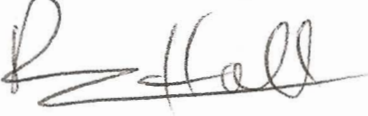


MEMORANDUM

Office of the Provost

Randolph W. Hall, Ph.D.
Vice Provost for Research
Advancement

TO: IRB Chairs and Staff, and Faculty Colleagues

FROM: Randolph W. Hall 

DATE: November 23, 2005

SUBJECT: Compliance with Institutional Policies and Government Regulations
Regarding Human Subjects Research

I am writing as USC's designated Institutional Official responsible for overseeing the Human Subjects Protection Program (HSPP), and as the USC Institutional Official listed on the Federalwide Assurance (FWA), as a supplement to my letter of August 31, 2005.

Among the duties of the Institutional Official are to:

- 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.

IRB Chairs and Staff

November 23, 2005

Page #2

These duties may at my discretion be delegated to University representatives including the Office for the Protection of Research Subjects, IRB Chairs, and the Office of Compliance, as appropriate.

I hereby delegate authority to approve, disapprove, or suspend human subject research projects to the Health Sciences and University Park IRBs. No USC faculty, staff, or student may conduct human subjects research without obtaining approval from the appropriate IRBs at either the Health Sciences or University Park Campuses.

The principles embedded in the FWA are implemented through the IRB and IRB Policy and Procedures. These Policy and Procedures will be periodically updated as best practices, ethics, and federal regulations evolve.

As USC embarks on the AAHRPP accreditation of the USC Human Subjects Protection Program (HSPP) it is an opportune time to remind human subjects research faculty, staff, and students of the strict obligation to follow all USC and IRB policies and procedures, as well as federal, state, and local laws and regulations regarding review and approval of research involving human subjects. We are committed to ensuring that USC remains in compliance with governmental regulations and with the highest ethical standards in the conduct of research.

cc: Tom Katsouleas
Mike Nichol
Howard Gillman
Laura LaCorte
Susan Rose