



## SAVE THESE DATES

### Research Webinar Series

- January 26, 2018: Investigator Initiated Trials: Administrative Considerations for Successful Study Start-Up and Close (from Health Care Compliance Association)
- February 23, 2018: How to Ensure Study Compliance and Integrity Through Training and Delegation of Authority (from Association of Clinical Research Professionals)
- 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)

See more details on page 7.

**Discover USC**  
Friday, April 20, 2018

## Human Research Protection Program: Institutional Review Board (IRB) Review Versus Palmetto Health Administrative Research Review (PHARR)

Palmetto Health's Human Research Protection Program (HRPP) is a comprehensive system that was created to comply with ethical and legal requirements for the conduct and oversight of human research to ensure the protection of the rights and welfare of subjects in human research. In recent years, Palmetto Health has made a commitment to ensure that our institution conforms with best HRPP practices by becoming accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP accreditation has earned a reputation as the benchmark for quality human research protection programs and demonstrates that organizations with accreditation have built extensive safeguards into every level of their research operation and they adhere to high standards for research.

Two of the primary means that Palmetto Health has established to adhere to the AAHRPP standards are the Institutional Review Board (IRB) and Palmetto Health Administrative Research Review (PHARR) processes. While these two processes are managed and reviewed separately, many of the components are shared to produce a comprehensive HRPP.



### What is the Institutional Review Board (IRB)?

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Palmetto Health.

The IRB is charged with the responsibility of reviewing, prior to its initiation, all research (whether funded or not) involving human participants. The IRB is concerned with protecting the welfare, rights, and privacy of human subjects. The IRB has the authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction as specified by federal regulations, State law and institutional policy. The IRB has at least seven members of varying backgrounds in order to provide complete and adequate review of human research and its institutional, legal, scientific, and social implications. The Board also will include at least one member who is not affiliated with the institution and one member who is not a scientist.

Palmetto Health's IRB utilizes the electronic IRB (eIRB) system for submissions. eIRB manages the IRB process for human subjects research by providing a single platform to unify and streamline the IRB operations. This is a shared electronic system managed through Health Sciences South Carolina which allows cooperative reviews of research with other South Carolina affiliated institutions.

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Staff within the Palmetto Health IRB Administration office are available to assist with questions. Please note that IRB Administration staff are not Board members, but their efforts are to create complete, comprehensive submission packages that can be readily reviewed by the Board members.

A comprehensive [Investigators Manual](#) is available and provides a how to guide for IRB submissions and reviews. Also, there is a plethora of information in the IRB's website at [www.PalmettoHealth.org/IRB](http://www.PalmettoHealth.org/IRB).

For further IRB information, please contact Thomasena Williams, MPH, Manager of IRB Administration, at [Thomasena.Williams@PalmettoHealth.org](mailto:Thomasena.Williams@PalmettoHealth.org) or 803-296-6091.

### What is the Palmetto Health Administrative Research Review (PHARR)?

The PHARR process focuses on providing a standard method for research compliance issues to be assessed. This [process](#) is integrated into the already established IRB review process, but is managed by the Research Compliance office. An investigator submitting their study within the eIRB system attaches the completed [Palmetto Health Administrative Research Review](#) form with signatures and appropriate documentation within the eIRB system at the time of study submission.

*Through the [PHARR process](#) the following items are reviewed, if applicable to the submitted study:*

• **Conflict of Interest Review:** Research Financial Disclosure Statements are required for investigators and any other person (regardless of title or position) that the Principal Investigator identifies as responsible for the design, conduct, or reporting of the research. These statements are used to assess potential conflicts of interest. If a potential conflict of interest is identified that is related to the research, Palmetto Health's Potential Conflict of Interest Committee reviews, and a management plan may be required if a conflict is determined. The IRB has final authority in regards to financial interest determination and management.

