OFFICE OF
THE INSTITUTIONAL
REVIEW BOARD

IRB Regulatory Changes

Discussion Topics

- Common Rule Changes
- NIH and NSF Changes
- Equivalent Protections
- Other UNM IRB Changes

Common Rule

Common Rule

- The Common Rule is 45 CFR 46 Subpart A
- It is the regulatory requirement for ethical conduct of human research
- Called Common Rule because the rule was adopted by several government agencies to govern human research (Not DOD, FDA)

Some History

- **1991** Common Rule was established
- **2000 - 2010** Compliance and Research community push HHS to revise the Common Rule
- **2011** Notice of Advance Notice of Proposed Rulemaking
- **2015** Notice of Proposed Rulemaking (comment period and articles)
- **2017** HHS announces implementation and compliance date for Final Rule January 19, 2018
- **January 17, 2018** implementation was delayed 6 months
- **April 18, 2019** proposal to delay an additional 6 months

Where are We Now?

- There have been **NO changes** to the Common Rule
- Federally funded research is expected to do everything exactly as we have been doing since 1991

NIH & NSF Changes

NIH Changes

- Certificates of Confidentiality
- Clinical Trials and GCP Training
- Single IRB Requirement

Certificates of Confidentiality

- CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations
- NIH funded researchers are automatically issued a CoC through their **award**
- COCs issued for “parent” grants (e.g. COBRE) automatically apply to pilot studies. Same with subawards
- If a project is originally funded by NIH, then continues with internal or other funding, the PI must apply for a COC for (now) non-NIH funded study through online application system
- If a researcher wants a CoC for non-NIH funded work, they will apply same as before

CoC Continued

- Recipients are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award
- Protects “all copies” of research record in perpetuity; prohibits disclosure of name, information, biospecimens
- Information is immune from legal process and not admissible as evidence
- DATA SHARING = Recipients are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate issued by this Policy understand they are also subject to the requirements of subsection 301(d) of the PHS Act
- SUBAWARDS = Recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a Certificate issued by this Policy understand they are also subject to subsection 301(d) of the PHS Act

NIH Clinical Trial

- The definition of clinical trial has expanded, particularly impact social, behavioral, educational research:
  - 1. Does the study involve human participants?
  - 2. Are the participants prospectively assigned to an intervention?
  - 3. Is the study designed to evaluate the effect of the intervention on the participants?
  - 4. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?

Clinical Trial Continued

- Researchers conducting clinical trials must complete GCP training
- Requires studies to be monitored; must describe plans for data and safety monitoring in applications and proposals
- Must be registered at clinicaltrials.gov
- Consent form and other info must be posted

Single IRB Review

- Effective January 25, 2018
- Policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after 1/25/18
- Establishes expectation that a single IRB of record (sIRB) will be used for NIH funded studies that are conducted at more than one site in the U.S.
- Applicants must include a plan for the use of an sIRB in the NIH applications/proposals
- The NIH's acceptance of the submitted plan will be incorporated as a term and condition in the NOA

NSF Changes

- Some NSF grants now require a social behavioral/evaluative component to the proposed research
- Researchers who previously never had to do HSR, are now having to do it
- Work with the IRB!!!! Reach out early and follow-up until review is completed
- 7 days from NOA to IRB approval; you could lose funding if you do not have IRB approval in place
- 118 decisions for certain projects

Equivalent Protections

Equivalent Protections

- Equivalent protections are applied to non-federally funded research
- Equivalent to (but different than) the Common Rule
- Allows for flexibility in the review process while maintaining a high standard for ethical conduct of research

Three Distinct Review Tracks

Fed Funded Minimal Risk

- Exempt
- Expedited
- Minimal Risk Reviewer

Greater than Minimal Risk

- Funded or NOT
- Apply Federal Regs
- Full Board Review

Non-Fed Funded Minimal Risk

- Equivalent Protections
- No CR Requirement
- Minimal Risk Reviewer

Other UNM IRB Changes

- No longer require Project Team amendments
  - Researchers are responsible for ensuring and tracking appropriate training and disclosure for researchers involved in the conduct of their research
  - Researchers will submit Project Team information at time of Continuing Review
- Increase administrative reviews of amendments by staff
  - Improves efficiency of IRB review, **nothing changes for researcher**
- No longer ‘approval stamp’ documents (consent forms, recruitment materials)
- Implement post approval monitoring (PAM) program

PAM Program

- Administrative check-in
- Full on-site assessment
- Self-assessment
- Consent document review
- Consent process review (conducted by the researcher)
- Consent process observation (conducted by OIRB staff)
- Project team review (for projects with many team members or that require specialized training)

Questions?

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