Potential Impact of the Revised Common Rule

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Transition provisions

- Pre-January 19, 2018 – Prior Common Rule applies to:
  - Ongoing research initially approved by an IRB
  - Ongoing research for which exemption determination was made

- On or after January 19, 2018 – Revised Common Rule applies to:
  - Research requiring initial IRB review

- On or after January 20, 2020 – Revised Common Rule applies to:
  - Cooperative research

NOTE: NIH Single IRB Policy becomes effective for grant applications submitted for receipt dates on/after September 25, 2017

Important Changes for NIH Applicants/Offerors

- Eliminates requirement for IRBs to review grant applications/contract proposals
- Flexible concept of “identifiable”
  - Will adapt to include advancing technologies that are determined to generate identifiable private information
- Revised exemptions
  - New requirement in Exemption 5 for NIH to publicly post, prior to initiation, research and demonstration projects conducted or supported by NIH
  - New exemptions for storage and use of identifiable private information/biospecimens for secondary research
  - Several exemptions require limited IRB review
- New options for consent
- New requirement to post Informed Consent documents for clinical trials

Important Changes: Consent

- Planned type of consent will likely be described in Protection of Human Subjects section of applications.
  - Broad consent for secondary research
  - Informed consent
  - Waiver of some or all elements of informed consent
  - Waiver of documented informed consent
  - Waiver of documented broad consent

Important Changes: Limited IRB Review

- Can be used for expedited IRB review
- Required for some exempt activities:
  - **Exemption 2**: Education tests, surveys, interviews, observations of public behavior
    - When identifiable private information will be recorded
      - ➢ Limited IRB review of privacy/confidentiality safeguards
  - **Exemption 3**: Benign behavioral interventions with adults
    - When identifiable private information will be recorded:
      - ➢ Limited IRB review of privacy/confidentiality safeguards
  - **Exemption 7**: Storage/maintenance of identifiable information/biospecimens for secondary research
    - ➢ Limited IRB review for privacy/confidentiality safeguards and broad consent
  - **Exemption 8**: Secondary research with identifiable information/biospecimens
    - ➢ Limited IRB review for privacy/confidentiality safeguards and broad consent

Important Changes: Vulnerable Populations

- Subpart C: Research including prisoners
  - Research with prisoners can be exempt only when research aimed at a broader population only incidentally involves prisoners. Examples:
    - Some information/biospecimens come from prisoners; or
    - When some research participants become prisoners during the study

- Subpart D: Research involving children
  - All exemptions apply, except for
    - Part of §46.104(d)(2)(iii): research involving surveys, interview procedures, or observations of public behavior when identifiable information is collected or investigator(s) participate in activities being observed; and
    - Exemption for research involving benign behavioral interventions (§46.104(d)(3))

Updates to NIH Processes

- Revise Application/Contract forms and instructions in Grants.gov
- NIH will likely no longer require certification of IRB approval for grant applications/contract proposals
- Informed Consent documents for NIH-funded clinical trials will likely be posted at ClinicalTrials.gov
- Identify website for posting research and demonstration projects supported by NIH (E5)

Training for Everyone

- Extramural staff
- Peer Reviewers
- Extramural Investigators
    - OHRP webinars
    - OHRP guidance
    - NIH Regional Seminars

Thank you