

Expedited review

Declaration of Helsinki 2008

The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins.

This committee must be independent of the researcher, the sponsor and any other undue influence.

It must take into consideration the laws and regulations of the country or countries in which there search is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events.

No change to the protocol may be made without consideration and approval by the committee

Council for International Organizations of Medical Sciences (CIOMS)

All proposals to conduct research involving human subjects must be submitted for review of their scientific merit and ethical acceptability to one or more scientific review and ethical review committees.

The review committees must be independent of the research team, and any direct financial or other material benefit they may derive from the research should not be contingent on the outcome of their review.

The investigator must obtain their approval or clearance before undertaking the research.

The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study

The Common Rules: Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects (45CFR46)

Subpart A Sec. 46.110

Expedited review process for certain kinds of research involving no more than minimal risk, and for minor changes in approved research

Expedited review procedures may be carried out by

- the IRB chairperson, or
- one or more experienced member designated by the chairperson

Expedited reviewers may exercise all all of the authority of the IRB except disapproval.

