Key Changes to the Common Rule – Regulations for the Protection of Human Subjects 45 CFR 46

Final Revisions to the Common Rule

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protections of Human Subjects (the Common Rule). The Final Rule was published in the Federal Register on January 19. 2017. It implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

~ HHS.gov website

Final revision available at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf

Key Changes

- **Eliminates continuing review** for most minimal risk research
- **Expands exemption categories** and changes the review processes
- **Reframes informed consent information** and adds required elements
- **Requires single IRB review** of research involving external collaborators

What's not Changing?

Minimal change to IRB review of projects that involve:

- More than minimal risk
- Drugs/biologics/medical devices (FDA-regulated)
- Collection of biospecimens
- Children
- Prisoners

Changes to Continuing Review

- Continuing review is eliminated for studies reviewed via expedited review
  - The IRB can require continuing review for a study if there is cause
- Also eliminated for full board projects once subject interaction is complete
- Amendments and Adverse Event/ORIO reports are still required
- Investigators will receive annual reminders about submitting amendments, AE/ORIOs and termination reports

Exemption Changes

Changes to Exemption Review Processes

New processes

- **Self-determination** – smart form questions will allow the investigator to issue a self-determination letter for some exempt projects

  Note – a quality assurance process to validate a sample of self-determinations will be implemented

- **Submit to IRB –**
  - Exemption with **"limited IRB review"** (new regulatory category)
    - For projects collecting sensitive, identifiable data, the IRB must review privacy/confidentiality protections (review an IRB member)
  - Standard **exempt review by IRB staff** member for certain types of exemptions or by investigator choice

The eResearch questions will direct the application to the correct review process

Exemption 1 – Educational Exemption

What's new?

- Now must consider "adverse affects" on student learning of required educational content or on assessment of educators
- Self-exemption permitted, except where research involves access to student education records under FERPA

Exemption 2 – Surveys/Interviews/Educational Tests/Public Observation ONLY

What's new?

- Projects collecting **sensitive** and **identifiable** data may be exempt after "limited IRB review" (for privacy/confidentiality protections)
- Clarifies that the exemption **does not apply** to projects involving:
  - Interventions
  - Collection of biospecimens
  - Linking to additional personally-identifiable data
  - Children (except for educational tests or some public observations)
- Self-exemption is permitted if information is not identifiable or not sensitive

Exemption 3 – Benign Behavioral Interventions

What's new?

- This exemption is completely new
- Limited to research with adults

What is a benign behavioral intervention?

- Brief in duration
- Harmless and painless
- Not physically invasive
- Not likely to have a significant adverse impact on subjects
- Not offensive or embarrassing

Exemption 3 – Benign Behavioral Interventions

- Information is collected via
  - Verbal or written responses (surveys/interviews)
  - Data entry
  - Observation of subject (including audiovisual recording)
- Does not permit data collection via physical procedures
  - Physical sensors (e.g. blood pressure monitors, EEG, FitBits)
  - Minimally invasive procedures (e.g. blood draw or saliva collection)

Examples

- Solving puzzles under various noise conditions
- Playing an economic game
- Being exposed to stimuli such as color, light or sound (at safe levels)
- Performing cognitive tasks

Exemption 4 – Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens

What's new?

- No longer limited to retrospective data review
- Permits secondary use of identifiable protected health information (PHI) (with HIPAA privacy board review)
- No self-exemptions

Exemptions 7 & 8 – Storage and Secondary Use of Data/Biospecimens

- Related new exemptions
- Exemption 7 covers the storage and maintenance of identifiable data and/or biospecimens for future research collected under broad consent (i.e. creation of a repository). More on broad consent later…
  - "Limited IRB review" required to assess the terms of the broad consent
- Exemption 8 covers the use of data or biospecimens collected under broad consent
  - "Limited IRB review" required to confirm that the proposed use is consistent with the broad consent and that privacy of subjects and confidentiality of data is appropriate

Informed Consent Changes

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- Provide a “concise and focused presentation of key information” up front
  - Key information:
    - Voluntary participation
    - Summary of research procedures
    - Risks
    - Benefits
- Brief social/behavioral consent documents may already meet this requirement
- New templates will be available on the IRB-HSBS website this fall

New Informed Consent Elements

- New required consent element
  - De-identified data or biospecimens may be shared for future research (or not)
- New consent elements (if applicable)
  - Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
  - Clinically relevant results will be returned (or not)
  - Research will involve whole genome sequencing

Broad Consent for Future Research using Identified Data or Biospecimens

- New provision to for future storage and research use of identified data or biospecimens
- Not required for storage and secondary research use of de-identified data or specimens or for uses consistent with the original informed consent

    - *New Exemption 7 covers the storage and maintenance of data/specimens collected with broad consent*
    - *New Exemption 8 covers the secondary use data/specimens collected with broad consent*

Other Consent-Related Changes

- Waiver of informed consent (for secondary use of data)
  - Must validate why use of identified data is necessary to the research
- For federally-sponsored clinical trials, a copy of the consent form must be posted on a "Federal Web site that will be established as a repository for such informed consent forms."

OHRP defines a clinical trial as: "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effect of the interventions on biomedical or behavioral health-related outcomes."

Single IRB Review Requirement

- Requires that all federally-sponsored research with multi-institutional collaborators be reviewed by one designated IRB of Record
  - Not required until January 2020

Note: NIH Single IRB (sIRB) requirement is effective as of January 25, 2018

Changes to eResearch Application

- Change to **Application Type** page
- Addition of **Exemption Screener** page
- Change to **Exemption detail pages**
  - Disqualifying response moves to next question in the full review path rather than sending back to select a new application type
- **New Secondary Use application** path for all projects involving only secondary analysis of data/specimens
- Changes to **Informed Consent**/Child Assent selections
- Changes to **Waiver of Informed Consent** and Waiver of Documentation criteria