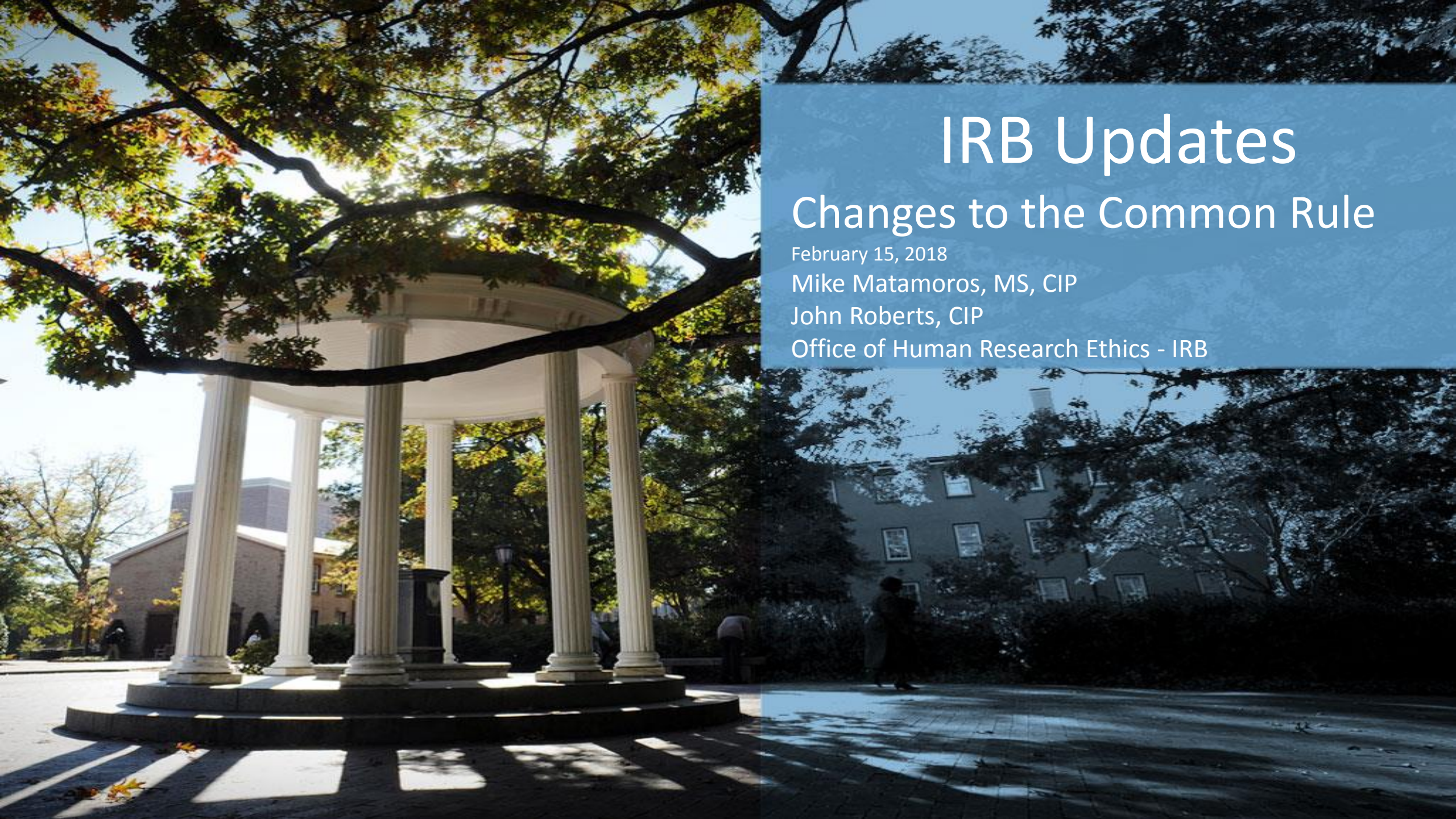


IRB Updates

Changes to the Common Rule

February 15, 2018

Mike Matamoros, MS, CIP
John Roberts, CIP
Office of Human Research Ethics - IRB

Objectives

- Summarize the history of the new common rule
- Summarize the new required elements of informed consent
- Summarize changes to the exemption categories
- Summarize the changes to continuing review
- Summarize changes in IRIBIS needed to reflect the new regulations
- Update on single IRB review

What is the Common Rule?

- Subpart A of the HHS regulations, 45 CFR part 46, is also known as the "Common Rule"
  - Published in 1991
  - Includes regulations for IRB membership, functions and operations, review of human subjects research, criteria for approval, requirements for and documentation of informed consent, etc.

