Palmetto Health Administrative Research Review Policy

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Policy Statement

Palmetto Health is committed to performing high quality healthcare research. This policy applies whenever Palmetto Health participates in research regardless of the type of funding or the type of research. The Investigators and Research Staff are expected to comply with applicable laws, regulations, codes, guidance and best research practices, to promote patient safety and the ethical treatment of research participants, and to support the furtherance of medical care in the community.

DEFINITIONS

1. **Designated Institutional Official**: The individual authorized by Palmetto Health who assumes the obligations of Palmetto Health’s Federalwide Assurance (FWA) with the Office for Human Research Protections and who assumes the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to research.

2. **Engaged in human research**: Palmetto Health is engaged in human research when its employees or workforce members interact or intervene with human subjects for the purpose of conducting research. Engagement is further described in Human Research Protection Program Policy.

3. **Good Clinical Practice (GCP)**: An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. GCP includes but is not limited to: the Food and Drug Administration (FDA) regulations that govern the studies used to support new product applications; the U.S Department of Health and Human Services (DHHS) regulations for studies conducted or supported by the department; the International Conference on Harmonisation (ICH) GCP: Consolidated Guidance; other federal regulations relevant to research, including the Health Insurance Portability and Accountability Act (HIPAA).

4. **Human Subject**: An individual as defined by either the DHHS or the FDA and further described in Human Research Protection Program Policy.
5. **Independent Contractor:** Self-employed person who provides certain services to a second-party or to a third party on behalf of a client. An independent contractor is under the control, guidance or influence of the client or second party and unlike an employee does not owe a fiduciary duty. To be legally designated as an independent contractor, an individual must (1) be free from the control of the client, (2) be able to exercise his or her judgment as to the manner and methods to accomplish the end-result and (3) be responsible for the end-result only under the terms of the contract.

6. **Investigator:** An individual having the background and training in scientific and administrative oversight necessary to conduct and manage research activities.

7. **Participates in Research:** Palmetto Health participates in research when its workforce members perform research activities at a Palmetto Health facility or involve Palmetto Health patients and/or employees.

8. **Research:** An experiment/investigation as defined by either the DHHS or the FDA and further described in [Human Research Protection Program Policy](#). Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research.

9. **Research Staff:** Individuals who assist in a research project overseen by an Investigator.

10. **Sponsor:** An individual, company, institution, government agency or organization responsible for the initiation, management and financing of research.

11. **Workforce Members:** Employees, independent contractors, volunteers, students, trainees, medical residents, fellows and other persons whose conduct in the performance of work for Palmetto Health is under the control of the organization, regardless of whether the individuals are receiving compensation from Palmetto Health.

**POLICY SPECIFICATIONS**

1. **PREPARATION.** The Investigator must first determine that a potential study meets the minimum criteria:

   1.1. The research is in accordance with the charitable mission of Palmetto Health. The Investigator may discuss the proposed research with appropriate Palmetto Health Vice President(s) to clarify this issue if necessary.

   1.2. Participation in the research is available to any appropriate patient, regardless of race, color, religion, sex, age, national origin, disability, veteran status, or the patient’s payor status.

   1.2.1. The study must include children in the research design unless there are scientific or ethical reasons not to include them.

   1.2.2. The study must include women and members of minority groups and their subpopulations, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

   1.3. The study meets and is conducted in accordance with applicable health and/or other appropriate regulatory requirements including, but not limited to, those
promulgated by the Office of Human Research Protections (OHRP), the FDA (Investigational New Drugs, Investigational Device Exemptions, and human subject protection), National Institutes of Health (NIH), and Public Health Service (PHS).

1.4. Sufficient resources are available to conduct the study.
1.5. The Investigator will assemble appropriate Research Staff for the project. The Research Staff may include other investigators, clinical research nurses, or other qualified research personnel.
1.6. The Investigator is willing to accept responsibility for the proper conduct of the research by complying with applicable regulatory requirements and Good Clinical Practice.
1.7. For clinical trials, a qualified physician who is an investigator, co-investigator, or sub-investigator will be responsible for trial-related medical decisions.

