

# THE RESEARCH INSIDER

Newsletter of the Palmetto Health Research Division



COMPLIANCE • CLINICAL TRIALS • INSTITUTIONAL REVIEW BOARD | RESEARCH TODAY . . . HOPE FOR TOMORROW

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[www.PalmettoHealth.org/ResearchDivision](http://www.PalmettoHealth.org/ResearchDivision)

803-434-2884

## SAVE THESE DATES

### 2017 Clinical Research Forum Meetings

12:30-1:30 p.m.

9 Richland Medical Park Dr.  
Room 130

Coffee and water are provided at the meetings, and attendees are encouraged to bring their own lunches. For more information, contact Helen Collins, Research Educator, at 803-296-2179 or [Helen.Collins@PalmettoHealth.org](mailto:Helen.Collins@PalmettoHealth.org).

Thursday., May 4

Thursday., July 13\*

Thursday., Sept. 14\*

Thursday., Nov 9

\*see topic details on page 3

## Fond Farewell

We wish **Cindy Nelson** and **Mary Prather** a fond farewell as their last days in the research office will be March 31, 2017.

Cindy has been employed at Palmetto Health for 6 months and has served as our CT Manager. She has been able to initiate many new processes within Clinical Trials with an eye on quality. I appreciate all her efforts and dedication to the team. I wish her well as she focuses her time on her family.

Mary has been with Palmetto Health for more than 14 years and most currently served as our IRB Manager. I greatly appreciate her continued efforts in obtaining AAHRPP accreditation for the institution: this has been a wonderful achievement for our Human Subjects Protection Program. Mary will be missed, but she will certainly be enjoying retirement.

—Rebecca Mariiliano, PhD

## Revised Common Rule

- > Final rule enhances protections for research participants, modernizes oversight system
- > Significant changes made in response to public comments

On Jan. 19, 2017, the U.S. Department of Health and Human Services and 15 other federal agencies issued a final rule to update regulations that safeguard individuals who participate in research. These revisions are an effort to modernize, simplify, and enhance the current system of oversight. Most provisions in the new rule will go into effect in Jan. 19, 2018.

The new rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment.

The current regulations, which have been in place since 1991, are often referred to as the "Common Rule." They were developed at a time when research was conducted predominantly at universities and medical institutions, and each study generally took place at a single site. Since then, research with human participants has grown in scale and become more diverse and data has become digital.

**Review important elements of the final rule on page 2. [Click here to view the final rule.](#)**

# DISCOVER USC

## Medical Scholarship Day of Focus Joins Larger Event

Join us for the first annual Discover USC showcase on Friday, April 21, 2017. The legacy event, Medical Scholarship Day of Focus, will be a component of this exciting new system-wide showcase of research, scholarship, leadership and creativity at every level of study. This new event will be held at the Columbia Metropolitan Convention Center and the adjacent USC Alumni Center. This day is designed to showcase work performed by medical students, residents, fellows and allied health professionals throughout Palmetto Health and USC School of Medicine.

Through the use of moderated poster and oral sessions, we will highlight health care delivery, quality and processes for improvement, case reports, and translational and basic research that address medical issues.

For more information, please visit [www.sc.edu/DiscoverUSC](http://www.sc.edu/DiscoverUSC).

## Important elements included in the final rule:

- The requirement for consent forms to include a concise explanation – at the beginning of the document – of the key information that would be most important to individuals contemplating participation in a particular study, including the purpose of the research, the risks and benefits, and appropriate alternative treatments that might be beneficial to the prospective subject, so they can make a more fully informed decision about whether to participate.
- Requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies. The proposal from the NPRM has been modified, however, to add substantial increased flexibility in now allowing broad groups of studies (instead of just specific studies) to be removed from this requirement. This requirement goes into effect Jan. 20, 2020.
- For studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. As under the current rule, researchers will still not have to obtain consent for studies on non-identified stored data or biospecimens.
- The establishment of new exempt categories of research based on the level of risk they pose to participants. For example, to reduce unnecessary regulatory burden and allow IRBs to focus their attention on higher risk studies, there is a new exemption for secondary research involving identifiable private information if the research is regulated by and participants protected under the HIPAA rules.
- The removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.
- The requirement that consent forms for certain federally funded clinical trials be posted on a public website.

Medical advances would not be possible without individuals who volunteer to participate in research. Oversight and protection of research participants is an important safeguard and essential to advancing the research enterprise. This action reaffirms the federal government's commitment to all those who participate in research studies.

[To view the final rule, click here.](#)

Additional information regarding implementation of the revised Common Rule and educational opportunities will be provided in future issues of Research Insider.

### *Change to CITI Training Approval Period*

Effective Dec. 1, 2016, the approval period for Palmetto Health required CITI training courses is three years.

