New Flexibility Policy for IRB

USC has implemented a new “Flexibility Policy” for unfunded, minimal-risk, non FDA regulated research. The new policy allows for two-year approval periods for certain studies that the IRB deems eligible as well as new exemption categories for certain kinds of minimal-risk research.

The new policy can be viewed at www.usc.edu/oprs/policies/hspp.html

Notifying Subjects of Significant New Information or Findings (SNIF)

When new information that might alter the subjects’ willingness to continue comes to light during the course of a study, researchers have options about how to contact current subjects:

a) to revise the study consent documents and reconsent
b) to provide only the “addendum” to the approved consent form

OPRS has added new guidance to the subject notification policy to help in this determination. An excerpt of the policy can be viewed at www.usc.edu/oprs/private/docs/oprs/pnp/SNIF_may2011.pdf

Updates to Online Education System (CITI)

The online education system used by USC (www.citiprogram.org) offers different courses such as Human Subjects Protections and Good Clinical Practices. Due to user confusion regarding the current program, changes have been made to better guide USC learners to the appropriate courses. Those who must fulfill the IRB Human Subjects education requirement will now see a notation next to the title for the course that satisfies the IRB requirement. Additionally, the registration process has been simplified for users who do not have a USC ID number or email.

To view an online demo about CITI registration visit:
www.usc.edu/oprs/private/docs/oprs/citi/CITI_Registration_Instructions.swf
IRB Education Sessions Update

OPRS will no longer be hosting monthly education sessions at the Health Sciences and University Park campuses. IRB education sessions can still be arranged for classrooms, faculty, staff meetings, or other events. Sessions can be adapted to fit the needs of the particular audience.

To arrange an educational session, contact oprs@usc.edu (213) 821-1154

FDA Inspection of USC Device Studies

The Health Sciences IRB was audited by an FDA inspector in January of 2011. The routine inspection examined studies using investigational devices. As in past inspections, there were no findings of concern, a tribute to the ongoing diligence of the Health Sciences IRB.

To view a redacted copy of the FDA inspection letter visit: www.usc.edu/oprs/private/docs/hsirb/FDALetter2011

Articles of Interest

FDA Issues Final Guidance for Industry on submission of bioequivalence (BE) data for abbreviated new drug applications (ANDAs)

“Lies, Damned Lies, and Medical Science” (The Atlantic)

Probe finds Indian medical trials unethical: Reveals gross ethical violations in obtaining consent

Facebook Makes a Bad Doctor

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