• **Ancillary Department Review:** Impacted Service Agreements are required if the study utilizes Palmetto Health ancillary departments. Many research studies require significant levels of support or collaboration from Palmetto Health staff and departments in order to fully execute the proposed study. In an effort to ensure Palmetto Health has the capability to perform the services and the necessary resources, the investigator must obtain agreement from the affected staff/departments.

• **Corporate Counsel Review:** Sponsored studies typically have agreements or subawards that must be reviewed to ensure that Palmetto Health protects our patients, our investigators, and our institution. We have dedicated staff to review these agreements and to negotiate the terms with outside parties. In addition, some studies even if not funded, may require specific agreements, such as Data Use Agreements, to ensure compliance with various regulations.

• **Financial Review:** Clinical research presents a unique challenge to assess financial implications of a study. For sponsored research, a typical Internal Budget (payments from the sponsor) is required. In addition, a Budget Feasibility Analysis is required to assess the feasibility of conducting the research from a financial viewpoint. This analysis is required for sponsored research and those studies that utilize Palmetto Health property, facilities, equipment, or services. Lastly, a Coverage Analysis, which denotes items/procedures/services that are routine care (i.e. billable to the patient/patient's insurance) or those that are not-routine care (i.e. cannot be billed and should be paid by the sponsor/department), is required for studies that will have routine items/procedures/services billed to the patient/patient's insurance or those studies that have protocol item/procedure/service be performed at Palmetto Health.

• **Miscellaneous Approvals and Notifications:** Following the submission of the completed PHARR form, Research Compliance coordinates other necessary approvals including Medical Privilege Review by Palmetto Health's Medical Staff Office for studies involving new devices and/or procedures and Medicare Administrative Contract Review by Palmetto GBA for projects involving investigational device exemption (IDE) studies approved by the Food and Drug Administration (FDA) prior to January 1, 2015, and humanitarian use devices (HUD). As necessary, Research Compliance will notify other Palmetto Health departments that have a need to know about the study, including but not limited to Supply Chain, Case Management, HIM/Coding, and Patient Financial Services/Billing.

For further PHARR information contact Rebecca Marigliano, PhD, System Director, Clinical Research and Operations, at [Rebecca.Marigliano@PalmettoHealth.org](mailto:Rebecca.Marigliano@PalmettoHealth.org) or 803-434-6365. Also, for additional information regarding the PHARR process, visit and [www.PalmettoHealth.org/ResearchCompliance](http://www.PalmettoHealth.org/ResearchCompliance).

## Research Involving Prisoners

The Palmetto Health Institutional Review Board (IRB) adheres to the regulatory requirements for research which involves a prisoner as outlined in 45 CFR 46 Subpart C. Since prisoners may be influenced by their incarceration to participate in research, and in order to assure that their decision to participate is not coerced, the Palmetto Health IRB has a prisoner representative with an appropriate background and experience to serve in this capacity. All studies involving prisoners will include a prisoner representative.

In addition to all the basic human subject protection requirements (45 CFR 46, Subpart A), the Palmetto Health IRB must review prisoner research and find that the research complies with seven additional requirements [45 CFR 46.305(a)]:

1. The study satisfies the criteria for permissible research.
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
5. The information is presented in language which is understandable to the subject population.
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.
7. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Additional information regarding prisoner research may be found in the guidance, [Prisoner Involvement in Research](#).

For more information, please contact Thomasena Williams, MPH, Manager of IRB Administration, at [Thomasena.Williams@PalmettoHealth.org](mailto:Thomasena.Williams@PalmettoHealth.org) or 803 296-6091.

**Prisoner** – A prisoner is defined as “any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.”

**Prisoner representative** – An individual who is currently or formerly a prisoner or an individual who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner (e.g., prison chaplain, prison social worker, prison health care worker.)

**Minimal Risk** – For research involving prisoners, the IRB will use the following definition for “minimal risk”: “Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.”

## Disclosing Intellectual Property

Palmetto Health's Policy on Inventions and Intellectual Property addresses the rights to, interests in, and protection and transfer of intellectual property created by staff and contractors of Palmetto Health. It is a goal of this policy to encourage research, discovery, and innovation through the staff and contractors of Palmetto Health.

