University of Miami
HRPPeNews
Your Guide to UM's Human Research Protection Program **2016, Issue #2**

University of Miami Celebrates 1 Year Anniversary of AAHRPP Accreditation

The **Human Research Protection Program (HRPP)** at the University of Miami is celebrating its one year anniversary as an accredited organization through the **Association for the Accreditation of Human Research Protection Programs (AAHRPP)**. This is reflective of our continued commitment to protect the rights and welfare of research participants. We strive to meet and exceed regulatory compliance standards while focusing on strengthening protections for study participants. Our HRPP diligently works towards putting measures in place to steadily improve the services we offer our colleagues within the research enterprise to support the dynamic needs of our program and the ever changing regulatory landscape.

Over the past year, we have focused on creating opportunities for increased collaboration and streamlining of information. A host of training opportunities were spearheaded in conjunction with key areas within our program to include conferences, targeted trainings, webinars and roundtable discussions.

We have put into motion various quality improvement initiatives and are looking at different ways to improve the comprehensive workflow.

A few HRPP highlights are listed below:

- Human Subject Research Office:
  - ⇒ Review of approximately 10,000 regulatory submissions (Initial, Continuing reviews, Modifications and Reportable New Information)
  - ⇒ 2015 HSR Community Conference
  - ⇒ Research Community Forum co-sponsored by the Office of Human Research Protection (Planning Committee/ Supporter)
  - ⇒ Hosted Huron Research Software User Group Meeting
  - ⇒ Major upgrade to the IRB 7 application, with improved workflow for Reportable New Information (RNI) submissions
  - ⇒ Launch of Central IRB initiative to include comprehensive workflow, SOP & implementation of functionality in IRB 7
  - ⇒ Greater flexibility for external IRB consideration
- Office of Research Compliance and Quality Assurance (RCQA):
  - ⇒ Conducted 45 audits, facilitated 9 federal (FDA and NIH) audits and assisted with corrective and preventive action plans and responses to federal audits
  - ⇒ Trained 677 research team members via approximately 60 live training sessions on research compliance
  - ⇒ Provided support to Principal Investigators with clinicaltrials.gov requirements and reduced the number of non-compliant records in clinicaltrials.gov from 19% in 2014 to 9% in 2015
- Clinical Research Office & Research Support (CRORS):
  - ⇒ Consultations to date (2015) – 27
  - ⇒ Required New PI Training (2015)-Number of Investigators – 55
  - ⇒ Requested Faculty Meeting Training – (MTI) for brief overview of monitoring requirements, relevant UM policies affecting clinical research
  - ⇒ CRORS training (2015)
  - ⇒ Number Clinical Research Professionals – 101
  - ⇒ Monitoring Visits
  - ⇒ Number of monitoring visits – 76; Number of days onsite – 243 (not including prep, follow up time)

We want to express our sincere gratitude for your ongoing support and contributions to our HRPP. Thank you!

We look forward to another great year!

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Updates from RCQA (Research Compliance and Quality Assurance)

CAPA (Corrective Action Preventive Action):

Please help me welcome **Luis Rochel, RN, BEc, CCRP, RQAP-GCP** to his new position as the CAPA Manager at RCQA. Luis has been with the University since 2007 and his experience encompasses study coordination and management, research education as well as research compliance. Luis will be essential in the creation and implementation of a university-wide CAPA system and CAPA- related education. In addition, he will be assisting our Investigators and research teams with federal audits and responses to such audits.

Please contact Luis at lrochel@med.miami.edu or at 305-243-0135 if you need his assistance.

FDA/RCQA Conference - SAVE THE DATE:

On September 14 and 15, 2016, RCQA in collaboration with the FDA will host a conference at the Bank United Center. The conference will include topics ranging from New Tools for Recruitment Challenges to FDA's Perspective on Investigator Initiated Trials. We will keep you updated – registration will start soon. Get the word out to colleagues at other institutions, Pharma and CROs and get ready for a great conference. Due to the successful conference in 2014, we are aiming for 600 attendees at this time. Attendees will receive up to 12 CEUs for participation at this conference.

Please contact Patty Tate at plt18@miami.edu or Johanna Stamates at jstamates@med.miami.edu for any questions.

Clinical Trials Disclosure (CTD):

CTD Captains are a multi-discipline, multi-functional and multi-departmental group, initiated and implemented by RCQA. The creation of this team embodies RCQA's commitment to the ongoing university-wide cultural change. The CTD Captains come from various departments, institutes, and functional areas and are committed to upholding the university's Common Purpose, Values, and Behaviors. The primary objective of this group is to serve as champions in support of compliance as it relates to the various regulations and requirements that govern CTD. The team meets quarterly to discuss the regulatory landscape of Clinical Trial Disclosure, how the University is faring with compliance with these regulatory requirements, and implementation of process improvements to increase our overall CTD compliance ratings. You may be asking why these individuals are called Captains?

CAPTAIN is an acronym for

C – change agents,
A – awareness builders,
P – problem solvers,
T – training facilitators,
A – assistance providers,
I – information seekers,
N – nucleus.

If you are interested in becoming a part of this team, please do not hesitate to contact Yolanda Davis at y.p.davis@med.miami.edu or at (305) 243-0494.

Your RCQA Team

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To Track Changes or Not To Track?

