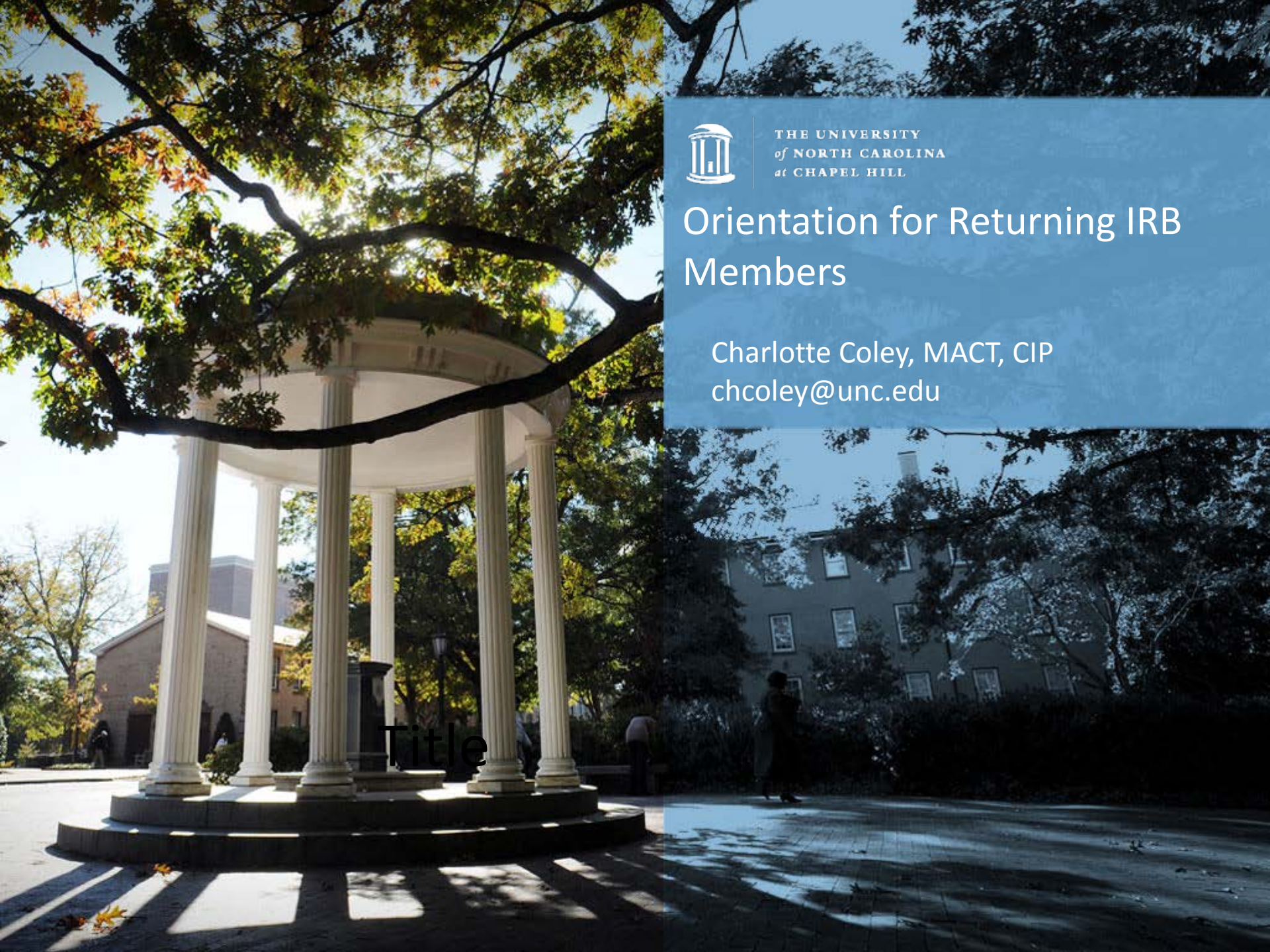
THE UNIVERSITY
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at CHAPEL HILL
Orientation for Returning IRB Members
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Title

What is an IRB?
(Institutional Review Board)

