A Quick Guide to Clinical Trials (Part 3: Ethical Requirements)

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Medical advancements save lives. However, new procedures, tools, and products require thorough testing to ensure they are at least as safe and effective as the current standard of care. Advancements in human medicine typically occur through two different phases of biomedical research: pre-clinical and clinical. Pre-clinical research is vital to gaining an understanding of biological mechanisms, to determining whether a new treatment might prove beneficial, and to predicting potential negative side-effects of a drug or procedure. However, without clinical research, the safety and efficacy of a new medical treatment cannot be known with certainty. In fact, due to low treatment efficacy and excessive negative side-effects, only about 7% of new drugs pass through clinical research and into general medical practice.

While clinical trials are necessary for the advancement of medicine, they also require close monitoring to ensure that they maintain scientific integrity and do not violate ethical standards. Many governments regulate these studies at both the clinical and pre-clinical levels. To ensure that clinical research meets both a scientific standard and an ethical standard, the World Health Organization (WHO) makes available a “recommended format for a research protocol.” Typically, a single drug goes through 25–30 separate trials on its way to the clinic, with each trial adjusting the research protocol based on knowledge acquired during previous stages of research.

Declaration of Helsinki

In 1964, the World Medical Association produced the Declaration of Helsinki, which has since been amended several times, most recently in 2013. This declaration established the first official set of guidelines for maintaining ethical standards in clinical research. However, while this document guides the structuring of local legislation and regulation, it is not law itself. Further, despite covering many vital components of ethical principles relevant to biomedical research in human subjects, the Declaration of Helsinki does not specifically instruct ethics committees, such as Institutional Review Boards (IRBs), in how they should function.

ICH Good Clinical Practice

In 1996, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) produced Guidelines for Good Clinical Practice, called ICH GCP E6. This group is composed of members from the European Union, the United States, and Japan and aims to speed the development of new therapies from the laboratory to the clinic, while upholding the highest ethical standards and measures of quality control regarding both safety and effectiveness. While the Declaration of Helsinki covers guidelines for good ethical practices in clinical research, the ICH GCP provides information on specifics pertaining to operational practices of running a clinical trial that will ensure the safety and rights of subjects in a trial, while also maintaining rigorous standards to guarantee that data collected are of sound scientific value. The ICH GCP has gained such wide-ranging acceptance as an international guide for clinical trials that results from studies conducted in one region can be used to apply for a new drug application in another region if the study has followed ICH GCP guidelines. Offering further guidelines on different legal rules and ethical standards across 96 different countries, the Office for Human Research Protections in the US department of Health and Human Services has compiled a list of more than one thousand laws and regulations pertaining to research involving human subjects in a document called the "International Complication of Human Research Protections."

Both the Declaration of Helsinki and the ICH GCP mention the importance of receiving supervisory support and approval from an ethics committee prior to the initiation and throughout the duration of a clinical trial. These ethics committees, sometimes called Institutional Review Boards (IRBs), typically reside over ethical considerations for clinical studies for only one institution, but ensure compliance with all local regulations and legislation.

Codes of Ethics

The Clinical Center at the US National Institutes of Health has established seven principles based on several codes of ethics meant to guide clinical research:

- Independent review: In the United States, several types of groups (granting agencies, IRBs, and data and safety monitoring boards) ensure that a trial follows

sound ethical practices.

- Informed consent: Participants must only be included in a trial if they give their voluntary consent after receiving all pertinent information on a trial. In the cases of children or individuals who are medically unable to give their consent, the individual should have the benefit of a proxy decision maker who is aware of the likely wishes of the subject.
- Fair subject selection: Subjects should be chosen to sufficiently address the intended query of the study, while "minimizing risks and enhancing benefits to individuals and society." Study subjects should include members of all groups (gender, race, age), unless members of a particular group must be excluded for a strong reason (scientific or health of the subject).
- Scientific validity: The study should be scientifically sound to ensure that resources are not squandered and subjects do not take unnecessary risks with no likely beneficial outcome.
- Favorable risk-benefit ratio: While clinical trials inherently include some risk, the potential benefits must be sufficient to balance these risks. Researchers must work to minimize the risks and maximize the benefits to the best of their abilities.
- Respect for potential enrolled subjects: Rights of study participants must be respected throughout the trial, including during the selection process:
    - Right to privacy
    - Right to withdraw
    - Right to new information gained during the study
    - Right to maintenance of their welfare, including monitoring and treating and removal from the study if required
    - Right to know the study results
- Social and clinical value: A clinical trial should seek to address a question whose answer has the potential to improve the current standard of care to a degree sufficient to justify the resources used and the risk taken by study participants.

Clinical research offers great value. However, subjects involved in clinical trials incur risk. Researchers must use extreme care in the design of their study to ensure that it provides the most value possible and that is strictly adheres to both local and international ethical guidelines.

Learn more about 'Introduction to Clinical Trials' and 'Conducting a Clinical Trial' – parts 1 and 2 of 'A Quick Guide to Clinical trials' series.

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