and IRB Members will carry out these procedures:

5 PROCEDURE

- 5.1 The COI Office will conduct a review of all new projects, continuing reviews, and modifications where there is a change of Principal Investigator.
- 5.2 The COI Office will provide the IRB Office with the written management plan so that the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.
- 5.3 IRB Analysts will ensure that all investigators have a COI status of "No Conflict" or "Conflict Managed". There must be a management plan uploaded into eIRB+ by the COI Office for any investigator with a status of Conflict Managed.
- 5.4 If an investigator has a status of Under Review, contact the COI Office to notify them that further IRB action is pending COI review completion.
- 5.5 The IRB Members have eIRB+ access to Investigator COI management plans. The IRB will review any identified conflict of interest and the management plan and determine whether the plan appropriately maintains objectivity, disclosure, and measures to protect the rights and welfare of participants. The IRB analysis of the COI may place additional restrictions on the



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conflicted individuals or the research in its entirety, up to and including disapproving participation of a conflicted individual or disapproving the research. IRBs have final authority to determine whether any disclosed interest and its management allows the research to be approved.

- 5.6 For a pending financial interest at the time of convened IRB review (Under Review), the IRB Analyst should indicate how the review will be conducted and by whom in the pending stipulations.
- 5.6.1 No Action will be required if there is a COI determination of “No Conflict.”
- 5.6.2 Conflict Managed:
- 5.6.2.1 Disclosure in the consent document: The management plan may be reviewed by the IRB Chair or a designee, to ensure the disclosure is appropriately explained and in lay language.
- 5.6.2.2 If a management plan involves more than a simple disclosure, the Designated Reviewer will consider whether it should be returned to the convened IRB for review.
- 5.7 The meeting minutes should document whether a conflict of interest exists, any management plans, and the convened IRB determination of the plan.
- 5.8 For Non-Committee Review, the Designated Reviewer will document whether a conflict of interest exists, any management plans, and their determination in the designated review within the eIRB+ system.

6 MATERIALS

- 6.1 POLICY: Institutional Conflict of Interest in Research (HRP-054)
- 6.2 POLICY: Conflict of Interest and Conflict of Commitment (HRP-053)
- 6.3 POLICY: Conflict of Interest in Research (HRP-055)
- 6.4 SOP: Non-Committee Review Conduct (HRP-032)
- 6.5 SOP: IRB Meeting Conduct (HRP-041)
- 6.6 WORKSHEET: Pre-Review (HRP-308)
- 6.7 WORKSHEET: Criteria for Approval (HRP-314)
- 6.8 NU Faculty Handbook
- 6.9 NU Patent and Invention Policy
- 6.10 NU Staff Handbook
- 6.11 Guidelines for COI Review and Management for Investigators Involved in Research Involving Humans

7 REFERENCES

- 7.1 42 CFR §50
- 7.2 45 CFR §94