Columbia University Medical Center

New Rule Information Session

2018 Regulatory Requirements

January 8, 2019

Human Research Protection Office
Institutional Review Boards

Agenda

- Regulatory Changes General Compliance: January 21, 2019
  - What you need to know
  - **What you should do now for new protocols currently under review**
- Current Regulations (Pre-2018 Requirements)
- Regulatory Changes (2018 Requirements)
- Rascal Changes
- Informational Sessions

Current Human Subjects Regulations

- HHS Protection of Human Subjects (45 CFR 46, Subpart A)
  - As written, apply to federally funded research
  - "Common Rule" – adopted by multiple federal agencies
  - Initially promulgated in 1991 and amended in 2005
    - Notice of impending revisions was announced in 2017
    - Amended twice to delay compliance date
    - "Pre-2018 Rule"
  - Currently, Columbia applies these regulations to all research, as per commitments in our federalwide assurance of compliance (FWA)
  - Regulations of other federal agencies followed as applicable

Regulatory Changes
General Compliance: Jan. 21, 2019

- "Revised Common Rule", "2018 Requirements", "2018 Rule"
- HHS and 15 other federal departments and agencies
- Significant changes include:
  - Definitions (e.g., *research, human subject, identifiable biospecimens, identifiable private information*
  - New requirements for the content of informed consent documents
  - Establishes new exempt categories
  - Revises IRB review criteria
  - Removes the requirement for continuing review of ongoing research for certain studies
  - Allows the use of *broad consent*

Definition of *research*

Pre-2018

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Revised Common Rule

The following activities are deemed not to be research: scholarly and journalistic activities; public health surveillance activities; collection and analysis of information/biospecimens/records for certain legal activities; certain activities in support of matters of national importance

Definition of *human subject*

Pre-2018

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Revised Common Rule

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Elimination of continuing review

- Eligible studies are those that:
  - Were reviewed by an expedited review process, unless the reviewer justifies why CR would enhance protection of subjects
  - Have progressed to the point that they involve only data analysis or “accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care”.
- A brief progress report that will be reviewed administratively will be required. Reasons for this include the need to:
  - Account for active research
  - Track recruitment
  - Update personnel

Elimination of requirement for grant

- The requirement for the IRB to review the complete grant for a federally funded project has been eliminated
- The IRB will no longer require a copy of the complete grant
- The IRB may require a copy of some sections of a grant if additional information is needed for the IRB review (e.g., Methodology, Human Subjects section)

Exempt Criteria – What's New?

- New Process for review (limited IRB Review)
  - For projects that collect sensitive, identifiable data, the IRB must review privacy/confidentiality protections (IRB criterion for review)
- Subpart C: Research that only incidentally includes prisoners may qualify for exemption
- **Exemption #1:** Now must consider "adverse effects" on student learning of required educational content or on assessment of educators
- **Exemption #2:** Expanded criterion for projects collecting sensitive and identifiable data which requires "limited IRB review" (for privacy/confidentiality protections). Does not apply to:
  - Interventions
  - Collection of biospecimens
  - Linking to additional personally-identifiable data
  - Children (except for educational tests or some public observation, i.e. (i) and (ii)

Exemption #3: Benign Behavioral Intervention

- Completely New! *Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection*
- 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 Intervention

- 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)
- Must obtain "prospective agreement to the intervention and information collection," i.e. **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
- "Limited IRB Review" required for projects collecting sensitive and identifiable data

Exempt Criteria – What's New? Continued

- **Exemption #4:** No longer limited to retrospective data review; Permits secondary use of identifiable protected health information (PHI) (with HIPAA privacy board review)
- **Exemption #5:** No Substantive Changes
- **Exemption #6:** No Change
- **Exemption #7: Completely New!** Storage and maintenance of identifiable data and/or biospecimens for future research collected under broad consent (i.e. creation of a repository); Limited IRB Review required
- **Exemption #8: Completely New!** Use of data or biospecimens collected under broad consent; Limited IRB Review required

No plans to review under Exemption Categories #7 & #8

Informed Consent Changes: Broad Consent

- One time consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
- Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) *is permitted as an alternative to the informed consent requirements.
- Specific consent elements required.
- Refusal of broad consent **eliminates future waiver by IRB.**
- *No plans to implement broad consent at this time*

Informed Consent Changes: Key Information

- "Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."
- 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 HRPO Website once finalized

Informed Consent Changes: Elements

- New required consent element:
  - De-identified data or biospecimens may be shared for future research (or not)
- New additional 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

Informed Consent Changes: Waivers

- Waiver of informed consent: What's New
  - Added criterion that the use of identifiable private information or identifiable biospecimens could not be practicably carried out without using such information/specimens in the identifiable form.
- Waiver of documentation of consent: What's New
  - Electronic Consent included
  - Key Information must be presented and documented as being presented first during the oral consent process
  - Added criterion that allows waiver of documentation of consent if subjects are members of a distinct cultural group or community in which signing forms is not the norm (provided there is an appropriate alternative mechanism for documenting consent was obtained and the study presents no more than minimal risk.

Informed Consent Changes: Posting ICF

- 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."*

Plans for implementation

- Revisions in the Rascal IRB module, release expected January 21
- Changes to IRB review processes
- Template for consent summary
- Multiple workshops and informational sessions to explain the new and revised requirements
- Information distributed via HRPO/IRB listserv
- Guidance posted on HRPO/IRB website

Researchers should consider now:

- Regulations apply to research approved by an IRB **on or after** Jan. 21, 2019
- Institutions have the option of transitioning “legacy” protocols
  - **Columbia does not plan to transition**
- New protocols submitted to the IRB before Jan. 21, 2019 but not yet approved on Jan. 21, 2019 must comply with the new requirements
  - This applies even if a convened review has been conducted
  - HRPO/IRB will facilitate compliance with new requirements
- ***Recommendation: Make every attempt to move new protocols under review to approval before Jan. 21, 2019.***

Information Sessions

- Tues, 1/8: 12:30-1:30p, HSC LL204
- Wed, 1/9: 1-2p, HSC LL204
- Thurs, 1/10: 3-4p, HSC LL204

- Mon, 1/14: 10-11a, HSC LL204
- Tues, 1/15: 11:30-12:30p, HSC LL203
- Thurs, 1/17: 3:30-4:30p, VP&S Amp 1

Revised Common Rule resources

- Federal Register notice, January 19, 2017: https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf
- Council on Government Relations summary of changes: https://www.cogr.edu/sites/default/files/Summary%20of%20Changes%20to%20the%20Common%20Rule_COGR.pdf
- OHRP Revised Common Rule Educational Materials: https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html

Questions?

Contact Us

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