Palmetto Health and the University of South Carolina are working together now in order to review any intellectual property developed at Palmetto Health. If you have an intellectual property disclosure to make, you will need to visit the "Inventor Portal" at: <https://east.inteum.com/sc/inventorportal/login.aspx> to make your disclosure in a timely manner.

- On the login page, click "Request Account" in order to create and activate your account by providing your e-mail address and the required information.
- After you create your account, you will be taken to the "Dashboard" page, which will display your recent activity and any disclosures you are working on or that you have submitted.
- Select "Add New Disclosure" on the left menu in order to create a new submission and provide the title of the invention and the name of your organization from the drop-down menu. Please provide as much information as possible and be sure to complete all required fields (marked with an asterisk).
- Add all of your fellow inventors. If they have accounts already, you can search for them by name. If they do not have accounts yet, you will be able to add new contacts by providing their basic information and e-mail addresses. Your fellow inventors will be notified by e-mail.
- Attach all relevant documentation, research, and manuscripts to the "Documents" section in the Portal, and list all sponsors in the "Funding" section.
- If you have any questions about this process, please contact the University of South Carolina at 803-777-0066.

## Struggle with creating a Coverage Analysis?

**You are not alone.** Palmetto Health has recently contracted with a vendor that specializes in coverage analysis and budget development, and now will provide this service to those submitting through the Palmetto Health IRB. As noted in the lead article of this issue of Insider, a coverage analysis is a required component of the Palmetto Health Administrative Research Review (PHARR) process. It is suggested that a coverage analysis is developed early in study start-up as it has direct implications for budgeting, informed consent form writing, and research billing/coding.

The process to request this coverage analysis/draft budget development service requires that the following be submitted to [Research-Assist@PalmettoHealth.org](mailto:Research-Assist@PalmettoHealth.org):

- Coverage Analysis Request Form
- Protocol (required)
- Draft Informed Consent Form (required)
- Draft Clinical Trial Agreement (required for sponsored research)

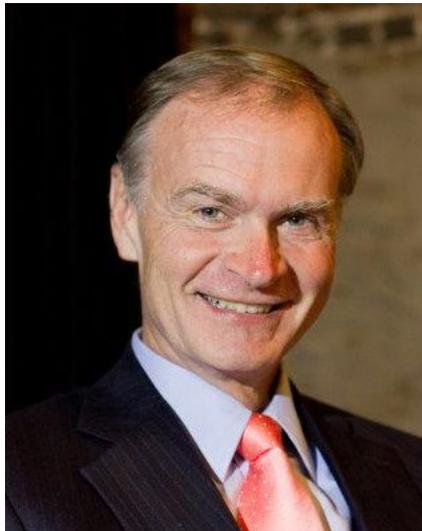
- Draft Sponsor Budget (required for sponsored research)
- Food and Drug Administration IND or IDE Letter (if applicable)
- CMS IDE study review letter (if applicable)
- Investigational Drug/Device Brochure (if applicable)
- Other pertinent documents (if applicable)

Once a complete request is received, you should allow at least 10 business days for obtaining the draft coverage analysis/budget. If there are any special circumstances/requests, you may identify these on the Request Form.

Please note that even if you do not utilize this new request process to create the required coverage analysis, Palmetto Health reserves the right to submit the necessary study information to the vendor to verify the accuracy of the submitted coverage analysis. If you have any questions, you may contact Rebecca Marigliano, PhD, System Director, Clinical Research and Operations, at [Rebecca.Marigliano@PalmettoHealth.org](mailto:Rebecca.Marigliano@PalmettoHealth.org) or 803-434-6365.

