Reference: Nothing contained in this policy or in any other policy creates a contract right. Consistent with South Carolina law, all team members are employed "at will," which means that the team members have the right to terminate his or her employment at any time, with or without notice or cause, and that Palmetto Health retains the same right. Exceptions to the policy that all team members are employed "at will" may be made only by written agreement signed by the President of Palmetto Health.

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| X | Palmetto Health Baptist (PHB) |
| X | Palmetto Health Baptist Parkridge (PHBP) |
| X | Palmetto Health Richland (PHR) |
| X | Palmetto Health Tuomey (PHT) |
| X | All Non-Hospital Locations |

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**Research Conflict of Interest Disclosure PGR**

Effective: 07/25/2018  
Reviewed: 07/25/2020

Name of Associated Policy: [Objectivity in Research (Potential Conflict of Interest)]

**Definitions**

**Responsible Positions**

**Equipment Needed**

**Procedure Steps, Guidelines, Rules, or Reference**

**References**

**DEFINITIONS:**

1. **Equity Interest**: Includes any stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

2. **Financial Interest**: Anything of monetary value, whether or not the value is readily ascertainable.

3. **Investigator**: An individual having the background and training in scientific and administrative oversight necessary to conduct and manage research activities.
4. **Palmetto Health Responsibilities**: Research Personnel’s professional responsibilities on behalf of Palmetto Health which may include but is not limited to activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

5. **PHS**: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

6. **Research Personnel**: The project director (PD) or principal investigator (PI) and any other person (regardless of title or position) that the PD/PI identifies as responsible for the design, conduct, or reporting of the research or proposed for such funding. Research Personnel may include Research Staff, collaborators, or consultants.

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

8. **Remuneration**: Includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

9. **Significant Financial Interest**: A financial interest that:

   9.1 Consists of one or more of the following interests of Research Personnel (and those of the Research Personnel’s spouse and dependent children) that reasonably appears to be related to the Research Personnel’s Palmetto Health’s responsibilities:

   9.1.1 With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.

   9.1.2 With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Research Personnel (or the Research Personnel’s spouse or dependent children) holds any equity interest.

   9.1.3 Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

   9.2 Consists of reimbursed or sponsored travel (i.e. that which is paid on behalf of the Research Personnel and not reimbursed to the Research Personnel so that the exact monetary value may not be readily available), related to their Palmetto Health responsibilities, that is valued at $2,500 for a single trip/destination or $5,000 for two or more trips/destinations paid by a single entity; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

9.3 The term does not include:
9.3.1 Salary, royalties, or other remuneration paid by Palmetto Health to the Research Personnel if the Research Personnel is currently employed or otherwise appointed by Palmetto Health, including intellectual property rights assigned to Palmetto Health and agreements to share in royalties related to such rights;

9.3.2 Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Research Personnel does not directly control the investment decisions made in these vehicles;

9.3.3 Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

9.3.4 Income from service on advisory committees or review panels for Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

RESPONSIBLE POSITIONS (TITLE):
- Investigators and Research Staff

PROCEDURE STEPS, GUIDELINES, or RECOMMENDATIONS

1. The Investigator and other Research Personnel must complete the necessary conflict of interest training as set forth in the Objectivity in Research (Potential Conflict of Interest) policy.

2. Research Personnel (and those of their spouses and dependent children) must disclose any financial interest, potential intellectual property rights and interest, consulting relationships, memberships on advisory boards/committees or review panels, and participation in speakers’ bureaus related to the Research Personnel’s Palmetto Health responsibilities to Research Compliance utilizing the Research Financial Disclosure Statement form. (A current form may be obtained from Research Compliance.) The completed form must be received by Research Compliance:

   2.1. No later than the time of application for PHS-funded research. The completed form may be sent to Research-Assist@palmettohealth.org; and

   2.2. At the time of study submission to the Institutional Review Board for all other research. The completed form may be uploaded into the eIRB system.

3. At continuing reviews, Research Personnel must verify the accuracy of previously disclosed interest information via the eIRB system. If the previous disclosure is not accurate, the Research Personnel must update:

   3.1. Any information that was not disclosed initially, and
3.2. New value of previously disclosed interests.

4. An updated completed form must be submitted to the Research Compliance within thirty (30) days of discovering or acquiring a new interest. The completed form may be sent to Research-Assist@palmettohealth.org.

5. Any potential intellectual property rights and interest, consulting relationships, memberships on advisory boards/committees or review panels, and participation in speakers’ bureaus related to the research must be disclosed in the informed consent document that will be presented to the study subjects.

6. Upon disclosure of an interest, the Palmetto Health Potential Conflict of Interest (PCOI) Committee may provide a management plan to the Investigator if it is determined that the interest is related to the research and that a significant financial interest exists. The Investigator and other Research Personnel must follow the plan.

7. If a conflict of interest related to the research is not identified or managed in a timely manner, the Investigator and other Research Personnel must follow the PCOI Committee’s plan of action(s) to eliminate or mitigate the effect of the bias if a bias is identified by the Committee.

8. The Investigator and other Research Personnel are required to submit, or permit, on site review of records pertinent to compliance with the Objectivity in Research (Potential Conflict of Interest) policy and its associated procedures.

9. Rare exceptions to the standard disclosure and designated Institutional Official review process may be made at the discretion of the Designated Institutional Official in collaboration with the Institutional Review Board Chair.

REFERENCES
42 CFR 50 Subpart F – Promoting Objectivity in Research
45 CFR 94 – Responsible Prospective Contractors