Objectivity in Research (Potential Conflict of Interest) Policy

Policy Statement
This policy is intended to promote objectivity in research by ensuring the design, conduct, and reporting of research will be free from bias resulting from conflicts of interests. Palmetto Health recognizes that conflicts of interest may exist when research is conducted. In order to ensure ethical conduct of the research in these situations, Palmetto Health requires disclosure of financial and other interests so that the conflicts may be identified and managed.

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. Also referred to as the designated Signatory Official.

2. Disqualified Person: Any person who is in a position to exercise substantial influence over the affairs of Palmetto Health per IRS regulations.

3. 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.

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

5. HHS: The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
6. **Institutional Conflict of Interest**: A situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or reasonably appear to affect the institutional processes for the design, conduct, reporting, review, or oversight of research. Institutional conflict of interest includes (1) licensing, technology transfer, and patents, (2) investments of the organization, (3) gifts, when the donor has an interest in the research, (4) financial interests of senior administrators and members of the Board of Directors, and (5) other financial interests.

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

8. **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.

9. **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).

10. **PHS Awarding Component**: The organizational unit of the PHS that funds the research that is subject to this PGR.

11. **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.

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

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

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

   14.1 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 responsibilities:

   14.1.1 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.

   14.1.2 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) hold any equity interest.
14.1.3 Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

14.2 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.

14.3 The term does not include:

14.3.1 Salary, royalties, or other remuneration paid by Palmetto Health to the Research Personnel if the Research Personnel are 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;

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

14.3.3 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;

14.3.4 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.

POLICY SPECIFICATIONS

1. APPLICABILITY

1.1. While Palmetto Health follows both Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations, this policy will follow DHHS regulations due to its more restrictive nature.

1.2. The following research must conform to this policy:

1.2.1. PHS-funded research or research applying for PHS funds excluding Small Business Innovation Research (SBIR) Program Phase I applications.

1.2.2. Other research whether funded or non-funded that is submitted to Palmetto Health Institutional Review Board for review excluding those studies that are categorized as Not Human Subjects Research, Exempt Human Subjects Research, or those studies in which Palmetto Health is not engaged in human subjects research.
2. INDIVIDUAL FINANCIAL CONFLICT OF INTEREST

2.1. Disclosure. Research Personnel (and the Research Personnel’s spouse and dependent children) shall disclose financial interests which shall be assessed by the Designated Institutional Official or designee to determine whether significant financial interests are related to the Research Personnel’s Palmetto Health responsibilities. The disclosures must be submitted:

2.1.1. No later than the time of application for the research for PHS-funded research or at the time of Institutional Review Board submission for all other research;

2.1.2. At least annually during the conduct of the research; and

2.1.3. Within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new significant financial interest.

2.2. Designated Institutional Official Review. The Designated Institutional Official or designee shall review all disclosures submitted by Research Personnel (and the Research Personnel’s spouse and dependent children) and shall assess if a financial interest is significant and related to the research.

2.2.1. The Designated Institutional Official may consult with the Investigator to assist in the determination as to whether a significant financial interest is related to the research.

2.2.2. A significant financial interest is related to the research when the significant financial interest:

2.2.2.1. Could be affected by the funded research, or

2.2.2.2. Is in an entity whose financial interest could be affected by the research.

2.2.3. If there is not a significant financial interest related to the research, the Designated Institutional Official or designee notifies the Institutional Review Board of this determination. The Institutional Review Board has final authority in regards to financial interest determination for the research.

2.2.4. If the Designated Institutional Office or designee identifies that the disclosed financial interest is a significant financial interest that is possibly related to the research, then the significant financial interest must be reviewed by the Potential Conflict of Interest (PCOI) Committee.

2.3. Committee Review. If a financial interest that is significant and possibly related to the research, the Designated Institutional Official or designee will request a called meeting of the PCOI Committee to further assess whether the significant financial interest that related to the research is a conflict of interest.

2.3.1. A conflict of interest exists when the significant financial interest could directly
and significantly affect the design, conduct, or reporting of the research.

