

**INSTITUTIONAL REVIEW BOARD  
HUMAN SUBJECTS PROTECTION OFFICE**

PENN STATE COLLEGE OF MEDICINE  
PENN STATE MILTON S. HERSHEY MEDICAL CENTER

## **TYPES OF REVIEW**

The following review levels and definitions are defined by the Code of Federal Regulations, Title 45, Part 46, published by the Office for Human Research Protections (OHRP).

### **1. EXEMPTION REVIEW**

The DHHS regulations identify certain activities that may be exempt from compliance with the regulations. PSU policy requires that an exemption determination be made by the IRB or assigned IRB staff and may not be an independent determination made by an investigator. See the [Exempt and Expedited Categories](#) list for the types of activities that qualify for exemptions.

### **2. EXPEDITED REVIEW**

Some minimal risk research may be reviewed and approved through an expedited review procedure by the IRB Chair or one or more experienced IRB members. The reviewer(s) may either approve the protocol or refer it for full IRB review. In the event the IRB does not approve the protocol under expedited review, the HSPO will contact the investigator about the next step in the review process. Expedited review may also be used to approve minor changes in the protocol of an approved project.

\* **Minimal Risk** is defined as "the risk of harm anticipated in the proposed research that is not greater, considering the probability and magnitude, than those ordinarily encountered in daily life of a healthy individual or during the performance of routine physical or psychological examinations or tests."

#### Applicability

For a new research project to qualify for expedited review, the following must apply:

- a) Research activities must:
  - Present no more than **minimal risk\*** to human subjects, **and**
  - Involve only procedures eligible as listed in federal regulations ([Exempt and Expedited Exempt Categories\\*](#)).  
*\*Inclusion on this list means that your research may qualify for expedited review by the IRB, but does not guarantee that it will be eligible. The IRB ultimately determines which research meets these criteria. The categories in this list apply regardless of the age of subjects, except as noted.*
- b) Reasonable and appropriate protections must be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.
- c) The expedited review procedure may not be used for classified (e.g., military) research with human subjects.
- d) The standard requirements for informed consent (or its waiver, alteration, or exception) apply.

### **3. FULL REVIEW**

Any research not covered by the conditions of Exemption Review or Expedited Review, including all research which involves more than "minimal risk," or which could not be approved using other review categories, will be referred to the appropriate IRB committee for full (convened) review.

Please contact the Human Subject Protection Office for additional information.