

MEMORANDUM

Office of the Provost

C. L. Max Nikias
Provost and
Senior Vice
President for
Academic Affairs

TO: IRB Chairs and Staff, and Faculty Colleagues
FROM: C. L. Max Nikias *C. L. Nikias*
DATE: November 22, 2005
SUBJECT: Compliance with Institutional Policies and Government Regulations
Regarding Human Subjects Research

I am writing to designate Randolph W. Hall, Vice Provost for Research Advancement, as USC's Institutional Official (IO) responsible for overseeing USC's Human Subjects Protection Program (HSPP) and grant him the authority to carry out those responsibilities associated with being the Institutional Official of the HSPP.

These responsibilities include:

- Ensure the protection of research subjects
- Ensure compliance with state and federal law.
- Ensure the independence of the IRB.
- Ensure that human research protection program has sufficient resources for conducting the activities under its jurisdiction.
- Ensure that the number of IRBs is appropriate for the volume and types of human research reviewed, and that reviews are accomplished in a thorough and timely manner.
- Create and approve policies and procedures governing the human research protection program.
- Conduct an annual review of the resources allocated to the human research protection program.
- Create the annual budget for the human research protection program.
- Allocate resources within the human research protection program.
- Bring unmet resource needs to the attention of a senior official, such as the Provost and the President of the University.
- Suspend or terminate research.
- Provide the IRB with access to legal counsel
- Place administrative sanctions on investigators for non-compliance, such as
 - ▶ Suspension or termination of research privileges
 - ▶ Require investigators or research staff to undergo additional training as a condition of continuing research
 - ▶ Appointment of an independent person to monitor ongoing research.

These duties are assigned to the Institutional Official, but at his discretion may be delegated to other University representatives as appropriate including the Office for the Protection of Research Subjects, IRB Chairs, and the Office of Compliance.

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