When submitting a new study (or "new to UM"), the IRB will ask that you upload clean versions of the Informed Consent Forms. Any subsequent revisions should be made using the tracked changes functionality in Microsoft Word. This will assist the HSRO and the IRBs in identifying any changes and help us to ensure as efficient an approval process as possible.

After approval, when you are submitting a modification to your study, you should

1) Download the DRAFT version of the form from the Documents tab in eProst (the Word version).
2) Accept all previous tracked changes, if applicable.
3) Ensure that "Tracked Changes" is on.
4) Modify the document.
5) Upload the revised ICF(s) using the "Update" feature.

Reporting Audit Findings to the IRB

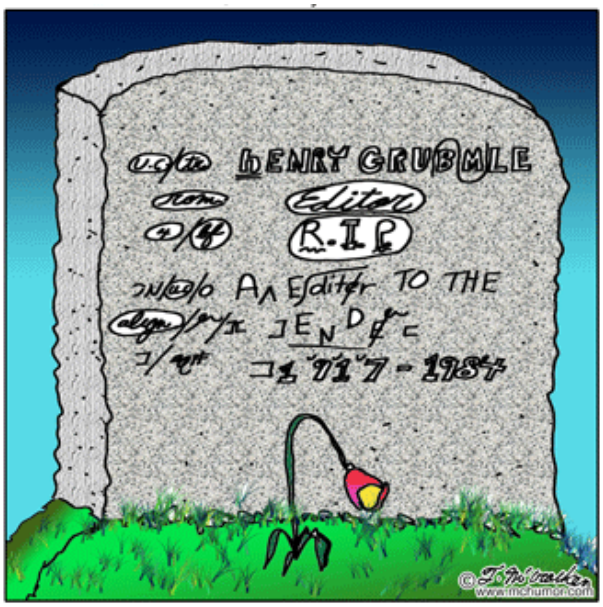
Upon completion of an audit (internal or external) which includes findings of noncompliance due to the action or inaction of the investigator or a study team member, a report needs to be submitted to the IRB. ***Effective immediately, the Human Subject Research Office is requesting that study teams include the full report and the PI response in a single "RNI" (Reportable New Information" submission.*** Some of the most common non-compliance issues found during these audits include incorrect enrollment numbers, missing signed consent forms or HIPAA Authorizations, and not following the study procedures.

If the IRB requires follow-up reporting once corrective and preventive actions are completed, you should open the RNI for the initial report and "Create a follow-up RNI" from the RNI workspace. eProst will indicate the report/submission is a follow-up and link the new information to the original submission.

You won't need to upload a clean version as eProst accepts the changes prior to applying the watermark.

In order for eProst to be able to watermark your documents with the IRB approval information, we need you to leave at least one inch of clear space in the header.

When translating your consent forms, please note that neither the watermark (header) containing IRB approval information nor the UM or JHS required footers should be translated.



Henry Grumble, an editor to the bitter end.

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.

Human Subject Research Office Launches Central IRB Review (UM CIRB)

The **Human Subject Research Office** is pleased to announce the Launch of the **University of Miami Central IRB (UM CIRB)** model for review of multicenter studies. A central IRB is a single board that provides regulatory and ethical review services for multiple research sites.

In 2006, the Food and Drug Administration (FDA) released a guidance document that encouraged using central IRBs to prevent "duplicative review" in multi-site research. The Office of Human Research Protections (OHRP) have since released draft regulatory guidance mentioning central IRB review, and announced additional draft guidance. The House of Representatives endorses this change and the NPRM (Notice of Proposed Rule Making) for the Common Rule includes a similar proposal.

With recognition of the changing regulatory landscape for human subject research, the University of Miami has positioned itself in the forefront of this national undertaking. In this model, University of Miami CIRB can be the "IRB of Record," to oversee and monitor the research conducted at multiple sites, accommodating timely and effective reviews through a single process.

To assist lead investigators, sponsors, and participating sites, the HSRO has a Reliance Team consisting of staff members with experience in collaborative research and IRB reliance agreements.

The HSRO is now equipped to receive electronic submissions of central IRB model protocols. If you are interested in pursuing human subjects research utilizing the UM Central IRB model, please or visit our website at hsro.miami.edu and click on UM CIRB or contact the Central IRB team at 305-243-3195.

UM CIRB contacts:

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HSRO Staffing Updates

Please join us in welcoming the newest addition to the HSRO team who will be dedicated to assisting researchers with their submissions, participating in educational outreach efforts, and supporting the operations of the Biomedical and Social and Behavioral Sciences IRBs.

Karla Fongyee joins the HSRO as an IRB Specialist. Her previous experience in the pharmaceutical industry will be a welcome addition to the Medical IRB-A team. Karla earned her Bachelor of Arts in Health Service Administration from Florida International University.
We would also like to recognize **Joseph Datko**, **Caroline Echeverri** and **Rachel Garcia**, who have been promoted to IRB Regulatory Analyst and **Adriana Robledo**, who was recently promoted to Senior IRB Regulatory Analyst. We are grateful for their years of hard work and dedication to the Human Subject Research Office.

The Institutional Review Boards welcome our newest members. **Lee Taylor** joins Medical IRB-A as an unaffiliated, non-scientist member. His background is predominantly in real estate development and consultancy. **Rachel Tolley** joins Medical IRB-B as an unaffiliated, non-scientist member. She is a practicing attorney with a private practice primarily in the areas of estate planning. **Dr. Anna Nichols** joins Medical IRB-C in representation of the Department of Dermatology after having completed her residency program. We are grateful for their time and service!