THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Minimal Risk and Administrative Review

Continuing Review or "Renewal"

- No approval is valid for longer than one year from the initial *review—depending on risk level, could be a shorter review period*.

- Expired (lapsed) approval = no approval

- Must meet same criteria for approval as at initial review

Continuing Review
Under Revised Common Rule

- 46.109(f)(1) **Unless an IRB determines otherwise**, continuing review of research is **NOT** required in the following circumstances:

- (i) Research eligible for expedited review in accordance with §46.110;
- 46.110(a) The Secretary of HHS has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the Federal Register for public comment. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

Continuing Review
Under Revised Common Rule

- 46.109(f)(1) **Unless an IRB determines otherwise**, continuing review of research is **NOT** required in the following circumstances:

- (b)(1) An IRB may use the expedited review procedure to review the following:
  - (i) Some or all of the research appearing on the list described in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk;

Continuing Review
Under Revised Common Rule

- Currently still the pre-2018 expedited categories.
- 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.

“No Continuing Review” at UNC

- UNC is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
  - All research approved under expedited procedures must receive an administrative review at least *annually*.
  - It is the Principal Investigator’s responsibility to submit a UNC administrative review report as requested by the IRB. Failure to respond to this request is considered non-compliance with IRB requirements and University policies.
- To satisfy AHHRPP requirements, UNC-CH OHRE conducts an ***Administrative Review***

Administrative Review

- This only applies to studies approved under expedited review.

- Administrative review report is due annually. Will include COI and other information, study progress information.
- Studies under Administrative Review do NOT expire, however, failure to submit administrative review report could is considered noncompliance.

What Administrative Review means during FB Review

- Expedited Category 9 – “Minimal Risk”
- IRB should discuss whether a continuing review is required.
- If so, a rationale must be provided.

Rationales for Continuing Review

- FDA regulated
  - Includes IND/IDE exempt or Non-significant Risk (NSR) device studies.
  - FDA has not signed on to the Revised Common Rule
- Department of Justice (DOJ) Funded
  - DOJ has not signed on to the Revised Common Rule
- Other potential concerns
  - E.g. enrollment of vulnerable populations re: sensitive topics in an international setting

Revised Common Rule Agencies (as of 1/21/2019)

- Department of Homeland Security
- Department of Agriculture
- Department of Energy
- National Aeronautics and Space Administration
- Department of Commerce
- Social Security Administration
- Agency for International Development
- Department of Housing and Urban Development
- Department of Labor
- Department of Defense
- Department of Education
- Department of Veterans Affairs
- Environmental Protection Agency
- Department of Health and Human Services
- National Science Foundation
- Department of Transportation

Continuing Review vs Administrative Review

Continuing Review	Administrative Review (No Continuing Review)
Allowed under Pre-2018 Requirements and under the revised Common Rule	Only allowed for expedited/minimal risk studies under the revised Common Rule
Required of all greater than minimal risk studies	Not allowed for greater than minimal risk studies
Includes expiration date	Includes a due date
Approval for no more than 12 months	Approval until study closure (by PI or OHRE)
Must provide PI a reason if required on a minimal risk study	Given to minimal risk studies unless otherwise communicated to investigator by IRB reviewer