University of Miami
HRPPeNews
Your Guide to UM's Human Research Protection Program **2015, Issue #2**

University of Miami Awarded Full AAHRPP Accreditation!

The University of Miami's Human Research Protection Program (HRPP) is pleased to announce that it has been awarded accreditation by the **Association for the Accreditation of Human Research Protection Programs (AAHRPP)** on June 16, 2015.

Accreditation demonstrates our ongoing commitment to the most comprehensive protections for human research participants and the highest quality and ethically sound research. Becoming accredited is a remarkable achievement and a true testament to what we can accomplish together. Although the Institutional Review Boards (IRBs), supported by our Human Subject Research Office (HSRO) are the backbone on which our HRPP is built, accreditation acknowledges the critical contributions and collective excellence of the entire HRPP team - **Principal Investigators and their study teams**, **Ancillary Committees**, **Research Compliance and Quality Assurance (RCQA)**, **Clinical Research Operations & Research Support (CRORS)**, **Research Information Technology**, **Disclosure & Conflict Management (DCM)** and **Office of Research Administration (ORA)**.

An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence-through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.

As the "gold seal," AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that an HRPP is focused first and foremost on excellence.

Save the Date: Human Subject Research Community Conference 2015

The Human Subject Research Office is pleased to be able to offer a two-day conference focusing on various aspects of the Human Research Protection Program (HRPP.) This year's conference is entitled ***"Charting the Course for Quality"*** and will take place at the Student Activities Center on **Thursday, September 10th and Friday, September 11th**.

This is an excellent learning and networking opportunity for professionals involved in every facet of an HRPP.

Informational sessions will focus on key aspects of human subject research to include but not limited to quality improvement, consent process and conflicts of interest. The sessions will also touch upon flexibility in the regulations, research in social media and Central IRBs.

Please refer to the conference webpage where information will be posted as it becomes available. http://hsro.med.miami.edu/2015commconf

Kindly direct any inquiries to hsrcommunityconf@med.miami.edu .

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From the Human Subject Research Office

Did You Notice The Newsletter's New Name?

We often hear the expression "change is good." Our newsletter's new name -- HRPP eNews -- positions us to meet the ever-growing need for up-to-date information from all stakeholders in the Human Research Protection Program. What hasn't changed is our commitment to the research community.

Upcoming Educational Opportunities

IRB Grand Rounds

The Human Subject Research Office, in conjunction with Research Compliance & Quality Assurance, Ethics Programs and the CTSI offers monthly Grand Rounds on a variety of topics. No prior registration is required and attendees may qualify for continuing medical education credits for each session. Our next session will be:

IRB7 System Updates and RNI
July 14, 2015 at 2:00PM
Lois Pope Life Center
7th Floor Auditorium
Presented by Raquel M. Zamora, MBA, MSMIS, Office of Research Information Management; and Amanda Coltes-Rojas, MPH, CIP, Human Subject Research Office

eProst Mentoring

Do you have questions related to IRB forms, policies/requirements, or review procedures? If yes, please sign up via ULearn to attend a help session intended to provide assistance to anyone who needs help preparing an IRB submission. You are encouraged to bring all of the necessary documentation on a jump drive so that an HSRO staff member may assist you with completing the submission. Sessions are available on alternate Thursdays and prior registration via ULearn is required as space is limited.

The Secret to Quick IRB Reviews

The HSRO staff and the IRB members want to help you receive timely determinations on your submissions and we will work with you to ensure this. Some of the common mistakes to avoid that can delay your submission include:

⇒ ***Unclear descriptions of the proposed research.***
Remember, this is the first time the HSRO and IRB members are reading this information! Clear, concise documentation will eliminate many questions from the reviewer. We also need a site-specific supplement to the protocol addressing information unique to the University that may not be included in the sponsor's protocol (e.g. recruitment procedures, who will be recruiting, where and how; where/how data is being kept; participation in substudies and other differences from the sponsor's protocol).

