Statutes, Regulations, Guidance, and FAQs: Process for Modification

Laura Odwazny

Andrew Zacher

Office of the General Counsel, HHS

March 12, 2013

Outline

- Statutory source of OHRP authority
  - How to amend a statute
- How to amend a regulation
  - Brief overview of the regulatory process
  - Amending Common Rule v. subparts of HHS protection of human subjects regulations (45 CFR part 46)
- How to modify agency guidance/FAQs

OHRP's Statutory Authority - 1

- 42 U.S.C. § 289(a)

  (a)The Secretary shall by regulation require that…any project or program which involves…research involving human subjects submit … assurances satisfactory to the Secretary that it has established…an "Institutional Review Board"…to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

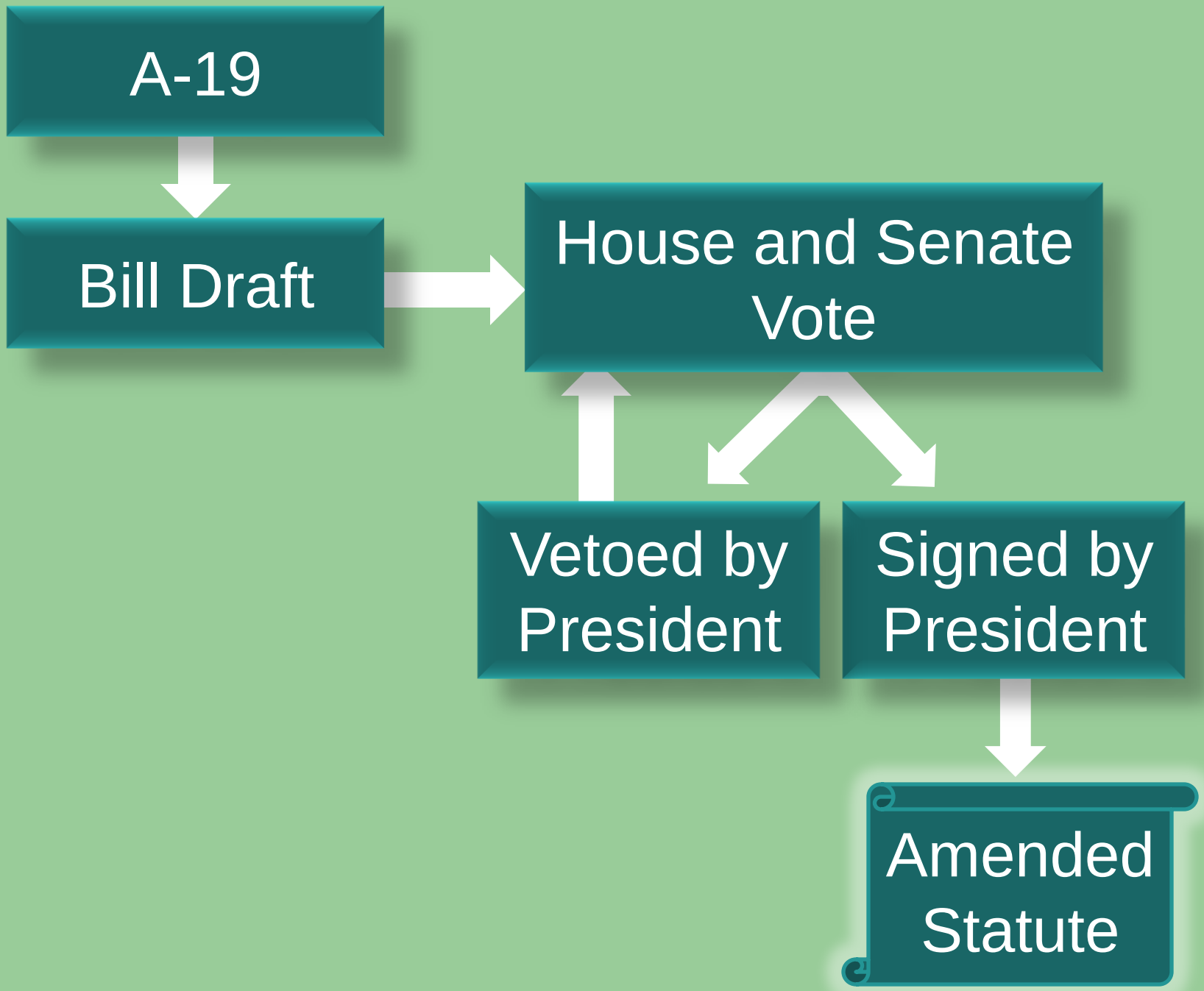
- Establishes assurance requirement
- Authorizes the Secretary to promulgate regulations requiring establishment of IRBs

OHRP's Statutory Authority - 2

- 42 U.S.C. § 289(b)(1)
  - *The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.*
- Authorizes the Secretary to establish OHRP

OHRP's Statutory Authority - 3

- 42 U.S.C. § 289(b)(2)
  - *The Secretary shall establish a process for the prompt and appropriate response…incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.*
- Establishes OHRP's compliance oversight authority
- Additional authority requires statutory amendment


A-19
Bill Draft
House and Senate Vote
Vetoed by President
Signed by President
Amended Statute

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 public 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

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

- HHS drafts NPRM; input may be sought from other agencies

- Clearance
  - Internal HHS clearance
  - OMB clearance; OMB may send to other Common Rule agencies for comment

Amending the Common Rule (Subpart A)

- Possible options:
  - HHS drafts NPRM with input from CR agencies
  - Interagency drafting/review committee
- Clearance by each of CR agencies (+ CIA and DHS)

Modifying guidance/FAQs

- Guidance/FAQs do not have the force of law or create new rights/duties; neither are binding on the regulated community or the Federal agency
- Usually, no notice and comment needed to change, and agency is free to adopt new interpretation if it is reasonable…EXCEPT:

Modifying guidance/FAQs (2)

- Long-standing or well established interpretations of regulations, which have been relied on by regulated entities, cannot be reversed or substantially altered without notice and comment

If SACHRP chooses to recommend a change to a current interpretation…

- Change in Common Rule language → rulemaking
- Change in language in HHS-specific subpart → rulemaking
- Changed interpretation ≠ changed regulatory language → may require notice and comment