GCP & HSP Module Part 1: Code of Federal Regulations (CFR)

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National Institutes of Health

Laws, Regulations & Guidances

BINDING

- Laws
  - Legislative Branch (Congress)
  - Published in the United States Code (USC)
- Regulations
  - Executive Branch (Departments & Agencies)
  - Code of Federal Regulations (CFR)

- Guidances
  - Agencies

Not Binding

Code of Federal Regulations

- Codification of general and permanent rules
- Published annually in the Federal Register
- 50 subject titles
  - Chapters
  - Parts
  - Subparts

Clinical Trial Regulations

- Title 45 Part 46
- Title 21 including Parts 11, 50, 54, 56, 312, 600, 812
- Regulations are open to interpretation
  - Title 45 Part 46: Office for Human Research Protections (OHRP)
  - Title 21 and its subparts: FDA

Title 45 Part 46

- Regulates protection of human subjects in HHS funded research
- *Human subject* means a living individual about whom an investigator conducting research obtains either:
  - Data through intervention or interaction with the individual
  - Identifiable private information

Title 45 Part 46 Subpart A

- Protection of Human Subjects (1974, revised in 1981, 1991, 2018)
  - Referred to as the Common Rule (1991)

http://www.hhs.gov/ohrp/

45 CFR 46: Subparts B - E

- Subpart B: Pregnant Women, Human Fetuses and Neonates in Research (1975, revised 2001)
- Subpart C: Biomedical and Behavioral Research Involving Prisoners as Subjects (1978)
- Subpart D: Children Involved as Subjects in Research (1983)
- Subpart E: Registration of IRBs (2009)

OHRP Guidance

Guidance

OHRP has published a variety of guidance documents to assist the research community in conducting ethical research that is in compliance with the HHS regulations. On this page, OHRP guidance documents are organized in categories that should be intuitive for members of the research community. In addition, all guidance documents can be accessed through an alphabetical list.

OHRP Guidance on COVID-19

Access guidance for the application of the 45 CFR 46 regulations to actions taken in response to the COVID-19 pandemic

OHRP Guidance on Elimination of IRB Review of Research Applications and Proposals

Access guidance on elimination of IRB review of grant applications and protocols

OHRP Guidance on Maintaining Consistency Regarding the Applicability of the 2018 or Pre-2018 Requirements

Options for How New Sites Added to Ongoing Cooperative Research Can Follow the Same Version of the Common Rule.

Frequently Asked Questions (FAQs)

Access FAQs about human research protections and OHRP's answers

Title 21 - FDA

- Part 11: Electronic records and signature
- Part 50: Protection of human subjects
  - Subpart D: Additional Safeguards for Children in Clinical Investigations
- Part 54: Financial disclosure by clinical investigators
- Part 56: Institutional review boards
- Part 312: Investigational New Drug application
- Part 600: Biologic Products
- Part 812: Investigational Device Exemptions

FDA Guidances

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The table below lists all official FDA Guidance Documents and other regulatory guidance. You can search for documents using key words, and you can narrow or filter your results by product, date issued, FDA organizational unit, type of document, subject, draft or final status, and comment period.

