HHS Regulations for the Protection of Human Research Participant

Basic Governance

Jaime O. Hernandez, J.D., M.Be.
Public Health Advisor
Department of Health and Human Services (HHS)
Office for Human Research Protection (OHRP)
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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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