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

http://research-compliance.umich.edu/human-subjects/common-rule-other-changes

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HHS.gov
Office for Human Research Protections

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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

Summary of Key Changes

- **Eliminates continuing review** for most minimal risk research
- **Reframes informed consent information** and adds required elements
- **Expands exemption categories** and changes the review processes
- **Requires single IRB review** of research involving external collaborators (beginning in January 2020)

IRB “Pilot Project”

- Last June, the IRBs released the revised eResearch application and implemented some of the new Common Rule burden-reducing provisions as a pilot project for non-federally-sponsored projects
- Key elements of the pilot
  - Elimination of continuing review for qualifying studies
  - Implementation of new exemption categories
  - Testing of exempt self-determination process for some categories of research
- As of January 21, 2019, these new categories and processes will apply to all research

Changes to Continuing Review

- Continuing review is no longer required 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

Informed Consent Changes

- Informed consent must provide the information “a reasonable person would want to have in order to make an informed decision to participate” (45 CFR 46.116(4))
- Must begin with a “concise and focused presentation of key information” (45.116(5)(i))
    - Voluntary participation
    - Summary of research procedures
    - Risks
    - Benefits

- Brief social/behavioral consent documents may already meet this requirement

New Required Informed Consent Element

- New required consent element (46.116 (b)(9))
  - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative if this might be a possibility;

  -or-

  - A statement that the subjects' information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

What does this mean?

- You must tell participants that their de-identified data (and/or biospecimens) may be shared with other researchers without additional informed consent

-or-

- You will not share their data with anyone, even if de-identified

New “When Appropriate” Informed Consent Elements

- A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in that profit (.116 (c)(7))
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (.116 (c)(8))
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (.116 (c)(9))

Other Consent-Related Changes

- New required element for waiver of informed consent (for secondary use of data)
  - Must validate why use of identified data is necessary to the research (.116 (f)(3)(iii))
- 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" no later than 60 days after the last study visit by any subject (.116 (h))

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."

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; can still submit to IRB

  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 by an IRB member)
  - Standard **exempt review by IRB staff** member for certain types of exemptions

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
- System-generated exemption permitted, except where research involves access to student education records under FERPA

Exemption 2 – Research that ONLY includes Surveys/Interviews/Educational Tests/Public Observation

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)
- U-M permits system-generated determination if information is not identifiable or not sensitive

Exemption 3 – Benign Behavioral Interventions

What's new?

- This exemption is completely new – similar to Michigan Exemption 2a but more complex!
- 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)

Exemption 3 – Benign Behavioral Interventions

- Must obtain “prospective agreement to the intervention and information collection”
- **No deception**, except where the subject is told that they will be unaware or misled about the nature or purposes of the research and they agree
  - Debriefing still encouraged
- System-generated exemption permitted for projects that do not involve deception and where information collected is not identifiable or not sensitive
- “Limited IRB Review” required for projects collecting sensitive and identifiable data

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) within a covered entity
  - At Michigan, this exemption applies only to research conducted within the Michigan Medicine covered entity (and reviewed by IRBMED)
- No system-generated exemptions

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

Single IRB requirement already in place for NIH-funded projects as of January 25, 2018 submission dates

Transition Considerations

eResearch Changes for Revised Common Rule

- Major system changes related to Common Rule changes were already implemented in June 2018
- January 2019 eResearch changes are minimal, primarily text changes that remove limitations related to federal funding and some clarifications to other questions

Transition Considerations

- Projects approved prior to January 21, 2019, are approved under the old rule and may remain under those rules for the duration of the project (or funding cycle)
  - Continuing review required
  - Informed consent consistent with pre-2019 standards
- Projects approved on January 21, 2019, and after must comply with new rules
  - No continuing review for minimal risk research (unless required by IRB)
  - New exemptions
  - New informed consent requirements
- Updated 2019 standard consent template available on the IRB-HSBS website; updated biospecimen consent available next week

Transition Considerations

- New applications involving subject interaction/interventions submitted in December and January should use the new consent templates (with new required elements)
- For studies approved before January 21, 2019, the IRB staff will consult with the study team regarding transition to the new rule at time of continuing review or amendment
  - For projects still actively interacting with subjects, updated consent document required to transition
- New application rather than amendment is required for existing projects that may qualify for new exemptions

U-M Common Rule Resources

- Check the HRPP Common Rule & Other Changes website for updates
  http://research-compliance.umich.edu/human-subjects/common-rule-other-changes
  - Important dates
  - Changes to institutional policies and procedures
  - Send questions/comments to the IRBs/HRPP via our survey tool

COMMON RULE FEEDBACK

- Check the IRB-HSBS website
  http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs
  - Updated IRB-HSBS guidance materials and case studies
  - New informed consent templates and guidance
  - Schedule of information sessions

Federal Common Rule Resources

- Federal Policy for the Protection of Human Subjects, Text of New Rule
  https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf

- Office of Human Research Protection (OHRP), Revised Common Rule Educational Materials

  https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html

Other NIH Policy Changes and Initiatives – New Certificate of Confidentiality Policy

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

- Now a provision for CoC as part of the terms and conditions of an NIH award
- Limits disclosure of "identifiable, sensitive" information
  - Information/biospecimens are also considered to be identifiable if there is a very small risk of deductive disclosure
  - Includes all identifiable human subjects data, biospecimens, individual level human genomic data, or other research data
- Effective October 1, 2017
- Applies to all NIH-funded research, on-going or commenced as of December 13, 2016 (part of the 21st Century Cures Act and amended Public Health Services Act)
- NIH will continue to issue CoCs for other research falling under its mission

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Questions?