2.3.2. If the Committee determines that there is no conflict of interest, the Designated Institutional Official or designee notifies the Institutional Review Board of this determination. The Institutional Review Board has final authority in regards to financial interest determination for the research.

2.3.3. If a financial conflict of interest exists, the PCOI Committee shall report the financial conflict of interest and recommend appropriate measures to manage the conflict of interest to the Designated Institutional Official or designee, who will notify the Institutional Review Board of the determination. The Institutional Review Board has final authority in regards to the financial interest determination and the management of the conflict of interest. The Institutional Review Board may modify the management plan as appropriate. The final management plan must be adhered to by the Research Personnel and report the financial conflict of interest.

2.4. Management.

2.4.1. The review of significant financial interests, determination of conflicts of interest, and the development and implementation of a management plan will occur:

2.4.1.1. Prior to Palmetto Health’s expenditure of any funds related to the research project;

2.4.1.2. For ongoing research, the review of significant financial interests, determination of conflicts of interest, and the development and implementation of at least an interim management plan must occur:

2.4.1.2.1. Within sixty (60) days after disclosure of a new significant financial interest by existing Research Personnel or Research Personnel new to the research project.

2.4.1.2.2. Within sixty (60) days after the identification of a significant financial interest by Palmetto Health that was not disclosed timely by Research Personnel or was not previously reviewed by Palmetto Health during an ongoing research project.

2.4.2. The conditions or restrictions that might be imposed on the Research Personnel to manage the financial conflict of interest include, but are not limited to:

2.4.2.1. Public disclosure of financial conflicts of interests (e.g. when presenting or publishing the research);

2.4.2.2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to the participants (e.g. within the informed consent document);
2.4.2.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
2.4.2.4. Modification of the research plan;
2.4.2.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
2.4.2.6. Reduction or elimination of the financial interest (e.g. sale of an equity interest);
2.4.2.7. Severance of relationships that create financial conflicts.

2.4.3. If a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by Palmetto Health to constitute a financial conflict of interest; failure by Palmetto Health to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan:

2.4.3.1. The PCOI Committee will facilitate within 120 days of Palmetto Health’s determination of noncompliance, complete a retrospective review of the Investigator’s activities and the research project to determine whether any research conducted during the time period of noncompliance, was biased in the design, conduct, or reporting of such research.

2.4.3.2. The retrospective review will be documented and include the following key elements:

2.4.3.2.1. Project number,
2.4.3.2.2. Project title,
2.4.3.2.3. Project Director/Principal Investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used,
2.4.3.2.4. Name of the Investigator with the financial conflict of interest,
2.4.3.2.5. Name of the entity with which the Investigator has a financial conflict of interest,
2.4.3.2.6. Reason(s) for the retrospective review,
2.4.3.2.7. Detailed methodology used for the retrospective review (e.g. methodology of the review process, composition of the review panel, documents reviewed),
2.4.3.2.8. Findings of the review, and
2.4.3.2.9. Conclusions of the review.

2.4.3.3. The PCOI Committee will specify the action(s) that will be taken to manage the financial conflict of interest going forward. The Institutional Review Board has final authority in regards to the financial interest determination and the management of the conflict of interest. The Institutional Review Board may modify the management plan as appropriate.
2.4.3.4. If bias is found, the PCOI Committee will

2.4.3.4.1. Create a mitigation report to include

2.4.3.4.1.1. Elements documented in the retrospective review (Section 1.4.3.2)
2.4.3.4.1.2. Description of the impact of the bias on the research project
2.4.3.4.1.3. Palmetto Health’s plan of action(s) taken to eliminate or mitigate the effect of the bias

2.4.3.4.2. Palmetto Health will notify the sponsor of the study (e.g. PHS awarding component, an industry sponsor, etc.) of the bias and provide the mitigation report if the sponsor is a PHS awarding component.

2.4.4. The PCOI Committee shall establish and oversee an appropriate monitoring plan until the completion of the funded research project to ensure compliance.