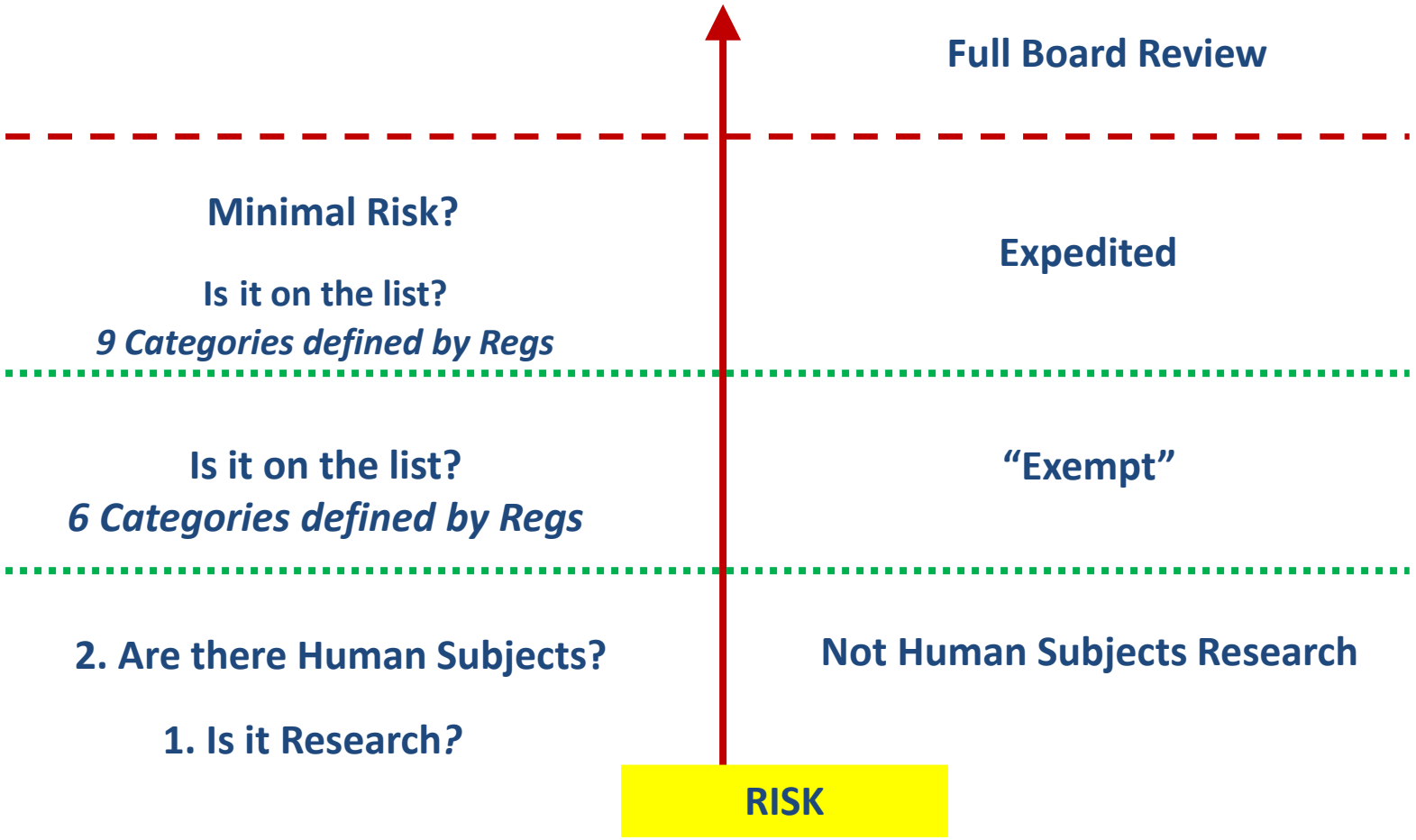
- A committee **mandated by federal regulations**.

- ***Protects the rights and welfare of human subjects*** in research activities through independent review of proposed research.

The Belmont Report

- Respect for persons: Informed consent
  - Individual autonomy
  - Protection of individuals with reduced autonomy
- Beneficence: Assessment of risks & benefits
  - Maximize benefits & minimize harms
- Justice: Selection of subjects
  - Equitable distribution of research costs & benefits

Level of Risk Generally Determines Level of IRB Review



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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.*

Types of Risk

- **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)

Criteria for IRB Approval

Whether expedited or full committee review

1. Risks minimized
2. Favorable risk:benefit ratio
3. Equitable selection of subjects
4. Informed consent sought
5. Informed consent documented
6. Monitoring plan for safety
7. Privacy and confidentiality protected
8. Additional safeguards for vulnerable populations

45 CFR 46.111 & 21 CFR 56.111
OHRE SOP 24.0

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

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**."

