



## *HLC Accreditation Evidence*

HHS.gov - HHS 45 CFR 46 - Office for Human Research Protections

URL: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

Office of Origin: HHS - Office for Human Research Protections

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- Director of Institutional Effectiveness

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## Office for Human Research Protections

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[HHS](#) > [OHRP](#) > [Regulations, Policy & Guidance](#) > [Regulations](#) > 45 CFR 46

## 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)** (</ohrp/regulations-and-policy/regulations/45-cfr-46/revise-d-common-rule-regulatory-text/index.html>)

**Exemptions (2018 Requirements)** (</ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html>)

**Subpart B Additional protections for research with pregnant women and fetuses**  
(</ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html>)

**Subpart C Additional protections for research with prisoners** (</ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html>)

**Subpart D Additional protections for research with children** (</ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html>)

**Subpart E Requirements for IRB registration** (</ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-e/index.html>)

**List of Expedited Categories (1998)** (</ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>)

**Annotated Comparison of the Pre-2018 and the 2018 Requirements** (</ohrp/regulations-and-policy/regulations/annotated-2018-requirements/index.html>)

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** (</ohrp/regulations-and-policy/regulations/regulatory-text/index.html>)

**Exemptions (Pre-2018 Requirements)** (</ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.101>)

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## **OHRP Headquarters**

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