

Guideline on Conducting Multicenter Projects and Theses

1. As per paragraph 2.8 of the "Guideline on Establishing, Ranking and Defining Terms of Reference for Ethics Committees for Biomedical Research (at National, Academic and Organizational Levels)", in regard to projects conducted in more than one university:
 - a. The project shall be approved by a minimum of two committees (at academic or organizational levels) of the two universities involved in the project.
 - b. For projects conducted in a number of centers supervised by a single academic committee, project approval by one committee (research ethics committee of that university, or any other organizational committee under its supervision) shall suffice.
2. For projects or theses approved in one university and conducted in another (not applicable to research centers or bases belonging to one university that are located within the geographical territory of another), the research proposal shall be approved by the ethics committee of the first (approving) university, and the ethical approval certificate of the project and proposal be forwarded to the second (executing) university. The executing university may accept the forwarded ethical approval, and permit the research to be conducted, or consider and decide on the project in its own ethics committee. The research shall be conducted only when approved by both universities involved.
3. In case the executing university approves the proposal with modifications or alterations, such modifications or alterations shall need to be approved by the first university as well.
4. As an established principle in research ethics, the lead researcher shall hold full responsibility for the project regardless of the center where it may be conducted, and conducting a project in a university or organization different from where the proposal was initially approved shall not refute this principle. The lead researcher shall ensure that the research is conducted at a venue where

precise and comprehensive supervision over the process is possible. For student theses, such responsibility shall rest with the related advising professor(s).

- . The responsibility for proper execution of the research shall rest with the ethics committee approving the project.
- ↯. For research projects involving human trials, telephone number(s) and precise postal address of the ethics committee approving the project shall be mentioned in the informed consent document. The person(s) appointed for responding to participants in research (trials) in regard to questions, side effects or problems arising from participating in the project shall be accessible at all times.
- ↰. Precise specification of the venue where the research is conducted is a fundamental principle in preparing research proposals. After the approval of a proposal by academic/organizational ethics committees, a copy of the approval shall be forwarded to the hospital, clinic, faculty, research center, etc. where the research is planned to be conducted, in order to inform them of the process. The related ethics committee may request the host health-research center to supervise and report on the proper execution of the research.
- ↱. As any biomedical research may be conducted only if approved by competent research ethics committees, research by personnel of universities (faculty members and others), private health care facilities such as hospitals, clinics, doctors' offices and the like, shall seek the approval of research ethics committees in the geographical area where the research is conducted. The responsibility for proper execution of this paragraph shall rest with the medical universities engaging in such research. The lead researcher shall cooperate with the research ethics committee approving the project, which shall also be responsible for supervising the proper execution of the research.

This guideline in ↱ paragraphs was approved by the Seventh Session of the National Committee for Ethics in Biomedical Research, on 22 June 2010.
