ACCREDITATION EVIDENCE

Title: 45 CFR 46: Terms of Assurance for Protection of Human Subjects for Institutions within the United States.

Evidence Type: Circumstantial

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Classification: Policy

PII: No

Redacted: No

HHS.gov

U.S. Department of Health & Human Services

Office for Human Research Protections

45 CFR 46

The HHS regulations for the protection of human subjects in research at 45CFR 46 include five subparts. Subpart A, also known as the Common Rule, provides a robust set of protections for research subjects; subparts B, C, and D provide additional protections for certain populations in research; and subpart E provides requirements for IRB registration. The Common Rule, subpart A, was revised in recent years. Access the regulatory language for all of the subparts using the links below. In addition, OHRP provides an annotated version of the Common Rule that highlights changes between the pre-2018 and 2018 versions of the Common Rule.

2018 Requirements (2018 Common Rule)

Exemptions (2018 Requirements)

Subpart B

Additional protections for research with pregnant women and fetuses

Subpart C

Additional protections for research with prisoners

Subpart D

Additional protections for research with children

Subpart E

Requirements for IRB registration

List of Expedited Categories (1998)

Annotated Comparison of the Pre-2018 and the 2018 Requirements

In general, research initiated before January 21, 2019 continues to comply with the pre-2018 Common Rule unless the institution chose to transition it to the revised Common Rule.

Pre-2018 Common Rule

Exemptions (Pre-2018 Requirements)

Content created by Office for Human Research Protections (OHRP)

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