2.5. Reporting of Financial Conflicts of Interest.

2.5.1. After the identification of a financial conflict of interest (FCOI), Palmetto Health shall notify:

2.5.1.1. The Institutional Review Board. The Institutional Review Board has final authority in regards to the financial interest determination and the management of the conflict of interest.

2.5.1.2. The PHS Awarding Component of the financial conflict of interest prior to Palmetto Health’s expenditure of any funds under a PHS-funded research project by providing an FCOI report and ensure that Palmetto Health has implemented a management plan. If the FCOI is eliminated prior to the expenditure of the funds, then an FCOI report does not need to be submitted.

2.5.1.3. The PHS Awarding Component of the financial conflict of interest identified subsequent to Palmetto Health’s initial FCOI report for a PHS-funded research project by providing an FCOI report within sixty (60) days after the identification, ensure that Palmetto Health has implemented a management plan, conduct a retrospective review, and notify the PHS Awarding Component if bias has been identified.

2.5.1.4. The Research Personnel to report the FCOI to the non-PHS entity sponsor of the research if not already identified through the sponsor’s own financial conflict of interest disclosure system. Documentation of the notification may be requested.
2.5.2. An FCOI report should include, but is not limited to:

2.5.2.1. Project number
2.5.2.2. PD/PI or Contact PD/PI if a multiple PD/PI model is used
2.5.2.3. Name of the Investigator with the financial conflict of interest
2.5.2.4. Name of the entity with which the Investigator has a financial conflict of interest
2.5.2.5. Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
2.5.2.6. The approximate dollar value of the significant financial interest with the dollar ranges ($0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
2.5.2.7. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution’s determination that the financial interest conflicts with such research,
2.5.2.8. A description of the key elements of Palmetto Health’s management plan including
   2.5.2.8.1. Role and principal duties of the conflicted Investigator in the research project
   2.5.2.8.2. Conditions of the management plan
   2.5.2.8.3. How the management plan is designed to safeguard objectivity in the research project
   2.5.2.8.4. Confirmation of the Investigator’s agreement to the management plan
   2.5.2.8.5. How the management plan will be monitored to ensure Investigator compliance.

2.5.3. Palmetto Health will provide annual FCOI reports for any ongoing PHS-funded research where a financial conflict of interest was previously reported to the PHS Awarding Component for the duration of the project period. The annual FCOI report should include:

   2.5.3.1. The status of the financial conflict of interest
   2.5.3.2. Any changes to the management plan
   2.5.3.3. Specification whether the financial conflict is still being managed or explanation why the financial conflict of interest no longer exists.

2.6. Public Accessibility.

2.6.1. The Designated Institutional Official or designee shall ensure that this policy related to financial conflicts of interest is available via the Palmetto Health external website.
2.6.2. Any individual may request information concerning significant financial interest disclosures made to Palmetto Health that meet the following three criteria:

2.6.2.1. The significant financial interest was disclosed and is still held by Investigators/Research Personnel,
2.6.2.2. Palmetto Health has determined that the significant financial interest is related to PHS funded research, and
2.6.2.3. Palmetto Health has determined that the significant financial interest is a financial conflict of interest.

2.6.3. The Designated Institutional Official and/or designee in consultation with the PCOI Committee and Palmetto Health’s Corporate Council will provide a written response to the requestor within five (5) business days and will include:

2.6.3.1. The Investigator’s name,
2.6.3.2. The Investigator’s title and role with respect to the research project,
2.6.3.3. The name of the entity in which the significant financial interest is held,
2.6.3.4. The nature of the significant financial interest,
2.6.3.5. The approximate dollar value of the significant financial interest with the dollar ranges ($0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value,
2.6.3.6. A statement that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of Palmetto Health’s identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

2.7. Record Retention. Research Compliance shall maintain all records relating to the Research Personnel disclosures of financial interests and Palmetto Health’s review of and response to such disclosures and all actions for at least three (3) years from the date of the final expenditures of the research.

