USC Human Subjects Updates

OPRS Launches Newsletter
To provide a more user friendly dialogue between the HSPP and the USC human subjects research community, the OPRS has created and launched a newsletter to replace the “plain text,” email format sent in previous listserv announcements. The newsletter will be available in both PDF and Word Versions via the OPRS website under the heading “USC Human Subjects Newsletter.” This newsletter can be easily downloaded and printed for distribution, so feel free to pass it onto others. If there is news, information, or ideas would like to include in future newsletters please send to the OPRS.

OPRS Email: oprs@usc.edu
OPRS WEB: http://www.usc.edu/admin/provost/oprs

AAHRPP Preliminary Application Submitted
On August 8, 2005, the USC HSPP submitted the Preliminary Accreditation Application to the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

After reviewing the Preliminary Application, AAHRPP will respond to USC within 60 days any changes, improvements, or practices that need to be completed by the HSPP. After these recommendations are addressed, the HSPP will begin the Formal Accreditation Process.

All USC human subjects researchers, administration, faculty, and staff as well as IRB members and staff may be requested for AAHRPP interviews. OPRS has study sheets available (http://www.usc.edu/admin/oprs/) for all and a standing offer of educational sessions for any department or school.

UPIRB Applications
All new study submissions to the UPIRB must be made via iStar (the online submission system). All continuing reviews and amendments of studies previously submitted via a paper application should still be submitted with the applications posted on the IRB website. http://www.usc.edu/admin/provost/oprs/upirb.

August 18th is the submission deadline for the September 8th full board meeting
There is no submission deadline for studies submitted for expedited and exempt review. Continued…
Human Subjects Updates continued...

If there is a question about whether a study is expedited, exempt, or requires full board review, please contact the UPIRB staff at (213)-821-5272 or upirb@usc.edu.

Regulatory Updates

Recommendations Accepted to Revamp NCI Clinical Trials System

The Federal Office for Human Research Protections has developed an International Compilation of Human Subject Research Protections. The Compilation lists the laws, regulations, and guidelines of over 50 countries where DHHS funded or supported research is conducted. The Compilation can be accessed on the OHRP website: http://www.hhs.gov/ohrp/international/index.html#. To use the Compilation, go to page 3 and then click on the country of interest.

OHRP has posted a revised, up-to-date version of the HHS regulations for the protection of human subjects, 45 CFR part 46, at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm on the OHRP website.

FAQs on Assurances and IRB Registration
OHRP announces the availability of two new sets of Frequently Asked Questions (FAQs), which help clarify assurance and IRB registration issues. You may access these FAQs from the OHRP website’s:

- Assurance page: http://www.hhs.gov/ohrp/assurances/assurances_index.html,
- IRB registration page: http://www.hhs.gov/ohrp/assurances, or

Final Misconduct Rule Applies To More Cases
The federal Office of Integrity (ORI) has updated its “FAQ” regarding the most recent Final Rule on Research Misconduct http://www.ori.dhhs.gov/policies/faq.shtml

News Items

Improving Medical Statistics and the Interpretation of Medical Studies
The following web-link is to a website that exposes statistical gaffes, shoddy study designs, and unwarranted conclusions that slipped past peer review and into pages of top journals. http://www.improvingmedicalstatistics.com/index.html continued…
News Items continued...

Databases on Medicine and Molecular Biology
The following web-link is a search engine to molecular biology and medical databases.
http://www.meddb.info

NIH finds ethics violations in 44 cases (AP) July 14, 2005

Program offers prescription help to poor (United Press International)
J July 28, 2005

Congress Blocks EPA on Pesticide Testing (washingtonpost.com)
J July 28, 2005

Playing It Safe With Research Risks (Chronicle of Higher Education)
August 12, 2005

Repeats from Previous Issues

Feedback on HSSP Websites
The HSSP websites are continuing to improve and evolve. The goal is to make these websites as useful and user friendly as possible. To achieve this, we would like your feedback, requests for additional kinds of information, navigation suggestions, or compliments. Please send to oprs@usc.edu. Remember to indicate which website you are addressing (OPRS, HSIRB, UPIRB).

Four human subjects brochures now available.
Multiple copies of brochures for principal investigators, student investigators, and research subjects, are available from the OPRS, HSIRB, and the UPIRB. They are also available on the OPRS website. Please take advantage of these informative and useful guides, and share them with appropriate users.

- Protecting Human Research Subjects-A Guide for Student Investigators
- Should I Participate in Research? Before deciding to participate in research, here are some things you NEED to know... (English, Espanol Version)
Contact Information

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Web: http://www.usc.edu/admin/provost/oprs/hsirb

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How to Sign Up for Our Newsletter

To receive periodic emails with links to our newsletter, please send an email in plain text to
listproc@usc.edu with the following information in the body of the message: SUB HUMANSUBJECT ECS-L
(FIRST NAME) (LAST NAME) - NO PARENTHESES NEEDED

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: SIG NOFF HUMANSUBJECT ECS-L

Archives

To view archives of previous Newsletters, please visit: