University of Miami
HSROeNews
Your Guide to the Human Subject Research Office, IRB & Human Subject Protection Information **Jan 2014**

HSRO Transitions to IRB7 and Launches New Website!

The HSRO and IRBs have recently upgraded the older eProst system to a system based on the latest version of Huron's IRB7 platform. The design of the new system has been vastly simplified in direct response to concerns expressed by the research community as well as those recently identified in the satisfaction survey conducted by the HSRO. Using this new system, the HSRO and IRBs will conduct reviews of submissions based on the documents uploaded to the new eProst system.

In support of this transition, the HSRO has also redesigned its website so that its visual identity is in keeping with the University's other departments as well as to provide better-organized access to all IRB resources. Please visit our new website at http://hsro.med.miami.edu and feel free to let us know what you think!

We've migrated to our new system… but where is your study?

The new eProst system was launched on 12/05/2013. Studies that were closed prior to 12/05/2013 will not be migrated to the new system and will remain housed on the older eProst site (eprostarchive.med.miami.edu/eprost). Studies that were active as of 12/05/2013 have been migrated to the new system if there were no related amendments, continuing reports, and reportable events submitted within the old system that have yet to be approved/acknowledged by the IRB.

Studies that are not yet IRB-approved, or that are IRB-approved and active but have pending amendments, continuing reports, or reportable events, have not yet been migrated – these can be found in the old system (https://eprostarchive.med.miami.edu/eprost/). Studies will be migrated once they are in a "stable" state – IRB-approved, active, and with no pending related submissions.

To locate your studies in the NEW system:

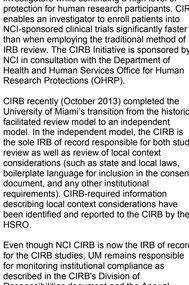
1. Go to https://eprost.med.miami.edu/eprost/ and log in.
2. Click on the IRB link in the top left hand corner of the page.
3. Click on the Active tab (2nd tab) to find your currently active studies, or go to the In-Review tab (first tab) to find submissions that are currently in Pre-Submission or somewhere in the review process.

To locate your studies in the OLD system (eprost Archive):

1. Go to https://eprostarchive.med.miami.edu/eprost/ and log in.
2. Click on My Home.
3. Click on the Protocols tab (next to the Inbox tab). This should show you the studies still in the old eProst system, as well as those that have been migrated. You can identify the migrated studies because the state says "(Exported)" after the name of the state.

If you are trying to figure out which of your studies has been migrated:

1. Go to the old eProst (https://eprostarchive.med.miami.edu/eprost) and log in.
2. Go to the 'Protocols' tab (located next to the 'Inbox' tab). This will list all of the studies you have access to, and the exported studies are now included in that list. Exported studies can be identified by the state of the study – if the study was "Approved" prior to the migration, then the state would now be "Approved (Exported)."



CIRB Now Conducting Independent Reviews

The National Cancer Institute's Central IRB (CIRB) Initiative was designed to help reduce the administrative burden on local IRBs and investigators while continuing a high level of protection for human research participants. CIRB enables an investigator to enroll patients into NCI-sponsored clinical trials significantly faster than when employing the traditional method of IRB review. The CIRB Initiative is sponsored by NCI in consultation with the Department of Health and Human Services Office for Human Research Protections (OHRP).

CIRB recently (October 2013) completed the University of Miami's transition from the historic facilitated review model to an independent model. In the independent model, the CIRB is the sole IRB of record responsible for both study review as well as review of local context considerations (such as state and local laws, boilerplate language for inclusion in the consent document, and any other institutional requirements). CIRB-required information describing local context considerations have been identified and reported to the CIRB by the HSRO.

Even though NCI CIRB is now the IRB of record for the CIRB studies, UM remains responsible for monitoring institutional compliance as described in the CIRB's Division of Responsibilities document and the Annual Signatory Institution Worksheet.

Studies approved by NCI CIRB will appear in the new eProst system as being in the "External IRB" state. Please note that you won't receive reminders about studies expiring in 30/60/90 days if the study is in the External IRB state. Researchers, or their study teams, will be responsible for updating the expiration date for their study by executing the "Update External IRB Status" activity. This lets you enter the expiration date ("last date of the approval period" field). It also lets you indicate when CIRB has closed the study, upload the external IRB's approval letter, and upload other supporting documents. Although the system won't be sending you reminders, you will want ensure you've updated the expiration date as we will be feeding the expiration date to Velos and will using it for reporting.

Do you have CIRB-approved consent documents? You would upload this in the "Update Study Information" activity and let the HSRO know that the document(s) needs to be finalized. The HSRO will then add it to the set of finalized consents.

Updated IRS Language

The IRS requires reporting of any compensation in the amount of $600 or more in a calendar year. Informed Consent Forms for studies in which participants will be paid (not including reimbursement for expenses incurred) now include the following revised language:

"You will be paid $___ for your participation in this study. You must complete a W-9 form in order to receive payment for participation. This information will not be linked to any of the study data and will only be used for payment purposes."

