

HSROeNews University of Miami

Your Guide to the Human Subject Research Office, IRB & Human Subject Protection Information

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Incidental Findings

Dushyantha T. Jayaweera MD, MRCOG (UK), FACP, CIP

Associate Vice Provost for Human Subject Research
Professor of Medicine, Division of Infectious Diseases

Increased use of advanced imaging methods for research has resulted in the detection of conditions of clinical significance in normal human subjects, termed incidental findings (IF). Researchers, institutional review boards, participants in human research, and their families face an important but largely neglected problem: how these should be managed. In addition to imaging, this problem has been encountered in other domains, such as genetic research.

If researchers, all of a sudden, stumble upon information of potential health or reproductive significance, should they seek expert evaluation, contact the participant's physician, tell the research participant, or respond with some combination? What should consent forms and the entire consent process say about how IFs will be handled in research? What should IRBs require? These are very difficult questions that the human research protection program (HRPP) has to ponder on and come up with answers. We are in the process of developing guidelines to better serve our research participants and their families as well as our University of Miami research community. Please feel free to contact us if you have any suggestions as we all are in this together.

Ref. Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations. Susan M. Wolf, Frances P. Lawrenz, Charles A. Nelson et al. The Journal of Law, Medicine & Ethics. 2008;36,2, 219-248.

AAHRPP Accreditation Steps 1 & 2 Complete

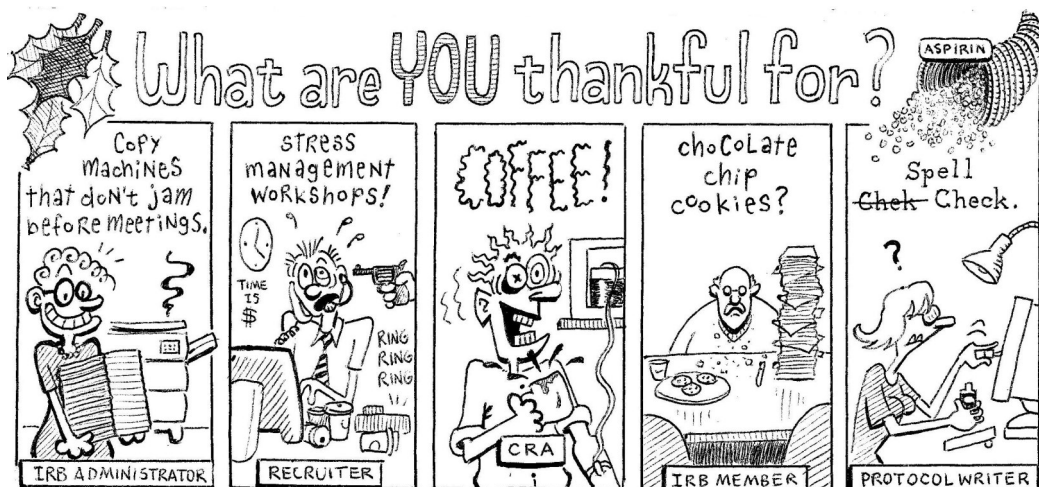
In April, the University submitted an initial application to the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), an independent, non-profit accrediting body for accreditation of our human research protection program. The initial feedback we received from AAHRPP was positive and "step 2" of our application was approved in September.

Our next step is to welcome the arrival of the AAHRPP site visitors this April, during which time they will have an opportunity to see our Human Research Protection Program (HRPP) in action and speak to many of our stakeholders. As we prepare for this visit, we will roll out an informative module via ULearn providing an opportunity to learn about the accreditation process and everyone's role in it as well as meeting with all departments over the next few months to speak at greater length on this effort and answer your questions.

Achieving full accreditation will be a testament to the dedication of all who support the UM HRPP, including PIs, administrators, and members of the IRBs, that research at UM will be conducted ethically, in a legally compliant manner, and using best practices that provide comprehensive protection to its research subjects. Prospective subjects can choose to participate in studies at UM with the confidence that their rights and welfare will be our highest priority.

"We are all in it together"

The administration and staff of the HSRO thanks you for your cooperation and support over the years. We wish you every happiness this holiday season and look forward to continuing to work with you in 2015!



