

Standard Operating Procedure (SOP)

SOP #: 401.122	HRP-122 Undue Influence of the HRPP
Executive Owner: Vice President Research Operations	Effective Date: 6/11/2018
	Review Date: 09/23/2019

Scope	This standard operating procedure (SOP) applies to the [Organizational Official] at AdventHealth Orlando.
Purpose	This procedure establishes the process to manage allegations of undue influence of the HRPP. This procedure begins when the [Organizational Official] learns of an allegation of undue influence of the HRPP. This procedure ends when any undue influence of the HRPP has been mitigated.
Qualified Personnel	The [Organizational Official] carries out these procedures or ensures that others carry them out.
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	<ol style="list-style-type: none"> 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. Staff may explain written procedures to individuals involved in the review process. 3. Individuals at AdventHealth Orlando may not <ol style="list-style-type: none"> 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. 3.2. Communicate AdventHealth Orlando’s financial issues regarding specific protocols to individuals responsible for the review process. 3.3. Answer questions about AdventHealth Orlando’s business issues posed by individuals responsible for the review process where the answers might influence or appear to influence review decisions. 4. When the IRB does not follow written procedures, AdventHealth Orlando can require the IRB to re- review the submission and disapprove research approved by the IRB. 5. All individuals in AdventHealth Orlando 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. 6. 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: <ol style="list-style-type: none"> 6.1. Interviews of individuals inside and outside AdventHealth Orlando 6.2. Review of records inside and outside AdventHealth Orlando 6.3. Consultation with internal or external entities 7. If the report has no basis in fact, take no further action under this SOP.

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8. 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:
 - 8.1. No action
 - 8.2. Verbal counseling
 - 8.3. Education
 - 8.4. Reassignment of duties
 - 8.5. Termination of employment
 - 8.6. Document the findings and actions, if any, related to undue influence of the HRPP.

Definition(s)

IRB: Institutional Review Board

Reference(s)

HRPP: Human Research Protection Program

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

Related Documents

Not applicable.

Keywords

IRB, institutional review board, IRB member