

# HUMAN RESEARCH PROTECTION PROGRAM

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## Announcements



December 15, 2011

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### **IRBNet Ethics in Human Subject Protection Award:**

Karen Christianson and the Baystate HRPP were presented with the fourth annual IRBNet Ethics in Human Subject Protection Award at the PRIM&R conference on December 3<sup>rd</sup>. The award is presented to the individual and institution that embody excellence in the human subjects protection field. Criteria include efficient and effective processing of human subject research oversight, cultivation of a culture of research ethics, commitment to drive change, and contribution to excellence in the field. Past recipients have included (2008) Elizabeth Bankert, Assistant Vice Provost, Dartmouth College, (2009) Paul Garfinkel, Director of the Nemours Office for Human Subjects Protection, and (2010) Judy Matuk, Assistant Vice President for Research Compliance at Stony Brook University (SUNY).

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### **New Educational Series:**

The HRPP is pleased to enhance our educational activities with a new series of presentations by investigators on various topics of interest. The Research Series kicks off on **January 27<sup>th</sup> at 12 noon** in Chestnut 1a&b with a presentation by our own Michael Rothberg titled **“Training and Mentoring of Residents in Research: Keys to Success”**. Many of us touch the residents experience as they fulfill their requirements for scholarly activity; please stop by to gain some insight into how we can all contribute to making this a meaningful and positive experience. A light lunch will be provided. Registration is available via the [continuing education website](#).

**Save the Date:** The following sessions are tentatively scheduled; a formal announcement with further details will follow once finalized. Please save the dates and times on your calendar.

**February 15<sup>th</sup> @ 12 noon:** “Community-Based Participatory Research” Chrystal Wittcopp, MD

**March 27<sup>th</sup> @ 12 noon:** “So You Want to Conduct a Clinical Trial” Glenn Markenson, MD; Jay Steingrub, MD; Paul Visintainer, PhD.

Please contact [Karen Christianson](#) or [Glenn Markenson](#) with suggestions for future topics and speakers.

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### **Restructuring within the HRPP/IRB Office:**

Please join us in welcoming Catherine McDougal to the HRPP/IRB Office in the role of IRB Coordinator. Catherine comes to us from Critical Care Research and can be reached by phone at 794-1700 and by email at [Catherine.McDougal@baystatehealth.org](mailto:Catherine.McDougal@baystatehealth.org). The addition of Catherine to the HRPP/IRB team will allow restructuring of roles to provide enhanced services to the research community. More to follow!

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### **TUSM Research Symposium:**

TUSM is in the process of planning a spring symposium. The agenda will focus on assessment of collective research strengths and working on ways to develop a strategic vision for the future. This year's event will occur on the morning of March 14, 8 am to 12 pm, in Sackler 114. Please save the date, additional details will follow.

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### **Compliance Tips:**

The HRPP office actively monitors federal warning letters to identify trends in federal oversight activities so that we can provide guidance to our research community. Since the 2009 release of the [FDA Guidance Document on Investigator Responsibilities](#) we have noticed an increase in enforcement activity related to the **Principal Investigator's responsibility to ensure that critical study tasks are (1) delegated to appropriately qualified personnel and (2) that these tasks are adequately supervised. Such efforts are intended to protect the safety of subjects and the integrity of research data.**

Tip: Critical study tasks such as determination of eligibility, the consent process, assessment of labs and other results, and assessment of adverse events should be delegated in writing to persons qualified and trained to conduct the tasks. A sample Delegation log and other worksheets and tools are available on the eWorkplace [Research Integrity and Education](#) webpage. Accompanying the delegation log in the Regulatory Binder should be CVs and training logs to evidence that study personnel are trained and qualified. Study documentation should clearly evidence the Principal Investigator's active involvement in the conduct and oversight of the study. This can be accomplished by reviewing, signing, and dating of worksheets and results in real-time, maintaining correspondence and meeting minutes or notes, and performing internal QA such as data verification for a subset of subjects at intervals throughout the life of the project. For additional guidance or if you would like an independent review of your study documentation, please contact [Marybeth Kennedy](#), HRPP Integrity & Education Specialist.

### **Sample Warning Letters:**

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm277338.htm>

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm268290.htm>

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm279184.htm>

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