

## The SNCC: Determination of Serious and/or Continuing Noncompliance in Human Subject Research Studies at the University of Miami

According to federal regulations the institution is required to report to OHRP and/or the FDA any instance of serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB. To meet these requirements the university needs to have a mechanism for identifying such noncompliance.

Serious noncompliance is defined as failure to comply with Federal or State regulations, University policies, or the determinations of the IRB, when, in the judgment of the institution, such failure actually or potentially increases the risks to subject rights or welfare, or to data integrity. Continuing noncompliance is defined as a recurring pattern of noncompliance that, if unremediated, may result in serious noncompliance.

In the past, individual IRB's were responsible for making these determinations, and did so each time they considered audit reports and audit responses at convened meetings. Last fall, we decided to move to a special committee approach, and set up the "Serious or Continuing Noncompliance Committee" (SNCC). This was done mainly to ensure uniformity in the decision-making process, regardless of the IRB overseeing the study under consideration. This committee approach was a "best practice" adapted from that of certain aspirational peer institutions. SNCC is not another IRB but rather an advisory committee to the IRB and the Institutional official.

Noncompliance issues are brought before the SNCC, most often as a result of an internal audit, but issues may also be identified in the course of IRB oversight. Most commonly, internal audit reports, together with the PIs' responses, are provided to the SNCC. If any member of the SNCC believes that there is a possibility of this noncompliance meeting the standards for "serious" or "continuing" noncompliance, the Committee meets to discuss the issues and make a determination. Decisions by the SNCC are delivered to the appropriate IRB to use during its deliberations prior to issuing a determination letter. The SNCC is charged with making decisions related to serious or continuing noncompliance by the study team only.

The members of the SNCC are chosen to represent the knowledge and expertise of the different IRB Boards, and also to represent UM's research community. As of March 2015, the voting members of the SNCC comprised Dushyantha Jayaweera, MD (Associate Vice Provost for Human Subject Research), Tom Sick, PhD (IRB Board A), Abdul Mian, PhD (IRB Board B), Gene Burkett, MD (IRB Board C), Nelson Claure, PhD (Pediatrics), Jean Sparling, RN (Surgery), and an alternate member Victoria Mitrani, PhD, representing the IRB SBS Board. The Institutional Official (Dr. Bixby) is the nonvoting chair of the committee and the Executive Director for Human Subject Research Compliance (Johanna Stamates) is an ex officio (non-voting) member of the SNCC.

## Important Information from your [clinicaltrials.gov](http://www.clinicaltrials.gov) Resource

Yolanda P. Davis, CCRP  
Sr. Research Compliance Officer, RCQA

The FDA mandated changes in consent form Language that includes a new element required for all "Applicable Clinical Trial" (ACT). All ACT's are required to include this element within the informed consent form for studies initiated on or after March 7, 2012.

As required by federal regulation, the required language must be incorporated verbatim and **cannot be altered in any way.**

***'A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.'***

If you would like to know if your study needs the required element as stated above, you can answer a series of questions found on the [Clinical Trial Disclosure at University of Miami web page](#) by clicking on the tool "Does my study need the ClinicalTrials.gov statement in the ICF?"

For more information, please contact Yolanda Davis from the Office of Research Compliance and Quality Assurance at (305) 243-0494 or via email at [y.p.davis@med.miami.edu](mailto:y.p.davis@med.miami.edu).

## FDA Issues Guidance on the Use of Electronic Consent in Clinical Investigations

On March 9, 2015, the US Food and Drug Administration (FDA) issued a new draft guidance (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf>) that could make it easier to conduct clinical trials by explaining how federal regulators will permit companies to use electronic media like interactive websites to help facilitate the informed consent process. As FDA explains in its new draft guidance document, Use of Electronic Informed Consent in Clinical Investigations, "the term informed consent is mistakenly viewed as synonymous with obtaining a handwritten signature... on a written consent form." Sponsors and investigators will be able to use graphics, audio and visual aids, podcasts, interactive websites, card readers and even "biological recognition devices" to convey and capture information related to the informed consent process.

The FDA explains: "When written informed consent is required, the use of electronic (including digital) signatures is permitted, provided the electronic signature is in compliance with applicable FDA regulations. In such cases, the electronic signature is considered by FDA to be trustworthy, reliable, and generally equivalent to handwritten signatures executed on paper (21 CFR part 11, subpart A (11.1)(a))." As long as the information provided is "adequate" and "understandable," FDA says it is OK with a variety of methods used to convey informed consent. Similar provisions are permitted under 21 CFR 50.27(b)(2), which permits oral presentations about clinical trial information.