⇒ ***Not responding to comments/questions posted by the reviewer(s).***
The longer it takes for the researcher to provide answers to questions posted in eProst or address issues that need to be corrected regarding the study, the longer it takes for approval.

⇒ ***Missing documentation/training.***
Study-related documentation that is not provided in a timely manner delays the review process.

⇒ ***Missing CITI certification.***
The IRB cannot issue an approval if the PI has not completed required CITI training.

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RCQA News

Featured Principal Investigator and Research Team for Audits Conducted in 2014:

Congratulations to **Dr. Arash Bornak** and **Lynne Sparling, RN, Research Support Manager**, both at the **Department for Surgery**, for their well conducted research. An audit conducted in 2014 revealed no (0) findings.

Excerpts from the audit report:

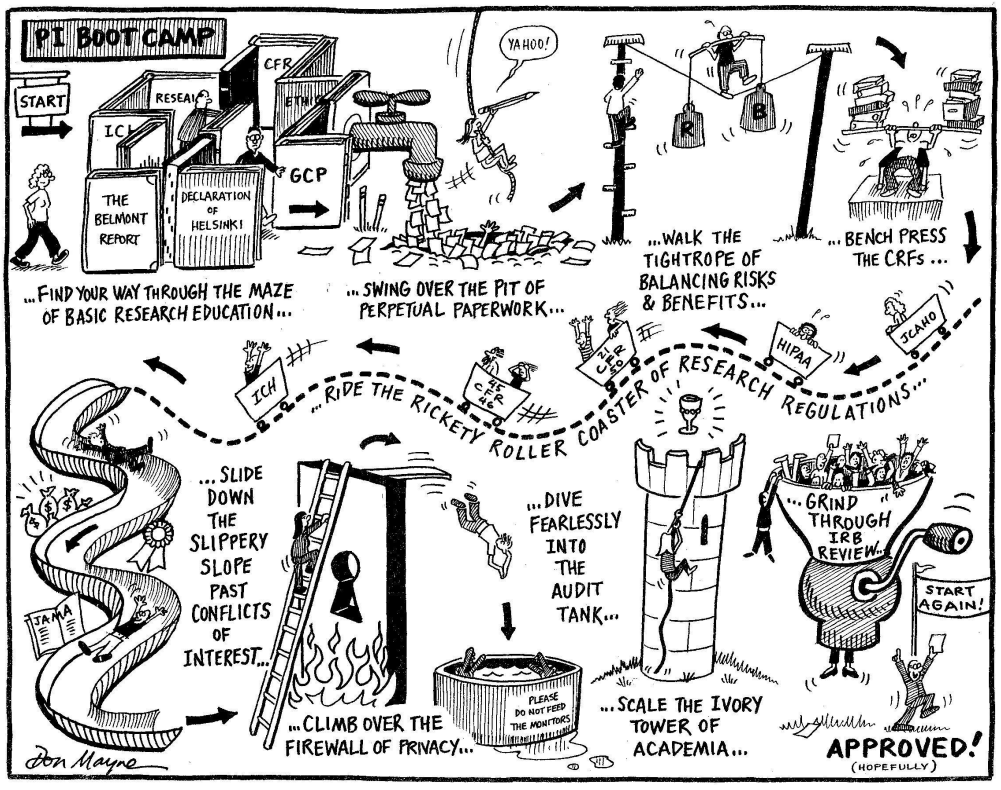
"All ICFs were found to be fully executed, and the documentation of the consent discussions was very clear and exceptionally detailed . . . Overall, this audit was outstanding. It was apparent from the outset of this audit that the lines of communication between the PI and the Coordinators are very clear and direct, and that the study team knows its research responsibilities, and the protocol, very well . . . the site's research and regulatory documentation is of high quality and very well organized. All aspects of this site's conduct of the study, from the Informed Consent Process, to Protocol Compliance, to Investigational Product handling appear to be well managed and the Regulatory

Thank you Dr. Bornak and Lynne for a job very well done and for your contributions to achieve high quality research at the University of Miami.