Continuing Review: What does the IRB need?

Joey Casanova, BBA, CIP

Associate Director for Educational Initiatives, HSRO

In order to assure the protection of the rights and welfare of human subjects participating in research, continuing review is required at least once a year. At the time of continuing review, identification of a new risk may cause the IRB to re-evaluate whether the benefits of the research still outweigh the risks. This may mean that a study that was previously approved may not continue without modification.

What to include in your continuing report?

Two of the first things the continuing report asks for are the number of subjects enrolled since last IRB approval and the number enrolled to date. These numbers include all subjects who signed a consent form even if they are later found to be ineligible to participate in the study. For studies consisting solely of retrospective review of records, numbers for these sections should be "0." The 'Supporting Documents' section offers you a location to upload summaries of your study activity including, but not limited to, enrollment reports from Velos (redacted to remove identifying information) or summaries of records review progress. Additionally, summaries of adverse events and/or instances of noncompliance over the course of the last approval period should be included in this section when completing the continuing report. Please refer to the Continuing Review checklist and supplement form posted on the HSRO Forms and Documents (Miscellaneous HSRO Forms) section of the HSRO website (<http://hsro.med.miami.edu/forms/miscforms>) for items that must be submitted with your continuing report.

When can the final report be submitted?

When completing the Continuing Review form, you will see a question that asks which research milestones have been reached. These include:

1. Study is permanently closed to enrollment
2. All subjects have completed all study-related interventions
3. Collection of private identifiable information is complete
4. Analysis of private identifiable information is complete



If all four of these research milestones are checked, all activities meeting the definition of "Human Subject Research" have been completed. The continuing review will be considered a closure (final) report and the study will be closed once the continuing review is approved thus discontinuing IRB oversight. When submitting a closure report, you must include sponsor close-out confirmation for studies that are industry-funded. (Note: Please be reminded that if you indicate that the study is closed to enrollment, you will not receive updated ICFs unless you notify the HSRO that you need them and why.)

Once you've closed your study, you must keep your study records for at least three years, according to federal regulations. However, the UM Investigator Manual describes some situations where the time required for record retention is extended. Be sure to check this document (and confer with study sponsor(s) for special requirements) before you destroy your study records.

Revising and Attaching Documents in eProst/IRB7

When responding to clarification requests or submitting a modification that changes a document that already exists in eProst (such as a consent form or questionnaire), it is important that you use the "Upload Revision" function to overwrite the current existing document in eProst instead of deleting the existing document and adding a new document. Making the revisions to existing documents and using the Track Changes feature in Word makes it easier for the IRB to identify all of the changes that have been made. It also helps both the IRB and the Investigator to more easily keep track of the history of approved versions of the study documents while keeping the current version available in Velos (as applicable) and on the top of a virtual pile of past versions in eProst.

For a reminder on how to make revisions to existing documents, please refer to the "Changing Documents on Your Study" section of the IRB Study Submission Guide (<http://hsro.med.miami.edu/documents/>)

eProst Mentoring Lunch and Learn Sessions

Do you have questions related to IRB forms, policies/requirements, or review procedures? If yes, please sign up 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 will resume in January on alternate Thursdays and prior registration via ULearn will be required as space is limited.

Please contact Joey Casanova at (305) 243-9232 or jcasanova@med.miami.edu to with any questions.



We are pleased to announce that the Human Subject Research Office has moved to a new location in Dominion Tower. Our old office in Jackson Medical Towers served us well, and we made great memories there, but we couldn't be more excited with our new space. We look at this new location as the start of another chapter in our history. We're still working on getting settled in and adding artwork to the walls, but though the address is different, the welcome's the same.

Thanks for everyone's support through the years and with the move.

