

## University Requirements for Good Clinical Practice (GCP) Training for Researchers Involved in NIH-funded Clinical Trials

The University of Miami's Human Research Protection Program (HRPP) encourages all investigators, co-investigators and study personnel listed on the IRB application to be proactive in support of National Institute of Health (NIH) issuance of new Good Clinical Practice Policy which will take effect on January 1, 2017.

**What:** The National Institutes of Health (NIH) issued a new Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials; ([NOT-OD-16-148](#)) stating that NIH-funded investigators and staff should be trained in Good Clinical Practice (GCP).

**How:** Completion of GCP training would demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training.

**When:** Policy takes effect January 1, 2017

**Who:** The policy applies to all NIH-funded investigators and staff "who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6 (R2)."

**Where:** The [CITI Program](#) offers several GCP courses that are acceptable GCP training for the NIH policy. University of Miami has selected the "GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)" course as part of the available training for UM and Jackson Health System employees. Existing CITI users may add this training by clicking "Add A Course" in the CITI system. New users are advised to add this at the time of account creation. For additional support, call 888-529-5929 and choose Option 1 or send email to [support@citiprogram.org](mailto:support@citiprogram.org).

## University of Miami HRPP Leadership Issues Guidance for Research Teams on the Florida Right to Try Act

Right to Try laws are designed to give patients who have exhausted all other treatment options the right to access investigational medications, devices, and biological products that have met Phase I safety milestones. However, they do not require manufacturers to provide the products, nor do they require insurance companies to cover the costs.

Proponents of such legislation believe that the laws are necessary because the FDA's expanded access programs do not provide quick enough access to experimental treatments. The FDA process can be a lengthy one, demanding extensive paperwork from the requesting physician and requiring IRB approval. The FDA may deny requests on broad grounds, effectively allowing the agency to disregard the views of patients and their treating physicians.

Concerns around open access to drugs still in the experimental stage include questions whether researchers would be able to recruit enough participants for the controlled double-blind studies needed to support claims regarding the safety and effectiveness of these drugs. This may lead to significant delays in the drug approval process and ultimately have negative consequences on the population at large as they await FDA approval for new drugs.

A copy of the University's Guidance is available on the [Guidance Documents and Policies](#) page of the [HSRO's website](#) or by following this link: [http://hsro.med.miami.edu/documents/Guidance for Research Teams on Right to Try Act.pdf](http://hsro.med.miami.edu/documents/Guidance%20for%20Research%20Teams%20on%20Right%20to%20Try%20Act.pdf)



## UM Hosts FDA Clinical Trials Symposium on “Improving Clinical Research in the Age of Precision Medicine”

This past September, the University of Miami’s Research Compliance and Quality Assurance (RCQA) office had the pleasure to host a Clinical Trials Symposium on “Improving Clinical Research in The Age of Precision Medicine,” in collaboration with the Food and Drug Administration’s (FDA) Office of Minority Health and Office of Regulatory Affairs. Attendees (from within and outside the US) met at the Bank United Center on the Coral Gables Campus to discuss crucial topics ranging from the challenges of recruiting for a diversified population to meeting and maintaining regulatory compliance in clinical research. The highlight of the symposium was the keynote speech given by Dr. Robert M. Califf, Commissioner of the U.S. Food and Drug Administration. Commissioner Califf addressed the need for researchers to use new and upcoming technology to further clinical research into the human genome to discover new medical treatments. An additional eight speakers from the FDA came to share the clinical trials knowledge and expertise of their various offices and departments.



From the University of Miami, welcoming remarks were provided by Dr. LeBlanc, Provost, Dr. Bixby, Vice Provost for Research and Dr. Jayaweera, Executive Dean for Clinical Research and presentations by Johanna Stamates, Executive Director of RCQA and Dr. Khemraj Hirani, Assoc. Vice Provost for Human Subject Research. Dr. Frenk, President of the University provided welcoming remarks via video and mentioned the importance of close collaboration between FDA and the University of Miami. Due to the overwhelming request from attendees and symposium speakers RCQA is considering a future conference in collaboration with the FDA.