## Research Spotlight: Mark Williams, MD, JD, MBA

Dr. Mark Williams is the first Chief Clinical Officer for Palmetto Health and joined the organization in June 2017. He was formerly the Chief Physician Executive for Tenet's Brookwood Baptist System in Birmingham, Alabama. He is a past president of the Southern Medical Association and from 2008 to 2014 he served as the chief medical officer of the North Mississippi Health System in Tupelo, Mississippi—the largest rural health care system in the United States and the recipient of the 2012 National Malcolm Baldrige Award for Organizational Performance.



He is a 1980 graduate of the University of South Alabama College of Medicine and, after an internship in general surgery and a residency year in internal medicine, he completed his post-graduate training in anesthesiology. He was the chief resident in anesthesiology after which he joined the University of Alabama at Birmingham (UAB) Department of Anesthesiology and practiced anesthesia and critical care medicine at Carraway Methodist Medical Center, a 617-bed

Level I Trauma Center and teaching hospital, for more than twenty years.

He is a former member of the governor's Medicaid redesign committee and Healthcare Workforce committee in Mississippi, past board chairman of the Alabama Quality Assurance Foundation, and served as chief of staff of Carraway Methodist Medical Center from 2004 to 2006. From 2006 to 2008 he was the Chief Medical Officer for the St. Vincent's system in Birmingham, Alabama and chairman of Ascension Health's Physician Informatics Committee and

the Task Force on Disclosure of Unanticipated Outcomes. Williams is a 2001 graduate of the Alabama School of Law and a member of the Alabama State Bar. He completed the MBA program at Samford University in 1995 and is a former medical director for Alabama Power Company.

In 2016, he was honored as a distinguished alumnus of the University of South Alabama. He enjoys white water rafting in the wilds of Idaho and Montana. He and his wife Sandi have four children and two grandchildren.

# DISCOVER USC

**Save the Date:** Discover USC 2018 will showcase research, scholarship, leadership and creative projects by undergraduate and graduate students, postdoctoral scholars and medical scholars representing the USC System and Palmetto Health. Next year's event will be held **Friday, April 20, at the Columbia Metropolitan Convention Center**. Please be aware the 2018 event will be limited to poster presentations only. More information regarding the [Discover USC 2018](#) will be distributed regarding the event upon availability.

## *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, 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 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](#).

### **Informed Consent for Research: Responsibilities**

The last edition of the *Research Insider* provided background information related to South Carolina law as it relates to research informed consent. This article continues an explanation of the specific responsibilities of the research informed consent process.

The physician investigator retains ultimate responsibility for the consent process of a clinical study that involves a diagnostic, therapeutic, or surgical procedure. The physician investigator, at a minimum, is responsible for the following:

1. providing an introduction and overview of the diagnostic, therapeutic, and/or surgical procedures of the study to the potential study subject;
2. explaining the potential risks and benefits of participating in the research to the potential study subject;
3. reviewing the available and reasonable alternatives to the proposed diagnostic, therapeutic, or surgical procedures that are a part of the study;
4. ensuring that the potential study subject understands the information that has been provided during the consenting process;
5. answering any questions that the potential study subject may have; and
6. signing the informed consent document as the individual obtaining the consent for the research study prior to performing any study procedures.



The physician investigator, however, may delegate other consenting tasks to an appropriately trained study staff member. For example, a study staff member may be utilized to review the consent in depth (i.e. review all sections of the consent) with the potential study subject to ensure that the subject has a complete understanding of his/her participation in the study. These study staff members would be viewed as educators for the study.

Minimal risk studies are studies that are not invasive and that do not involve a diagnostic, therapeutic, or surgical procedure. For minimal risk studies, the investigator may delegate the entire informed consent process to appropriately trained study staff members.

The Palmetto Health IRB retains the right to determine who may consent for a study and will base its decision on a number of factors, including the above noted state law and the experience/training of the study staff member/investigator.

Electronic consent processes are becoming popular for research due to an increased use of technology, but this does not negate the responsibilities of the physician investigator and study staff members outlined above. Again, the investigator retains the ultimate responsibility for the research consent process. The Palmetto Health IRB has posted a standardized approach to an electronic consent process.

