

Changes to the Common Rule

*On behalf of John L. Bixby, Ph.D.
Vice Provost for Research*

You may have heard that the federal government is updating the regulations governing human subjects research, as outlined in the "Common Rule" (45 CFR Part 46). These changes touch on critical issues such as informed consent, increased protections for participants, and the expansion of exempt categories of research. While these changes are designed to reduce the administrative burden associated with research, they will come with additional responsibilities that will affect both the university administration and our research community.

What is being done to prepare for these changes?

The University of Miami (UM) is committed to excellence in research. In furtherance of this commitment, a committee comprising representatives of the Office of the Vice Provost for Research, Research Compliance and Quality Assurance, Human Subjects Research Office, Office of Research Administration, Office of Privacy & Data Security, Office of Research IT, and Clinical Research Operations & Regulatory Support is working with key stakeholders to identify areas of policy, draft templates, and guidance documents that will need to change to bring our institution into compliance with the new Common Rule stipulations.



The committee's goal is to serve as a resource to the research community in navigating the impending rule changes. In the upcoming weeks, further notifications and bulletins will be disseminated to explain changes to UM process, policy, and procedure made in response to the Common Rule revisions.

Timing Question

The majority of rule changes are scheduled to take effect on January 19, 2018. While it is possible that this deadline could be delayed, we are assuming no change so that the university will be fully prepared.



AAHRPP Reaccreditation Update

We are just a few months away from our program re-accreditation site visit from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). This visit is scheduled for Thursday, February 15- Friday, February 16, 2018.

As you may be aware, the University of Miami's Human Research Protection Program (HRPP) earned full accreditation status in June 2015.

Over the coming weeks, we will receive confirmation from AAHRPP team as to who they have selected at random to interview. We will communicate with the respective parties as soon as agenda details become available .

Our AAHRPP contact is Kenia Viamonte, please direct any inquiries to her at 3052-243-9672 or kviamonte@med.miami.edu.

Clinical Trials Protocol Template for Investigator-Initiated NIH-FDA Phase 2 and 3 IND-IDE Clinical Trials

The [National Institutes of Health \(NIH\)](#) and [Food and Drug Administration \(FDA\)](#) have developed a clinical trial protocol template with instructional and example text for NIH-funded investigators to use when writing protocols for phase 2 and 3 clinical trials that require Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications. Through their development of this template, both agencies hope to facilitate the preparation of protocols that contain all information necessary for review and are organized consistently. The template follows the International Conference on Harmonization (ICH) E6 (R2) Good Clinical Practice.

The template is available in the IRB library within eProst under the Templates tab, under the name [HRP-503\(b\) - TEMPLATE PROTOCOL \(NIH-FDA Phase 2 and 3 IND-IDE Clinical Trials\)](#) - *NOTE: you must sign into eProst to access link.*



Contacting Potential Research Participant/Clinical Trial Recruitment and HIPAA

Without patient authorization ([HIPAA Research Authorization Template—Form B](#)), the only persons who may use Protected Health Information (PHI) to contact a current or former patient about a research opportunity are:

- Health care providers **who have or have had a treatment relationship with the patient**
- those in a Business Associate relationship with a Covered Entity for purposes of providing research review and recruitment services that provide verification that the health care provider has or had a direct treatment relationship with the patient and the patient has agreed to be contacted for the proposed research opportunity.

The IRB may grant a partial waiver of patient authorization which permits the Covered Entity to disclose patients' PHI to other parties (e.g., third party researchers, clinicians who have not had a treatment relationship with the potential research participant, etc.) for the limited purpose of contacting patients about a research opportunity.

For each disclosure of patient information based on a waiver of authorization, investigators must prepare and submit to the Privacy Office a [HIPAA Accounting for Disclosure Form \(Attachment 45\)](#).

Alternatively, the patients themselves may authorize the treating healthcare teams to provide their contact information to colleagues conducting research via a Referral Release of Individually Identifiable Health Information for Research (separate [UM version](#) and [JMH version](#) available).

For detailed information on HIPAA Compliance, please contact the Office of Privacy & Data Security at 305-243-5000 or privacy@med.miami.edu.

HRPP Training Partnership

The Human Subject Research Office (HSRO), together with the office of Clinical Research Operations and Regulatory Support (CRORS) and the Office of Research Compliance and Quality Assurance (RCQA), have partnered to offer a comprehensive training initiative customized to meet the needs of your departments as related to human subject research.

These educational opportunities are offered in a personalized approach with your department in an effort to:

- Provide overview of the Human Research Protection Program at the University
- Offer snapshot of our respective offices
- Discuss best practices
- Address policy/ procedural questions

Representatives from all three offices are available to attend your regularly scheduled department or division faculty meeting and we will gladly tailor our presentation to fit the allotted time. Should this be something you wish to consider, please contact Kenia Viamonte at 305-243-9672 or at kviamonte@miami.edu. We value your contributions to our HRPP and want to ensure you are afforded the avenue, tools and support you deserve.

