

June 6, 2000

William Gerberding, PhD  
Chair, Clinical Research Roundtable  
Institute of Medicine  
Foundry Building  
1055 Thomas Jefferson Street, NW  
Washington, DC 20007

Dear Dr. Gerberding:

The phenomenal success of basic biomedical research has led to an exponential growth in opportunities for translational research. Moreover, this pace will continue to accelerate as the Human Genome Project leads to revolutionary advances in the diagnosis and treatment of disease. In this environment of expanding biomedical research opportunities and support, we must ensure that we adhere to the highest standards of protection for human research subjects. In order to safeguard human subjects and meet the needs of patients anticipating new therapies, we must make the human subjects review process more efficient in order to ensure its maximum effectiveness. We hope that our suggestions in this regard will be of assistance to you and your Clinical Research Roundtable colleagues as you develop your program.

Institutional Review Boards (IRBs) charged with governing the interface between basic research and human application were established at a time when the volume of investigation was much smaller. This increased volume of clinical investigation places new demands on the IRBs and threatens to overwhelm the human subjects review system. Compounding this problem, Academic Health Centers that traditionally provide the funding support for IRBs are under unprecedented financial strain because of an increasingly price-sensitive healthcare marketplace combined with the loss of many traditional sources of revenue mandated by the Balanced Budget Act. As a result, existing IRBs are overworked, understaffed, and under-funded at many institutions.

The infrastructure for managing and overseeing human subjects research needs to be augmented to maximize the potential for making progress and bringing the benefits of progress in medical research to our patients. We applaud the recent changes implemented at NIH to improve the efficiency of the IRB review process. That is, IRB approval is no longer required prior to peer review of an application, and teleconferencing can be used to conduct IRB review. Presently, efforts are underway to improve patient protection through individual investigator education, accreditation of IRBs and enhanced oversight of the human subjects review process. We await the outcomes of these initiatives, and hope they generate viable and beneficial proposals. If successful, these efforts should make a significant contribution to medical research. We believe, however, that these necessary steps will not be sufficient to meet all of the challenges before us.

We believe that the IRB process, whose primary concern must be the safety of patients, can become

much more efficient without sacrificing patient safety. Without this increase in efficiency, these processes themselves will stifle clinical investigation and discourage young people from entering this field so in need of additional researchers.

Improved efficiency could be achieved by greater use of administrative staff for routine tasks, employment of specialists to prepare informed consent documents and other commonly used materials, and development of web-based submission tools combined with prompt email feedback of protocols. In addition to more intensive education of investigators, we need to encourage an open and scientific interface between investigators and IRBs. This should include participation and appearance of investigators at the non-Clinical Research Roundtable confidential portions of the discussion of research protocols. Doing so would improve the science as well as the efficiency of the approval process. We point out, however, that these suggestions would result in substantial additional costs to the institution and would require increased faculty effort. Mechanisms will need to be developed, therefore, to offset these costs and recognize this higher level of commitment.

While each Academic Health Center will form its own unique responses to the current problems, FASEB believes that there will be significant opportunities for inter-institutional collaboration including new training programs. FASEB recommends that the Academic Health Centers not only continue their efforts to catalog research compliance resources, but also open a dialogue to facilitate identification of best practices for human subjects review with the goal of rapid and wide dissemination of these practices throughout the community. Doing so will insure the best protection for the public and the most efficient use of research resources. Failure to make this investment now will result in greater financial burdens downstream.

We are at a critical juncture for biomedicine. The issues that the Roundtable will confront have enormous implications for research, medicine, and our entire society. Please call upon us if we can help you in any way to develop, refine, or execute your program.

Sincerely,

David G. Kaufman, M.D., Ph.D.  
FASEB President

Mary J.C. Hendrix, Ph.D.  
FASEB President-Elect

Cc: Jordan Cohen, M.D.  
President, Association of American Medical Colleges  
Nils Hasselmo  
President, Association of American Universities

---

Return to the [FASEB Office of Public Affairs](#) homepage