3. INTELLECTUAL PROPERTY RIGHTS AND INTERESTS

3.1. Monetary intellectual property rights and interests are captured in Section 1 of this policy. However, intellectual property rights and interests may exist without the Research Personnel currently in receipt of income from the interest.

3.2. Potential intellectual property rights and interests should be disclosed to the Designated Institutional Official or designee for review in efforts to minimize the bias that may result in the potential interest. Refer to Inventions and Intellectual Property Policy for further information regarding disclosure.
3.3. If the potential intellectual property rights and interest is related to the research, then the Research Personnel must disclose their potential rights/interest (whether or not the rights/interest has resulted in income) in the informed consent document that will be presented to the study subjects.

4. CONSULTING RELATIONSHIPS AND ADVISORY BOARD PARTICIPATION

4.1. Consulting relationships, participation on advisory boards/committees or review panels, and/or participation in speakers’ bureaus of research funding agencies/companies should be disclosed to the Designated Institutional Official or designee for review in effort to minimize the bias that may result in a potential interest. These consulting relationships, participation on advisory boards/committees or review panels, and/or participation in speakers’ bureaus may or may not be financial in nature.

4.2. If the consulting relationship, advisory board/committee or review panel, and/or participation in speakers’ bureaus is related to the research (e.g. it is formed by/for the sponsor of the research), then the Research Personnel must disclose their relationship and/or participation in the board/committee/panel in the informed consent document that will be presented to the study subjects.

5. INSTITUTIONAL CONFLICT OF INTEREST

5.1. Licensing, technology transfer and patents will be capture through the Inventions and Intellectual Property Policy.

5.2. Investments of the organization are managed as set forth by the Palmetto Health Statement of Investment Objectives, Goals and Policy Guidelines.

5.3. Financial interests of senior administrators will be assessed as set forth in the Palmetto Health Corporate Compliance Potential Conflict of Interest PGR.

5.4. Financial interests of members of the Board of Directors are assessed on an annual basis as set forth in the Palmetto Health Rules of Conduct Board Policy.

5.5. Palmetto Health Corporate Compliance with the assistance of the Potential Conflict of Interest Committee will be responsible for identification of other Institutional Conflicts of Interest including but not limited to those set forth in the Palmetto Health Corporate Compliance Business Courtesies and Gifts PGR and Corporate Compliance Potential Conflict of Interest PGR.

5.5.1. Palmetto Health Corporate Compliance will notify the Department of Research Compliance and/or the Institutional Review Board promptly after identifying conflicts of interest that may relate to research conducted at Palmetto Health.

6. TRAINING

6.1. As of October 1, 2012, Research Personnel are required to take the Conflict of Interest course through the Collaborative Institutional Training Initiative (CITI) during initial
and refresher training. CITI training is required prior to Institutional Review Board review.

6.2. Notifications and/or additional training will be provided promptly when any of the following occurs:

   6.2.1. When Palmetto Health revises its Objectivity in Research (Potential Conflict of Interest) policy and its associated procedures that affects the requirements of Research Personnel;
   6.2.2. When Palmetto Health finds that Research Personnel are not in compliance with the Objectivity in Research (Potential Conflict of Interest) policy.

7. DISQUALIFIED PERSONS

   7.1. Non-employed Research Personnel (and the Research Personnel’s spouse and dependent children) conducting research at Palmetto Health must notify the Department of Research Compliance if they are a Disqualified Person.

8. NON-COMPLIANCE

   8.1. Failure to comply with this policy may result in disciplinary action up to and including discharge.

   8.2. If required by HHS for a PHS-funded project, the Investigator shall disclose their financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations

REFERENCES

- 42 CFR 50 Subpart F – Promoting Objectivity in Research
- 45 CFR 94 – Responsible Prospective Contractors
- Inventions and Intellectual Property Policy
- Palmetto Health Statement of Investment Objectives, Goals and Policy Guidelines
- Corporate Compliance Potential Conflict of Interest PGR
- Palmetto Health Rules of Conduct Board Policy
- Corporate Compliance Business Courtesies and Gifts

Mark Williams
Chief Clinical Officer
08/27/2018