USC Human Subjects Updates

CITI (human subjects education program) Required July 1, 2006

CITI, available for use on May 1, 2006, is now offered on a voluntary basis but will be MANDATORY beginning July 1, 2006. This means that all “key personnel” listed on an iStar IRB application must have completed CITI, or similar program, for the application to be approved. This applies to all “key personnel”, including students regardless of the funding source. To find out more about CITI, how to access the program, and see the CITI updated FAQ sheet click on the following link: http://www.usc.edu/admin/provost/oprs/citi

iStar Model Application Templates Available

The OPRS has posted on its website several examples of exemplary iStar applications. These are available to investigators to utilize as a resource in completing their applications. To see the templates click on: http://www.usc.edu/admin/provost/oprs/research/templates.html

Annual IRB Survey

The annual IRB Survey is now available. The useful suggestions from last year’s survey encouraged the HSPP to issue it again. It is now shorter and more applicable to the USC review process. This voluntary survey is not intended to be quantitative, rather it is an opportunity to express positive and negative experiences so better practices may result. THE SURVEY WILL CLOSE JUNE 16, 2006. Please click below to participate in the survey. ALL RESPONSES WILL REMAIN ANONYMOUS. http://www.surveymonkey.com/s.asp?u=940561079963

Hard Copies of the Not Human Subjects Brochure Available

Copies of the brochure, “Is Your Project Human Subjects? A Guide for Investigators” are available. Please contact the OPRS, HSIRB, or UPIRB to get your copy. Electronic copies are also available online at: http://www.usc.edu/admin/provost/oprs/news/newsupdates.html

Health Sciences IRB Updates

Adverse Event Reporting in iStar

Just a reminder, all Adverse Events for studies converted from paper to iStar studies or initially submitted iStar studies, are required to be submitted through iStar. For studies that have not been converted or were not initially submitted through iStar, continue submitting Adverse Events on paper.

OPRS to Issue HSIRB Newsletter

The USC Human Subjects Newsletter will annex the HSIRB Newsletter. In future issues of this newsletter, check out the Health Sciences IRB section for important announcements, news, and guidance. Please send to the OPRS (oprs@usc.edu) any Health Sciences human subjects related information you would like to share.
University Park IRB Updates

iStar Conversion for Full/Expedited Studies
For all studies expiring as of April 1, 2006, continuing reviews should be submitted using the iStar system. This means that existing paper studies will be converted to electronic studies by the iStar technical team. Once your study goes through this process, all future submissions (including adverse events, reportable events, amendments/revisions and any other correspondence) will need to be submitted electronically via iStar. Paper submissions after a study has been converted to iStar will not be accepted. To learn more about the conversion process click below.
https://istarchla.usc.edu/istar/Rooms/DisplayPages/LayoutInitial?PageID=Con

Regulatory Updates

NIH Conflict of Interests Rule
The final rule on conflicts of interest issued by the National Institutes of Health on August 25, 2005 is available at:
http://www.nih.gov/about/ethics_COI.htm

FDA Guidance on Informed Consent...Leftover Human Specimens
On April 25, 2005 the FDA issued the following guidance—Guidance on Informed Consent for In Vitro Studies Using Leftover Human Specimens that are Not Individually Identifiable. The 10-page pdf version may be viewed at

FDA Guidance on the Use of a Centralized IRB
In March 2006, the FDA has issued draft guidance on the use of a Centralized IRB. Click below to see the guidance.
http://www.fda.gov/cber/gdlns/irbclintrial.pdf

News Items

FDA Staff Travels on Drug Industry Dollars: Group tied to FDA-regulated industry paying for agency officials’ trips by Alexander Cohen, Center for Public Integrity (March, 30 2006).

Bioethics Banter Blog
This bioethics blog launched in September 2004 by the editors of the American Journal of Bioethics offers not only news, but the blog format allows broader coverage and better explanations of bioethics issues. To see the blog, click below.
http://blog.bioethics.net/

The article discusses the tissue-industrial complex and specimen ownership.
http://www.nasw.org/users/skloot/TakingTheLeast.pdf

continued…
News Items continued...

