CHAPTER 6 Types of IREC Review: Exempt, Expedited, and Full Board

Research involving human subjects requires IREC review under one of the following three levels: exempt, expedited, or full-board. Studies involving minimal risk* (or less than minimal risk) generally qualify for review at the exempt or expedited level. For studies that are deemed greater than minimal risk, review by the full-board is required. An explanation of each review level is described below.

** "Minimal risk" is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".*

EXEMPT REVIEW

Exempt research involves research with human subjects, but because of its nature and "minimal risk" it is "exempt" from IREC oversight. The following are exempt categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.**
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (b) 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.**
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement).
4. Research involving the collection or study of existing data, documents, records, pathological 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.

***Studies involving children can only be exempt if the PI plans to only observe and not interact with the children.*

Exempt 2 may not be used for minors.

EXPEDITED REVIEW

If the level of risk in a research project is considered to be no greater than minimal, and the research meets at least one of the expedited categories below, the IREC may review the project as expedited. Expedited review covers the same considerations as a full committee review; however the project can be reviewed and approved by the IREC Chair or one Designated Reviewer, rather than the whole convened IREC

committee. In reviewing research, expedited reviewers may exercise all of the authorities of the IREC, except the reviewer may not disapprove the research. In this case, the expedited reviewer must defer review to the full IREC committee. The expedited categories include:

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults. 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, 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.
2. Prospective collection of biological specimens for research purposes by noninvasive means.
3. 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).
4. 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.)
5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. 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.

FULL BOARD REVIEW

Studies that involve more than minimal risk require full board review at a convened meeting, at which a quorum of IREC members is present, including a community member. For the research to be approved, it must receive the approval of a majority of those members present. While federal regulations do not specifically list categories that would fall under full board review, below are certain criteria that may require full board review.

1. Clinical procedures involving drugs, devices, or biologics;
2. Studies using vulnerable populations;
3. Studies where information may be disclosed to researchers that could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.);
4. Studies involving deception which raise the risk level;
5. Studies where the IREC chair determines to be greater than minimal risk.