2. APPROVAL PROCESS. Before research is initiated, the following steps must be completed to aid in assuring the project is in compliance with research regulations, guidelines, best practices, and this policy:

2.1. When Palmetto Health is engaged in human research, the Investigator will complete the Palmetto Health Institutional Review Board (IRB) requirements per the Human Research Protection Program Policy and other related policies and procedures/guidelines/rules/references (PGRs). When Palmetto Health is considered to be not engaged in human research, the Investigator will adhere to Not Engaged in Human Subjects Research.
2.2. The Investigator or Research Staff will complete the Palmetto Health Administrative Research Review (PHARR) form as administered by Research Compliance. The form facilitates review and provides information to the applicable departments and/or entities for each research project.
2.3. The Investigator(s) 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 or proposed for such funding discloses his/her potential interests, including those of their spouses and dependent children per the Objectivity in Research (Potential Conflict of Interest).
2.4. For research performed at Palmetto Health, the Investigator and/or designee should review the protocol to determine whether the study utilizes any property, facilities, equipment, or services of Palmetto Health (i.e. impacted services). The Investigator should consult with each of the identified impacted services. The agreement of the impacted services’ individuals/departments that the study is feasible and the individuals/departments can participate should be documented with Impacted Services Agreement for Research forms.
2.5. Scientific merit and scholarly validity review will be administered through the Investigator’s submission of the study protocol to the IRB. The scientific merit and scholarly validity review will be completed per the Scientific Review Committee.
2.6. A Coverage Analysis (CA) must be completed by the Investigator for clinical research that either (1) bills protocol items/procedures/services to the subject or a third party payer, including Medicare, or (2) requires Palmetto Health to perform any of the items, procedures or services as dictated by the research protocol. The CA identifies conventional care and research-related items/procedures/services
required by the study protocol and is further described in Coverage Analysis Creation. Non-interventional based research (e.g. retrospective studies) does not require the completion of a CA.

2.7. For research that is funded and/or research that is requesting funding (e.g. being submitted for grant support), the Investigator and/or designee must create a reasonable internal budget including an allocation budget (refer to Internal Study Budget Creation) that should include start-up costs, variable and/or invoiceable costs, study procedure costs (including identified impacted services costs), Investigator and Research Staff effort, and other necessary costs needed to conduct the study. This budget should be negotiated with the Sponsor until both the Sponsor and the Investigator come to an agreement on study costs.

2.7.1. Palmetto Health services must be reimbursed at fair market value to maintain the institution’s non-profit status.

2.7.2. For any federally sponsored research, the funds shall not be used to pay the salary of an individual through the grant or other extramural mechanism at a rate in excess of the salary limitation (i.e. salary cap) set forth by the awarding agency.

2.7.3. The Facilities and Administrative (F&A) rate (also known as indirect rate or overhead) is negotiated periodically by Palmetto Health with the Division of Cost Allocation within the Department of Health and Human Services (DHHS) and is applicable for cost reimbursement agreements. With approval from the Designated Institutional Official or designee, the F&A may be negotiated at a lower rate on a case by case basis. Refer to Research Facilities and Administrative Costs PGR.

2.8. For research that is funded and/or non-funded research that involves impacted service(s), a Budget Feasibility Analysis (BFA) must be performed. The BFA provides a summary of the anticipated costs associated with the conduct of the study and, if funded, the negotiated budget provided by the sponsor. Thus, the total profit/loss for the study is estimated. Refer to Study Budget Feasibility Analysis.

2.9. Investigator will forward any study agreement, contract, grant and/or other research legal document to Research Compliance for review and negotiation. Refer to Research Contract Terms PGR. Budgets created per Section 2.7 will be included in the final version of the document. In addition, Research Compliance may request appropriate legal documents (e.g. data use agreement, material transfer agreement) to be executed, as needed. Upon agreement of the terms within the research legal documents, Research Compliance will forward the document to the Designated Institutional Official and to the Investigator, as appropriate, for execution.

2.10. The Investigator will ensure that any qualified clinical trial complies with federal requirements for clinical trial registration and results reporting by registering the study per Clinical Trial Registration.

2.11. The Investigator will certify that he/she and other Research Staff are not debarred or suspended from participating in research. Refer to Debarment and Suspension in Research Projects.