The three-year approval period is consistent with other HSC institutions including USC and MUSC.

If you have any questions please call  
803-434-2884.

### **Need Research Help?**

The Research Division receives requests from undergraduate and medical students looking for research opportunities. Some students are willing to participate in an unpaid internship, but others may need monetary compensation for their work.

If you or your department have a need for a student to assist in your research processes, please contact Rebecca Marigliano, PhD, Director of Research, at [Rebecca.Marigliano@PalmettoHealth.org](mailto:Rebecca.Marigliano@PalmettoHealth.org) or 803-434-6365.

Contact the research department at 803-434-2884 or visit our website at [www.PalmettoHealth.org/ResearchDivision](http://www.PalmettoHealth.org/ResearchDivision).

## Research Spotlight: Christine B. Turley, MD

Christine B. Turley, MD, serves as chief medical officer of Health Sciences South Carolina (HSSC), and professor of clinical pediatrics in the University of South Carolina School of Medicine, and the vice chair for research in the Department of Pediatrics. Dr. Turley has practiced pediatrics for more than 25 years in settings including public health, rural communities, and academic practice. With her support, HSSC has established a collaborative model of governance and engagement that allow health systems to collaborate with researchers, and supports research and improvement using large data sets. She has been working with HSSC members and other partners across South Carolina to pursue the Learning Health System model of linking improvements in health care to research that allows further improvements in health care. With this approach, she has been working to decrease hospital readmissions across the region, improve the safety of surgery, enhance the safety of health care systems, and evaluate changes to the delivery of care in order to improve health. She recently has been awarded, along with Co-PIs at USC (Lisa Knight) and MUSC (Andrew Atz), a National Institutes of Health (NIH) grant to establish a network in South Carolina for pediatric clinical trials, which will focus on improving outcomes for high priority health conditions in the state, increasing research capacity, making clinical trials available



for new populations, and decreasing health disparities.

Prior to coming to South Carolina, Dr. Turley served as associate chief medical director at the University of Texas medical branch in the faculty practice plan and vice chair for clinical services for the department of pediatrics. She has had key leadership roles in inpatient, outpatient and community settings and served as a leader for quality and safety initiatives, as well as technology

based projects for many years. In addition to her clinical leadership, she led a vaccine research program with research funding support that has included multiple NIH awards, the Centers for Disease Control, the Bill and Melinda Gates Foundation, as well as industry sponsors. She has served as principal investigator on wide-ranging projects from first-time-in-human trials of a universal influenza vaccine to vaccines protecting against select agents such as smallpox and avian influenza, and received an award for extraordinary service from the NIH for her research during the H1N1 influenza pandemic in 2009.

Dr. Turley received her undergraduate degree from the University of South Florida, and her medical degree from the University of Miami School of Medicine. She completed her residency in pediatrics at Jackson Memorial Hospital/University of Miami. Prior to her work in Texas, she practiced pediatrics in Florida, and rural Colorado and Nevada. She is board certified in pediatrics and clinical informatics.

### Upcoming Clinical Research Forum Topics

Meetings are held from 12:30–1:30 p.m., 9 Richland Medical Park Dr., Room 130. Coffee and water are provided at the meetings, and attendees are encouraged to bring their own lunches. For more information about Clinical Research Forum meetings, contact Helen Collins, Research Educator, at 803-296-2179 or [Helen.Collins@PalmettoHealth.org](mailto:Helen.Collins@PalmettoHealth.org).

#### **CRF Meeting Topics for 2017**

- Thursday, May 4 – TBD
- Thursday, July 13 – Tisha Felder, PhD, MSW, presenting a research study: *Mocha Mamas Milk: A mixed method pilot study of African Americans' attitudes toward and perceptions of breastfeeding*
- Thursday, Sept. 14 – Souvik Sen, MD, MPH presenting a research topic: *Informed Consent* (CME credit will be offered)
- Thursday, Nov. 9 – TBD

## Revisions to the ICH GCP Guidelines

[The International Council on Harmonisation](#) (ICH) is an organization that joins the drug regulatory authorities and the pharmaceutical industry of Europe, Japan, and the United States. ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. The key goal of ICH is to promote international harmonization by bringing together representatives from both regulatory agencies and pharmaceutical industry to discuss and establish common guidelines.

The Food and Drug Administration (FDA) requires compliance with ICH GCP standards. In their [Guidance for Industry- E6 Good Clinical Practice: Consolidated Guidance](#), it states that ICH GCP "should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities." The FDA also notes that the principles established in ICH GCP may also be applied to other clinical investigations that have an impact on the safety and well-being of human subjects.

