WELCOME NEW RESEARCHERS! Back to School with IRB University

The PPHS offers a series of three classes on a monthly basis:

**IRB 101**—Basic Steps of the Submission Process (1 hour with short lecture and exercises)

**IRB 201**—Document Analysis & Evaluation: Protocol and Consent (90 minutes with short lecture and exercises)

**IRB 301**—Special Projects and Specific Submissions

In order to receive notifications about classes be sure you subscribe to the CRC listserv. Email IRB@mssm.edu to be added.

Completion of CITI education modules is strongly encouraged prior to attending a class.

UPCOMING PPHS GRAND ROUNDS: De-bunking the myths and legends from the IRB, GCO, and FCOIRC

Wednesday, September 19, 2012, 2:00-3:00 pm, ICAHN building, 1st Floor Seminar Room

REMINDER — HUMAN RESEARCH APPLICATION PROCESS:

1. Disclosure of financial relationships with the research study through Sinai Central— this gives you an IF#
2. Email your complete human research submission to IRB@mssm.edu (include the IF#). See the July Newsletter for submission tips or call our office at 212-824-8200
3. Submit your research (regardless of funding source) to the GCO through InfoEd

PPHS Suggestion Box
Submit your suggestions, comments, feedback, questions and concerns to IRB@mssm.edu

July 2012 PPHS Activity:
Approvals: 409
Submissions: 384

Consent documentation:
In keeping with “CMS (Centers for Medicare & Medicaid Services) Interpretive Guidelines” for Medical Records, a properly executed informed consent form contains the date and time the informed consent form is signed by the patient. This is true for research consent forms as well as clinical consent forms.

HRP-224- New Information:
June 2011-June 2012 Summary

OHRP and FDA require reporting of serious or continuing noncompliance and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO).

Out of 1,768 active studies, researchers here have reported:

**Protocol Deviations:** 250—out of these, there were 8 investigations of non-compliance leading to 2 reports of serious or continuing non-compliance over the past 12 months.

Serious or continuing non-compliance is defined as affecting the welfare or risk to subjects or an established pattern of noncompliance requiring remediation or intervention.

**UPIRTSOs:** 13 investigations of possible UPIRTSOs led to 3 cases that required external reporting over the past 12 months.