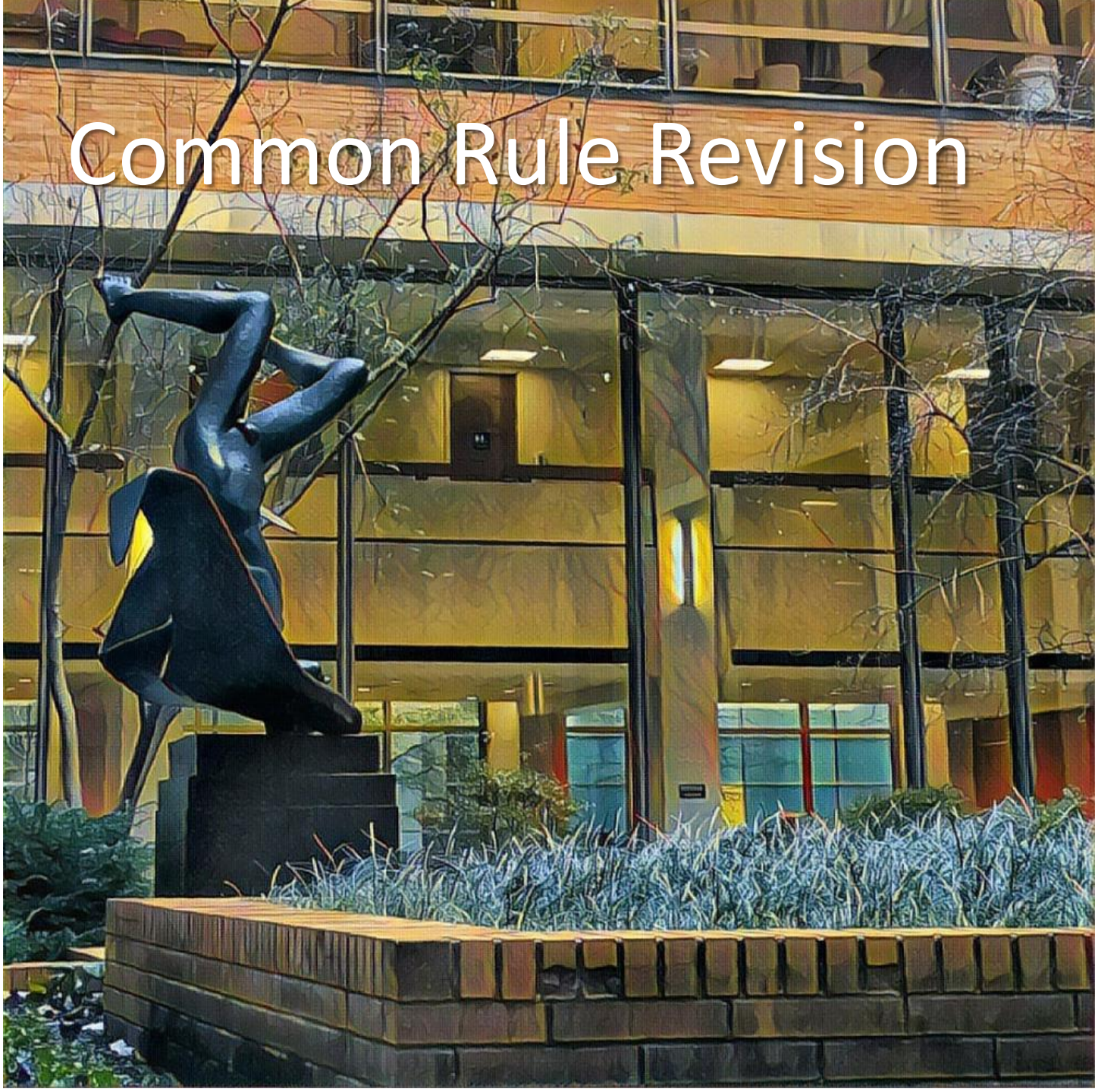
Common Rule Revision



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- U.S. Department of Health and Human Services (HHS) adopted the Common Rule, and is adhered to by 15 federal agencies that fund research in 1991

- Subpart A- define “human subject,” “identifiable private information,” and “minimal risk.” compliance, IRB membership, criteria for approval, informed consent; and waiver of consent

- Subpart B — Human Fetuses and Neonates, Pregnant Women, and Human In Vitro Fertilization

- Subpart C —Prisoners

- Subpart D —Children

History

Advanced Notice of Proposed Rulemaking (ANPRM). The ANPRM was published July 26, 2011. More than 2000 comments were sent to HHS on the ANPRM.

History

September 2, 2015, HHS and the 15 other federal departments and agencies that have agreed to abide by the Common Rule published a Notice of Proposed Rulemaking (NPRM)

Vigorous response

Consent

- Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process
- Public posting of federal research

Biospecimens

- Final rule does not require that research involving nonidentified biospecimens be subject to the Common Rule, and that consent would need to be obtained in order to conduct such research.
- Broad consent
- Non-identified biospecimens not covered

Continuing Review

Removes the requirement to conduct continuing review of ongoing research

- expedited
- In data analysis only
- In observational follow up

Other features

- Behavioral research
- Multi-site studies
- International
- Updates definitions


Questions?