

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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Research Policy/ PGR Updates

Many of Palmetto Health's research policies and procedures, guidelines, rules or references (also known as PGRs) are currently being revised in preparation for the AAHRPP reaccreditation. 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](#).

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.



Preparing for the AAHRPP Reaccreditation Site Visit

Palmetto Health received full accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) in March 2016, and now it is time for our three-year reaccreditation process. We have already provided some necessary documentation related to internal reviews of our human subjects protection program. AAHRPP has now determined that our written documents are satisfactory, and a site visit has been scheduled. In preparation of the site visit, further information is outlined below.



When is the site visit?

The site visit is scheduled for **Thursday, Nov. 29 through Friday, Nov. 30, 2018.**

What is AAHRPP?

AAHRPP promotes high quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs). An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.

What is AAHRPP's mission?

AAHRPP accredits high-quality human research protection programs in order to promote excellent, ethically sound research. Through partnerships with research organizations, researchers, sponsors, and the public, AAHRPP encourages effective, efficient and innovative systems of protection for human research participants.

What is Palmetto Health's HRPP program?

Palmetto Health's Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in human research. The HRPP involves all individuals in this organization along with key individuals (the signatory official/vice-president for research, the IRB chair/vice-chairs, the IRB members and staff, Research Compliance, Corporate Compliance and legal counsel to the HRPP) and committees (COI, Radiation). The HRPP policy describes the roles and responsibilities associated with the program.

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What happens during the site visit?

The site visit team meets with the HRPP team and senior management to ask some organizational questions and conduct a record review. They then conduct interviews of senior management, IRB members, staff, and chairs, as well as investigators and research staff. They also interview key organizational officials, such as those who review contracts, manage financial conflicts of interest, lead departments involved in research and provide legal advice.

Who will be interviewed?

AAHRPP will send information on individuals selected for interviews and a preliminary agenda to Palmetto Health no later than Oct. 18, 2018. In preparation for the interviews, IRB Administration will offer education sessions to provide information, answer questions, and prepare interviewees for the site visit.

IRB Helpful Hint of the Quarter Start early!

Applications submitted in eIRB can take at least 14–30 days from the date of submission to approval (not including time the application needs revisions from the study team), assuming no revisions are needed. During particularly busy times, it may take longer for an approval to come through, so plan ahead and be sure to get your submission in as soon as possible.

When planning your research, be sure to give yourself enough time to prepare your IRB application, receive IRB approval, conduct your research, analyze results, and compose your results.

Save these dates

Build resilience and beat burnout: Wellness for researchers

Friday, Sept. 28, 2018, Richland Auditorium, 12:30 p.m.

Rachel S. Brown, MD, Palmetto Health's medical director of health and wellness, will describe the causes and impact of burnout; discuss short, practical, effective resilience tools and resources to promote wellness; and recommend practical approaches to incorporating resilience tools into the research culture.

All about research: YouTube video presentation

Friday, Oct. 26, 2018, 9 Medical Park Classroom 130, 12:30 p.m.

From the popular Vanderbilt Program in Research Administration Development (VPRAD) YouTube series, this video presentation covers these topics in five sessions: *What is Research?*; *Basic and Applied Research*; *Quantitative and Qualitative Research*; *Other Types of Research*; and *Translational Research*. Developed by the Vanderbilt Institute for Clinical and Translational Research.

SC DHEC/USC 2019 Health Data Symposium: Call for abstracts

Friday, Feb. 1, 2019, USC Alumni Center, 900 Senate St., Columbia, SC

The submission deadline for abstracts is Monday, Oct. 15, by 11:59 p.m.

The 2019 Health Data Symposium is an all-day event jointly hosted by the South Carolina Department of Health and Environmental Control (SC DHEC) and the USC Department of Epidemiology and Biostatistics. The theme for this year's symposium is "Data-Driven Approaches to Promote Equity." For details and to submit an abstract, please visit <https://www.surveymonkey.com/r/ZVF272S>. Questions? Contact Chelsea Richardson at richardc@dhec.sc.gov or 803-898-1047.

Discover USC 2019

Friday, April 26, 2019, Columbia Metropolitan Convention Center

Discover USC annually showcases research, scholarship, leadership and creative projects by undergraduate and graduate students, postdoctoral scholars and medical scholars representing the USC System and Palmetto Health. More information regarding Discover USC 2019 will be distributed regarding the event upon availability.



Collaborative Institutional Training Initiative (CITI) GCP Training Available Through CITI Program

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected (consistent with the principles that have their origin in the Declaration of Helsinki), and that the clinical trial data are credible. Traditionally, GCP has been supported by a collection of related regulations and guidelines that define the clinical study-related responsibilities of sponsors, clinical investigators, monitors, Institutional Review Boards (IRB) and others involved in the clinical research process.

