

Human Research Protection Program Announcements

September 28, 2011

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Updated HRPP/IRB Policy Manual:

The HRPP/IRB Policy Manual has undergone substantial revision in response to changes in regulations, guidance, and accreditation standards as well as feedback from our research community. Revised policies go into effect on Monday, September 26th and will be posted electronically on the IRBs page on [eWorkplace](#) and on the [Researcher Resources](#) page on Baystatehealth.org.

Pilot of new IRB submission form for studies involving the retrospective review of medical records:

The IRB is piloting a new submission form and companion IRB reviewer form for studies involving the retrospective review of medical record data. Revisions to the forms will be made as needed based on feedback from researchers and IRB members participating in the pilot before the form is offered out to the larger research community. Assuming this approach is successful, additional specific purpose submission forms will be developed for high-volume minimal risk research protocols.

ResearchMatch now available to Baystate investigators:

ResearchMatch is now available to Baystate investigators to utilize as a recruitment tool for their research studies. ResearchMatch is a national voluntary registry developed through the CTSA to connect researchers with potential participants. Like any recruitment tool, investigators must seek the approval of the IRB before utilizing. Additional information is available [online](#) and by contacting the HRPP/IRB office at 413-794-4356.

Record Retention:

The HRPP has received many inquiries recently regarding requirements for retention of research records. Several sets of regulations and guidance govern record keeping which makes it difficult for investigators to

identify which set of standards they must adhere to. Complicating this are varying contractual obligations for industry-sponsored research and obligations specified by grantors. The BH HRPP recommends that investigators take a conservative approach by maintaining records for a minimum of 7 years after completion of the research or longer if the time frame is dictated in a contract or by a grantor. This practice will ensure compliance with retention requirements set forth by [HIPAA](#), [OHRP](#), [FDA-Drugs](#), [FDA-Devices](#), and [ICH GCP](#).

Records should be maintained in an organized fashion so that monitors, auditors, and inspectors can readily verify the validity of the data and adherence to the protocol and regulations. For additional guidance on record keeping, please consult with [Marybeth Kennedy](#), HRPP Integrity & Education Specialist.

Additional Resources:

[Partners Virtual Regulatory Binder](#)
[NIH Guide to Scientific Record Keeping](#)
[FDA Inspection Guidance](#)

ANPRM: Proposed changes to the Common Rule:

The federal government is soliciting feedback on [proposed revisions to the Common Rule](#). While the intent behind the proposed changes is positive, there is growing concern regarding the elimination of flexibility that currently exists within the regulations and the costs and difficulties to operationalize some of the proposed requirements across a wide variety of research settings. The Baystate HRPP is carefully reviewing the proposal and considering the submission of comments. If you would like additional information or to discuss this topic further please contact [Karen Christianson](#) or [Glenn Markenson](#).

Educational Videos:

OHRP produced educational videos are now available on the [Research Integrity & Education](#) page on eWorkplace. Topics include: Informed Consent, Research Involving Vulnerable Populations, Research Use of Human Biological Specimens and Other Private Information, Unanticipated Problems and Adverse Events, and IRB Records.

Upcoming Educational Events:

1. October 13th 2 – 3:00pm in Chestnut 1a&b; “Strategic Recruitment Planning and Participant Registries”

Videoconferenced from Dartmouth-Hitchcock. Speaker: Charles Rathmann, BS. Continuing education credits available through Dartmouth. Please sign in at the event.

2. November 17th 12n – 1:00pm in Chestnut 1a&b; “FDA Clinical Trial Requirements, Regulations, Compliance and GCP”

Speaker: CAPT Patricia Murphy, FDA Bioresearch Monitoring Specialist, New England District
Continuing education credits applied for, light lunch provided
On-line Registration available through [Continuing Education](#).

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