The Christ Hospital Health Network

Institutional Review Board

Types of IRB Review
-Exempt, Expedited and Full Board-

Research that involves human subjects may be either exempt from IRB review, undergo expedited review, or full board review under certain circumstances. The 3 types of IRB review are Exempt, Expedited, and Full Board.

Exempt from IRB Review consists of review of minimal risk[i], non-FDA-regulated research and subsequent exempt determination by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.104.

Expedited Review consists of a review of minimal risk research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

Full Board Review consists of a review of greater than minimal risk research involving human subjects by the convened IRB in accordance with the requirements set forth in 45 CFR 46.109.

A. Categories of Research that are EXEMPT [as referenced in 45 CFR 46.104]
Note: These categories do not apply to FDA-regulated research or greater than minimal risk research.

Category #1	Education Research Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior and: • Recorded information cannot readily identify the subject (directly or indirectly/linked) *OR* • Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation) Examples: A program evaluation of pharmacy continuing education Evaluating the use of accepted or reviewed standardized tests Testing or comparing a curriculum or lesson
Category #2	Surveys, Interviews, Educational Tests, Public Observations Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior and: • Recorded information cannot readily identify the subject (directly or indirectly/linked) *OR* • Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation) Examples: Surveying teachers, nurses, or doctors about a technique or an outcome Interviewing managers about a management style or best practice Conducting a focus group about an experience or an opinion of a community program

Category #3	Benign Behavioral Interventions Research involving Benign Behavioral Interventions through verbal, written responses, (including data entry or audiovisual recording) from adult subjects who prospectively agrees and ONE of following met: • Recorded information cannot readily identify the subject (directly or indirectly/linked) *OR* • Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation) Examples: Being exposed to stimuli such as color, light, sound (at safe levels) Solving puzzles under various noise conditions Performing cognitive tasks
Category #4	Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens Secondary research with identifiable Information/specimens collected for some other initial activity, if *ONE* of following: • Biospecimens or information is publicly available • Information recorded so subject cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects • Collection and analysis involving Investigators Use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes" • Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities Example: Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers.
Category #5	Federal Research or Demonstration Projects Research and demonstration projects supported by a Federal Agency/Dept. *AND* designed to study, public benefit or service programs. Note: Federal agencies must publish a list of projects covered by this exemption prior to research commencing
Category #6	Taste and Food Evaluation and Acceptance Studies Taste and food quality evaluation and consumer acceptance studies, • if wholesome foods without additives are consumed *OR* • 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 U.S. Department of Agriculture.
If the criteria for one of the above exempt categories are met, the research is considered Exempt from IRB Review. The Exempt Application is required for review and designation of exempt status.	
B. Categories of Research that are EXPEDITED [as referenced in 45 CFR 46.110 and 21 CFR 56.110] Note: Research may fall into more than one category.	
Category #1	Clinical studies of drugs and medical devices only when condition (a) or (b) is met. a) Research on drugs for which an investigational new drug application (IND) 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.), *or* b) Research on medical devices for which (i) an investigational device exemption application (IDE) is not required; or (ii) the medical device is approved (cleared) for marketing and the medical device is being used in accordance with its approved (cleared) labeling.
Category #2	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a) Collected 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) Collected from other adults and children, 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	Research that proposes the prospective collection of biological specimens for research purposes by non-invasive 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
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 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 in this document 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 involving 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. 46.101(b)(2) and (b)(3).
Category #8	Continuing review (i.e. renewal) 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.
Category #9	Continuing review (i.e. renewal) 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.

C. FULL BOARD [as referenced in 45 CFR 46.110]

Research that meets does not meet exempt or expedited criteria. In addition, if the proposed research involves any of the following, it will require full board review.

- Children under the age of 18
- Prisoners
- Individuals with impaired decision-making capacity
- Economically or educationally disadvantaged persons
- Procedures that might cause physical harm
- Procedures that might cause significant psychological/emotional distress
- Collection of information about highly sensitive topics
- Collection of information about illegal behavior
- Collection of identifiable information that could seriously harm the participant legally, socially, financially, etc.

[i] Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests