Guideline on Responsibility for Conducting Clinical Trials in Cooperation with Pharmaceutical Companies, Medical Equipment Companies or Other Private Entities

This guideline serves as a supplementary document for other national regulations and guidelines for medical research, in order to clarify responsibility for conducting clinical trials in cooperation with pharmaceutical companies, medical equipment companies or other private entities, with the aim of seeking final approval or license for introducing a new drug into the market.

١. Considering the necessity for clinical trials to be conducted by researchers possessing sufficient scientific and technical competence, the ethics committee shall first ensure such competence exists with the lead researcher and the related research team.

٢. Research ethics committees shall consider projects only after approval by competent scientific bodies, such as research councils of universities, research centers and training groups, or research and postgraduate studies councils of faculties in universities and scientific-research institutes with relevant and required licenses. Considering research proposals without their previous approval in a scientific committee shall thus lack any ethical and technical validity.

٣. In all research projects, the lead researcher shall hold full responsibility for the research process, especially observing the rights of research participants, and compensating damages resulting from their participation. In research projects with executive and financial sponsorship, the lead researcher shall take measures such as having the sponsoring company or institute insure the participants, in order to guarantee the sponsor fulfills its obligations pertaining to damages resulting from participation in the projects and the like, and submit documents and evidence on such measures to the relevant ethics committee. The sponsor's undertaking in this respect shall not relieve the lead researcher of the full responsibility of the research project.

٤. The requirements stipulated in paragraphs ١ to ٣ above shall also apply to cases where competent clinical research organizations (CROs) participate in conducting clinical trials, including pharmaceutical, medical equipment, biotechnological and bioequivalence studies, and they shall be held responsible for precise and proper execution of the research proposal(s) approved by competent scientific and research ethics committees.

This guideline in ٤ paragraphs was approved by the Tenth Session of the National Committee for Ethics in Biomedical Research, on ١٥ February ٢٠١٦.

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