



**TITLE:** External Exempt Reviewers  
**PURPOSE:** Departmental review of exempt projects  
**RESPONSIBILITIES:** HSPP Director

**PROCEDURES:**

Allow specific departments who have trained individuals, External Exempt Reviewer (EER), who have sufficient information, training, and knowledge to make a determination of exemption for projects originating from faculty/staff/students within the same department.

1. Individuals designated to be the units' EER will receive a letter from HSPP designating their status.
2. No EER member may review or approve their own research or a research project for which they are an advisor/mentor, collaborator or are listed on the VOTF.
3. The EER may fill the role of the Unit Reviewer and/or Departmental review and also serve as the External Exempt Reviewer as long as item 1 above is met.
4. Each EER must undergo training from the Director before reviewing and approving exempt projects. Training will address:
  - a. Exempt categories and IRB approval criteria in 45 CFR 46.111
  - b. Institutional requirements for conducting human research
  - c. Consent requirements
  - d. Vulnerable populations
  - e. Human research involving HIPAA/FERPA
5. Projects that must be reviewed by the Human Subjects Protection Program (HSPP) are:
  - a. Projects that are federally funded, supported or conducted or become federally funded, supported or conducted after initial approval.
  - b. Any project involving personnel health information (PHI) or FERPA protected information.
  - c. FDA regulated research.
  - d. Research with prisoners, pregnant women, or Native Americans.
6. Modifications to approved projects should follow institutional procedures for amendments to exempt projects. These may be reviewed by the EER without forwarding to the HSPP.
7. Designated EER may be called on to provide consultation for projects requiring expedite or full committee review.

**Submission Requirements**

1. Completed 'F200: Application for Human Research' is submitted to EER in designated department. Submission may be via email if all signatures can be verified.
2. EER reviews the completed application based on training items noted above.
3. If EER approves the research a copy of the completed application and approval are stored according to HSPP storage requirements in UA Box.



4. An approval letter should be sent to the PI/contact using the approval letter template.
5. EER must keep a spreadsheet of all projects and modifications approved. This report is used for auditing purposes by the HSPP.

#### **Approval Letters**

- Each letter will be on the department's letterhead and the original template will be housed in the HSPP office.
- Any changes to the letters will be handled by the HSPP office and redistributed to EER.
- Each letter requires a signature be created and used to authenticate the document.

#### **Project Tracking**

- A tracking spreadsheet will be distributed to all departments.
- The original template will be housed in the HSPP, and any changes to the tracking log will be handled by the HSPP and redistributed to individuals.
- Project numbers will be assigned by the reviewers as follows: YY-###-Departmental Abbreviations.
- Electronic copies of materials reviewed must be kept for auditing purposes as determined by the HSPP.

#### **MATERIALS**

- Tracking Log
- Department Specific Approval letters
- Exempt Level Explanations
- Reviewer Checklist

#### **Revisions to previous:**

- Removed requirement for Exempt reviewer to be designated IRB Member.
- Included description of UA Box for storage of EER reviewed items.