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Guidance Document Search

FDA Clinical Trials Guidance Documents

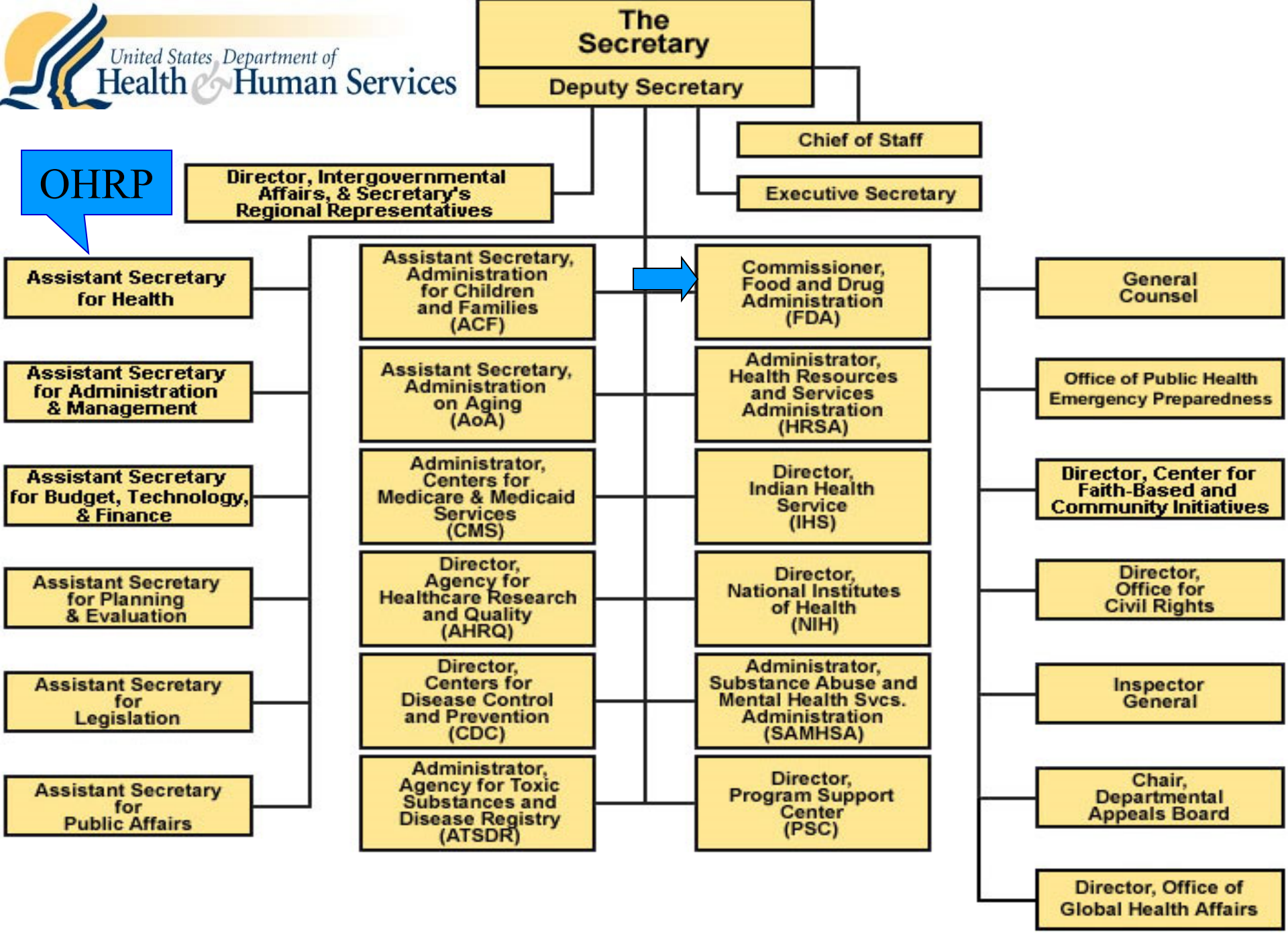
Clinical Trials Guidance Documents

Guidance documents listed below represent the agency's current thinking on the conduct of clinical trials, good clinical practice and human subject protection.

Guidance documents are not binding for FDA or the public. Guidance should be viewed as recommendations unless specific regulatory or statutory requirements are cited. An alternative approach may be used if the approach satisfies the requirements of the applicable statute and regulations.

Some links embedded within guidance documents may have changed since the document was published. If a link does not work, please search for the document by title or contact FDA for assistance.

Withdrawn or Expired Clinical Trial Guidance Documents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Director, Office of Global Health Affairs

Summary

- Regulations come from laws passed by Congress
- Existing laws and regulations may change to address new issues or concerns
- Guidelines provide direction and are not legally binding