

Running an Ethical Trial

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Foundations for the Conduct of Ethical Clinical Research

- Nuremberg Code (1947)
- The Declaration of Helsinki - World Health Organization (1975, 1983, 1989, 2000)
- (USA) The Belmont Report (1979)
- (USA) The Common Rule (Code of Federal Regulation – Protection of Human Subjects) (Established concept of Institutional Review Boards)

Conduct of Ethical Clinical Research (Nuremberg Code)

- Voluntary consent is **absolutely essential**
- Experiment should yield fruitful results for the good of society
- Design based on results of animal experimentation and knowledge of natural history of disease; the anticipated results will justify performance of the experiment
- Designed to avoid all unnecessary physical and mental suffering and injury

Conduct of Ethical Clinical Research (Nuremberg Code)

- No experiment conducted where there is an *a priori* reason to believe death or disabling injury will occur (except where experimental physicians will also serve as subjects)
- Degree of risk should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment

Conduct of Ethical Clinical Research (Nuremberg Code)

- Proper preparation and adequate facilities for research required
- Study conducted by scientifically qualified persons, employing highest degree of skill/care
- Research subjects must be permitted to leave the study at any time
- Study should be stopped if information obtained demonstrating continuation not in the best interest of the research subjects

Additional Requirements for Ethical Clinical Research

- Fully inform patients of potential investigator/ institutional “conflict-of-interest” or (if necessary) remove “conflict”
- Avoid perceived/real inappropriate inducements for study participation
- During conduct of study fully inform patients of developments that may influence their willingness to continue participation in the research program

Additional Requirements for Ethical Clinical Research

- Mandate adequate monitoring of the conduct of a clinical trial, specifically to insure research subject safety and the integrity of study results
- **Publish** results of all clinical research efforts (the investigator's "contract" with a research subject)