The Joint Commission and Research

The Joint Commission accredits and certifies nearly 21,000 health care organizations and programs in the United States and is recognized nationwide as the symbol of quality that reflects an organization’s commitment to meeting performance standards. Since Palmetto Health’s programs are accredited through the Joint Commission, we must follow certain standards to maintain accreditation. One such requirement relates to research and clinical trials.

The Joint Commission research requirement closely parallels the general requirements for informed consent requirements and the documentation of informed consent as outlined by the Department of Health and Human Services Code of Federal Regulations (45 CFR part 46, Protection of Human Subjects) and International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice, E6. Research must be clearly explained to the patient prior to participation, and documentation of the research consent process must occur. Following the Federal regulations, Good Clinical Practice, and Palmetto Health’s research policies and procedures will ensure that compliance is maintained for the Joint Commission.

RI.01.03.05: The hospital protects the patient and respects his or her rights during research, investigation, and clinical trials.

To help the patient determine whether or not to participate in research, investigation, or clinical trials, the hospital provides the patient with all of the following information:

- An explanation of the purpose of the research
- The expected duration of the patient’s participation
- A clear description of the procedures to be followed
- A statement of the potential benefits, risks, discomforts, and side effects
- Alternative care, treatment, and services available to the patient that might prove advantageous to the patient

The hospital informs the patient that refusing to participate in research, investigation, or clinical trials or discontinuing participation at any time will not jeopardize his or her access to care, treatment, and services unrelated to the research.

The hospital documents the following in the research consent form:

- That the patient received information to help determine whether or not to participate in the research, investigation, or clinical trials
- That the patient was informed that refusing to participate in research, investigation, or clinical trials or discontinuing participation at any time will not jeopardize his or her access to care, treatment, and services unrelated to the research
- The name of the person who provided the information and the date the form was signed
- The patient’s right to privacy, confidentiality, and safety
The “Research Billing Form” Gets a New Look
Over the past few years, the information needed by the Research Compliance Department from our Research Billing Form has changed. As we have added campuses to our institution, have received feedback from our users, and are using the form for multiple communication purposes, we felt it was time for an upgrade. The new user-friendly form will now be referred to as the Research Subject Encounter Form. A blank version of this form can be located at www.PalmettoHealth.org/ResearchCompliance.

New Common Rule Update
The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (Common Rule). The Final Common Rule was published in the Federal Register on Jan. 19, 2017. It implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

The effective date of the revised Common Rule was Jan. 19, 2018. Research begun before that date was to be regulated under the pre-2018 Common Rule unless the institutional review board overseeing the research decided to apply the revised Common Rule. Research begun after Jan. 19, 2018 would have been regulated under the revised Common Rule.

On Jan. 17, 2018, an interim final rule (IFR), titled Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects, was released. The IFR delays the effective date and general compliance date of the revised Common Rule for six months. All provisions are covered except the cooperative research (“single IRB”) provision, whose compliance date remains Jan. 20, 2020.

The announcement stated that the Pre-2018 Common Rule would continue to be effective until July 19, 2018 and that institutions were not allowed to implement provisions of the Revised Common Rule, except for those “that do not conflict with the pre-2018 Common Rule.”

In that announcement, the HHS Office of Human Research Protections (OHRP) included two examples to expand on the quoted exception above:

1. Example 1: Permissible. Incorporation of new elements of consent at §___.116(b)(9), (c)(7)-(9).

On Jan. 17, team members from the Research Division participated in a day-long session where Huron Consulting provided a customized HRPP Toolkit Updated SOP, worksheets, checklists, forms and templates complete with training on for understanding and implementation.

Additional Information and Updates are published in the Federal Register which is the official journal of the federal government of the United States that contains government agency rules, proposed rules, and public notices, and the Office of Human Research Protections websites.

