University of Miami

HRPPeNews

Your Guide to UM's Human Research Protection Program **2016, Issue #1**

HSRO Issues Guidance Documents on Informed Consent

The Human Subject Research Office (HSRO) recently created and distributed four Investigator Guidance Documents to assist researchers and their study teams in creating document that are compliant with federal regulations and institutional requirements for the informed consent process. The guidance documents (and any previously issued ones) are posted on the HSRO website at http://hsro.med.miami.edu/researchers/piguidance. These guidance documents address general Informed Consent requirements as well as some of the special considerations that must be kept in mind when your studies involve vulnerable populations. The topics of these guidances are:

- Translation Requirements
  (Issued 22 December 2016)
- Child Assent
  (Issued 8 January 2016)
- How To Prepare A Readable Consent Form
  (Issued 11 January 2016)
- Elements Of Consent
  (Issued 12 January 2016)

We are also currently reviewing our consent templates to ensure any recommended language is understandable to subjects and appropriate. Please keep an eye out in the near future for the rollout of these new consent templates.

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.

Ensuring Readability

HSRO Staffing Updates

Please join us in welcoming 3 new additions 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.

Prior to joining the HSRO, **Aisha Usher** served as a research coordinator in the Department of Human Genetics and has previous experience working with the IRBs in the VA system. Aisha earned her Master of Arts in Educational Psychology

Anthony Fernandez brings an administrative and customer service background to his new role with Medical IRB-B. Anthony earned his Bachelor of Science in Recreation and Sports Management from Florida International University.

Edward Santander's previous customer service and data management experience will be a welcome addition to the Medical IRB-C team. Edward earned his Bachelor of Arts in Political Science from Florida International University.

What are Waivers and When Do I Need Them?

The IRB may waive or alter the requirements for consent, waive the requirements for documentation of consent (signed consent) and/or waive the requirements for HIPAA authorization provided certain criteria are met.

Waiver of Consent:

Waivers of consent are typically used for retrospective record reviews where researchers will not have contact with subjects prior to the use of data and therefore cannot reasonably obtain consent. The criteria that must be met include:

- No more than Minimal Risk Research
- Waiver does not adversely impact subject rights and welfare
- Obtaining consent from the participant not "practicable" (e.g. no contact with subjects)
- Subjects given additional information after participation when applicable

Waiver of Documentation of Consent:

The requirements for a signed consent form are most often waived for web-based or phone-based survey studies. Alternatively, the IRB may use this type of waiver when the main risk in a study is the ability to identify someone as a participant in a study and their participation places them at risk (e.g. a study where all participants are recreational drug users and the signature on the consent is the only identifying information—employability may be at risk). The information is provided to the potential subject, but a signature is not required. This can be in writing or read to the potential subject. The criteria that must be met include:

- Use when the only link to the participant would be the signed consent form and the principal risk is disclosure OR;
- There are no study procedures or risks for which consent is typically required outside of research

HIPAA Waiver of Authorization:

Requirements for subject authorization prior to access to Protected Health Information (PHI) may be waived for record review studies or if access to PHI is required prior to informed consent and HIPAA authorization being signed (e.g. PHI is being obtained in the screening process by a researcher who is not part of the treatment team). The criteria for such a waiver include:

- Use or disclosure of PHI involves No more than a Minimal Risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - adequate plan to protect the identifiers from improper use and disclosure;
  - adequate plan to destroy the identifiers at the earliest opportunity; and
  - adequate written assurances that PHI will not be reused or disclosed to any other person or entity, except as required by law,
- Research could not practicably be conducted without the waiver or alteration; and
- Research could not practicably be conducted without access to and use of PHI

I don't need informed consent to ask you if you liked your dinner

RCQA Educational Programs

Research Compliance and Quality Assurance

	COURSE NAME	DATE	DESCRIPTION	DURATION
1	**Introduction and Overview of Clinical Trial Disclosure**	3/30/16	This presentation is intended as an introduction to clinical trial registration and results disclosure requirements.	1.5 Hours
2	**The Audit Process**	4/14/16	This course provides an overview of the Office of Regulatory Support and Quality Assurance (RSQA) and the auditing process.	1 Hour
3	**Preparation for an FDA Audit**	4/20/16	This course provides an overview of the preparation for and the conduct of an FDA audit. Describes 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.	1 Hour
4	**Registering Your Record on ClinicalTrials.gov**	4/26/16	Participants will have the opportunity for hands-on data entry within the ClinicalTrials.gov Protocol Registration System (PRS) system with guidance.	3 Hours
5	**Managing Your Record on ClinicalTrials.gov**	5/4/16	Participants will have the opportunity for 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.	1.5 Hours
6	**Quarterly Review of FDA Warning Letters**	5/12/16	This presentation includes a review and discussions of Warning Letters for Principal Investigators (Clinical Investigators), Sponsor-Investigators and Institutional Review Boards, issuced by the FDA during the past three to six months.	1 Hour
7	**Result Reporting on ClinicalTrials.gov**	5/17/16	Participants will have the opportunity for hands on data entry within the ClinicalTrials.gov Protocol Registration System (PRS) system with guidance. This class is intended for those who are new to results data entry or need additional assistance in navigating the ClinicalTrials.gov results data entry system.	4 Hours
8	**Achieving Compliance in Human Subject Research**	5/27/16	This course highlights the importance of research compliance at an academic institution and identifies the elements of compliance, research compliance and quality systems. Additionally, attendees will be able to recognize how research compliance protects subjects, Principal Investigators, their research teams and the University.	1 Hour
9	**Coercion and Undue Influence**	6/9/16	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.	1 Hour
10	**FDA Enforcement Actions Beyond the Warning Letter**	6/16/16	This course will describe operations of FDA's Office of Criminal Investigations and discuss examples of recent court cases and criminal enforcement actions by FDA, strategies will be identified to mitigate compliance risk.	1 Hour
11	**Responding to FDA Observation/483**	6/24/16	Provides detailed information in regards to Form FDA 483 responses. It includes examples of FDA Warning Letters, outlining acceptable and inadequate PI responses.	1 Hour