HHS Regulations for the Protection of Human Research Participant

Basic Governance

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HHS Regulations for the Protection of Human Research Subjects (45 C.F.R. 46)

- **HHS will conduct or support** non-exempt human subject research only if:
  - The institution has an OHRP-approved assurance, and
  - The institution has certified to HHS that all covered research has been reviewed and approved by IRB, and
  - The research will be subject to continuing review if applicable

§46.103(b), (f).

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Assurance of Compliance

Institutional Review **B**oard

Legally Effective
Informed **C**onsent

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Assurance of Compliance: In General

- Any **institution** engaged in research covered by this policy
  - Must provide **written assurance** that it will comply with the requirements in this policy

§46.103(a)

  - Federalwide Assurance (FWA) - only option

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THE COMMON RULE:

- 19 agencies (including HHS) follow the CR
  - 15 agencies are official signatories with the rule codified in their own CFR sections
  - 4 agencies follow the CR because of executive order or statutory mandate
- 20 agencies (including HHS) intend to follow the revised CR (published January 2017, effective January 2018)
  - There is 1 new signatory to the revised CR (Department of Labor)

- Applies to **institutions** generally engaged in:
  - Research (§46.102(d))
  - Involving human subjects (§46.102(f))
  - Not otherwise exempt from this policy (§46.101(b))
  - Conducted, **supported** or otherwise subject to HHS regulations or the regulations of any federal department or agency which has adopted this policy

§46.101(a)

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FWA: What Does It Require?

- Conduct human subjects research according to a Statement of Principles
- Commit to comply with the 45 C.F.R. 46 and other applicable laws and regulations
- Certify that all covered research will be reviewed and approved by an IRB
- List at least one IRB that institution will rely on
  - This IRB must be registered with OHRP
  - Institutions are NOT required to have an IRB: reliance on external IRB
- Establish required written procedures*
- Provide institutional support to the IRB(s) (space, time, resources, staff, etc.)
- Renew FWA every 5 years

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https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html

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IRB Review

- FWA: Certify that all covered research will be reviewed and approved by an IRB
  - IRB membership requirements (§46.107)
  - IRB functions and operations (§46.108)
    - FWA: establish required written procedures
    - IRB: Follow written procedures
  - IRB criteria for approval of research (§46.111)
    - Privacy of subjects and confidentiality of data protections when appropriate
    - Obtain informed consent and documentation of consent
  - IRB record keeping requirements (§46.115)

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Legally Effective Informed Consent

"[N]o **investigator** may involve a human being as a subject in research covered by this policy unless **the investigator** has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."

(§46.116)

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Compliance and Oversight

- For-cause compliance visits and not-for-cause compliance visits:
  - Ensure institutions operate according to their FWA (see Slide # 7)
  - Ensure IRBs operate according to their written procedures in FWA (see Slide # 8)

FWA: Establish written procedures
IRB: Follow written procedures

- Mandatory reporting:
  - FWA Requirement: Establish required **written procedures** for prompt reporting to the IRB, appropriate institutional officials, OHRP, and the funding Agency:
    - Unanticipated problems involving risks to subjects or others,
    - Serious or continuing noncompliance with the regulations or the IRB,
    - Suspension or termination of IRB approval

45 CFR 46 103(a), 46.103(b)(5) and 46.108(a)

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THANK YOU

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