Research Webinar Series

Palmetto Health has developed a new educational program which will provide webinars from various research professional organizations. This Research Webinar Series will cover a variety of research topics from investigator-initiated research to study coordination best practices to reviews of research regulations. The webinars will be shown the fourth Friday of every month at noon, Richland Medical Park 9, Room 130. Most webinars are approximately one hour in length but the room has been reserved until 2 p.m. to ensure adequate time to complete the webinars. Attendees are encouraged to bring their own lunches.

Come join us to kick off your weekend! For more information about the Research Webinar Series, contact Melanie Griswold, 803-296-5249 or Melanie.Griswold@PalmettoHealth.org.

Upcoming Research Webinar Series

• March 23, 2018 – Research and Patient Privacy: HIPAA and Beyond (from Association of Clinical Research Professionals)
• April 27, 2018 – Sponsor/CRO Identified Best Practices of High Performing Sites (from Association of Clinical Research Professionals)
• We will not have a presentation in May, but will resume the series in June.

Notable Accomplishments

Congratulations to Souvik Sen, MD, and his team for the publication of their research in the American Heart Association Journal: Stroke!

Souvik Sen, MD; Lauren D. Giamberardino, MHA; Kevin Moss, ASCS; Thiago Morelli, DDS; Wayne D. Rosamond, PhD; Rebecca F. Gottesman, MD; James Beck, PhD; Steven Offenbacher, DDS. Periodontal Disease, Regular Dental Care Use, and Incident Ischemic. Stroke. 2018; 49: 355-362. DOI: 10.1161/STROKEAHA.117.018990.

Congratulations to Daniel Clair, MD, who was recently featured by WISTV10 describing an investigational device clinical trial that was successful for his patient.

The Palmetto Health Clinical Trial staff are excited about their ability to assist Dr. Clair in this innovative procedure.

Jill McHale joined our team as the interim manager of the Clinical Trials Department on Dec. 18, 2017. Jill holds a Bachelor of Science in Nursing and a Master of Business Administration. She has more than 30 years of experience in health care and clinical research and specializes in clinical research operations and management, most recently with Huron Consulting Group.

Prior to joining Huron, Jill served as the manager of a Phase I clinical research unit and the research infusion/treatment unit for a Comprehensive Cancer Center in the Southeast. She managed the day-to-day operations of the units, including staffing, training, finances, auditing and interdepartmental collaborations with laboratory and pharmacy services.

During her consulting tenure, Jill has assisted universities, health systems and hospitals with clinical research operational oversight, management of financial conflicts of interest and clinical trial audits.

Jill provides oversight and support of clinical research administration at Palmetto. She is responsible for the day-to-day management of the Clinical Trials department and will promote collaborative communication with investigators, study teams and ancillary departments. Jill will assist with the post’s transition when Palmetto Health’s search for a permanent manager concludes.

Originally from central Illinois, Jill has lived in the Tampa, Florida, area for more than three decades. She enjoys movies and watching sports, particularly football, hockey and baseball. She is mother to three grown children and in her free time, she spoils her three grandchildren as much as possible.

Research Policy/PGR Updates
No new updates to 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, however, 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.

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.

Reminder: CITI Training Approval Period
Effective since 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 HSSC 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, System Director, Clinical Research and Operations, at 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.
Save the Date: Undergraduate and graduate students, postdoctoral scholars and medical scholars representing the University of South Carolina and Palmetto Health take their skills beyond the classroom, seeking new insights and solutions. At Discover USC, these talented young achievers show how they have turned ideas into results. Join us for a glimpse into the Palmetto State’s bright future by attending the second annual Discover USC on Friday, April 20, at the Columbia Metropolitan Convention Center. The event is free and open to the public. Visit www.sc.edu/DiscoverUSC for more information and a schedule of events.

Don’t miss Keynote Speaker Caroline Potter, DPhil
11:30 a.m., Richland Meeting Rooms (lower level)
A Palmetto State native, Potter completed undergraduate studies in chemical engineering, with a minor in dance, at the South Carolina Honors College in 2000. After graduation, she entered Oxford University as a Rhodes Scholar for graduate study in medical anthropology. Potter currently is an Oxford Research Officer conducting qualitative research with patients of England’s National Health Service.