CQI/Audit Guidance and Resources Available Online

As part of the Continuous Quality Improvement (CQI) Program, the Office for the Protection of Research Subjects has produced new guidance for PI’s and Research Coordinators who are preparing to be audited by a sponsor or the IRB.

The new documents can all be found on the updated OPRS CQI webpage:
http://www.usc.edu/admin/provost/oprs/policies/cqi.html

New OHRP Guidance on IRB Approval of Research with Conditions

This finalized guidance includes a new definition of “IRB approval with conditions” as well as information on how conditions on IRB approval at the time of initial review affect the initiation of research and how conditions on IRB approval at the time of continuing review, or at the time of review of proposed changes in previously approved research, affect ongoing research. The new guidance can be seen on the OHRP website:

FDA Releases Summary of 2009-2010 Accomplishments

The FDA notes the following rules and guidance among its other accomplishments:

- Expanded Access to Investigational Drugs for Treatment Use – Final Rule.
- Exception from Informed Consent Requirements for Emergency Research – Final Guidance.

To view the list and pending FDA guidance visit:
Ed Sessions: Human Subjects Research Basics

In-person presentations on Human Subjects Research including how to submit an application to the IRB are offered each month at both University Park and Health Sciences campuses.

NOTE: In-class or individual sessions can be arranged upon request. Please call OPRS (213) 821-1154 for more information.

UPC ed session is scheduled for January 12, 2011 12-1 pm in the USC Credit Union Bldg, 3rd floor conference room located at 3720 S. Flower St.

HSC ed session is scheduled for February 10, 2011 12-1 pm McKibben Hall 256.

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

NOTE: Session dates and locations are subject to change, visit the schedule online for the most current dates: http://www.usc.edu/admin/provost/oprs/oprs/education.html

Repeat Item: New Informed Consent Cost/Injury Template Language

The Informed Consent Template and Instructions for the Health Sciences IRB have been revised. Major changes in the template include the addition of sample language in the “What Are the Costs?” and “What Happens if You Get Injured or Need Emergency Care?” sections. The template now contains sample language based on the type of funding for the study (such as industry-sponsored, federal grants, foundation grants, or no sponsor).

Please use the new Informed Consent Template when submitting new studies to the HSIRB.

The new template is available at http://www.usc.edu/admin/provost/oprs/hsirb/forms/#informed

REMINDER: All full-board clinical trials require an HRA Consistency Checklist, regardless of the source of funding.

If you have questions about HRA Consistency Checklists, contact HRA at 323-223-4091.

OPRS Soon On FACEBOOK

Articles of Interest

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

- FDA prober, under fire, steps down
  [http://www.philly.com/philly/business/20101124_FDA_prober__under_fire__steps_down.html#ixzz16PcxrHmc](http://www.philly.com/philly/business/20101124_FDA_prober__under_fire__steps_down.html#ixzz16PcxrHmc)


- Multicenter Trials Raise Patient Safety Concerns
  [http://www.medpagetoday.com/PublicHealthPolicy/Ethics/22748](http://www.medpagetoday.com/PublicHealthPolicy/Ethics/22748)

- Drug Maker Wrote Book Under 2 Doctors' Names, Documents Say

- “Pres. Obama Orders Investigation of Guatemalan Syphilis Experiment”
  [http://www.ahrp.org/cms/content/view/736/9/](http://www.ahrp.org/cms/content/view/736/9/)

- Federal Report Linking Dr Mark Midei and Abbott Finds “Potential Fraud, Waste, and Abuse”

- State's stem cell agency seeks more time, money
  [http://www.latimes.com/health/la-me-stem-cell-20101122,0,586087.story](http://www.latimes.com/health/la-me-stem-cell-20101122,0,586087.story)

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