New Rules Proposal

- Advanced Notice of Proposed Rule Making (ANPRM) – 2011
- Notice of Proposed Rulemaking (NPRM) – 2015
- Final Rule – January 19, 2017
  - The goal of these revisions is to reduce administrative burden and better protect subjects in the modern research context.
  - Included January 19, 2018, as the compliance and effective date

Final Rule

- Final Rule – Was set to go into effect January 19, 2018
  - On October 7, 2017, HHS proposed a one-year delay of the general implementation date of the revised Common Rule.
  - On January 4, 2018, HHS submitted a final rule titled Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects. This final rule, which would delay the implementation date of the revised Common Rule for an unspecified amount of time.

Final Rule - Delay

- January 17, 2018 - The "Delay of the Revisions to the Federal Policy for the Protection of Human Subjects" published.
  - This rule delays the effective date and general compliance date of the revised Common Rule to **July 19, 2018**, 6 months after the original date of January 19, 2018.
- What now?
  - We continue to work on preparing for new regulations
  - May provide further comments on possible further delay or changes to the final rule

What may have been (and may still be)...

New Elements of Informed Consent

New additional elements included in the final rule:

(1) a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit (§ll.116(c)(7)); and

(2) statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (§ll.116(c)(8))

(3) when appropriate for research involving biospecimens, subjects be informed of whether the research will (if known) or might include whole genome sequencing (WGS) (§ll.116(c)(9))

New Elements of Informed Consent – Concise Summary

(4) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Concise Summary

The purpose of this study is to compare the gastrointestinal (GI) tract in children with Inflammatory Bowel Disease (IBD) and healthy children. The information we learn by doing this study may help us to develop some target treatments for GI complications in children with IBD.

Participants in this study will have a blood sample collected and a small piece of tissue removed from their intestine during their clinically scheduled procedure. The comparison of tissue from IBD and healthy children will be done in the laboratory after collection of the tissue. Parents of participating children will also be asked to complete a questionnaire. Your child's participation is complete once the medical record and questionnaire have been reviewed, and the tissue and blood sample have been collected.

There is a risk of bleeding after the tissue from the intestine is removed. Risks of taking the blood sample are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting are also possible.

If you are interested in learning more about this study, please continue to read below.

