USC Human Subjects Protection Program Receives Accreditation until 2015

The Council of the Association for the Accreditation of Human Research Protection Programs has voted to reaccredit the USC Human Subjects Protection Program. By continuously monitoring and improving its human subjects research policies and practices, USC ranks among an elite group of institutions internationally renowned as promoting exceptional ethical and professional standards in the conduct of human subjects research.

New Staff Member Joins University Park IRB

We are pleased to welcome Ryan Brooks as the newest member of the UPIRB staff. As a University Park IRB Program Specialist, Ryan will be primarily reviewing exempt and expedited projects and participating in UPIRB activities. Ryan Brooks can be contacted at the Stonier Hall UPIRB Office 224a (213) 821-5272 or via email: ryan.brooks@usc.edu.

REMINDERS:

Emergency Use of Investigational Drug, Biologic or Device Requires Approval

Physicians and practitioners providing investigational drugs, biologics, or devices for emergency use must comply with federal and institutional regulations. To view the University policy on Emergency Use of a Test Article see Human Subjects Policies and Procedures Section 18.5 (page 275).
http://www.usc.edu/admin/provost/oprs/private/docs/oprs/pnp/PnPsFinalWeb.pdf

For additional information, refer to the FDA Information Sheet on Emergency Use of Investigational Products
www.fda.gov/regulatoryinformation/guidances/ucm126491.htm
USC Policies Regarding Product Endorsements*

- **Endorsement of Commercial Products**
  “Any action of a faculty member that might seem to commit the University to an endorsement of a commercial product should be avoided unless expressly authorized in advance by the Provost.”
  [Faculty Handbook 2010, Section 3-I (5)]

- **Conflict of Interest in Employment and Business Practices**
  In regard to endorsing or authorizing the endorsement of any product or service on behalf of the University, such arrangements require the explicit prior written approval from the President, Provost and Senior Vice President for Academic Affairs or Senior Vice President for Administration.
  “...a University faculty member or non-faculty employee also must obtain the prior written approval from the Provost and Senior Vice President for Academic Affairs or Senior Vice President for Administration before he or she may endorse or authorize endorsement of any product or service on behalf of the University”.
  [USC Conflict of Interest and Ethics: Policy and Procedure Section 5.2]

**"Endorsement" includes product advocacy used in advertising.**

**iStar Training Sessions**

In-person iSTAR training sessions will be held this semester at both the Health Sciences and University Park Campuses. Training at the Health Sciences Campus is scheduled for **September 29, 10-11 am** in the Health Sciences IRB Conference Room, General Hospital, Suite 4700.

Training at the University Park Campus is scheduled for **October 20, 10-11 am** in the USC Credit Union Bldg 3rd floor conference room located at 3720 S. Flower St.

Please RSVP to istar@usc.edu if you would like to attend.

**FDA Humanitarian Device Exemption (HDE) Guidance Published**

The updated FDA document on HDE includes new guidance for IRB review of HUDs as well as answers to questions commonly asked by clinical investigators and HUD holders such as “What is required in an HDE application?”

Articles of Interest

- **OHRP issues “Finalized Guidance on Withdrawal of Subjects from Research”**

- **Don't Mess with the DSMB** (New England Journal of Medicine July 29, 2010)

- **Pentagon Probes Alleged Research Misconduct on Wounded Troops**

- **AAHMC report “Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research”**

- **NIH Proposed Changes on Financial Conflict of Interest Regulations**

- **Feds admit storing checkpoint body scan images**

To Subscribe/Unsubscribe

To receive the USC Human Subjects Newsletter, please send an email in plain text to listproc@usc.edu with the following information in the body of the message: SUB HUMANSUBJECTS-L (FIRST NAME) (LAST NAME)

example: SUB HUMANSUBJECTS-L TOMMY TROJAN

To unsubscribe from our list send an email in plain text to listproc@usc.edu with the following information in the body of the message: SIGNOFF HUMANSUBJECTS-L example: SIGNOFF HUMAN SUBJECTS-L

Archives

To view archives of previous USC Human Subjects Newsletters, please visit: