

“How Would YOU Revise the Human Subject Research Regulation?”

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HOW Would You Revise the Human Subject Research Regulation?

- Objectives:
 - Brief overview of the regulatory process
 - Amending Common Rule v. Subparts B, C, D of HHS protection of human subjects regulations (45 CFR part 46)
 - Discussion of authority for 45 CFR part 46, and some history of the scope of the current regulations

Overview of Regulatory Process

- Initial agency decisions:
 - ANPRM
 - NPRM
 - Interim Final Rule
- “Informal” rulemaking requires publication of NPRM, 60-day comment period, publication of final rule 30 days prior to effective date

“Informal” Rulemaking

- NPRM components: preamble, rule text and required analyses
 - Internal agency clearance
 - OMB clearance and agency revision, if necessary
- After publication and comment, revise: preamble including summary of comments and agency response, final rule text, and revised analyses
 - Internal agency clearance
 - OMB clearance and agency revision, if necessary

Time frame?

- Drafting NPRM + agency clearance + OMB review (90-120 days) + comment period (60 days) + analysis of comments + drafting final rule + agency clearance + OMB review (90-120 days)=?
 - Often 1 year between publication of NPRM/final rule
- Subpart C – NPRM 1/5/78; final 11/16/78
- Subpart D – NPRM 7/21/78; final 3/8/83
- Subpart B – NPRM 5/20/98; final 1/17/01 (replacement final 11/13/01)

Amending the Common Rule

- Possible options:
 - HHS drafts with input from Common Rule agencies
 - Interagency drafting/review committee
- Clearance
 - 15 Common Rule agencies
 - CIA (required by E.O. to comply) and SSA (pursuant to statute)

Amending subparts B, C, or D of 45 CFR part 46, or adding new subparts

- HHS drafts; input may be sought from other agencies
- Clearance
 - Internal HHS clearance
 - OMB may send to other Common Rule agencies for comment

Statutory authority

- 42 U.S.C. 289(a)
 - Requires that entity seeking HHS funding for biomedical/behavioral research involving human subjects must assure IRB review
 - Creates program to provide guidance on ethical issues involved with human subjects research
 - Establishes compliance process
- 5 U.S.C. 301
 - Secretary's broad rulemaking authority

Historical HHS Interpretation and Rationale from 46 FR 8366 (1/26/81)

- Prior to passage of National Research Act (7/12/74), HHS required IRB review of HHS-funded research only.
- 8/14/79: NPRM (44 FR 47698) proposed to require IRB review for conduct of all human subjects research not funded by HHS and conducted at or supported by any institution receiving funds from HHS for the conduct of human subjects research.

Historical HHS Interpretation and Rationale from 46 FR 8366 (1/26/81)

- Nearly 100 public comments on this issue directly
 - Most felt it inappropriate to extend to non-federal research
 - Legal authority challenged; claims of First Amendment violation
 - Other federal agencies saw potential for conflict with their mission
- HHS reconsidered proposal in light of comments received and statutory basis for the more expansive interpretation.
 - Significant amount of public objection
 - HHS General Counsel advised that there is no clear statutory mandate in the National Research Act to support requirement for IRB review of all research, regardless of funding source.

Historical HHS Interpretation and Rationale from 46 FR 8366 (1/26/81)

- Decision: regulations applicable only to research conducted or funded by HHS
- HHS urged institutions to employ IRB review and other methods of protecting human subjects, regardless of funding source of the research.

Assurance Requirements

45 CFR 46.103(b)(1): Assurance applicable to federally supported or conducted research must include:

“a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation.”