New Elements of Informed Consent

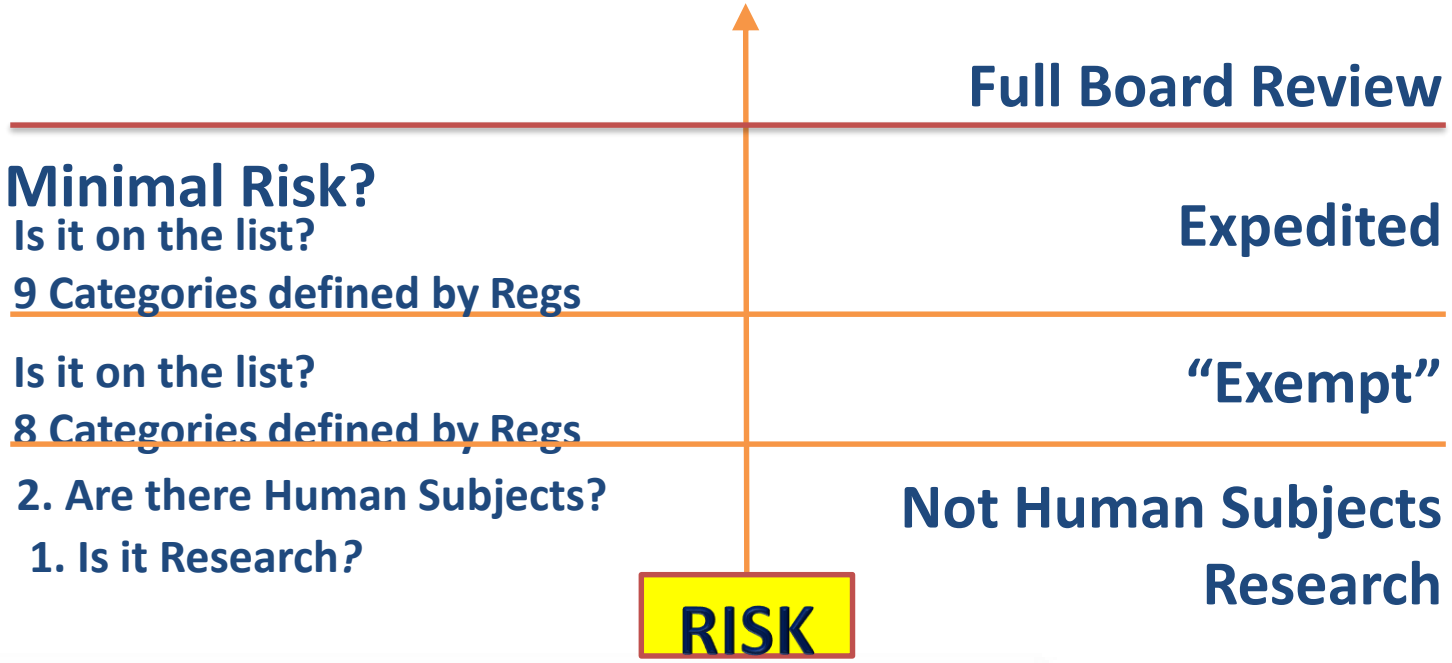
Changes to IRBIS

- New elements of consent will be included in consent form templates created by IRBIS
- Language will be loaded depending on responses to specific application questions.
  - E.g. A.4.A. select “Genetic Testing” prompts “For Whole Genome Sequencing (WGS): A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable).”

What may have been (and may still be)…
New Exemption Categories

Reminder

Exempt ≠ Not Human Subjects Research (NHSR). Exempt determinations require a determination by the IRB prior to beginning research.



New Exemption Categories

Exemption Category 1 – Educational Practices

- The research is to be conducted in established or commonly accepted educational settings. Note: This applies to the location where education research will actually be conducted (e.g., public schools) and NOT to your location at a university.

And the research ~~will involve~~specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:

- Research on regular and special education instructional strategies.
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Change notes that educational practices in the research are not likely to adversely impact on students' learning or assessment of educators and focuses on the practices themselves.

New Exemption Categories

Exemption Category 2 – Surveys

This category has undergone some minor revisions:

- Still only covers survey research. I.e. no interventions.
- Audio and video recording is allowed.
- Old version of category 2 included only survey studies that were anonymous OR would not yield potentially damaging information about a subjects.
- This new version of category 2 allows for exemption of surveys that are identifiable where risk of breach of confidentiality does not exceed minimal risk as long as the IRB conducts a *Limited Review*. Previously these studies were approved under expedited category 7 and required continuing review.

New Exemption Categories

Exemption Category 3 – Benign Behavioral Interventions VERY NEW!

Research involving benign behavioral interventions in conjunction with the collection of information through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

A. Data is collected and stored completely anonymously.
B. Any disclosure of the responses would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
C. The identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a *limited IRB review to make the determination required by .111(a)(7).

Note: This category is only applicable to adults.

New Exemption Categories

Exemption Category 3

Benign Behavioral Interventions and Deception

- Benign behavioral interventions are:
  1. brief in duration
  2. harmless
  3. painless
  4. not physically invasive
  5. not likely to have a significant adverse lasting impact on the subjects, and
  6. the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
     - Examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

New Exemption Categories

Exemption Category 4 - Existing Data and Specimens

- Previously this category was limited to data/specimens that were “on the shelf” at the time of IRB review and where NO identifiers were collected.
  - E.g. going into medical records and abstracting a research data set without any HIPAA identifiers or link.
  - All secondary data that required the use of identifying information had to be approved under expedited procedures.
- Under new rule the study may be exempt if at least one of the following is true:
  - Data/specimens are publicly available
  - There is no identifying information nor link to identifiers recorded and the investigator will not contact subjects nor attempt to re-identify them. This is most analogous to previous exempt 4.
  - The research involves only information protected by HIPAA. This would be chart reviews previously approved under expedited.
  - Research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities
  - Data/specimens is no longer required to be “on the shelf” at the time of IRB review to be determined exempt.

New Exemption Categories

Exemption Category 5 - Federal research and demonstration projects

- This version of the category is very similar to its previous version for Federal research and demonstration projects.
- Previously was limited to projects conducted by a Federal department or agency.
- Now includes conducted **or supported** by a Federal department or agency.
- Research must be listed on a federal website (or other similar mechanism)

New Exemption Categories

Exemption Category 6 - Taste and food quality evaluation

- No change!
  - E.g Coke vs. Pepsi

Limited IRB Review

- **Limited IRB review is required under exemption categories 2 & 3 (also 7 & 8).**

- **As part of the limited IRB review, the IRB shall ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens**

  - **requirements are designed to provide privacy safeguards to reduce the chances that the disclosure of identifiable private information will occur and lead to harm**

New Exemption Categories

IRBIS Changes

- Starting on the implementation date IRBIS will show you the new set of exemption categories that your study may now fit.
- If you have questions about whether your study could be exempt, you may call the IRB Office at 919-966-3113.

