University of Miami
HSROeNews
Your Guide to the Human Subject Research Office, IRB & Human Subject Protection Information 1st Qtr '14

IRB7: Lessons Learned

Since the implementation of the new eProst/IRB7 system in early December, the vast majority of feedback to date has been positive. In order to assist the HSRO in achieving our goal of efficiency and improved turn-around times, we ask researchers to keep some of the following tips in mind:

Who May Submit Clarifications

Only the PI can currently execute the 'Submit' activity for any submission to the IRB or submit requested clarifications. This is because a key principle of the system's design is that the PI is the one responsible for ensuring information provided in the smartforms and related documents for IRB review is accurate and complete. Based on initial feedback, we are exploring the possibility of changing the security policy on the 'Submit Clarifications' activity so that study team members will be able to execute it but there are some PIs who do not want their study personnel to submit anything on their behalf. As an alternative, a PI can designate a PI proxy to execute activities on his/her behalf, but current HSRO policy requires that the proxy must be UM faculty. The PI is the only one who can execute the 'Assign PI Proxy' activity from the parent/main study page (i.e. not in the Modifications, CR, etc.). Please refer to the Investigator Manual located at http://hsro.med.miami.edu/documents/HRP-103_-_INVESTIGATOR_MANUAL.docx for more information.

Watermarked vs. non-watermarked documents

In IRB7, only certain document categories are watermarked. These include consent forms, recruitment materials, press releases and data collection sheets. If the documents don't fall into one of these categories, they will not be watermarked (e.g. questionnaires, surveys, etc.). Also, please note that for some studies that were migrated from the old eProst system, in the early stages, not all watermarked documents may have transferred over to the new system. We encourage PIs and their study teams to review their study documents to ensure all approved documents are available on the 'Documents' tab within the parent study workspace.

Altering Modification Scope and Creating Multiple Modifications

IRB7 users are unable to change the scope of a modification once selected. This occurs because we now have the ability to have more than one Modification open at a time. It is a trade off; things would get complicated quickly if you could have more than one modification and both could impact the study team or both could impact the protocol. As such, not allowing the study team to change the scope of a Modification is a necessity. When this situation arises, you must open another modification to address the other type of change or discard the original modification.

For Studies Under the Oversight of NCI CIRB/External IRBs

Investigators and their study teams should use the "Update Study Information" activity to upload external IRB-approved informed consent forms and/or other approved documents and notify Evelyne Bital, Associate Director for Privacy and Regulatory Affairs, via email (ebital@med.miami.edu) when this is done. HSRO staff will then be able to finalize the documents so that they can be properly exported to Velos.

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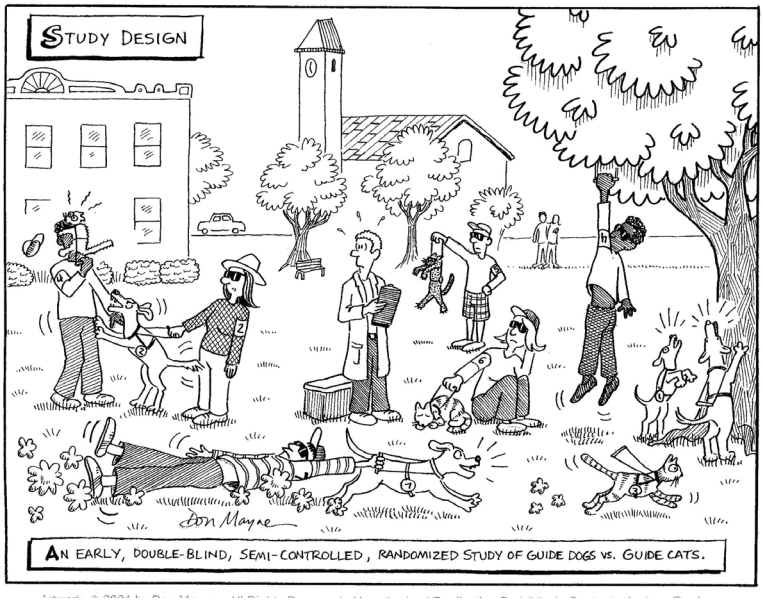

eProst Archive: Lapsed Studies and Pending Submissions

As communicated on 2/25/2014, this is a reminder that the following changes took place.

