The Office of Human Research Ethics

The University of North Carolina at Chapel Hill

The 9 Expedited Research Categories for IRB Members

Federal regulations allow an IRB chair or their designee to approve certain types of research applications instead of going to full board. These reviews are called "expedited reviews." They're limited to certain types of minimal risk research that fall into one of nine categories defined by federal regulations.

This video...

- explains the regulatory framework for expedited review of human subject research,
- breaks down the nine Expedited Review Categories, and
- illustrates how board members can apply the categories to distinguish minimal risk from greater than minimal risk when determining the overall risk level of studies they review.

What is Expedited Review?

At UNC, about 95% of IRB submissions are approved through Expedited Review by experienced IRB analysts, IRB chairs, and vice chairs. Board members are informed about these reviews in the IRB meeting agendas.

Why Should IRB Members Be Familiar with the Expedited Review Categories?

Understanding Expedited Review categories helps board members distinguish minimal risk from more-than-minimal research risk, which can be tricky, because the terms "ordinary" and "routine" are somewhat subjective.

The Expedited Review categories provide clear examples of activities that can be considered minimal risk in the eyes of federal regulators.

Expedited Review Categories

Category 1: Clinical Studies of Drugs and Medical Devices

This category covers clinical studies of drugs and devices when neither an Investigational New Drug (IND) application nor an Investigational Device Exemption (IDE) is required. It also applies when the research involves a medical device that is being used according to its cleared or approved labeling.

For example, if the study uses a new scale to rate headache relief of over-the-counter ibuprofen taken according to labeling in healthy adults, or it compares data accuracy and user preferences for two commercially available at-home vaginal swab kits, expedited review is appropriate.

However, if the aim is to study headache relief of over-the-counter ibuprofen at triple the recommended dose, or to compare the effectiveness of a new type of pill camera used to diagnose Crohn's Disease, then expedited review is not appropriate.

Category 2: Blood Sample Collection by Finger Stick, Heel Stick, Ear Stick, or Venipuncture.

The volume limit of blood collection is differentiated based on the participant population. Healthy adults who aren't pregnant can give up to 550 mL in 8 weeks. Others, such as minors and patients with active disease, can give up to 50 mL or 3 ml/kg in 8 weeks.

If blood sampling will occur more than 2 times per week, neither study is eligible for expedited review.

A full board would not need to review a research application studying glucose levels obtained by 5 mL venipuncture before and sixty minutes after children ages 14-17 consume a Diet Dr. Pepper.

A full board would need to review a research application studying blood glucose levels obtained by 5 mL venipuncture before and sixty minutes after three low-fat meals consumed on consecutive days in healthy adults, because the blood draw frequency falls outside the expedited review limitation.

Category 3: Noninvasive Biological Specimen Collection

This includes the prospective collection of biological specimens for research purposes using methods that are noninvasive.

For instance,

- hair and nail clippings that are non-disfiguring,
- teeth extracted for clinical care,
- saliva or sweat,
- amniotic fluid during delivery,
- buccal swabs and sputum after saline mist,

are all usually considered noninvasive.

Studies that obtain samples by swabbing past the opening of the cervix, the rectum, or past the internal nares require full board review because the methods are considered more than minimal risk.

Category 4: Noninvasive Clinical Data Collection

This category involves collecting data through noninvasive procedures routinely used in clinical practice such as MRI, ultrasound, hearing tests, and moderate exercise tests where appropriate given the age, weight and health of the individual fall into this category.

Studies involving X-rays, microwaves, or general anesthesia or sedation do not.

Expedited review would be okay for a study that will measure body composition using skin calipers or bioimpedance methods, but not a study using DEXA, which is an x-ray technique.

Category 5: Use of Existing Materials

Research using data, documents, records, or specimens that were collected for non-research purposes, such as medical treatment. Medical records research is the most common type eligible for expedited review under this category.