The Palmetto Health Institutional Review Board's [Human Research Protection Policy](#), section 5.1, also commits to apply the ICH GCP for clinical trials as adopted by the FDA at Palmetto Health.

Since the acceptance of the ICH Good Clinical Practice (GCP) Efficacy (E) 6, clinical trials have evolved substantially, with increases in globalization, study complexity, and technological capabilities. To keep pace with the scale and complexity of clinical trials and to ensure appropriate use of technology, an update to the GCP approach was needed. In November 2016, The ICH E6 GCP Guidelines were amended to encourage implementation of improved and more efficient approaches to clinical trial design, management, conduct, oversight, recording, and reporting while continuing to ensure human subject protection, data quality, and reliability of trial results.

The ICH has integrated the addendum directly into several different sections of the parent E6 Guideline.

There are new sections on Investigator Responsibilities, including oversight;

"The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site" (section 4.2.5)

"If the investigator/institution retains the services of any individual or party to perform trial-related duties and functions, the investigator/ institution should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated" (section 4.2.6)

There is now the inclusion of an extra "C" in ALCOAC;

"The investigator/ institution should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source data should be traceable, should not obscure the original entry and should be explained if necessary (e.g. via an audit trail)" (section 4.9.0)

"Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained)." (section 4.9.3)

Other revisions to the ICH guidelines include: expectations for a confirmation of process when "certified copies" are provided in lieu of direct access to electronic or other source documents; a section on quality management that impacts sites, ethics committees, and sponsors; and risk management expectations for all aspects of clinical study conduct.

The full revision is available to view online on at the website, ICH.org, with the title, [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice E6 \(R2\)](#). A slide presentation outlining the changes is also available on the website, ICH.org, with the title, [E6 \(R2\) Step 4- Presentation](#).

## SMART IRB

Palmetto Health has joined the Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance platform. SMART IRB is designed to harmonize and streamline the IRB review process for multisite studies, while ensuring a high level of protection for research participants. SMART IRB is funded by the National Center for Advancing Translational Sciences (NCATS) and intended to serve as a roadmap for institutions to implement The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board for Multi-Site Research. SMART IRB was created to enable collaborative research using a single IRB review. For more information contact Tejal Patel, JD, at [Tejal.Patel@PalmettoHealth.org](mailto:Tejal.Patel@PalmettoHealth.org) or 803-543-1673.

## New Look for the Research Division Web Pages

The Research Division, Resident Research, Clinical Trials, and IRB webpages have been revised to make it easier to navigate and find the information you are looking for. Take a look at [PalmettoHealth.org/ResearchDivision](http://PalmettoHealth.org/ResearchDivision). In addition to a better organization, new educational materials have been included. Please take the time to check it out. The Research Compliance webpage is currently being revised and will soon reflect these updates as well.

## Update to IRB Consent Template

The Palmetto Health IRB voted to remove the subject initials requirement from the Palmetto Health Consent template in the February convened IRB meetings. The Consent template has been revised to denote this change and can be found in the eIRB system as well as on the main IRB page under forms and templates.

## Research Policy/PGR Updates

The following table outlines the Palmetto Health's Research Policies and Procedures, Guidelines, Rule, or References (also known as PGRs) have been approved since the last issue of the *Research Insider*. Please remember that it remains the responsibility of research personnel to regularly visit our websites to obtain the most current versions of Palmetto Health's Research Policies and PGRs.

Policy or PGR Name	Revisions	Approval Date
Effort Reporting PGR	Major revision to make effort reporting method more broad	2/2/2017
Human Research Protection Program Policy	Section 7.1 removed 'international/transnational research'.	In review
IRB Reporting New Information PGR	Section 2.1.5 added, 'Written reports of study monitors'.	In review, effective date 5/1/2017
IRB Non-Committee Review PGR	Added 1.6 to definitions '1.6 Review of submissions when Palmetto Health has ceded review to an external IRB'.	In review
Notification of Research Billing PGR	Change of PGR title from Request for Research Billing. Clarification of when a Research Billing form is needed and the notification to the investigator. Clarification of the timing of when the Research Billing form needs to be submitted. Other editorial changes.	2/2/2017
Reliance on an External IRB PGR	New	12/15/2016

Research policies and PGRs are available in PolicyTech accessed from myPal. Externally, the IRB Policies and PGR can be found on the IRB webpage, and Research Compliance Policies and PGRs on the Research Compliance webpage.

\*"Final Rule Enhances Protections for Research Participants, Modernizes Oversight System."  
HHS.gov. N.p., 18 Jan. 2017. Web. 15 Feb. 2017.

Call us at 803-434-2884. Find everything you need online at [PalmettoHealth.org/ResearchDivision](http://PalmettoHealth.org/ResearchDivision).