Lapsed Studies: Studies were administratively closed if the expiration of IRB approval extended beyond 90 days and no continuing or final report had been submitted or if a continuing or final report was submitted but a request for clarifications had received no response for 30 days or more.

Items in Pre-Submission: All items in the Pre-Submission state (never submitted to the HSRO/ IRB for review) were withdrawn. If these items must be submitted for IRB review, the PI must now create and submit them in the IRB7 system according to the requirements of that system.

Items with Clarifications Requested: All submissions were withdrawn if a request for clarifications was pending for 30 days or more and no response had been received.

COI Training Notification

According to University of Miami policy, every four (4) years, all UM faculty, staff and trainees (collectively, "Investigators") who work on research must complete conflict of interest (COI) training on the nature of COIs, and on UM's COI policy and review process. The training entitled "*Conflict of Interest Course*" is administered through the online CITI system and *is separate and distinct from any other CITI training*.

Starting **April 4, 2014**, investigators who have not completed the COI training will not be permitted to participate in human subject research at UM. Directions on how to access and complete the required UM COI CITI training are available on the web (http://uresearch.miami.edu/COICITI).

Please contact the Office of Research Compliance (researchcompliance@med.miami.edu or 305-243-0877) if you have questions or concerns. Thank you for your cooperation with this important compliance activity.

Office News: New Hires at the HSRO

With the beginning of a new year, we are pleased to welcome several new members that have joined the HSRO team. We are excited to welcome Joseph Datko, Caroline Echeverri and Rachel Garcia to the HSRO team . We are so very excited to have them onboard!

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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. Upcoming sessions include:

University of Miami Compliance and Accountability Program
April 8th, 2014 at 2:00PM
Lois Pope Life Center Conference Room (7th Floor Auditorium)
Presented by Rudolph H. Green, Vice President and Chief Compliance Officer and Douglas Horr, Executive Director, Compliance

Conflicts of Interest
May 13th, 2014 at 2:00PM
Mailman Center for Childhood Development (8th Floor Auditorium)
Presented by Lori Hayes, Associate Director, Office of Research Compliance

Please check with the HSRO for the latest schedule as the presenters, topics and locations is subject to change.

IRB7: Problems with ICF Migration

As you may know, studies exported from the old eProst system to IRB7 are partially populated as a result of data migrated. Not all documents related to a particular study were migrated; rather, only consent forms and other watermarked documents were included in the data migration process.

When the first modification (excluding those limited to study personnel changes) is submitted in IRB 7, the PI/ study team will be prompted to complete any missing fields in the study smart form including uploading any other applicable documents. Study teams are able to access the archived studies in the old eProst system to retrieve documents or copy/paste information as needed.

While the data migration was intended to reduce the data entry burden on the research community, we have discovered that the IRB approved consent forms available in IRB 7 cannot be edited for watermarking at the time of continuing review if no changes/ modifications are being made. As a result, the Human Subject Research Office (HSRO) requires that along with the submission for continuing review, PIs/study teams must also create and submit a modification to include the clean consent forms with the old eProst headers removed so that the HSRO is able to properly watermark the documents.

We are diligently working with our vendor to resolve this issue. In the meantime, however, modifications submitted ONLY to provide the HSRO with clean consent forms for watermarking will not be billed for IRB fees. Modifications submitted for any other reason but which may include the submission of consent forms for this purpose will be billed according to the current IRB fee schedule. We ask for your cooperation and partnership in this task, recognizing that this is extra work for investigators. We hope you will understand that the eventual goal is to reduce substantially the overall burden on our investigators, and we are confident that this goal will be achieved.