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

Protected Health Information - "PHI"

18 HIPAA Identifiers

1. Name
2. Address (Street, City, Zip except for first 3 digits)
3. Dates (all elements directly related to individual; all ages >89)
4. Telephone number
5. FAX number
6. E-mail address
7. Social Security Number
8. Medical Record Number
9. Health Plan Beneficiary Numbers
10. Account Numbers
11. Vehicle identifiers (e.g., serial numbers and license plate numbers)
12. device identifiers and serial numbers
13. URL addresses
14. Biometric identifiers (e.g., finger or voice prints)
15. Full face photographs or comparable images
16. Internet Protocol address numbers
17. Any other unique identifiers
18. Certificate or Professional License Numbers

Confidential vs. Anonymous

- ***Anonymous*** means the research participant's identity is not known, even to the interviewer.

- ***Confidential*** means we have identifying information about the research participant (in some cases, only a phone number and/or first name) but will not reveal that information to anyone.
- ***Privacy*** means freedom from unauthorized intrusion *<one's right to privacy>* ***Merriam-Webster Dictonary***

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

Some studies are also covered by FDA regulations

- Drugs (including nutritional supplements)
- **Devices (including mobile apps, software, etc)**
- Biologics

Limits of IRB Approval

- Valid for ***no more than 1 year*** and not 5 minutes longer,
- Authorized to do **ONLY** what is in the protocol as approved by the IRB,
- ALL changes **MUST** be submitted to the IRB for review and approval ***PRIOR*** to implementation of the change(s)

UNC IRB Process

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IRB Office Basic Facts

- ~ 6000 active protocols/year
- ~12,000 activity items/year
- 6 IRBs
- 6 IRB Chair and Vice-Chairs
- 2 Senior IRB Analysts & 6 IRB Analysts
- 4 Managers: QA/QI; Compliance; Education & Training and Data & Information
- 4 Administrative staff

IRB Member Responsibilities

1. Your mandate is to protect those who volunteer to be research subjects.
   - They are your only priority as an IRB member.
   - This is done by balancing the study risks against potential benefits; remember Beneficence.
2. Recuse yourself if you have a conflict of interest
3. Be prepared
   - Read & review all protocol submissions on the agenda
   - Prepare and upload your Primary or Secondary Review **PRIOR** to the meeting
4. Make a succinct, organized presentation to the IRB Meeting Members.
   - Use the guides for preparing an oral presentation or create your own guide & upload into IRBIS.
5. Allow for other perspectives and viewpoints. Dissention is OK, even encouraged.

How to Review & Present Protocols as the Presenter

Pre-Meeting:

- Begin early, so you have time to get answers to any questions you may have about the research.
- Reading the consent form first. , it will give you an overview of the study. If you don't understand it, then subjects won't either. Also, great way to see disconnects between it and the protocol.
- Call the PI or Coordinator with any questions you have.
- Only ask for clarification or additional information about a study. **NEVER** direct the study team to make any changes to their study at this point. ***Until the IRB votes on stipulations, there are no changes to be made.***
- Read the following sections of the study submission or protocol:
  - Primary & secondary objectives
  - Study design
  - Recruitment
  - Safety Plan

How to Review & Present Protocols as the Presenter

Pre-Meeting:

- Read the Investigational Brochure (IB) for:
  - FDA information on the Investigational New Drug (IND)
  - Study drug pregnancy rating
  - Is this a new drug or new indication or route of administration for an approved drug?
- Identify and resolve, if possible, deferrable issues ***PRIOR*** to the meeting. Communicate with the study team or IRB Analyst ***early*** to reduce the chances of deferral at the meeting
- **Alert the Chair** of any potentially deferrable or controversial issues **PRIOR** to the meeting for **ANY** study on the agenda.
- **Draft recommended solutions** to controverted issues for presentation at the meeting.

At the Meeting

Be brief: Present key issues as outlined below.

