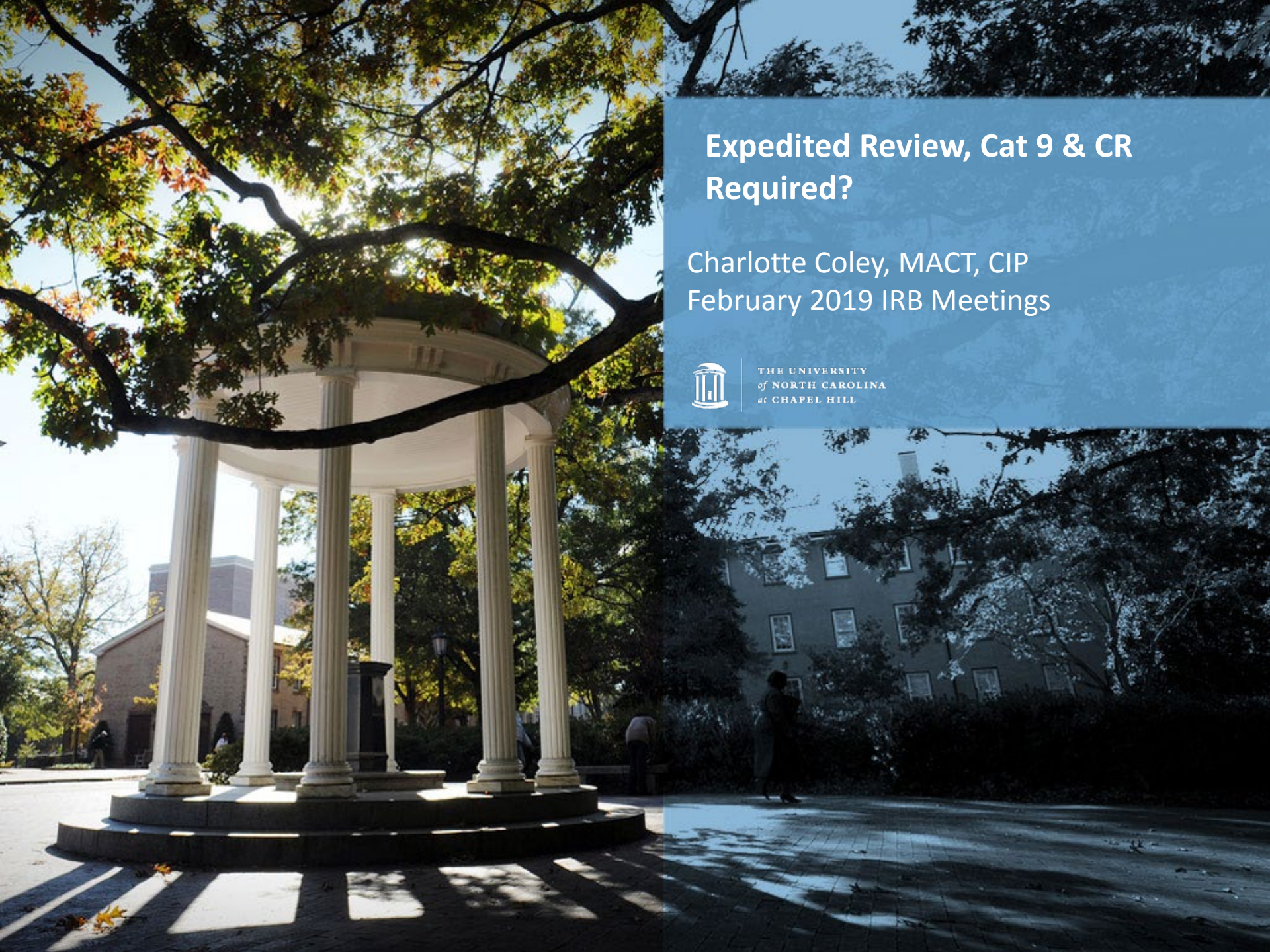

Expedited Review, Cat 9 & CR Required?

Charlotte Coley, MACT, CIP

February 2019 IRB Meetings

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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 or during the performance of routine physical or psychological examinations or tests."***
- The IRB makes the determination of risk level.
- Minimal risk studies may qualify for exemption or expedited review.

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 Review

- Involves no greater than minimal risk or…
- Involves a minor change in previously approved research
- May be carried out by IRB Chair or designee
- IRB may choose to provide additional measures of protection
- Described in (45 CFR 46.110 and 21 CFR 56.110)—must be “on the list” (63 FR 60364-60367, November 9, 1998)
- Can only approve &/or request changes
- Can NOT disapprove an expedited study, requires full board 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)

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.*

Category 9

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

- The research is not conducted under an investigational new drug application (IND) or an investigational device exemption (IDE);
- Expedited review categories (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.)

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 & document 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?