## 2017 Grant In Aid Awardees

The Richland Memorial Hospital Research and Education Foundation recognizes the importance of resident involvement in research and quality improvement activities as part of a comprehensive graduate medical education experience. It therefore supports meritorious, resident-initiated projects by providing funds on an annual basis through the Grant In Aid program. Congratulations to the following 2017 award recipients:

- **Jaime A. Catalá-Fuster, MD, Infectious Disease** - Proof of concept study to demonstrate the validity of FibroScan® in pregnancy
- **Edwin Hayes, MD, Infectious Disease** - Effect of Antiretroviral Therapy on Stool Microbiome in Treatment Naive HIV Infected Adults
- **Stephanie Hrisko, MD, Psychiatry** - Physician Knowledge of and Adherence to Opioid Prescribing Guidelines
- **Judson Lewis, MD, Pulmonary and Critical Care Medicine** - N-Acetylcysteine nebulization administered early in the course of the Acute Respiratory Distress Syndrome
- **Stella Okoye, MD, Infectious Disease** - Analysis of Inappropriate Clostridium difficile Testing at Palmetto Health
- **Philippa Elizabeth Robinette, PharmD, Pharmacy** - Impact of venous thromboembolism prophylaxis in patients with aneurysmal subarachnoid hemorrhage

## 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 beginning in January 2018 at noon in Room 130, 9 Richland Medical Park. 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.

### Upcoming Research Webinars

- January 26, 2018: Investigator Initiated Trials: Administrative Considerations for Successful Study Start-Up and Close (from Health Care Compliance Association)
- February 23, 2018: How to Ensure Study Compliance and Integrity Through Training and Delegation of Authority (from Association of Clinical Research Professionals)
- 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)

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](mailto:Melanie.Griswold@PalmettoHealth.org).



# Update to CITI Program Training Modules for Palmetto Health

On August 30, 2017, Palmetto Health Institutional Review Board (IRB) announced significant changes to the CITI Program Human Subjects Protection (HSP) training requirements for Palmetto Health. After hearing your concerns and investigating the continually changing HSP educational requirements, the Palmetto Health IRB has reduced the number of modules for both the Biomedical and Social-Behavioral-Educational learner groups by 39 percent and 48 percent, respectively. In addition, the Palmetto Health IRB introduced an even more abridged learner group for studies involving biomedical data and specimens only. This learner group would be applicable to those investigators conducting retrospective chart reviews.

A more comprehensive summary of the changes is listed below. You may access the updated training by logging in and affiliating with Palmetto Health at [www.citiprogram.org](http://www.citiprogram.org). If you have recently completed your initial or refresher training, no additional training will be needed: you will only see changes at your next renewal. If you have any questions regarding the HSP training update, please contact Thomasena Williams, IRB Manager, at 803-296-6091 or [Thomasena.Williams@PalmettoHealth.org](mailto:Thomasena.Williams@PalmettoHealth.org).

## Summary of changes:

- There are now three learner groups for researchers – (1) Biomedical, (2) Social-Behavioral-Educational, and (3) Biomedical Data or Specimens Only.
- Written criteria for inclusion in each of these learner groups, as defined by federal regulations, is available on Instructions Page which will assist learners in selecting the appropriate required course for their research role and the type of research in which they are involved.
- In select situations, a learner may be required by the Palmetto Health IRB or the Palmetto Health Research Compliance Department to complete supplemental modules. For example, a vulnerable population module may be required if the population is included in your study.
- There are three refresher courses for the Biomedical learner group and two refresher courses for the Social-Behavioral-Educational learner group. All refresher courses must be completed in sequential order every three years, and then completion of the basic course is required to start the cycle over again. Please note that the number of the required refresher modules are also reduced significantly.
- The new basic course for Biomedical Data or Specimens Only learners consists of seven modules from the Biomedical basic course, and there are three refresher courses.
- Biomedical researchers whose protocols include data or specimens research components are not required to complete the Biomedical Data or Specimens Only course, as these modules are already required in the Biomedical courses.

