In order to prepare for the site visit, and as part of our HRPP Education program, we ran a successful series of Boot Camps over the summer months. We plan to offer encore sessions in the future.

Key points from the sessions are highlighted below. Even though our site visit is over, these are important points to consider every day as we work to protect the subjects who participate in our studies.

**Boot Camp Highlights**

**Session 1: Human Research, Resources & Feasibility**

- Activities that involve both research and human subjects require IRB approval. Refer to HRP-421: Human Research or contact the IRB if you aren’t sure whether you need approval.
- Bookmark HRP-800: Investigator Obligations. Know it and refer back to it often!
- Feasibility means making sure you have enough staff, time, training and resources to conduct a study. This helps to protect the subjects who participate in our studies.

AAHRPP’s final decision will be issued mid-December. If successful, UMMS will receive a 3 year accreditation.

The UMMS AAHRPP accreditation site visit took place September 1-3, 2015.

The site visit included a records review and interviews with selected investigators, study personnel, IRB members and key individuals within human research administration.

The site visitors remarked on the strength of our human research protection program and the dedication of investigators and study personnel in protecting human subjects, evident from interview sessions. Site visitors were impressed by the collaboration and teamwork demonstrated by study teams and throughout program.

(continued on page 2)
Helpful Hints from the IRB

Submitting a Modification for an IRB-approved study?
Use the Modification Summary to tell the IRB how many subjects are already enrolled, when and how subjects will be re-consented, or why re-consenting is not necessary.

eIRB Job-Aids can help you reduce common audit findings!
Job aids are now available on:
♦ How to print IRB-stamped consents
♦ How to edit/update study personnel in eIRB

*If you’re having trouble with a specific action, the IRB is always available to help. First, please visit the Job Aids page to see if there is a Job Aid or video to assist you.

(Boot Camp Highlights—continued from page 1)

Session II: Conflict of Interest
Investigators should be familiar with and know where to find the following documents (click on each link):
♦ HRP-120: Management of Financial Interest
♦ UMMS Procedure for the Oversight of Individual and Institutional Financial Interests in Human Subjects Research
♦ University of Massachusetts Policy on Faculty Consulting and Outside Activities - Lowell and Worcester
♦ Committee on Oversight of Individual Conflicts of Interest in Research with Human Subjects

Session III: Informed Consent
♦ HRP-802: Informed Consent provides guidance about the generally suitable process to obtain informed consent.
♦ Seek IRB guidance & approval to consent special populations (cognitively impaired adults, children, non-English speaking subjects, and others).
♦ NEVER sign or date a consent form for a subject.
♦ If participation in a study might impact a subject’s clinical care, be sure to place a copy of the informed consent form in the subject’s medical record.

Session IV: PI Responsibilities, Oversight & Reportable New Information (RNI)
♦ You must report any unforeseen or unexpected incident that: adversely affects the rights, safety, or welfare of the subjects or others involved in the research; or suggests that the research places subjects or others at a greater risk of harm related to the research than was previously known or recognized.
♦ Be familiar with what constitutes Reportable New Information (RNI), and know that RNIs must be reported to IRB within 5 days (or sooner if especially serious), even if corrected/addressed.
♦ Know what constitutes a Serious Adverse Event.

Upcoming Education Opportunities

Clinical Research Professionals Group (CRPG) Meetings
Monday, 10/19/15
12-1 PM
Hiatt S1-608

Monday, 11/16/15
3-4 PM
Hiatt S1-608

Wednesday, 12/16/15
12-1 PM
Lazare S1-607

Webinars
Join us as we broadcast an AAHRPP sponsored webinar on:
Vulnerable Populations
Tuesday, October 27
10:00–11:30 AM webinar with discussion to follow.
Location TBA
Please RSVP HERE

Coordinator Training
Intermediate level Clinical Research Coordinator training
♦ Coming in January!
♦ Watch for announcement and registration link.