New Exemption Categories

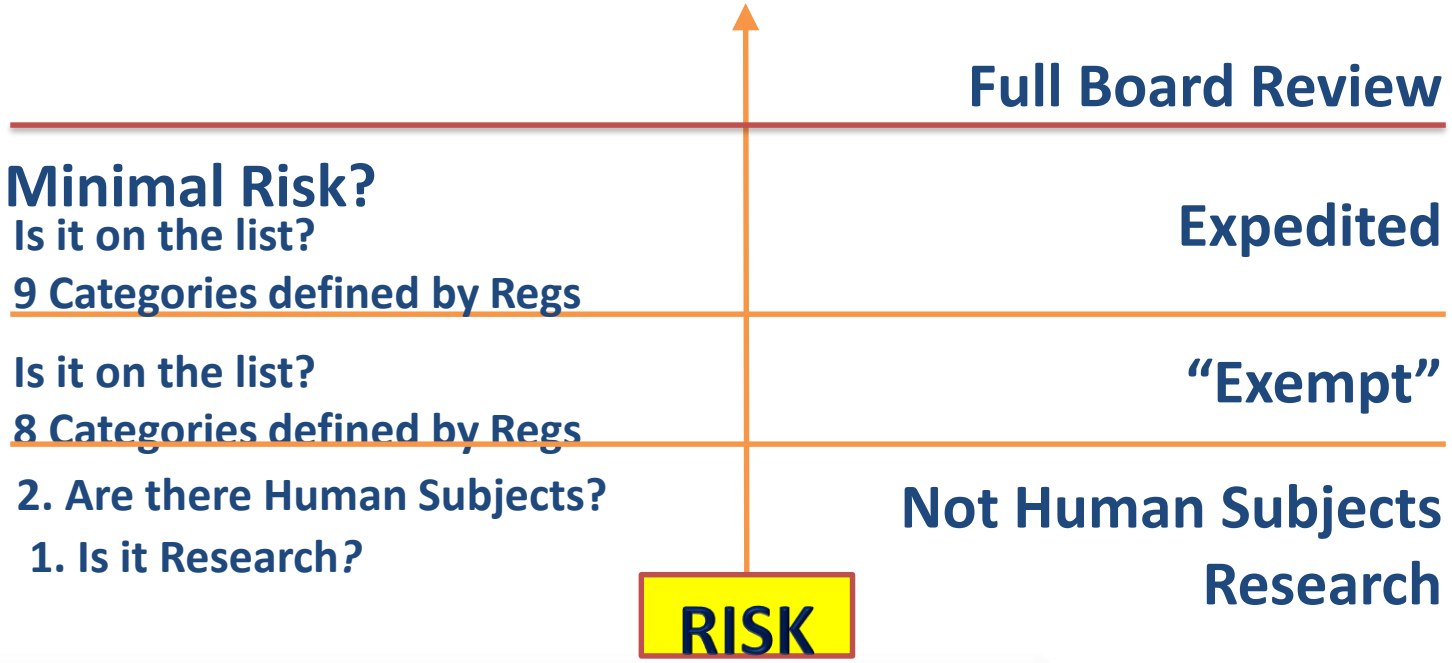
Exemption Categories 7 & 8 – Broad Consent

- UNC will NOT adopt broad consent procedures, so these categories will not be used.
  - This would require a tracking mechanism at the institutional-level that is currently not supported.

What may have been (and may still be)…
Changes to Expedited Review

Reminder

Exempt ≠ Not Human Subjects Research (NHSR). Exempt determinations require a determination by the IRB prior to beginning research.



Changes to Expedited Review

- Expedited categories remain the same.
- Starting on the implementation date, any studies approved under expedited review will **no longer require continuing review**.
- However, there may still be institutional requirements that need to be assessed annually or less frequently.
- The process that will take place of the current continuing review process is TBD.

Expedited Review Changes

IRBIS Changes

- Changes will be determined once an alterative is the continuing review is established.
  - E.g. annual email, truncated progress report, COI disclosure requirement
- Once the new rule goes into effect, there will be other minor application changes throughout IRBIS.
  - E.g. new waiver of signed consent rules

Reduced Regulatory Burdens

- *Most social/behavioral research that previously required expedited review will now be exempt after limited IRB review.*
- *Continuing review will not be required for minimal risk studies.*
- *In greater than minimal risk studies, continuing review will not be required once a greater than minimal risk procedures are completed (i.e. only follow-up or data analysis remain).*
- *New "research exceptions"*
  - *Public health initiatives*

Update on single IRB

(Related and unrelated to Common Rule)

FOR MORE INFORMATION

- Webpage: www.ohre.unc.edu
- E-mail: irb_questions@unc.edu
- Telephone: 919-966-3113
- Address: 720 Martin Luther King, Jr. Boulevard, Chapel Hill (second floor)