Improving Informed Consent

Issues with the informed consent (IC) process are the # 1 findings at the university (RCQA and FDA audits). To avoid or minimize such findings, below is a listing of the most coming findings related to the IC process.

- Missing ICs
- Incomplete ICFs (missing signatures, missing or contradicting dates, checkmarks, etc.)
- Incorrect IC version used (either the IC approval expired or the IC was updated with new information)
- Re-consenting not done
- Re-consenting done late
- Issues with witness signatures (who can witness the IC process; is a witness really needed; what is witnessed? – the entire IC process or the signature process only; etc.)
- Issues with proxy signatures (proxy not verified; relationship proxy/subject not indicated; etc.)
- No documentation of IC process
- HIPAA Authorization Form B issues (no HIPAA form; boxes defining the information to be accessed in the MRs either not or incorrectly checked;)



If you would like more information, please sign up (Ulearn) for our "Audit Process" class or contact us. RCQA team members should be seen as a resource to investigators and their research teams. Please contact us for any questions or if you need assistance.

With best regards,
Johanna Stamates and the RCQA team

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eProst/IRB7 Tip: Understanding My Inbox

The list called **My Inbox** contains studies or other submissions that require you (or your team members) to take action. See the examples below to understand what you should and should not expect to appear in My Inbox.
Tip: *Look at the State column in* ***My Inbox****, and see the explanation for that state in the table below.*

Your role	In My Inbox		Not in My Inbox
	State	Explanation	
Research Team			
Study team member or study's primary contact ***Note:*** *Any team member can make changes to the study, but the PI must personally submit the changes or response to the IRB.*	Pre-Submission	Complete the study forms. The PI must submit it to the IRB to let the review begin.	Studies the IRB is reviewing
	Clarification Requested	Change the study to clarify as needed, and provide summary notes to the IRB when submitting the changes. ***Note:*** *If the clarification was requested from Committee Review, you can only provide notes. You are not allowed to change the study.*	Approved Studies
	Modifications Required	Modify the study to meet IRB requirements and submit it with changes.	Closed Studies
Reviewers and committee members			
IRB committee member or occasional reviewer	Non-Committee Review	You have been designated as the reviewer for this exempt or expedited study. You must submit your final review before the IRB decision can be communicated to the study team. If you request clarifications, the study comes back to you to finish the review after the clarifications are made.	Studies assigned to other reviewers
	Committee Review	You may be part of the committee that will review this study. If so, review the study details in advance. You can request clarifications. Record your notes and recommendations in the system before the meeting as described in the online help.	Studies assigned to other committees
Ancillary Reviewer	One of several	You have been selected as a reviewer (either by name or representing a specific organization). The IRB can begin its review before you submit your review. The IRB may or may not wait for your input before completing its review of the study.	Studies not yet submitted for review
IRB administrative staff			
IRB Coordinator (IRBC)	Pre-Review	Newly submitted studies appear in all coordinators' inboxes until a coordinator is assigned. (See the Coordinator column of My Inbox.) The assigned coordinator must submit a pre-review and assign the study to designated review or a committee.	Studies not yet submitted to the IRB
	Post-Review	The IRB decision has been made. You must prepare correspondence and send it to notify the investigator of the decision. You can also finalize study documents to create a permanent record.	Studies being reviewed by individual reviewers
	Committee Review	You can assign the study to a particular meeting, remove it from a meeting agenda and reassign it to another, and assign specific reviewers. The IRB director, IRB chair, or you must submit the committee's review decision.	Studies assigned to other IRBCs
Committee chair	Committee Review	The study has been assigned to your meeting. The IRB director, IRB coordinator, or you must submit the committee's review decision.	Studies assigned to other committees