The U.S. Food and Drug Administration (FDA) maintains that its GCP regulations are entirely consistent with the ICH guidelines, even though the ICH guideline is clearly more specific in several areas. At Palmetto Health the Human Research Protection Program Policy states, "For clinical trials, Palmetto Health commits to apply the 'International Council on Harmonisation–Good Clinical Practice E6' as adopted by the FDA."

Is GCP training the same as human subjects protection training?

No. GCP training is a separate training and is not basic human subjects protection training. GCP principles are specific to clinical trials and include international ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials.

Does CITI Program offer GCP training that is compliant with the NIH policy?

On Sept. 16, 2016, the National Institutes of Health (NIH) issued a new policy (Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials; NOT-OD-16-148) that says NIH-funded investigators and staff should be trained in GCP. CITI Program offers GCP courses that are acceptable GCP training for the NIH policy.

Who should take GCP training?

GCP content is suitable for research teams involved in clinical trials of drugs, biologics, and devices, as well as those involved in behavioral intervention and social science research studies.

How do I know which GCP course I should take?

Learners should take the GCP course that best meets the type of research they conduct:

- *GCP for Clinical Trials with Investigational Drugs and Medical Devices* (U.S. FDA Focus) and *GCP FDA Refresher* are suitable for individuals proposing to conduct clinical trials of drugs and devices primarily in the U.S. and/or who would prefer a more U.S. FDA-centric curriculum.
- *GCP for Clinical Trials with Investigational Drugs and Biologics* (ICH Focus) and *GCP ICH Refresher* are suitable for individuals involved in clinical trials of drugs and biologics when the research may be international or where the individuals would prefer a more ICH-focused curriculum.
- *GCP for Clinical Investigations of Devices* and *GCP Device Refresher* are most appropriate for organizations or individuals who desire a more international-focused GCP curriculum and a more device-focused program. These device courses cover FDA regulation as well as International Organization for Standardization Guidelines ISO 14155:2011.
- *GCP - Social and Behavioral Research Best Practices for Clinical Research* and *GCP SBR Advanced Refresher* are suitable for social and behavioral investigators and staff who must be trained in GCP.

What are the advantages of CITI Program's GCP training?

GCP provides research-specific, peer-reviewed training written by GCP experts. Along with CITI Program's advantages, including our experience, customization options, cost effectiveness, and focus on organizational and learner needs, this makes it an excellent choice for GCP training.

Do social and behavioral researchers need to take GCP?

All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of research that meets the definition of a clinical trial should be trained in GCP. A clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

<https://about.citiprogram.org/en/series/good-clinical-practice-gcp/>

Researcher Spotlight: Julian Kim, MD, MS

Julian Kim, MD, MS, joins the Palmetto Health research team as medical director. He was most recently the chief medical officer at Seidman Cancer Hospital in Cleveland, Ohio, and Charles A. Hubay Chair in Surgery at Case Western Reserve University. Dr. Kim has served as Principal Investigator on clinical research trials for the past 24 years. He has experience with FDA audit, holds an IND and has mentored young investigators as part of the NIH K12 program.

Dr. Kim said, "I am really excited to serve in this role at Palmetto Health which can be so very impactful in the lives of patients and the careers of our academic physicians. It is a great honor and I foresee a vibrant research enterprise ahead of us. In meeting with key stakeholders, the priorities appear to be:

1) Develop a close knit research community, which will involve collaboration between all investigators and research personnel, regardless of affiliation. It is only through teamwork and shared governance that we will achieve our potential.



2) Protect human subjects, protect our investigators and protect the organization. We need to create an infrastructure that balances compliance and oversight with operational efficiency and customer service.

3) Have fun! Discovery is what differentiates us from our competitors. Translational research with our basic science counterparts, clinical trials which advance state-of-the-art medicine and quality research which defines new models of care are central to the research mission."

Dr. Kim is married to Amy and they have two grown children, Elizabeth, an elementary school teacher in Cleveland, Ohio, and Justin who works in digital advertising in New York City. The whole family likes to meet up in Hilton Head any chance they can, where grandson Austin is the center of attention.

Dr. Kim will also serve as senior medical director of the oncology service line in Columbia. He looks forward to meeting more of his Palmetto Health colleagues, so feel free to reach out to him.



Eeeeeek!

Follow this link for some legendary research horror stories—if you dare!

"Top 10 clinical trials that went horribly wrong"

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.