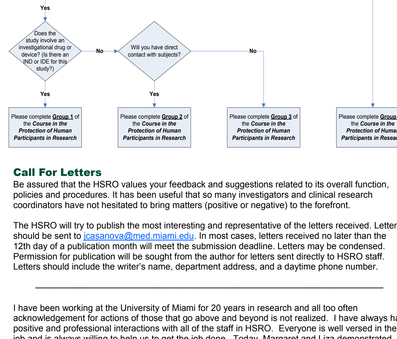
Updated Language for Studies Involving Category B Devices

FDA regulations for Informed Consent (21 CFR 50.25(b)(3)) requires that participants are informed of any costs for which they will be liable as a result of their participation in research. Informed Consent Forms for studies involving the use of Category B devices (refer to Medicare Benefit Policy Manual, Chapter 14) must now include the following template language in the "Costs" section:

"You or your insurance company will be billed only what the University will pay to obtain the device from the manufacturer."

All medical boilerplate language is available on the HSRO website under HSRO Forms & Documents > Consent Templates.

Which CITI Course Should I Complete?



University of Miami to Pursue AAHRPP Accreditation

The HSRO, in conjunction with our partners in UM's Human Research Protection Program (HRPP), are excited to kick-off our accreditation efforts with the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

AAHRPP, an independent, non-profit accrediting body, promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs). As the "gold seal," AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that UM is focused first and foremost on excellence.

We are pleased with the prospect of working closely with our partners as we commence this process for our program and are confident that with their assistance and the many talented hands that contribute to the success of our HRPP, our efforts will result in full accreditation being awarded.

Office News

Newest Member on the HSRO Block

Cristina de la Portilla has joined the HSRO team as the newest member of Pod B and we are so very excited to have her onboard. We are currently recruiting for a second IRB Specialist position and welcome your applications through the UM career page. Thank you as always for your cooperation and support during the recruitment process!

Newly Certified Institutional Review Board Professionals

As the two-year IRB-experience requirement is met for eligibility, HSRO staff are encouraged to pass the testing criteria necessary to attain CIP Certification. This proficiency demonstrates high qualifications to discharge HSRO/IRB duties pursuant to federal, state and local regulations, professional guidances, institutional policies and administrative best practices. Attainment of this certification affirms the HSRO's commitments to protecting human subjects, facilitating research and supporting the University of Miami's research community.

The HSRO congratulates:

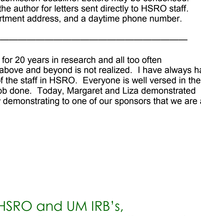
- Dushyanthi Jayaweera, M.D, CIP
  Associate Vice Provost for Human Subject Research
- Stephen P. Richman, M.D., CIP
  Assistant Vice Provost for IRB Affairs
- Phi Ngo, MA, CIP
  IRB Regulatory Analyst

These individuals have recently attained CIP certification and join other CIP holders at the HSRO:

- Amanda Coltes-Rojas, MPH, CIP,
  Director for Regulatory Affairs and Educational Initiatives
- Evelyne Bital, MA, CIP
  Associate Director for Privacy and Regulatory Affairs
- Vivienne Carrasco, MPH, CIP
  Sr. IRB Regulatory Analyst
- Jose Casanova, BBA, CIP
  Associate Director for Educational Initiatives and Community Outreach
- Natalie Francis, BS, CIP
  Sr. IRB Regulatory Analyst
- Meghan Stein, BA, CIP
  Sr. IRB Regulatory Analyst
- Simonnette Thompson, BA, CIM, CIP
  Sr. IRB Regulatory Analyst
- Liza Gordilio, BA, BA, CIP
  Sr. IRB Regulatory Analyst
- Margaret Rankovic, M.Ed., CIP
  IRB Regulatory Analyst
- Adriana Robledo, BS, CIP
  IRB Regulatory Analyst

Newly Certified Healthcare Research Compliance Professional

We would like to congratulate Amanda Coltes-Rojas for recently attaining her certification in Healthcare Research Compliance. Given the varied and complex scope of Amanda's responsibilities, this certification allows for a more complete understanding of the wide gammut of compliance processes and obligations within the healthcare industry. Coupled with the CIP certification, Amanda is most certainly a valued member of the HSRO Leadership team and an expert consultant on a broad range of compliance matters.



Call For Letters

Be assured that the HSRO values your feedback and suggestions related to its overall function, policies and procedures. It has been useful that so many investigators and clinical research coordinators have not hesitated to bring matters (positive or negative) to the forefront.

The HSRO will try to publish the most interesting and representative of the letters received. Letters should be sent to jcasanova@med.miami.edu. In most cases, letters received no later than the 12th day of a publication month will meet the submission deadline. Letters may be condensed. Permission for publication will be sought from the author for letters sent directly to HSRO staff. Letters should include the writer's name, department address, and a daytime phone number.

I have been working at the University of Miami for 20 years in research and all too often acknowledgement for actions of those that go above and beyond is not realized. I have always had positive and professional interactions with all of the staff in HSRO. Everyone is well versed in their job and is always willing to help us to get the job done. Today, Margaret and Liza demonstrated the spirit of "team"; they made us look good by demonstrating to one of our sponsors that we are all here to put our best foot forward.

Thank you to Liza and Margret on this day.

Julie Steele, RN,CRC
Research Regulatory Support
Department of Neurology

On behalf of the HSRO and UM IRB's, we graciously thank you for your time, contributions and support this past year.

We sincerely appreciate the opportunity to work with you and look forward to better serving you in 2014.