Human Research News

Subject: The Revised Common Rule Coming in January

December 19, 2018

Dear UCLA Research Community,

On January 21, 2019 the Federal Government is implementing revised regulations that oversee research involving human subjects (aka – The Revised Common Rule). While most of the changes impact IRB review and OHRPP process, there are some things you should be aware of. Below is a general list of upcoming changes, and we will send out additional information in the coming weeks.

It is important to note that most of the Common Rule is not changing – the concept of IRB review, with different review levels based on study risk, informed consent, etc. The Common Rule changes will have minor changes on your research.

For any research approved on or before January 20, 2019, you will not need to change anything. These research projects will continue to follow the current regulatory requirements. The Revised Common Rule goes into effect for research approved by the IRB on or after January 21, 2019. You can expect to see the following changes:

- Informed Consent Forms:
    - Consent forms will need to have a "Key Information" Section, which discusses study summary information that a 'reasonable person' would be interested in knowing immediately. Please see the OHRPP Consent Form templates for specific guidance on what to include
        - Note that UCLA will be using some flexibility allowed in the regulations in certain circumstances. For example, consent forms under 3 pages will not need a "Key Information" section.
    - Some new additional elements of consent have been added for research involving biospecimens
    - Posting of clinical trial consent forms must be done on a public website within 60 days of enrolling the last study subject. This responsibility will generally fall on the study sponsor.
- Exempt Research:
    - The Revised Common Rule includes new categories of research that are exempt from IRB oversight. Please see the Exempt research guidance on the OHRPP website for additional details
- Continuing Review:
    - The IRB will be able to allow certain research projects (projects that are minimal risk or that have no more subject interaction) to eliminate Continuing Review. If your project qualifies, the IRB will inform you. This does not mean that there is no more IRB oversight, only that annual continuing review submissions are not required. Study amendments and Post-Approval Reports are still required to be submitted to OHRPP.
- Definitions and General Changes:
    - Changes to include that the Common Rule provides regulatory oversight over information and biospecimens (instead of just information or data). This includes research obtaining, studying,

using analyzing or generating biospecimens, and is how OHRPP has always interpreted the regulations.

- Changes to the definition of what meets the criteria of human subject research, specifically eliminating from oversight:
  - scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
  - Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
  - Criminal justice, including collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
  - National security. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Please see the OHRPP website or contact OHRPP if you have any questions.

Thank you,

UCLA Office of the Human Research Protection Program

Contact Information
