Category 9 --Only the IRB can declare a Cat 9

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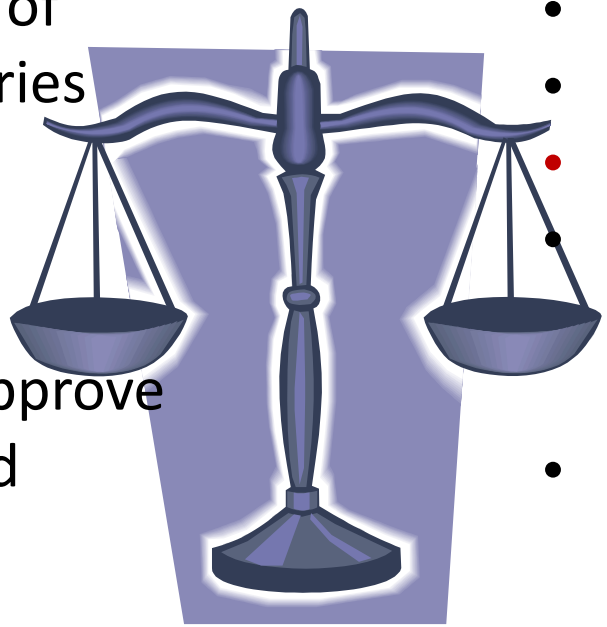
To Be or Not To Be – Full Board or Expedited Review, That is the Question!

Expedited Reviews

- One of **#1-8** on list of Expedited Categories of research
- Minimal Risk
- Not FDA
- Only Approve or approve with stips allowed



Full Board Reviews

- #9 of Expedited
- Categories –ONLY IRB
- More than minimal risk
- Require IRB assessment of risk level, i.e. Minors, vulnerable populations,
- Those issues needing review, discussion by the full board.

Minimal Risk

45 CFR 46.102(i) defines minimal risk 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*** ***(for the average person, not the daily life of someone ill)*** ***or during the performance of routine physical or psychological examinations or tests."***

Levels of IRB Review

Human Subjects Research

Greater than Minimal Risk	Full Board Review
Minimal Risk? 9 Categories defined by OHRP	Expedited
Is it on the list? 8 Categories defined by OHRP	Exempt
Is UNC Engaged	Not under UNC's IRB purview
2. Are there Human Subjects? 1. Is it Research?	Not Human Subject Research

Risk

Expedited Category 9

Continuing review 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.*

Expedited Category 9

(9) Continuing review of research previously approved by the IRB at a convened meeting that meets the following conditions:

- No IND or IDE;
- Expedited rcategories (2) through (8) do not apply to the research;
- ***The IRB has determined and documented at a convened meeting that the research, or the remaining research activity involving human subjects, involves no greater than minimal risk to the subjects; and***
- **No additional risks of the research have been identified**.

(**Note:** ***"no additional risks have been identified"*** means that neither the investigator nor the IRB has identified any additional risks from any institution engaged in the research project or from any other relevant source since the IRB's most recent prior review.)

Expedited Review Categories

1. Studies of drugs and medical devices when no IND or IDE is needed.

2. Blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. Biological specimens for research purposes by "noninvasive" means.

4. Data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

5. Materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes. Evaluation of public benefit service programs

6. Data from voice, video, digital, or image recordings made for research purposes.

7. Research employing survey, interview, oral history, focus group, etc.

8. Continuing review where: (a) only-follow-up remains, (b) no subjects enrolled, or (c) only data analysis remains.

9. Continuing review where:
(1) not conducted under an IND/IDE,
(2) other expedited categories n/a, **and**
(3) Board considers minimal risk.

Types of Risk per 45 CFR 46.101.b.2.I & ii

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**."

Additional Examples

- **Physical** (e.g. pain, drug side effects, or injury)
- **Psychological** (e.g. emotional distress)
- **Social** (e.g. stigmatization)
- **Economic** (e.g. loss of job—breach of confidentiality that relates to stigma, or workplace competency issues)
- **Legal** (requirements to report some illegal activities, whether the focus of the study, or which emerge without prompting)

Example 1

- Study of 18-21 age college students' drinking & smoking habits
- On-line survey responses collected
- 600 ml of blood collected for genetic analysis
- Identifiers kept through data collection year 1, then anonymized
- Year 2 & 3 data analysis & publication only
- What is the justification for the action & documented in the minutes?

Example 2

- Clinical study of diabetes in both children & adults, a 2-year pilot study.
- Objective: Are there markers to indicate future diabetes risk -- either genetic or environmental.
- Collecting blood specimens, surveys of lifestyle habits—job exposures, food consumption, domestic & international travel, age of diagnosis
- Year 1 data collection, Year 2 analysis
- What is the justification for the action & document in the minutes

IS Continuing Review Needed?

- What is the risk level?
- Is Continuing Review Needed?
- Is Documentation Required?