Lax oversight by Pitt enabled Schatten Fiasco by Jennifer Bails and Luis Fabregas Pittsburgh Tribune Review (April 23, 2006). This article discusses the collaboration between Pitt biologist Gerald Schatten and Korean scientist Hwang Woo-Suk and the fabrication in the stem-cell breakthrough.
http://www.pittsburghlive.com/x/pittsburghtrib/search/s_446555.html

AAHRPP Updates
There are no AAHRPP updates. Click below to see the AAHRPP website.
http://www.aahrpp.org

Human Subjects Training/Education

IRB/Human Subjects Education Sessions
The OPRS IRB/Human Subjects education sessions will continue in fall 2006. The OPRS will keep you posted on the next session.

iStar Training Continues
iStar training sessions are still occurring. Dates/locations for the next session follow...

Health Sciences Campus—
Please click here to find information about the next training session

University Park Campus—
Please click here to find information about the next training session

Registration is required. To find out how to register, click here or visit the iStar website http://istar-chla.usc.edu .

Repeats

New Online Human Subjects Education Program and Policy Announced
The Vice Provost for Research Advancement, Randy Hall, announced on March 21, 2006, that USC is implementing a new human subjects education program and policy. The policy requires all human subjects investigators and key personnel, whether or not funded, to participate in CITI; the premiere online human subjects education program. To learn more about CITI and read the announcement click below.
http://www.usc.edu/admin/provost/oprs/citi

Unsure if a Project is Human Subjects Research?—New iStar Application Process Created to Make this Determination
A new, short, efficient application process has been created for projects that may not need IRB approval. The process requires only a three (3) page application summary, rather than the full iStar application (25–40 pgs). IRB staff will review this application and determine whether the project falls under one of four categories.
Continued...
Repeats continued...

1. Not Human Subjects Research
2. Exempt
3. Coded Private Information or Biological Specimens Policy or
4. Requires full or expedited IRB review.

Please review the brochure mentioned below before using the new process. The new application process is being finalized and will be available soon.

Brochure Created to Help Investigators Decide if Project is Human Subjects Research.
The OPRS has created a new brochure titled, “Is Your Project Human Subjects Research? A Guide for Investigators”. The purpose of this brochure is to assist investigators in determining if a particular project is human subjects research needing IRB review. As there are many gray areas which make this decision difficult, use of the “short” application process described above will assist in this determination.

The brochure has already been featured in the April 2006 issue of IRB Advisor, a leading human subjects research newsletter. This article has sparked interest in the OPRS brochure from other universities nation-wide.

The brochure is being printed and will be distributed. It can be found online now at: http://www.usc.edu/admin/provost/oprs/news/newsupdates.html
Contact Information

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E-mail: oprs@usc.edu.
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Health Sciences IRB (HSIRB)
IRD Building
2020 Zonal Avenue, Room 425
Los Angeles, CA 90033
Phone: (323) 223-2340
Fax: (323) 224-8389
E-mail: IRB@usc.edu
Web: http://www.usc.edu/admin/provost/oprs/hsirb

University Park IRB (UPIRB)
University Park Institutional Review Board (UPIRB)
Grace Ford Salvatori Hall (GFS), Room 306, MC: 1695
Los Angeles, CA 90089-1695
Phone: (213) 821-5272
Fax: (213) 821-5276
E-mail: upirb@usc.edu
Web: http://www.usc.edu/admin/provost/oprs/upirb

iStar (IRB Submission Tracking And Reviewer System)
Web: http://istar-chla.usc.edu
Help Desk:istar@usc.edu or (213)-821-4219

How to Sign Up for Our Newsletter

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 HUMANSUBJ ECTS-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 HUMANSUBJ ECTS-L example: SIGNOFF HUMAN SUBJECTS-L

Archives

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