UMKC
Office of Research Services

Executive Summary

Changes to the Common Rule (45 CFR 46)

Compliance deadline: January 21, 2019 (There is no grace period, we are either in compliance on this date or not. This is still subject to delay or change at the Federal level).

Largest Areas of Change (not an exhaustive list)

New Definitions

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.

Clinical trial:

- Clinical trial means 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 effects of the interventions on biomedical or behavioral health-related outcomes.

Deemed to NOT be research, thus not requiring IRB review:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- 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).

- 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.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

  Note: The UMKC IRB already considered these activities as not meeting the definition of human subjects research. These are now specifically defined in the changes to the Common Rule.

New exempt categories:

- Exempt categories added for secondary research on identifiable private information and identifiable biospecimens collected prior to and after the time of IRB review and approval.
- Exempt category 2 now includes the use of 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.
  - For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and **the investigator has no reason to think the subjects will find the interventions offensive or embarrassing**. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- Exempt categories 2iii, 3iii, 7, & 8 added that require limited review. The limited review will be similar to an expedited review process.
- We would like to clarify that while the proposed changes to the Common Rule included commentary regarding an exemption decision tool for researchers to utilize in making their own exemption determinations, this was not part of the Final Rule published in the Federal Register in January. Exemption determinations will continue to be made by UMKC IRB staff, particularly considering the addition of new exempt categories, limited review categories and our current work to meet very short funding deadlines.

Continuing review:

- Unless the IRB determines otherwise, continuing review will no longer be required for projects under an expedited category, projects requiring limited IRB review, or projects that have progressed to data analysis.

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Informed consent:

- The informed consent process, for non-exempt studies, must now begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. The informed consent must also be "organized and presented in a way that facilitates comprehension." Current thinking on this equates to providing a brief summary paragraph or bulleted listing at the beginning of each consent form. We recognize this may introduce redundancies in the consent itself in certain instances. Information within the opening paragraph is not required to be repeated in the body of the consent form, but no further Federal guidance has been presented.
- **Added requirements** to include one of two statements about collection of private information or identifiable biospecimens for future research (either that identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject; or, that the subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed).
- **Three new requirements** requiring 1) biospecimens, even if identifiers are removed, may be used for commercial profit and whether the subject will share in the profit 2) whether clinically relevant research results will be disclosed to subjects 3) whether the research project might include whole genome sequencing.
- A new option for "broad consent," may be used in lieu of informed consent only with respect to the storage, maintenance and use of private information and identifiable biospecimens.
- In addition, there is an added requirement for posting clinical trial consent forms on a publicly available Federal website that will be established (i.e., not yet been confirmed how this posting process will occur - likely through clinicaltrials.gov) as a repository for consent forms. One consent form for each study must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

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