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Announcement of Notice of Proposed Rule Making to Federal Standards

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have announced proposed revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. A Notice of Proposed Rulemaking (NPRM) was published in the Federal Register on September 8, 2015. This document details the major changes to the Common Rule and how they may impact your research.

8 Major Changes

1) **Improve Informed Consent – content and organization, to facilitate understanding.**

Provide information a *reasonable person* would want to know. Essential information presented first. Within 60 days of study closure the informed consent must be posted on a government website.

2) **Almost always require informed consent for secondary use of biospecimens – regardless of identifiability.**

Consent must be obtained before a researcher can conduct research on a biospecimen even if it has been de-identified. Currently, de-identified biospecimens are considered non-human and no consent is required for their use. Only research designed to test information already known about a person will be allowed (e.g. new in vitro test)

This consent requirement for secondary research can be met by obtaining broad consent for unspecified future research when the biospecimen is collected. Any such sample would be exempt from review for storage and use. Waivers of consent would be very rarely be allowed. These new rules do NOT apply to data obtained from biospecimens.

3) **Mandate single IRB review of multi-site research conducted at U.S. Institutions.**

Allows for a single IRB for multi-site research conducted within the U.S. unless required by law or a federal department deems a single IRB inappropriate. The rule also states that the reviewing IRB and not the institution will be found at fault if there is a failure to comply with the Common Rule.

4) **Eliminate continuing review for certain minimal risk research.**

No continuing review (CR) required for expedited studies and studies in longitudinal status. Investigator however must provide annual confirmation that the study is still active and there have been no changes. Local IRBs can override this change.

5) **Extend the scope of rules to cover all clinical trials, regardless of the source of funding.**

Expand coverage to all clinical trials regardless of funding source if the research is done at a U.S. institution that receives federal funding. This rule does not apply to clinical trials subject to regulation by the FDA.

6) **Require privacy safeguards.**

New standards that apply to non-exempt research. Secretary of HHS will promulgate new standards. If these safeguards are met, there is no requirement for additional IRB review for privacy.

7) **Exclude certain activities from coverage.**

Excluded activities do not require review. Activities deemed not to be research, low risk, or where protections are separately mandated are excluded. There are 11 activities that can be excluded. For example: quality assurance, research already covered by HIPAA, secondary research using data that does not record any identifiable information.

8) **Expand the categories of research that are exempt from the rules, better calibrating the level of review to the level of risk.**

New categories of exempt that currently require IRB review. Excluded activities do not require review, while exempt activities do have procedural requirements to be deemed exempt. This determination must take place and be documented. Exemption can be made either through a government produced web-based decision tool or through an IRB. There are 8 total activities that can be excluded. For example: surveys, interviews, benign interventions, secondary use of identifiable information as long as notification and privacy protections are in place.

These changes are currently in the "open comment" stage of review. How to submit comments directly to OHRP and additional information about the proposed rule changes can be found here:

http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html

Additional information can also be found through informational videos produced by OHRP or on the HHS website:

https://www.youtube.com/playlist?list=PLrl7E8KABz1FtLMpK2zPa8nqV-F-xhW2C

http://www.hhs.gov/ohrp/humansubjects/regulations/nprm2015summary.html

If you have questions or concerns about how these proposed rule changes could impact your research, please contact the College of Pharmacy's Regulatory and Compliance Office.

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