JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Section D

Good Clinical Practice

GCP: “Good Clinical Practice”

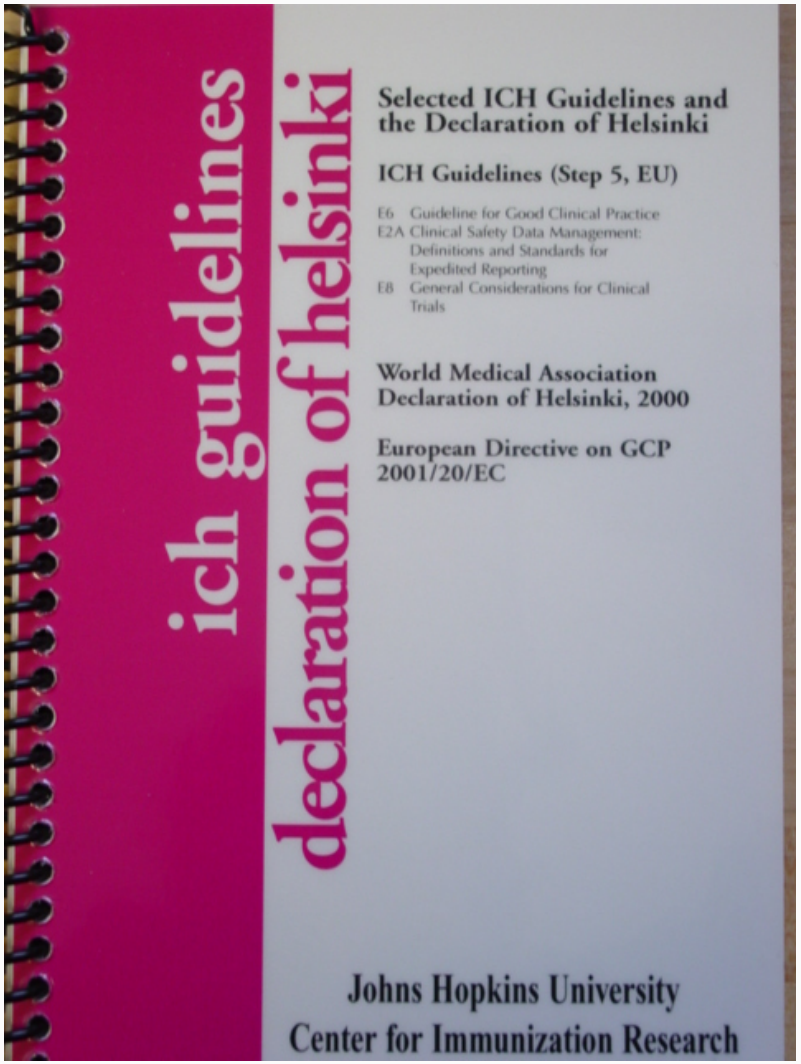
- International standard for ethical and quality research with human subjects

- Describes how research should be . . .
  - Designed
  - Conducted
  - Recorded
  - Reported

Guidelines for Good Clinical Practice (GCP) ICH Section E6

- Guidance documents developed by multi-country expert working group in 1996

- 1.24. A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected



Examples of Principles of GCP

- Clinical trials should be conducted in accordance with ethical principles
- Available clinical and clinical information on the product should be adequate to support the proposed trial
- Staff and investigators should be qualified by experience and training
- Clinical trial information should be recorded, handled, and stored to allow accurate reporting and interpretation
- Systems with procedures to assure the quality of every aspect of the trial should be implemented

Record Keeping

- Raw data must be . . .
  - Attributable (who collected it—ID and date)
  - Original (first hand)
  - Accurate (what was observed, not corrected)
  - Contemporaneous (at the time, not from memory later)
  - Legible (readable, recorded in permanent ink or unalterable electronic records)

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