2014 FDA Seminar in South Florida

The U.S Food and Drug Administration (FDA), Florida District/Investigation Branch, in collaboration with the Office of the Vice Provost for Research, is offering a two-day seminar on clinical trials titled "Improving Human Clinical Research" at the BankUnited Center, 1245 Dauer Drive, Coral Gables, on Wednesday, April 2, and Thursday, April 3, from 8 a.m. to 5 p.m.

This is an excellent opportunity to meet FDA officials and learn more about the agency's policies and procedures. Informational sessions will cover topics invaluable to the scientific community, such as Understanding Principal Investigators' Responsibilities, Oversight of Clinical Investigations, FDA Inspectional Processes, and Quality Aspects, Emerging Issues and Trends in Clinical Research Trials. The seminar will feature officials from FDA headquarters, the Florida District and local FDA office, as well as speakers from the University of Miami. Please see the conference agenda for detailed information, uresearch.miami.edu/2014fdaseminar.

We encourage all Investigators and research team members to attend this seminar, and recommend completing the registration process as soon as possible to ensure space for this important event. We expect approximately 500 attendees from the US Southeast and Latin America.

Continuing medical education credits and continuing education units will be provided to all registered participants. Registration has been extended to Friday, March 28. The cost for the two-day seminar is $60, with breakfast and lunch for both days included. To register, please visit the University of Miami website. For more information, contact Johanna Stamates (jstamates@med.miami.edu) or Julie Sampson (jsampson@med.miami.edu).

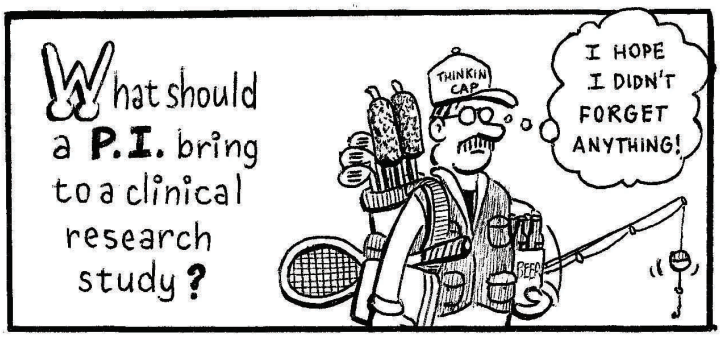
Research Compliance Tip from the Office of Research Compliance and Quality Assurance (RCQA)

As stated in the University of Miami Investigator Manual, HRP-103, University of Miami researchers are to follow the requirements of the International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) guidance documents for applicable research studies. For the Investigator Manual, please use the following link: http://hsro.med.miami.edu/documents/HRP-103_-_INVESTIGATOR_MANUAL.docx

For the complete ICH-GCP guidance document, please go to http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Please contact the RCQA team at (305) 243-4538 for any human subject research related compliance questions.

Make it a compliant day!



Revised Administrative Policy: Submission of Executed Contracts for IRB Review

With the launch of the new eProst/IRB7 system on December 5, 2013, the IRB no longer requires executed contracts to be submitted for review.

An executed contract is still required prior to study initiation. The Office of Research Administration (ORA) is responsible for reviewing and executing contracts that are compliant with University, Sponsor and IRB policies. In addition to providing PIs and study teams with fully executed contracts, the ORA will now provide the IRB with executed contracts.

Some studies approved prior to the December 5th launch of the new IRB system may include a requirement in the determination letters to submit the executed contract for IRB review . You are hereby informed that Investigators will not be responsible for providing the IRB with an executed contract as indicated in those letters.

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 our attention.

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.

Revised IRB Policy: Submission of External SAEs/IND Safety Reports for IRB Review

As of the December 5, 2013 transition to the new eProst/IRB7 system, the University of Miami IRB changed its policy on the submission of external SAEs/IND Safety Reports.

The IRB no longer requires the submission of external SAEs/IND Safety Reports for review. If submitted, they will not be reviewed and must be discarded by the PI/study team.

Instead, the IRB requires that a copy of the sponsor's analysis of these events or a recent DSMB report, and a summary of all external unanticipated problems must be submitted by the study investigator at the time of continuing review. Please refer to the Investigator Manual for additional details.