

1. PURPOSE

- 1.1. This procedure establishes the process for an individual designated to review and approve exempt <Human Research> to conduct such a review.
- 1.2. This procedure begins when an individual designated to review and approve exempt <Human Research> has received a research proposal.
- 1.3. This procedure ends when the reviewer has either:
 - 1.3.1. Approved the proposal as exempt <Human Research>
 - 1.3.2. Referred the proposal to the IRB

2. POLICY

- 2.1. Individuals designated to review and approve exempt <Human Research> are to:
 - 2.1.1. 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.
 - 2.1.2. Maintain the records required by this SOP for three years after the last reviewer action or after withdrawal by the submitter.
 - 2.1.3. Ensure that records are accessible for inspection and copying by the IRB at reasonable times and in a reasonable manner.

3. RESPONSIBILITY

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

4. PROCEDURE

- 4.1. Review submitted materials.
- 4.2. Determine whether the project is <Human Research>.
 - 4.2.1. Use "WORKSHEET: Human Research (HRP-421)"
 - 4.2.2. If the project is not or may not be <Human Research>, refer the submission to the IRB.
- 4.3. If the project is <Human Research>, determine whether the project can be approved as exempt <Human Research> by using "WORKSHEET: Exemptions (HRP-423)."
 - 4.3.1. If unsure whether the project is exempt <Human Research>, request that the submitter submit the project to the IRB.
 - 4.3.2. If not approvable as exempt <Human Research>, request that the submitter modify the project or submit the project to the IRB.
 - 4.3.3. If approved as exempt <Human Research>, ensure the submitter will comply with:
 - 4.3.3.1. POLICY: Investigator Obligations (HRP-070)
 - 4.3.3.2. POLICY: Prompt Reporting Requirements (HRP-071)
- 4.4. Document the project name, investigator name, date approved, and category of exemption
 - 4.4.1. Project name
 - 4.4.2. Investigator name
 - 4.4.3. Date approved
 - 4.4.4. Category of exemption
- 4.5. File the records required by "POLICY: IRB Records (HRP-023)"

5. REFERENCES

- 5.1. None