

IRB Review Types:

There are five types of IRB review: (a) exempt, (b) expedited, (c) full, (d) continuing, and (e) limited.

EXEMPT REVIEW

An **exempt review** doesn't require monitoring by the IRB. Exempt categories are outlined by the Department of Health and Human Services in [45 CFR 46.101\(b\)](#). The significance of an exempt review is that the research activity is not monitored by the IRB. It is important to note that while a project may be exempt from IRB regulations, the ethical principles of conducting human subject research still apply. More importantly, **it is not up to the researcher to determine whether a project is exempt**. Researchers that believe their project is exempt should submit their research application to the IRB, selecting exempt for their category of review. Exempt reviews are carried out by the IRB Chair or their designee.

Exempt types of research include:

- a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on: (1) regular and special education instructional strategies or (2) the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
- b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and (2) 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.
- c. 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 paragraph two of this section, if: (1) the human subjects are elected or appointed public officials or candidates for public office or (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- d. Research involving the collection or study of existing data, 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.

e. Research and demonstration projects which are conducted by or subject to the approval of program or agency heads, and which are designed to study, evaluate or otherwise examine: (1) public benefit or service programs, (2) procedures for obtaining benefits or services under those programs, (3) possible changes in or alternatives to those programs or procedures or (4) possible changes in methods or levels of payment for benefits or services under those programs.

f. Taste and food quality evaluation and consumer acceptance studies: (1) if wholesome foods without additives are consumed or (2) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the United States Department of Agriculture.

EXPEDITED REVIEW

An **expedited review** is typically carried out by the IRB Chair or their designee and involves research that doesn't involve more than minimal risk to participants. Minimal risk is defined as: *the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or through the performance of routine physical or psychological exams/tests*. While the IRB Chair can review and approve expedited review research, the Chair cannot disapprove research proposals without moving the research project to full review.

Under federal regulations certain types of research qualify for an [expedited review](#). These activities: (1) present no more than minimal risk to human subjects and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

a. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.

(1) 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.)

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

b. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:

(1) 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

(2) from other adults and children, considering the: (i) age, weight and health of the subjects, (ii) collection procedure, (iii) amount of blood to be collected and (iv) 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.

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

Examples include: (1) hair and nail clippings in a nondisfiguring manner, (2) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction, (3) permanent teeth if routine patient care indicates a need for extraction, (4) excreta and external secretions (including sweat), (5) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue, (6) placenta removed at delivery, (7) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, (8) supra- and sub gingival 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, (9) mucosal and skin cells collected by buccal

scraping or swab, skin swab or mouth washings, (10) sputum collected after saline mist nebulization.

d. 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: (1) 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 subjects privacy, (2) weighing or testing sensory acuity, (3) magnetic resonance imaging, (4) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow and echocardiography, (5) moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight and health of the individual.

e. 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 federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

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

g. 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 federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

h. Continuing review of research previously approved by the convened IRB as follows:

(1) 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

(2) where no subjects have been enrolled and no additional risks have been identified; or

(3) where the remaining research activities are limited to data analysis.

i. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories b through h 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

A **full review** is necessary when the IRB Chair deems participant risk is more than minimal or when the Chair disapproves an expedited review and moves the research project to full committee review. If your research doesn't meet the aforementioned criteria under exempt and expedited reviews, please submit your research as full review.

CONTINUING REVIEW

A **continuing review** is necessary when a research project is not complete after one year. A continuing review reevaluates a project's: (a) risks, (b) benefits, (c) informed consent and (d) participant safeguards. If it is deemed that there is less than minimal risk for participants, the continuing review will be reviewed by the IRB Chair. If there is more than minimal risk, the project will be reviewed by the full IRB. Full reviews require the researcher to provide a summary protocol and a status report on: (a) the number of subjects accrued or withdrawn, (b) a summary of adverse events, (c) any research complaints received, (d) new risks that may be present, (e) new informed consent and (f) summary of any new literature regarding the research topic. As part of continuing review, researchers must submit a closure form to the IRB when they have completed their research.

LIMITED REVIEW

Limited IRB review is required for certain exemptions and does not require an IRB to consider all of the IRB approval criteria at §46.111.

There are 4 exemptions that may require it:

- **Exemption 2:** Educational tests/surveys/interviews/observations of public behavior – if identifiable information is recorded, limited IRB review is required to protect privacy and confidentiality.
- **Exemption 3:** benign behavioral research – same as Exemption 2.
- **Exemption 7:** Storage and maintenance of identifiable private information or biospecimens for secondary research use obtained with broad consent – limited IRB review is required to determine that the elements of broad consent are met, that it is appropriately documented or documentation has been waived; and that there are adequate provisions to protect privacy and confidentiality.
- **Exemption 8:** Secondary research involving identifiable private information or identifiable biospecimens obtained with broad consent – adequate provisions to protect privacy and confidentiality and that the research is within the scope of the broad consent.

What is limited IRB review?

The revised Common Rule requires studies that are minimal risk, qualify for exempt review, and maintain subjects' identifiable information or identifiable biospecimens, to include a "limited IRB review" whereby the security, privacy, and confidentiality of identifiable private information are adequately protected.

Limited IRB is increased oversight by the IRB for low-risk research (e.g. certain exempt categories) to ensure that either:

- The identifiable private information or biospecimens collected have the appropriate data security and privacy protections in place to reduce the chance of inappropriate disclosure; or
- Broad consent was obtained for the use of stored identifiable data or biospecimens.

How is limited IRB review conducted?

The IRB will conduct limited IRB review during the initial review of the submitted project. In addition, Investigators are required to submit changes to the IRB when the context or conditions of the original limited IRB review change. (e.g. if the location for the storage and protection of the data change). Continuing review of research is not required for research that had limited IRB review.

The IRB will assess whether the data collected as part of the proposed study require increased protections based on the following criteria:

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;

- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.