AdventHealth Orlando

Standard Operating Procedure (SOP)

SOP #: 401.135	HRP-135 Designated Exempt Review Conduct	
Executive Owner: Vice President Research Operations		Effective Date: 7/15/2015 Review Date: 09/23/2019

Scope

This SOP applies to individuals designated to review and approve exempt <Human Research>.

Purpose

This procedure establishes the process for an individual designated to review and approve exempt <Human Research> to conduct such a review. This procedure begins when an individual designated to review and approve exempt <Human Research> has received a research proposal. This procedure ends when the reviewer has either:

- Approved the proposal as exempt <Human Research>
- Referred the proposal to the IRB

Qualified Personnel

Individuals designated to review and approve exempt <Human Research> carry out these procedures.

Training

Not applicable.

Supplies & Equipment

Not applicable.

Procedure

1. Individuals designated to review and approve exempt <Human Research> are to:
   - 1.1. By January 1 and July 1 of each year, provide the IRB office with a list of approved exempt <Human Research> documented as required by this SOP.
   - 1.2. Maintain the records required this SOP for three years after the last reviewer action or after withdrawal by the submitter.
   - 1.3. Ensure that records are accessible for inspection and copying by the IRB at reasonable times and in a reasonable manner.
2. Review submitted materials.
3. Determine whether the project is <Human Research>.
   - 3.1. Use "WORKSHEET: Human Research (HRP-421)"
   - 3.2. If the project is not or may not be <Human Research>, refer the submission to the IRB.
4. If the project is <Human Research>, determine whether the project can be approved as exempt <Human Research> by using "WORKSHEET: Exemptions (HRP-423)."
   - 4.1. If unsure whether the project is exempt <Human Research>, request that the submitter submit the project to the IRB.
   - 4.2. If not approvable as exempt <Human Research>, request that the submitter modify the project or submit the project to the IRB.
   - 4.3. If approved as exempt <Human Research>, ensure the submitter will comply with:
     - 4.3.1. POLICY: Investigator Obligations (HRP-070)

	4.3.2. POLICY: Prompt Reporting Requirements (HRP-069) 5. Document the project name, investigator name, date approved, and category of exemption 5.1. Project name 5.2. Investigator name 5.3. Date approved 5.4. Category of exemption 5.5. File the records required by "POLICY: IRB Records (HRP-023)"
Definition(s)	IRB: Institutional Review Board
Reference(s)	Not applicable.
Related Documents	Not applicable.
Keywords	IRB, institutional review board, IRB member