Institutional Review Board

Types of Review

Review Categories

The GSU - IRB will review applications as they are received. There are three categories of review. The extent of the review of the proposal will be based on the following criteria:

- **Exempt Research** – Most research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior in which the identity of the subject cannot be established will be categorized as exempt. This includes collecting or studying existing data, records or specimens, if these sources are publicly available or if the information is recorded in a way that the subjects cannot be identified. The IRB chair makes the determination of whether a research project is "exempt" from further IRB review. Thus, even if an investigator expects that a project will be exempt from research, he/she **must submit** it to the GSU-IRB for review. Investigators will be informed in a timely manner if their protocol has been deemed exempt.

- **Expedited Review** – This includes research in which the probability and magnitude of harm or discomfort anticipated are not greater than those encountered in daily life or during the performance of routine physical or psychological tests. The expedited review procedure may not be used 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. A sub-committee of the IRB will review projects eligible for expedited review, and the investigator will be notified of a decision in a timely manner.

A determination that research is exempt or eligible for expedited review will be communicated to the investigator via the official IRB Decision Letter.

- **Full Committee Review** – Procedures that are potentially harmful to the subjects (even if the investigator views the harm as not unreasonable) are subject to full committee review. The full committee must review research involving prisoners, pregnant women, fetuses, and the seriously ill or mentally or cognitively compromised adults as subjects. Research published with the identity of the subject, invasive collection of body fluid or tissue samples, manipulative observations including deception, or stressful physiological recordings fall into this category. Full Committee Review must take place at a convened meeting of the IRB with a quorum present. Determinations regarding the status of the application will be communicated to the investigator via the official IRB Decision Letter.

Expedited Review

From www.hhs.gov/ohrp

The categorization of human subjects research as "exempt" from IRB review or appropriate for "expedited" IRB review is intended to streamline IRB procedures with no diminution of protection for human subjects.

For expedited review, the IRB Chair or one or more experienced reviewers, designated by the Chair from among members of the IRB, will review the research and approve it or refer it to the IRB for full IRB discussion.

Research Categories for Expedited Review

1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
    a. (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

    b. from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. **Prospective collection of biological specimens for research purposes by noninvasive means.**

    Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. **Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or**

microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. **Continuing review of research previously approved by the convened IRB as follows:**
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.

9. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.**

Full Review

From www.hhs.gov/ohrp

A full board review is required for research that is not eligible for exempt or expedited review. In short, research that is judged to involve more than minimal risk, or involves protected populations such as children, prisoners, or disabled individuals, must undergo a full board review. Individuals intending to conduct research that requires a full board review should allow ample time to complete the review process.

The following categories of research require full IRB approval:

1. Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
2. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
3. Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals).
4. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).