Institutional Review Board

Penn State College of Medicine • Penn State Milton S. Hershey Medical Center

EXEMPT AND EXPEDITED CATEGORIES

EXEMPT CATEGORIES - *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. Only the activities listed below qualify for exemption.*

Note: Exemptions do not apply for research involving prisoners, nor for FDA- regulated research (except category 6).

Exemption 1: Evaluation/Comparison of Instructional Strategies, Techniques or Curricula –
Research conducted **in established or commonly accepted educational settings**, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. *(This category may include children.)*

Exemption 2: Educational Tests, Surveys, Interviews or Observation –
Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior**, **unless**:
(i) information obtained is recorded in such a manner that **human subjects can be identified**, directly or through identifiers linked to the subjects; **and**
(ii) **any disclosure** of the human subjects' responses outside the research **could reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- *When research in this category involves children, this exemption must be limited to the following activities:*
  - *Educational tests (cognitive, diagnostic, aptitude achievement)*
  - *Observation of public behavior where the investigator(s) do not participate in the activities being observed.*

Note: Research with children that involves survey or interview procedures, or observation of public behavior where the investigator(s) participate in the activity being observed cannot be granted exemption.

Exemption 3: Tests, Surveys, Interviews, Observation – Public officials/candidates or federal statutes apply
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the category 2 above if:
(i) the human subjects are elected or appointed **public officials** or **candidates** for public office; or
(ii) **Federal statute(s) require(s**) without exception that the **confidentiality** of the personally identifiable information will **be maintained** throughout the research and thereafter.

Exemption 4: Research with Existing Data/Samples – Publically available or de-identified
Research involving the **collection or study of existing data[1], documents, records, pathological specimens, or diagnostic specimens,** if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. *(This category may include children.)*

- *To qualify for this exemption, the data, documents, records or specimens must be in existence before the project begins.*
- *Under this exemption, an investigator may inspect identifiable records, but may only record information in a non-identifiable manner.*

Exemption 5: Public Benefit or Service Programs –
Research and **demonstration projects** which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. *(This category may include children.)*

- *This category applies to federally funded projects only and requires authorization or concurrence from the funding agency. Specific criteria must be satisfied to invoke this exemption. The category does not apply if there is a statutory requirement that the project be reviewed by an IRB or if the research involves physical invasion or intrusion upon the privacy of subjects.*

Exemption 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies –
Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or [USDA Food Safety].

(This category may include children. This category may be FDA regulated.)

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[1] 'Existing data' means the items exist before the research is proposed to the IRB to determine whether the research is exempt and the data were collected for a purpose other than the proposed research.

EXPEDITED CATEGORIES - *Research involving only minimal risk procedures as identified in the regulations, outlined below, may qualify for expedited review by the IRB Chair or designee in lieu of the convened board review. Minimal Risk is defined in regulations 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."*

Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

1a 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.)

1b 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.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

2a From healthy, nonpregnant 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

2b 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.

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

Examples:
a. Hair and nail clippings in a nondisfiguring 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.

Category 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.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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.)

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

Category 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 eligible for exemption as determined by the IRB in accord with 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.)

Category 8 & 9: Continuing review of research previously approved by the convened IRB as follows:

[... activities in long-term follow-up; or where no subjects have been enrolled and no additional risks identified; or where the remaining research activities are limited to data analysis; or for research not conducted under an IND or IDE where categories 2 - 8 do not apply but the convened IRB determined it involves no greater than minimal risk.]

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[2] Federal law defines "children" as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Under Pennsylvania law, persons under the age of eighteen (18) generally meet the definition of "children".