Overview of Important Changes to Human Subjects Research and Institutional Review Board (IRB) Policies associated with Final Rule

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The Final Rule

- The Final Rule updates the current regulations at 45 CFR 46, Subpart A "Federal Policy for the Protection of Human Subjects" (the Common Rule).
    - i.e., the federal regulations regarding research with human subjects.
- These updates impact the IRB application process and the conduct of human subjects research here at WOU.

Purpose of Final Rule

- "Modernize, strengthen, and make more effective" current system of oversight under the Common Rule since 1991.
- Revisions aim to better protect human subjects, facilitate research, remove ambiguity, and reduce regulatory/administrative burden.
- In particular, the update in regulations facilitates the conduct of "minimal risk" research.

Major Changes to 45 CFR 46, Subpart A (Selected)

- *The following list is not exhaustive of changes associated with Final Rule. Investigators are responsible for being aware of any changes in the regulations that impact how they conduct their research.*
- Updates to Definitions
    - New terms: "Clinical trial," "Public Health Authority," "Written" or "In Writing"
    - Revised terms: "Vulnerable," "Human Subject," "Legally Authorized Representative"
- Updates to Informed Consent Process and Document
    - Changes meant to facilitate participants' understanding of research
        - Requires that key information receive priority by being presented first in the consent document and in discussion
        - "Reasonable person" criteria for making informed decision
    - Broad consent
        - Allowed for storage, maintenance, and secondary research uses of private information and identifiable biospecimens
- New Exempt Categories
    - Establishes new exempt categories, of which the majority of survey research and research involving "benign behavioral interventions" are now exempt from IRB review[1]
- Elimination of Continuing Review for Some Research (i.e., elimination of annual renewals)
    - Removes requirement for continuing review of:
        - Studies that undergo limited review or expedited review (i.e., minimal risk research)

[1] Researchers that conduct human subjects research that qualifies for exemption from IRB review still need to complete and submit an IRB application.

        - Studies that are merely analyzing data and/or involve only observational follow-up in conjunction with standard clinical care
- Choosing a Single IRB (sIRB) for Multisite (Cooperative) Research
    - Multisite research must use sIRB (i.e., the IRB of record)

Transition Dates

- January 19th, 2018: Effective date for all changes (except cooperative research)
- January 20th, 2020: Effective date for cooperative research

What this Means for WOU Researchers involved in Human Subjects Research

- Investigators involved in human subjects research should become familiar with how the Final Rule impacts the conduct of their research here at WOU (resources provided below).
- WOU IRB documents, policies, and procedures will be updated to be consistent with new regulations.
- In practice, many researchers will be unaffected by the changes associated with the Final Rule.
- In most cases, where there are changes, there will be facilitation of human subjects research and increases in the efficiency and speed of processing/administration of applications.

Resources

- Final Common Rule, as appearing in the Federal Register (includes preamble and text)
    - https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html
- CITI Resources for Final Rule
    - Overview of the Final Rule Revisions: https://about.citiprogram.org/wp-content/uploads/2017/07/Final-Rule-Material-Overview-of-the-Final-Rule-Revisions.pdf
    - CITI Final Rule resources website: https://about.citiprogram.org/en/final-rule-resources/

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