To learn more about RCQA, please visit our website at <http://uresearch.miami.edu/regulatory-compliance-services/rcqa>.

You RCQA team



## HSRO Staffing Updates

**Swarna Pothur** joined the HSRO as an IRB Specialist. Swarna's professional experience and education in the pharmaceutical industry is a welcomed addition to Medical IRB-C.

**Saloni Vahia** joined the HSRO team as our Quality Assurance Auditor in September. Her experience encompasses a rich variety of research compliance, data analytics and process improvement functions and will play an essential role in further streamlining the IRB workflow.

**Dr. Thomas (Tom) Street** as Director for Regulatory Affairs in early October. Tom has experience with regulatory affairs, research compliance, contracts and agreements, research integrity, science review boards, funded research, health care law and compliance, and privacy matters.

**Stephanie Venero** will join the HSRO in late October as an IRB Regulatory Analyst. A recent MBA graduate with an educational background in science, healthcare and medicine, she will support the Medical IRB-B, concentrating on Oncology studies.

## 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.



"Once I learn how to use Google, isn't that all the education I really need?"

## RCQA Educational Offerings

- Compliance with the Informed Consent Process—10/26/16, 12/15/16
- Managing Your Record on ClinicalTrials.gov—10/28/16, 12/8/16
- Achieving Compliance in Human Subject Research—11/2/16
- Registering Your Record on ClinicalTrials.gov—11/3/16
- Preparation for an FDA Audit—11/11/16
- Coercion and Undue Influence—11/15/16
- The Audit Process—11/16/16
- Introduction and Overview of Clinical Trial Disclosure—11/17/16
- Result Reporting on ClinicalTrials.gov—11/29/16
- Quarterly Review of FDA Warning Letters—12/1/16
- FDA Enforcement Actions Beyond the Warning Letter—12/2/16
- Responding to FDA Observation/483—12/6/16
- Protocol Compliance from Start to Finish—12/7/16
- Lessons Learned from FDA 483 Observations at UM—12/14/16

**Coming Soon!**  
**Look for us at various events during**  
**Compliance & Ethics Week 2016**  
**We would love to see you there!**

**SAVE THE DATE!**  
**COMPLIANCE & ETHICS**  
**WEEK 2016**  
**November 7<sup>th</sup> - 11<sup>th</sup>**

In celebration of Compliance & Ethics Week, University Compliance Services is excited to invite the university community to come learn about our various compliance, ethics, and risk initiatives. It is our commitment to support a culture reflecting our **D-I-R-E-C-T** values, and will host events on the Coral Gables, RSMAS and Medical campuses.

### SEMINARS

**CORAL GABLES**  
Wednesday, November 9<sup>th</sup>

**MILLER SCHOOL OF MEDICINE**  
Thursday, November 10<sup>th</sup>

## Carnival

**FREE!**  
Snowcones  
Popcorn  
Games  
Prizes  
Raffles  
Giveaways

**CORAL GABLES**  
Monday, November 7<sup>th</sup>

**ROSENSTIEL MARINE**  
Tuesday, November 8<sup>th</sup>

**MILLER SCHOOL OF MEDICINE**  
Friday, November 11<sup>th</sup>



**Foibles, Fixes & Future**  
Effectively and Efficiently meeting the needs of the Research Community while Maintaining Compliance

**PANEL DISCUSSION FROM**  
**OFFICE OF VICE PROVOST FOR RESEARCH**  
*'Compliance and Ethics Week 2016'*  
*Presented by University Compliance Services*

**PANELISTS:**  
**RCQA** - Johanna Stamatēs  
**HSRO/IRB** - Dr. Khemraj Hirani & Vivienne Carrasco  
**IACUC/IBC/ESCRO** - Dr. Sari Izenwasser  
**COI** - Dr. Lory Hayes

*Panel Discussion will be moderated by*  
**Dr. Karin Scarpinato, Associate Vice Provost for Research**

**UNIVERSITY OF MIAMI**

**Wednesday, November 9, 2016**  
**3pm to 4pm**  
Miller School of Medicine  
Campus Sylvester Service  
Support Building (SSSB) 110