



SOP: Undue Influence of the HRPP

Document No.:	Edition No.:	Effective Date:	Page:
HRP-122	001	23 Dec 2013	Page 1 of 2

1. PURPOSE

- 1.1. This procedure establishes the process to manage allegations of undue influence of the HRPP.
- 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 where the discussions might influence or appear to influence review decisions.
- 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, aside from relevant information regarding conflicts of interest.
 - 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.
- 2.4. When the IRB does not follow written procedures, the [Organization] can require the IRB to re- review the submission and/or 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 your 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, document the findings and take no further action under this SOP.
- 4.3. Take appropriate steps to eliminate the undue influence using your 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. Reassignment of duties
 - 4.3.5. Termination of employment



SOP: Undue Influence of the HRPP

Document No.:	Edition No.:	Effective Date:	Page:
HRP-122	001	23 Dec 2013	Page 2 of 2

4.3.6. Evaluate policies and procedures

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