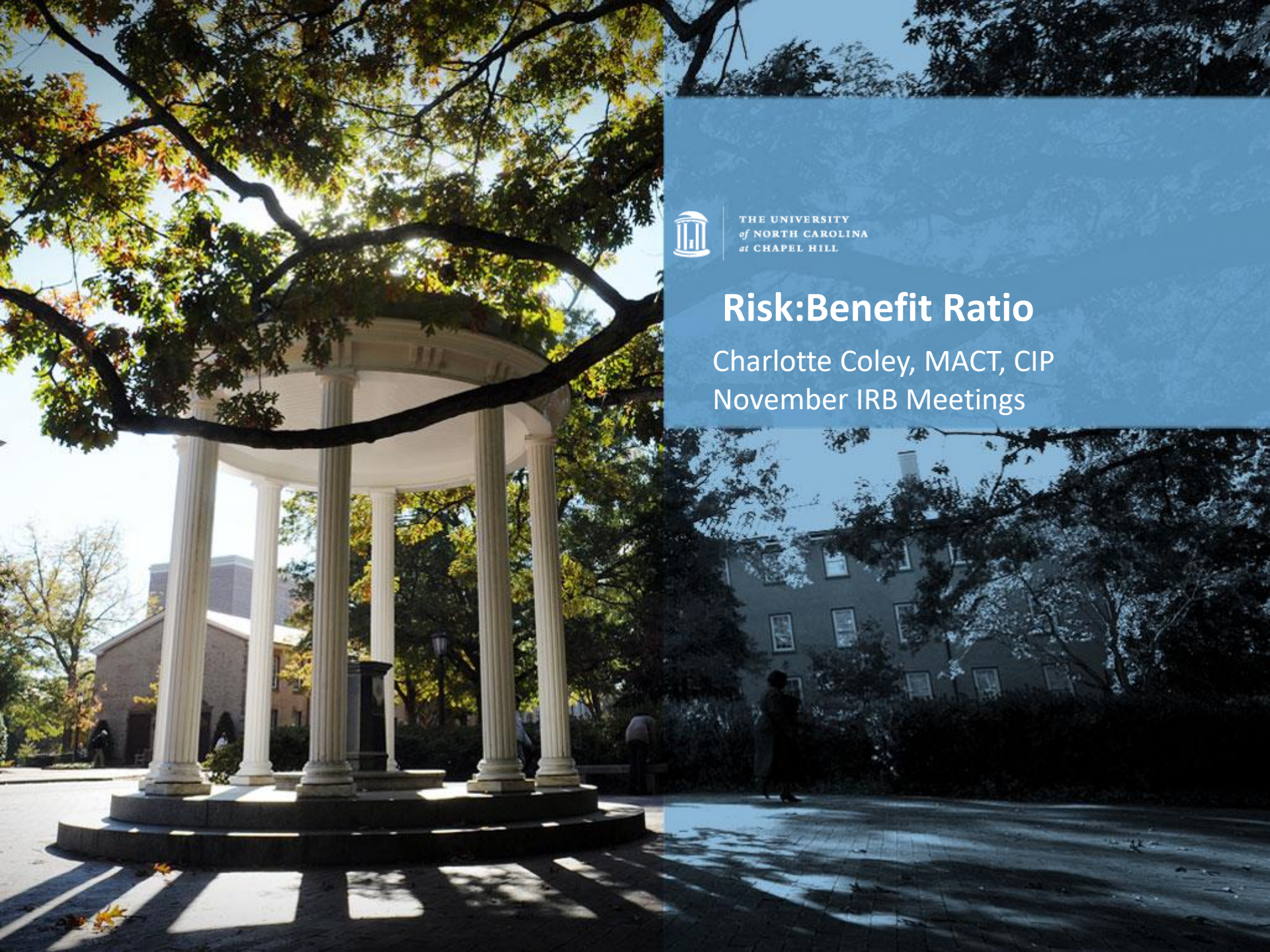

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

# Risk:Benefit Ratio

Charlotte Coley, MACT, CIP

November IRB Meetings

# What Color is Your Lab Coat?

# Definitions

- Research: a *systematic* investigation designed to develop or contribute to *generalizable knowledge*
- Human subject: a (~~*living*~~)* individual about whom an investigator conducting research obtains:
  - Data through intervention or interaction with the individual, **or**
  - Identifiable private information

* HIPAA (Health Insurance Portability & Accountability Act of 1996) Change

# 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.

# Risk/Benefit Ratio

"Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."

*Institutional Review Board Guidebook, 1993*

# 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)

# Levels of IRB Review

- **EXEMPT** – Applies to specific categories of research, most often with extremely low risk or anonymous data
- **EXPEDITED REVIEW** – Applies to specific categories of research with no more than minimal risk.
- **FULL COMMITTEE REVIEW** – All studies which do not qualify as exempt or expedited must be reviewed by a full IRB.

***Note:*** ***The level of review is determined by IRB, not by the investigator or by the client. The requirements for each level are given in the regulations.***

# Level of Risk Generally Determines Level of IRB Review


**Minimal Risk?** — **Full Board Review**

**Is it on the list?**
**9 Categories defined by Regs** — **Expedited**

**Is it on the list?**
**6 Categories defined by Regs** — **"Exempt"**

**2. Are there Human Subjects?** — **Not Human Subjects Research**

**1. Is it 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.

# Food and Drug Administration (*FDA*) Regulations Related to Human Research

## Some studies are also covered by FDA regulations

- Drugs (including nutritional supplements)
- Devices (*including mobile apps, software,*)
- Biologics
- FDA regulations differ from 45 CFR 46 in areas of reporting of adverse events, informed consent waivers, and confidentiality.

# Category 9 & FDA

- 21 CFR 56.109 (c): (1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form ***if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or***

# Category 9 & FDA

Remember by definition a study involving a drug (IND) or device (IDE) is always more than minimal risk and waivers do not apply; nor would Cat 9 for continuing review.