DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

JUN 21 1991

TO: Dr. Robert C. Gallo
Chief, Laboratory of Tumor Virus Biology, NCI, NIH

FROM: Director, NIH
Deputy Director for Intramural Research, NIH

SUBJECT: Protection of Human Research Subjects

The Office of the Director, NIH, today completed its review of the preliminary report from the Office for Protection from Research Risks (OPRR) entitled "Findings and Required Actions Regarding Allegations of Noncompliance with HHS Regulations for the Protection of Human Research Subjects Involving the National Institutes of Health Intramural Program." This preliminary report identifies significant deficiencies in the NIH procedures for protection of human subjects in collaborative research projects involving scientists and institutions outside the NIH, especially those in foreign countries. The report also identifies specific instances where you and employees supervised by you failed to comply with HHS Regulations for the Protection of Human Subjects (45 CFR 46) in this regard.

We are mindful that, since July 23, 1990, you and the other members of the Division of Cancer Etiology (DCE), National Cancer Institute, have been subject to special restrictions regarding collaborative research with foreign scientists or institutions whenever human subjects research is involved. Initially, the restrictions were limited to collaborations with certain French scientists or institutions; since February 7, 1991, the restrictions have applied to collaborations with any foreign scientists or institutions. The fundamental requirement throughout this period has been prior approval by the OPRR for any ongoing or proposed collaborative activities including the transfer of funds, information, or chemical/biological materials between the DCE and the foreign partner(s).

The Office of the Director has taken action to remedy the deficiencies identified by the OPRR. As part of this, we are strengthening the oversight and review role of the Office of Intramural Research (OIR). Effective immediately, any proposed collaborations involving human subjects by you and your staff with scientists or institutions outside the NIH, domestic or foreign, will require review and approval by the OIR after the Institute Clinical Research Subpanel and the Director, NCI, have approved the project. Once the (Acting) Deputy Director for Intramural Research (DDIR) approves a project, the OIR will request concurrence by OPRR.

Please recognize that we are extending these restrictions and requirements for review on you and your laboratory to all collaborative domestic research involving human subjects. These actions governing your collaborative research activities will be in effect until further notice.

Additionally, your Institute Director, Dr. Samuel Broder, will be conducting a complete audit of human subjects research conducted by the NCI as described in the attached memo. We expect your full and complete cooperation.

You must act immediately (1) to comply with these requirements, (2) to ensure that you are knowledgeable about the regulations for the protection of human subjects in research and, (3) to inform your staff of these regulations as well as the activities that constitute restricted collaborations. Be advised that these steps are being taken in advance of the final report from OPRR because of the need to respond immediately to the deficiencies identified. Further action may be taken pending the receipt of the final report. Please feel free to seek assistance from the the Director of NCI, or the Acting DDIR, as necessary.

Bernadine Healy

Bernadine Healy, M.D.

Carl Kupfer

Carl Kupfer, M.D.

Attachment

cc:
Director, NCI
Director, OPPR
Legal Advisor, NIH