RCQA Educational Program

The Educational Program offered by RCQA is a research compliance training program for Principle Investigators (PIs), Research Nurses, Clinical Coordinators, Study Team members, and anyone involved in human subject research. It is recommended that employees involved in Human Subject Research complete this training program on a yearly basis.

The group of classes is offered multiple times throughout calendar year 2017. There is no registration fee for the program. Registration is available in [ULearn](#). Please visit the [ULearn](#) calendar to view current offerings by using RCQA in the search field.



eProst Mentoring

Do you have questions related to IRB forms, policies/requirements, or review procedures? If so, please contact Joey Casanova at 305-243-9232 or at jcasanova@miami.edu to schedule a one-on-one 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 or have uploaded them to eProst or a cloud storage solution so that an HSRO staff member may assist you with completing the submission.

FOR SINGLE IRB/CENTRAL IRB HELP

For further information on using CIRB for a multi-site research protocol, for assistance on multi-site research issues, or to request presentations for your department visit please contact Evelyne Bital at Ebital@med.miami.edu or 305-243-9977 or visit our UM Central IRB page on the HSRO website.

Did you Know...?

The Clinical Trial Disclosure (CTD) group provides a range of services to support the UM research community, including the following:

- QC your record on ClinicalTrials.gov before release,
A detailed review that compares the ClinicalTrials.gov record to the latest IRB approved study protocol, ICF, and/or published articles for data integrity, accuracy, and consistency.
- Assist you with registering your study on ClinicalTrials.gov,

Facilitate the correction of problems on ClinicalTrials.gov records, and more!

If you have additional questions regarding CTD support, do not hesitate to contact us at ctgovum@miami.edu.

FDA Mock Audits

RCQA will be offering a new service beginning in 2018! You can request RCQA to conduct an **FDA Mock Audit** of your clinical trial. Mock Audits are a great way to find out if your research team is ready for an actual FDA inspection.

At the conclusion of the Mock Audit, RCQA will issue a report to the Principal Investigator and study team for informational purposes only. This report will NOT go to leadership or the IRB, and no audit response is needed.

Mock Audits can be a great learning experience! Contact RCQA today at 305-243-4538 to learn more about it.



Upcoming Classes

- November 29, 2017
Result Reporting on ClinicalTrials.gov
9:00 AM EST
- November 29, 2017
Protocol Compliance from Start to Finish
2:00 PM EST
- December 1, 2017
Preparation for an FDA Audit
1:00 PM EST
- December 5, 2017
Compliance with the Informed Consent Process
9:00 AM EST
- December 7, 2017
Achieving Compliance in Human Subject Research
10:30 AM EST
- December 14, 2017
Responding to FDA Observation/FDA Form 483
2:00 PM EST
- December 15, 2017
FDA Enforcement Actions—Beyond the Warning Letter
10:00 AM EST

HSRO Staff News

Please join us in congratulating the following members of the HSRO staff who have recently attained the following certifications:

Certified Clinical Research Professional (CCRP); issued by the *Society of Clinical Research Associates (SOCRA)*

- Swarna Pothur, IRB Specialist
- Aisha Usher, IRB Regulatory Analyst
- Saloni Vahia, Quality Assurance Officer

Certified in Healthcare Privacy Compliance (CHPC); issued by *Health Care Compliance Association (HCCA)*

- Tom Street, Director of Regulatory Affairs

Certified in Healthcare Research Compliance (CHRC); issued by *Health Care Compliance Association (HCCA)*

- Joey Casanova, Associate Director for Regulatory Initiatives and Education

Certified Information Privacy Professional (CIPP/US); issued by the *International Association of Privacy Professionals (IAPP)*

- Odetta Clarke, IRB Regulatory Analyst

Regulatory Affairs Certification (RAC); issued by the *Regulatory Affairs Professionals Society (RAPS)*

- Adriana Robledo, Sr. IRB Regulatory Analyst

UM Has Joined Smart IRB

In support of the NIH Single IRB Review policy, UM has signed on to SMART IRB's master reliance agreement. SMART IRB (*Streamlined, Multisite, Accelerated Resources for Trials Institutional Review Board*) is a national initiative funded by NCATS to streamline the single IRB review process for multi-site studies. This platform includes an IRB reliance agreement signed by many universities, research institutions and hospitals. Through this platform, participating sites can use the online system to request use of the master reliance agreement for a specific research protocol.

SMART IRB only addresses the need for a reliance agreement when participating sites agree to cede IRB oversight. All other UM institutional processes to track and review research protocols when an investigator requests that UM serves as the single IRB or requests that we rely on another IRB still need to be followed. Please contact Evelyne Bital at ebital@med.miami.edu or 305-243-9977 for more information.



UM Central IRB Open House

Thursday, Dec. 14, 12-1
Dominion Tower, 12th Fl. Conf. Room

Please join us to:

- Meet the Central IRB staff
- Ask questions about the IRB submission process for multi-site research
- Learn about the NIH single IRB mandate

For more information, visit <http://hsro.med.miami.edu/CentralIRB> or contact Evelyne Bital at 305-243-9977 or ebital@med.miami.edu.



CERTIFIED