- **Provide a 3-5 minute review of key points in your oral presentation .**
  - One sentence description of the study objectives;
  - Short summary of the study design;
  - Short summary of risks, benefits;
  - Identification of subjects (is a HIPAA waiver needed to ID potential subjects?);
  - How the consent process will occur; and
  - If applicable:
    - evaluate the pediatric risk level and/or appropriateness of inclusion of children,
    - inclusion of vulnerable groups in the study -- pregnant women, prisoners, adults incapable of consent
    - IND/IDE status of investigational drugs/devices/biologics, remember to consult the information sheet provided by staff

At the Meeting

Address any conditions of approval, such as:

- Legally Authorized Representative (LAR)
- Declaration of Concordance if NIH funded,
- If children in the study, what is your recommendation for risk level and number of parent signatures
- Recommend Category 9 eligibility at the time of Continuing Review to allow future expedited review of the study. If the study is no greater than minimal risk and does not involve an IDE/IND.
- Recommend any stipulations citing specific sections to be modified. All stips should be entered in the appropriate section.

At the Meeting

Make your final motion to:

- Approve, including period of approval, approval for LAR or not; child risk level & number of parents to sign the consent and any other regulatory findings as appropriate.
- Based on the risk assessment by the IRB, the approval period can be 1-year or less than 1-year or can be less (3, 6, or 9-months), ot after enrollment of “X” number of subjects.
- Approve with stipulations
- Defer/Table (**If it does not meet the 111 Criteria: You MUST defer the study!)**
- Disapprove

Guidelines for using Reviewer Checklists

- Prefer that checklists be completed electronically.
- If checklists completed electronically, email to IRB Analyst prior to IRB meeting. Checklists will be scanned and uploaded to IRBIS as OHRE attachment following meeting.
- If paper checklist used, to be collected by the admin assistant **following** presentation. Checklists will be scanned and uploaded to IRBIS as OHRE attachment following meeting.

Guidelines for using Reviewer Checklists

- Presenting a study:
  - Primary/Secondary Reviewer Summary (in IRBIS): Use to summarize study for presentation to committee
  - Reviewer Checklist: Use to present overall review (concerns)
  - Complete presentation by reviewing all stipulations entered. Committee to collectively agree to accept, remove or revise each stipulation.
- *Members should not alter stipulations in IRBIS during the meeting unless requested to do so by Chair.*

Initial Application Checklist

- Both Primary & Secondary Reviewer need to complete checklist & submit before 8am the day of the meeting
- Add a stip for any answers with (*), concerns or questions you want to raise with the full board
- Don't forget to complete the Regulatory Findings on page 3
- As appropriate, complete the Additional Considerations checklist for:
  - Prisoners
  - Department of Defense Research (DOD)
  - Department of Navy Research (DON)
  - Department of Justice Research (DOJ)
  - Bureau of Prison (BOP) Research
  - Environmental Protection Agency (EPA) Research
  - Department of Energy (DOE)
  - Department of Education (ED)
- Complete the recommendations section

Renewal Application Checklist

Only the Primary Reviewer completes & submits before 8am the day of the meeting

Modifications Checklist

- Only the Primary Reviewer completes & submits before 8am the day of the meeting
- Should the modification include the addition of a vulnerable population or the addition of one of the sponsors listed below, complete the appropriate checklist.

-
  - Prisoners
  - Department of Defense Research (DOD)
  - Department of Navy Research (DON)
  - Department of Justice Research (DOJ)
  - Bureau of Prison (BOP) Research
  - Environmental Protection Agency (EPA) Research
  - Department of Energy (DOE)
  - Department of Education (ED)

Email your completed checklist by 8am on meeting day to your IRB Analyst who will upload it into IRBIS.

Deferrals

- ***"OPRR recommends the following guidelines in such cases:***

  When the convened IRB requests substantive clarifications, protocol modifications, or informed consent document revisions, IRB approval of the proposed research must be deferred, pending subsequent review of responsive materials by the convened IRB.

  Only when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB chair or designated reviewer subsequently approve the research on behalf of the IRB."

Resources

- IRB Staff (see website for listing: http://research.unc.edu/offices/human-research-ethics/)
- Website: *IRB and Office of Human Research Ethics - UNC Research*
- **Telephone: 919-966-3113**
- **Address: Bolin Creek, 720 Martin Luther King, Jr. Blvd, CB # 7097 Second Floor**
- Education Programs
  - ***http://www.hhs.gov/ohrp/***
  - ***https://www.youtube.com/watch?v=hsUS0k3Ie_q&list=SP5965CB14C2506914&index=8***