

# USC UNIVERSITY OF SOUTHERN CALIFORNIA Human Subjects Newsletter

Published by the Office for the Protection of Research Subjects (OPRS)  
Susan L. Rose, PhD, Executive Director



## AAHRPP Accreditation Site Visit: March 2-4, 2010



OPRS intern, Narendran Murugan (MS MDDE '10), prepares education packets for AAHRPP interviewees.

The Association for the Accreditation for Human Research Protection Program (AAHRPP) will be visiting the USC campus March 2-4, 2010 to assess the University's Human Subjects Protection Program (HSPP). The three day site visit to both campuses will include 100 interviews with students, staff, and faculty. The site visit is an integral part of the accreditation process and is used to gauge the USC human subjects protections commitment and process. Education sessions to prepare the USC community are currently underway. More information about AAHRPP and interview educational materials can be found on the OPRS website (see below).

**USC AAHRPP Webpage:** [www.usc.edu/admin/provost/oprs/aahrpp](http://www.usc.edu/admin/provost/oprs/aahrpp)

## Penalty Credits Not Permissible in Student Subject Pools

OHRP recently provided guidance regarding Subject Pools and student no-shows (<http://www.hhs.gov/ohrp/policy/correspond/OHRP20100108.html>). USC will implement the OHRP guidance for subject pools for all studies regardless of funding.

### ***USC Policy on Student No Shows/No Penalty Credits Permissible***

*If a student fails to show up for a study appointment, previously earned study credits cannot be deducted. To encourage student participation, partial credit for showing up to the appointment may be awarded. Additionally, the number of credits that can be earned through study participation may be decreased if students are given an alternative to study participation that will result in the same maximum number of credits possible and involve comparable time and effort as study participation.*

## Classroom Policies Clarification

Classroom assignments, as a general rule, do not require IRB approval. These projects typically fulfill a course requirement, are often completed in one semester, and are designed to teach research methods. Faculty members design these assignments to engage students in interaction with potential study subjects, gather data about individuals, and/or illustrate concepts covered in the course. Primarily classroom projects are not intended to create new knowledge or to lead to scholarly publication. These assignments do not meet the federal definition of human subjects research. If students or faculty are uncertain if a classroom project must be reviewed by the IRB, they should contact the IRB.

***“Classroom assignments, as a general rule, do not require IRB approval.”***

Dissertations, theses, independent study projects and honors projects, however, do require IRB review and approval. These projects are designed to contribute to generalizable knowledge and do use human research subjects, thus meeting the federal definitions of human subjects research.

In the event that data obtained from a classroom project later results in new knowledge or useful/publishable information, it should then be submitted to the IRB as a secondary data analysis of existing data.

Students can experience submitting an IRB application by using the iStar training Sandbox:

<http://istartraining.usc.edu/>

Research methods students are encouraged to complete the online human subjects education program, [CITI](#).

## Research (RCR) Training Required for All Students Supported by the National Science Foundation (NSF)

All students (including undergraduates, graduate students and postdoctoral scholars) supported by the National Science Foundation are required to complete an approved course in Responsible Conduct of Research. Students supported on certain NIH programs, including training grants, are also required to complete RCR training.



On-line instruction satisfies USC's requirement for NSF funded students, and will be available after 2/15/2010. For more information visit the VPRA website (below).

**Vice Provost for Research Advancement (VPRA) RCR Webpage:**

[http://www.usc.edu/research/about/policies/responsible\\_conduct\\_of\\_research\\_rcr/](http://www.usc.edu/research/about/policies/responsible_conduct_of_research_rcr/)

## OPRS Welcomes New Staff Member: Jennifer Hagemann



Jennifer Hagemann, MS

The OPRS welcomes Jennifer Hagemann as the Program Director. In this capacity, Ms. Hagemann will be involved in: human subjects education, IRB policy development and implementation, the continuous quality improvement program, and other duties related to ensuring a successful human subjects protection program. Ms. Hagemann spent the last 12 years serving in various capacities within the Keck School of Medicine, most recently as a study coordinator. Jennifer earned her BA (Psychology) and MS (Regulatory Science) from USC. We welcome Jennifer to the OPRS as she brings lots of energy, enthusiasm, and experience to our team. She can be reached at (213) 821-4218 or [hagemann@usc.edu](mailto:hagemann@usc.edu).

## Good Clinical Practice (GCP) Requirement Clarified.

In April 2009, the Vice Provost for Research Advancement, Randolph W. Hall, announced that GCP training would be required for key personnel serving on full board clinical trial/clinical research e.g.

FDA regulated research, drugs, biologics, or device trials. GCP training is not required for Exempt or Expedited studies.

## Did You Know? Helpful HSPP Website Resource

The OPRS maintains a dynamic and comprehensive human subjects research website. In the next few Human Subjects Newsletters, web resources will be highlighted to inform the USC research community of the site. Two highlights are below.

- **IRB Reviewer Guidelines/Checklists**

The IRB Reviewer Guidelines/Checklists can be used by IRB members and staff to aid in the review of applications. These guidelines serve as excellent resources when completing IRB applications for investigators as well. The guidelines are available at:

<http://www.usc.edu/admin/provost/oprs/research/#guidelines>

- **iStar Training/Resources**

iStar (IRB Submission, Tracking, and Review) is the online IRB application system used to review all USC human subjects research studies. This page provides some training resources and info to successfully navigate the system.

<http://www.usc.edu/admin/provost/oprs/training/istar.html>

1. PROJECT DESCRIPTION AND METHODOLOGY		Yes	No	NA
a. Are the aims and objectives/rationale of the research stated clearly?				
b. Have the research use procedures consistent with sound research design?				
c. Have the research design/aim the proposed research questions to address the proposed study objectives and result in scientific and/or socially valid results?				
d. Does the research contribute to generalizable knowledge?				
e. Is there an adequate justification for enrolling human subjects?				
f. Is there an adequate explanation of the research aims?				
g. Is there an adequate description of the activities involving human subjects?				
h. Is there a detailed description of the data collection and methods of recording?				
i. Have the questionnaires and interview tools been validated?				
j. Is there an adequate justification for the sample size?				
2. RISK AND BENEFIT CONSIDERATION		Yes	No	NA
a. Are the risks (physical, psychological, legal, economic, and social) to subjects assessed by using procedures which are consistent with sound research design and which do not unreasonably expose subjects to risk?				
b. Are the risks minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?				
c. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result?				
d. Are the risks to subjects reasonable in relation to the importance of the knowledge that may reasonably be expected to result?				
e. Are both risks and anticipated benefits accurately identified, evaluated, and described?				
f. Have the risks and benefits of the research interventions been evaluated separately from those of the diagnostic intervention?				

## Articles of Interest

- [NIH Announces First National Research Study Recruitment Registry](#), *NIH News* (November 10, 2009)
- [Letter from PharmedOut to NIH requesting that NIH fund studies on medical ethics, conflict of interest and prescribing behavior](#) (November 17, 2009)
- [Eyes Wide Open: The Personal Genome Project, Citizen Science and Veracity in Informed Consent](#), *Medscape* (December 9, 2009)
- [Test a vax, fly to Mexico](#), *The Scientist.com* (January 6, 2010)
- [F.D.A. Aims at Doctors' Drug Pitches](#), *NY Times* (February 1, 2009)
- [NCI Checklist for Easy-to-Read Informed Consent Document](#), *NCI* (2009)