Using electronic media to facilitate the informed consent process may have potential benefits, such as enhancing a patient's understanding of the trial risks and their ability "to retain and comprehend the information," the FDA explained. Additionally, it could be used to update trial

participants about new risks of participating in the trial, speed up the trial enrollment process, and allow for subjects to consent from "remote locations," such as a patient's home.

However, these innovations will come with several new requirements, however. For example, if a subject enrolls in a trial remotely, the sponsor will need to allow that subject to "ask questions and receive answers prior to signing the electronic informed consent document to participate in the study," FDA noted. In addition, sponsors will need to ensure that data captured in the electronic informed consent process cannot be altered, and that a patient's privacy is adequately protected.

FDA is accepting comments on its draft guidance until May 8th.



***"Ever since they invented cloud computing, I keep getting data stuck between my toes!"***

### Poetic Interlude

***Your study sounds super, for me it might cure.  
I need more information to reassure.  
You say it's confidential.  
But I say it's essential.  
Just give me the Investigator's Brochure.***

***— Anonymous***

## Do I need IRB review and approval for my project?

Joey Casanova, BBA, CIP  
Associate Director for Educational Initiatives

I am frequently asked this question, and the answer may seem simple and straight-forward enough — but the regulatory process requires time and attention. When determining whether an activity meets the regulatory definition of Human Subject Research, we need to consider whether there is any intervention or interaction with living individuals, whether we are accessing identifiable data about living individuals, whether you are conducting a systematic investigation and whether your findings will contribute to generalizable knowledge.

For example, if you want to conduct a study using a brain bank, you are working with human brains and that must surely equal human subjects research — and therefore require IRB oversight, right? However, since the federal regulations define human subjects as “living individuals,” a brain bank project would likely not require IRB review, because the donors of the brains no longer meet that “living individual” criteria.

Even when it is clear that your proposed activity involves living human subjects, this question can't always be answered with a straight “yes” or “no” response. A second consideration may include considering where “quality assurance/quality improvement activities” end and where “research” begins. I often receive phone calls from investigators asking this question and I always recommend submitting your question in writing to the HSRO so we can determine if a project needs IRB oversight. *Prestigious Journal #1* is unlikely to accept your manuscript for publication if you note “I spoke to Joey on the phone and he said it wasn't human subject research.”

Fortunately, we have developed a short form to request such a determination. The Non-Human/Non-Research Determination Application asks the questions we need to think about. This form can be found on the HSRO website at <http://hsro.med.miami.edu/forms/miscforms>. But, should you err on the side of caution and decide to go straight to eProst and submit your activity as a study, we are still able to document a determination of “Not Human Subjects Research” from within eProst.

## My Modification Requires Revision to the Informed Consent Form(s) – What's Next??

Simonnette Thompson, MPH, CIP  
Sr. IRB Regulatory Analyst

If your Informed Consent Form(s) require revision, what is the best way to make the revisions?

⇒ If you said “Make the revisions via tracked changes on the currently approved word document,” YOU ARE RIGHT!!!

Once you make the changes and the document(s) is/are saved to your computer (desktop, shared drive with the study team, etc.), what is next?

⇒ Upload the revised ICF(s) OVER the one(s) previously approved by using the “Update” feature. You don't need to upload a clean version (eProst “cleans” it for you) and only the latest version of each document will be listed – making it easier to identify!

Did you remember to indicate that the ICF was revised in the summary of changes included in the modification?

⇒ The summary of changes becomes the easiest way to tell what was changed in the modification when you come back to it in the future, so you will want to make sure it is complete.

## Now you are a pro at revising ICFs!!!

### IRB Grand Rounds

The HSRO, in conjunction with RCQA, Ethics Programs and the CTSI offers monthly Grand Rounds on a variety of topics. Optional prior registration is available via ULearn and attendees may qualify for continuing medical education credits for each session. Copies of past presentations are available on the HSRO website at <http://hsro.med.miami.edu/researchers/edarchive> and include:

- **How the Miami CTSI helps advance human protections and quality in clinical research**  
Jonelle E. Wright, PhD, DPNAP
- **State of the HSRO**  
Dushyantha Jayaweera, MD, MRCOG (UK), FACP, CIP
- **Consenting Study Participants in the 21st Century**  
Guillermo (“Willy”) Prado, PhD

*Please keep an eye out for future sessions to be announced via the humansubjects listserv.*

## **University of Miami's Human Research Protection Program progresses to next phase of AAHRPP Accreditation: Site Visitors will be at UM April 1-3, 2015**

The University of Miami has advanced to the final stages of receiving institutional accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). As an independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that Human Research Protection Programs (HRPPs) meet rigorous standards for quality and protection. With support from all the many components of our HRPP, the Human Subject Research Office worked closely with AAHRPP to successfully complete the first two steps of the accreditation application.