The new address is:

1400 NW 10th Ave
Dominion Tower, Suite 1200A
Medical Campus Locator M-809
Miami, FL 33136

IRB Grand Rounds

The HSRO, in conjunction with RCQA, Ethics Programs and the CTSI offers monthly Grand Rounds on a variety of topics. Prior registration is available via ULearn but not required and attendees may qualify for continuing medical education credits for each session. Our next session is:

State of the HSRO

January 13th, 2015 at 2:00PM
Lois Pope Life Center
7th Floor Auditorium

*Presented by Dushyantha Jayaweera, M.D.
Associate Vice Provost for Human Subject
Research*

Modification of HIPAA Authorization Form (Form B)

The HIPAA authorization (**Form B**) has been updated with the new HSRO location. **Use of the revised form is effective November 10, 2014.** The English and translated versions are available on the HSRO website.

Investigators and their research staff are responsible for ensuring that the modified Form B is used with all new studies submitted on or after November 10, 2014 requiring HIPAA authorization from subjects. Please make sure to note that the form reflecting the new HSRO address is also to be used for **new** enrollment in previously submitted and **previously approved** studies. However, already enrolled subjects who have previously provided an authorization should not be asked to sign the new authorization. Investigators are instructed to submit a modification to update the authorization forms as appropriate.

Any mail sent to the old HSRO address will be forwarded to the new address.

Updates to IRB7 “Toolkit”

Minor revisions have been made to HRP314 (Worksheet—Criteria for Approval and Additional Considerations) and HRP502 (Consent Document Template) in the IRB7 Library to reflect the FDA's and the Institution's policy regarding the requirement that controlled drug, device and biologic trials must include required language indicating that the study description will be listed on www.clinicaltrials.gov. Researchers and their study teams are reminded that the following statement must be included verbatim in the consent documents for applicable trials:

“A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

Please contact Yolanda Davis at 305-243-0494 or at y.p.davis@med.miami.edu if you have any questions related to clinical trial registration.

Updates to the HSRO Website

Recent updates to the HSRO website include revision to the **IRB Rosters** (<http://hsro.med.miami.edu/irbs/rosters>) to include all members of the UM Medical and Social & Behavioral IRBs listed on the latest IRB registration effective 12/9/2014 and posting all of the **2015 IRB Meeting Dates and Deadlines** (<http://hsro.med.miami.edu/irbs/calendar>).

We ask that any items requiring Full Board Review must be submitted a minimum of 6 weeks prior to a scheduled meeting to be considered for that meeting. However, there is no guarantee that all protocols submitted will be placed on a particular meeting agenda. Protocols will be evaluated based on the date of receipt, the number of projects received and completeness of the application.

Successful submission of a research protocol for review is dependent upon the investigator satisfying all of the procedural and substantive requirements. The purpose of timely submissions is mandatory to ensure that a sufficient amount of time is available for IRB members to complete a comprehensive review of all of the submitted materials.

Media Coverage for Ongoing Human Studies

The media can be a great tool to publicize studies where human subjects are being used. However, if principal investigators and researchers intend to publicize ongoing studies in the news media, it should be indicated as part of their recruitment protocol for study submissions to the Institutional Review Board.

If the intent to use media as a form of recruitment or publicity was not included in the initial submission, please revise the protocol and submit a modification to the IRB for approval.

For more information on media usage, contact the HSRO at 305-243-3195

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2014 HSR CommUnity Conference

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In collaboration with our many community partners both within and external to UM, the HSRO hosted the 2014 HSR CommUnity Conference on September 11th and 12th, 2014. Presenters at this conference included University administrators as well as representatives from federal agencies, industry leaders, and other academic and healthcare institutions. Attendees included researchers, research coordinators, IRB members and staff, HRPP stakeholders, institutional officials and anyone with an interest in research involving human subjects from the South Florida area and represented UM, JHS, the Miami VA, FIU, Baptist Healthcare Systems and Miami Children's Hospital. So far, we have received very positive feedback from this thought-provoking, dynamic and Interactive two-day conference.

We have made all of the presentations available on the HSRO website at <http://hsro.med.miami.edu/2014hsrcommconf/hsrconf-schedule> and encourage everyone to review these materials as they may serve as a resource when planning for and conducting human subject research. Preparations are underway to provide access to the videos of these presentations in the near future.

Our sincerest gratitude goes out to all of our supporters and community partners, as well as all of the attendees, for making this conference a success!