For example, a study that aims to analyze immune biomarkers in discarded healthy and diseased tissue obtained from renal cancer patients during standard of care surgery may be approved through expedited review.

A study that aims to study cocaine levels in identifiable cord blood samples collected after birth may not, because the legal risks could be greater than minimal.

Category 6: Recordings for Research

This category includes the collection of voice, video, digital, or image recordings made specifically for research.

For example, studying the religious and spiritual content in audio recorded poems obtained from students at a public poetry slam event. Expedited Review is appropriate.

However, evaluating religious and spiritual content of facial tattoos obtained using full face photography among ex-gang members could increase legal risk. Studying emotional processing during video and audio recorded exposure therapy sessions in childhood abuse survivors could increase psychological risk. Therefore, these two studies would require full board review.

Category 7: Behavioral and Social Research

Studies that fall into this category focus on individual or group characteristics or behavior.

If the study seeks to interview college freshmen about their class summer reading assignments and comparing satisfaction ratings across U.S. colleges and universities or compare body image in teens who attend private versus public school using a validated body image questionnaire, Expedited Review would be appropriate.

However, if the study plans to conduct group interviews of teens transitioning from inpatient to outpatient psychiatric care to assess home factors that relate to their mood and self-harm behaviors, the full board may need to evaluate the risk management plans in detail

Category 8: Continuing Review of Greater than Minimal Risk (Full Board) Studies Submitted for Renewal

Expedited Review can be used to approve a greater than minimal risk study for annual renewal under certain circumstances.

Expedited Review is used to renew studies that,

- are open to enrollment but have not enrolled any new participants in the past year and have not identified any new risks.
- have been closed to enrollment for the past year and are either in long-term follow-up only or are in data analysis only, such as
    - a cancer study where all treatments are done, and only follow-up surveys remain, or
    - a cognitive behavioral therapy intervention study which completed long-term follow-up of all participants and is now moving into data analysis.

This category allows for the renewal of full board studies to eventually shift from the convened board to the expedited review process as study risks change over time.

Category 9: Continuing Review of Research Determined by the Board to be Minimal Risk

If a study does not fit in categories 2-7 at initial review, board may still determine that the planned research procedures pose no more than minimal risk to the participants in that study. There are several common procedures that a convened board may decide are minimal risk:

Returning to our example from Category 2, venipuncture that is only slightly different than the limits for volume or frequency, or that occurs in a patient population that the board considers "healthy". For example, patients with pre-diabetes who manage their condition with lifestyle modifications rather than medications. The board may decide that expedited review is appropriate for a study drawing 550 mLs of blood from patients with prediabetes because they see them as "healthy."

Returning to our example of Category 3 involving routine clinical procedures except for X-rays. Based on their understanding of the risks of a single DEXA scan, the board may determine that the study poses minimal risk to participants, and that expedited review is appropriate.

If you are assigned as a Primary or Secondary Reviewer on a new submission and you think Category 9 may be appropriate, you are expected to provide your rationale in your presentation, For instance, you might reference published guidelines from national organizations regarding blood draw safety, or the UNC Radiation Safety Subcommittee's published risk guidelines for different X-ray procedures.

Conclusion

Understanding the expedited review categories supports board members' reasoning about a study's overall risk level. IRB members must consider the specific circumstances of each proposal separately when deciding if a study is eligible for expedited review. The Reviewer Template for Initial Submissions lists the Expedited Review Categories.

Expedited Review is not a shortcut. The same ethical considerations and regulatory criteria for approval apply during expedited review and convened board review. Expedited reviewers may engage the convened board at any time if they're uncertain that all criteria for approval are met. The board can offer different perspectives and types of expertise in the review.

Expedited Review is not necessarily faster, but it does provide a pathway for reviewing minimal risk research. That allows the convened board to concentrate its efforts on greater than minimal risk research.

Thank you for your commitment to protecting human subjects in research and thanks for watching!