AAHRPP accredits only the highest quality HRPPs that promote excellent, ethically sound research, surpassing state and federal regulations. The accreditation signifies that an organization follows rigorous standards for ethics, quality, and protections for human research, fostering public trust and confidence in human research at UM and placing us among the most respected, and trustworthy research organizations in the world. The benefits of AAHRPP's comprehensive approach to accreditation extend beyond participants to our HRPP as a whole.

The upcoming site visit is the next step in the accreditation process. The AAHRPP site visitors are peers chosen from institutions that have received AAHRPP accreditation. They will be completing a thorough assessment of our HRPP, which will include interviews with faculty and staff who are engaged in human subject research. Individuals to be interviewed were selected by AAHRPP in early February and have been notified accordingly. Representatives from the HSRO will conduct a one-hour training and interview preparation session with those selected.

For more information on the accreditation process, please visit <http://hsro.med.miami.edu/aahrpp>

## **External Audits**

Johanna Stamates  
Executive Director, RCQA

This serves as a friendly reminder that the office of Research Compliance and Quality Assurance (RCQA) must be contacted in the event of a visit from any federal agency such as FDA, NIH, DOD, EMA, etc. Upon notification of external federal audits, the RCQA team prepares the PI and research team 1) regarding communication/interaction with the FDA, NIH, EMA; 2) for the inspection process, discussing "Do's and Don'ts," etc. Assistance is provided for PIs and study teams during the conduct of any external federal audit by being present at the beginning of the audit, during interviews, at debriefings, at the exit interview. After the conclusion of the audit RCQA provides assistance with responses to federal agencies: Form FDA 483, Untitled Letters, Warning Letters, EMA audit reports, NIH audit reports, etc.

A copy of the policy on external audits for research can be found here:

[http://uresearch.miami.edu/documents/RCQA/HSR-P-002\\_External\\_Audits\\_for\\_Research\\_signature\\_on\\_file.pdf](http://uresearch.miami.edu/documents/RCQA/HSR-P-002_External_Audits_for_Research_signature_on_file.pdf)

For any human subject research or human subject research compliance related questions, and questions about federal audits please contact our office at 305-243-4538.

## **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](mailto:jcasanova@med.miami.edu) to with any questions.

# Research Compliance and Quality Assurance



At the U, we transform lives through teaching, research, and service.

## Upcoming Classes...

March 30th	Achieving Compliance in Human Subject Research	This course highlights the importance of research compliance at an academic institution and identifies the elements of compliance, research compliance and quality assurance.
April 6th	Responding to FDA Observations/ Form FDA 483	Provides detailed information in regards to form FDA 483 responses. It includes examples of FDA warning letters, outlining acceptable and inadequate PI responses.
April 8th	Introduction and Overview of Clinical	This presentation is intended as an introduction to clinical trial registration and results disclosure requirements.
April 9th	The Audit Process	This course provides an overview of the Office of Research Compliance and Quality Assurance (RSQA) and the auditing process.
April 15th	Protocol Registration on ClinicalTrials.gov	Participants will have the opportunity for hands on data entry within the ClinicalTrials.gov Protocol Registration System (PRS) system with guidance.
April 21st	Quarterly Review of FDA Warning Letters	This presentation includes a review and discussions of Warning Letters for Principal Investigators (Clinical Investigators), Sponsor-Investigators and Institutional Review Boards, issued by the FDA during the past three months.
April 23rd	Preparation for an FDA Audit	This course provides an overview of the preparation for and the conduct of an FDA audit. What is involved in an FDA inspection, know how to prepare for an FDA audit, the Do's and Don'ts during and what takes place after the inspection.
April 28th	Managing your Record on ClinicalTrials.gov	Participants will have the opportunity to learn various methods and helpful hints that can be used to manage the records that have been placed on ClinicalTrials.gov to ensure compliance with the regulations and UM Policies.
April 30th	Coercion and Undue Influence	This course will define coercion and undue influence and the professionals' perceptions of both. This course will also discuss the ways in which coercion and undue influence manifest in research and examples of both.

Register for classes and find additional session offerings in [ULearn](#).

Contact us:  
 Research Compliance and Quality Assurance  
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