2.12. The Investigator or Research Staff will upload the completed PHARR form with appropriate attachments and/or forms to Research Compliance into the electronic Institutional Review Board (eIRB) system when submitting the study for review.

2.13. The Investigator and/or Research Staff may be contacted by Research Compliance staff for clarifications or additional documentation as needed.
2.14. The Investigator and Research Staff will assure necessary Palmetto Health staff education is complete including requests for education, training, and clarification related to the protocol.

2.15. Unless otherwise stipulated in written documentation from Research Compliance, the Investigator must not begin screening, recruiting, and/or enrolling subjects until receipt of a letter of notification from the Research Compliance staff noting the completion of the PHARR process.

3. IMPLEMENTATION. The following steps are required once the research is approved:

3.1. The Investigator must properly conduct the research by complying with applicable regulatory requirements, Good Clinical Practice, Palmetto Health policies and PGRs (e.g. Research, IRB, investigational drug pharmacy), and other appropriate best research practices. Any research misconduct should be reported and handled per Research Misconduct.

3.2. The Investigator and Research Staff must follow the Informed Consent for Research and Research Uses and Disclosure of Protected Health Information Policy, unless waivers have been granted by the IRB.

3.2.1 A completed (signed/dated/initialed) copy of the IRB approved Informed Consent Form and Authorization for Access, Use, and Disclosure of Protected Health Information for Research should be placed in the subject’s Palmetto Health medical record (if the research is conducted at a Palmetto Health facility).

3.3. For sponsored research, Investigators must abide by Palmetto Health’s Sponsored Research Award Policy.

3.4. The Investigator and Research Staff must perform appropriate effort reporting if their salaries (all or a portion) are expended on federally sponsored research whether by a prime award, subaward, collaborative agreement, or contract or if required as a condition of participation in the research project. Refer to Effort Reporting.

3.5. The Investigator or Research Staff must notify Palmetto Health of subject encounters (subject visits) that occur at a Palmetto Health facility. Refer to Request for Research Billing.

3.5.1 The studies requiring this notification process will be identified in the approval letter sent by Research Compliance staff (Section 2.15).

3.5.2 The Investigator and Research Staff shall ensure appropriate research coding/billing is performed if the encounter is performed at other facilities/locations and for professional services.

3.6. Research Compliance and/or Corporate Audit Services may conduct audits of the research activities performed by the Investigator to verify compliance with the regulations and institutional policies.

3.7. The Investigator, Research Staff, and representatives from Palmetto Health including, but not limited to, Research Compliance staff, Corporate Counsel, Corporate Compliance, Corporate Audit Services, Patient Accounts, Patient Access Services, and Budget & Reimbursement Services may hold periodic meetings for the purposes of monitoring the progress of the study, addressing issues that may arise, and assuring and documenting compliance with appropriate regulations.

3.8. The Investigator must obtain approvals for any changes in the research protocol
from the IRB and Research Compliance who in turn may notify the appropriate departments and/or entities of the changes if necessary.

3.9. The Investigator must ensure appropriate on-going reporting to the IRB as necessary (e.g. continuing review, unanticipated and serious adverse events, and protocol deviations).

4. **COMPLETION.** The following steps are conducted at the conclusion of the research activity:

4.1 The Investigator must obtain approval for the publication/presentation of the research results per the [Publication/Presentation of Research Results](#).

4.2 The Investigator must notify the IRB of the closure of the research activity, as necessary.

4.3 The Investigator should notify Research Compliance and other departments and/or entities involved in the research activity of the research closure.

4.4 Research Compliance and/or Corporate Audit Services may conduct audits of the research activities performed by the Investigator.

**REFERENCES**

- Human Research Protection Program Policy
- Not Engaged in Human Subjects Research
- Objectivity in Research (Potential Conflict of Interest)
- Scientific Review Committee
- Coverage Analysis Creation
- Internal Study Budget Creation
- Research Facilities and Administrative Costs PGR
- Study Budget Feasibility Analysis
- Research Contract Terms PGR
- Clinical Trial Registration
- Debarment and Suspension in Research Projects
- Research Misconduct
- Informed Consent for Research
- Research Uses and Disclosure of Protected Health Information Policy
- Sponsored Research Award Policy
- Effort Reporting
- Publication/Presentation of Research Results

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