

SOP: Undue Influence of the HRPP

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1. PURPOSE

- 1.1. This procedure establishes the process to manage allegations of undue influence of the HRPP.
 - 1.1.1. Undue influence is defined as a real or perceived action that may influence the review of human subjects research outside of the scientific, regulatory and ethical principles that guide review of such research. Such action may include, but is not limited to, attempts to influence decisions based upon financial concerns of the Organization or a department; personnel actions such as denying promotion or tenure; or verbal harassment.
- 1.2. This procedure begins when the [Organizational Official] learns of an allegation of undue influence of the HRPP.
- 1.3. This procedure ends when any undue influence of the HRPP has been mitigated.

2. POLICY

- 2.1. Individuals responsible for business development may not serve as IRB members and may not be involved in daily operations of the review process, and may not discuss business development with IRB members.
- 2.2. Staff may explain written procedures to individuals involved in the review process.
- 2.3. Individuals in the [Organization] may not
 - 2.3.1. Provide information beyond an explanation of written procedures that might influence or appear to influence the review process determinations made as part of the criteria for approval.
 - 2.3.2. Communicate the [Organization]'s financial issues regarding specific protocols to individuals responsible for the review process.
 - 2.3.3. Answer questions about the [Organization]'s business issues posed by individuals responsible for the review process where the answers might influence or appear to influence review decisions.
 - 2.3.4. Attempt to influence the review of human subjects research through real or perceived action on any performance review, promotion or tenure decision of any IRB member, IRB staff or any individual involved in the conduct or review of human subjects research.
- 2.4. When the IRB does not follow written procedures, the [Organization] can require the IRB to re- review the submission and can disapprove research approved by the IRB.
- 2.5. All individuals in the [Organization] are required to ensure that allegations of undue influence of the HRPP or review process are reported to the [Organizational Official] within 5 days of becoming aware of the allegation.

3. RESPONSIBILITY

- 3.1. The [Organizational Official] carries out these procedures or ensures that others carry them out.

4. PROCEDURE

- 4.1. Gather information to determine the veracity of the report using discretion regarding the most efficient and effective methods. Methods to gather information can include, but are not limited to:
 - 4.1.1. Interviews of individuals inside and outside the [Organization]
 - 4.1.2. Review of records inside and outside the [Organization]
 - 4.1.3. Consultation with internal or external entities
- 4.2. If the report has no basis in fact, take no further action under this SOP.

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- 4.3. Take appropriate steps to eliminate the undue influence using discretion regarding the most efficient and effective methods. Steps may include, but are not limited to:
 - 4.3.1. No action
 - 4.3.2. Verbal counseling
 - 4.3.3. Education
 - 4.3.4. Recommend reassignment of duties
 - 4.3.5. Recommend termination of employment
- 4.4. Document the findings and actions, if any, related to undue influence of the HRPP.

5. REFERENCES

- 5.1. 21 CFR §56.109(a), §56.109(f), §56.112, §56.113
- 5.2. 45 CFR §46.109(a), §46.109(e), §46.112, §46.113