



Mexico City. September 07, 2004
David A. Lepad
Office for Science and Health Coordination
Good Clinical Practice Programs (HF-34)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 2004N-0018: Human Subject Protection; Foreign Clinical Studies not Conducted Under an Investigational New Drug Application

Dear Dr. Lepad:

The Latin American Forum for Ethics Committees for Health Research (FLACEIS) joins the concerns raised by other people and organizations, regarding the proposal to require foreign clinical studies conducted without a U.S. Investigational New Drug application (IND) to comply only with Good Clinical Practice (GCP) guidelines.

FLACEIS is particularly concerned and interested in expressing our thoughts, since we represent a very relevant number of recipient countries of US companies and Institutes clinical research, both for drugs and other kind of studies. Since we significantly contribute to the drug and knowledge development, we see ourselves as key stakeholders affected by this initiative.

As a network devoted to the protection of human participants in any kind of health research, we acknowledge ethics as the core of our work and the Declaration of Helsinki, is the best document available, with the widest acceptance and consensus, which serves as a paradigm document for the international community, both medical and non medical.

Even though we recognize and agree that the good science, the quality of the data and a sound scientific protocol are a basic requirement, it is not enough to ensure the ethics of the research. ICH and GCP are useful tools to achieve the quality and to ensure compliance to regulations, but the Declaration of Helsinki, aims and guides the researchers towards the ethical conduction of the study, and thus, the adequate protection of participants. Therefore, FLACEIS considers an unnecessary, extremely risky and unacceptable decision to substitute DOH (an ethical document) for GCP (normative document).

We truly hope that FDA and the USA will consider the international opinion and act as a genuine partner.

Yours sincerely

Dafna Feinholz, Chairperson
Andrés Peralta, Vicechairperson
Stella Cerruti, Secretary
Cristina Torres, Treasurer