



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 MEMBER HAS THE RIGHT TO TERMINATE HIS OR HER EMPLOYMENT AT ANY TIME, WITH OR WITHOUT NOTICE OR CAUSE, AND THAT PRISMA HEALTH AND/OR ITS AFFILIATED ENTITIES RETAIN THE SAME RIGHT.

Conflict of Interest Annual Disclosure Requirement (S-015-03)

Approved Date: 04/01/2020	Effective Date: 04/01/2020	Review Date: 04/01/2023
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Scope:

Prisma Health-Midlands		Prisma Health-Upstate	
X	Prisma Health Baptist Hospital	X	Prisma Health Greenville Memorial Hospital
X	Prisma Health Baptist Parkridge Hospital	X	Prisma Health Greer Memorial Hospital
X	Prisma Health Richland Hospital	X	Prisma Health Hillcrest Hospital
X	Prisma Health Tuomey Hospital	X	Prisma Health Laurens County Hospital
X	Prisma Health Children’s Hospital-Midlands	X	Prisma Health Oconee Memorial Hospital
X	Prisma Health Heart Hospital	X	Prisma Health North Greenville Hospital
X	PH USC Medical Group	X	Prisma Health Patewood Hospital
X	Provider based facilities associated with Prisma Health-Midlands hospitals	X	Prisma Health Surgery Center - Spartanburg
		X	Prisma Health Marshall I. Pickens Hospital
		X	Prisma Health Children's Hospital-Upstate
		X	Prisma Health Roger C. Peace Hospital
		X	Prisma Health Baptist Easley Hospital
		X	University Medical Group UMG/PIH
		X	Provider based facilities associated with Prisma Health-Upstate hospitals

Policy Statement:

It is the policy of Prisma Health to identify, manage, and resolve conflicts of interest that may affect the decisions, transactions and operations of Prisma Health. This policy applies to the following:

All Prisma Health Team Members, employed Prisma Health physicians and non-physicians; investigators, researchers and other medical staff members of Prisma Health. Moreover, where applicable this policy covers the activity of students, fellows, residents and other learners who work directly with all physician providers of Prisma Health. While we acknowledge that students, fellows, residents and other learners may belong to an institution that has its own Conflict of Interest policy, those individuals (and any other) interacting with Prisma Health are required to abide by the standards of Prisma Health and must be met

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unequivocally. A more stringent standard may be followed so long as adhering to such would not in any way compromise or negatively affect this policy.

In terms of advancing knowledge, it is understood that members of the Prisma Health medical staff may undertake research activities as an investigator consistent with the mission of Prisma Health. As such, those engaged in research as Investigator or designated as "Key Personnel" on research project and/or clinical trial must have on file a current (12 months or less) standardized disclosure document. This document will serve as the instrument of record for internal/external auditing purposes and for use in external funding applications.

In addition; this policy applies to interactions with sales, marketing, or other personnel who represent industry (i.e., pharmaceutical and device manufacturers, biotechnology and information technology companies, and companies that market and sell equipment and supplies for clinical care or research).

In addition to submitting the corporate disclosure statement to the Office of Corporate Integrity (OCI), Physicians may be required to submit an individual Conflict of Interest acknowledgement form or disclosure statement pursuant to Medical Staff Policy.

All Prisma Health Team Members are to refer to Section 3; Responsibilities of Prisma health regarding Conflicts of Interest. This section is applicable to all Team Members, Investigators and medical staff members.

Associated Policies and Procedures:

The following Prisma Health policies are pertinent to the provisions of this policy and have reference to specific conditions related thereto:

- Prisma Health Office of Human Research Protection policy HRPP
- IRB Member Conflict of Interest Policy No. 6.0
- Conflicts of Interest in Research Policy No. 9.0
- Office of Human Research Protection policy – 501 HRPP

42 CRF 50.601 et seq. and 45 CRF 94.1 et seq.

Associated Lippincott Procedures: (as applicable)

N/A

Definitions: IMPORTANT

1. Refer to Appendix A of S-015-03 attached to this policy for a list of definitions
2. Refer to Appendix B of S-015-03 attached to this policy for a list of Specific Activities

Responsible Positions:

All Prisma Health Team Members

Equipment Needed:

N/A

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Procedural Steps:

1. Purpose:

The purpose of this policy is to promote objectivity in Prisma Health business, including research, by establishing standards that provide a reasonable expectation that Prisma health business, including the design, conduct, and reporting of research, is free from bias resulting from financial and non-financial conflicts of interest. A conflict of interest may be defined as a set of conditions in which one's primary interest (as determined by one's professional duties) tends to be unduly influenced by a secondary interest. Conflicts of interest may affect the behavior and judgment of clinicians, educators, and researchers. For members of the Prisma Health and our professional medical community, primary professional interest includes (a) the provision of patient care that reflects best practices, (b) student and resident education that is free from bias, and (c) the ethical integrity of research. An important secondary interest that has the potential to influence these primary interests is financial gain.

2. Responsibilities of Prisma Health – In General

- 2.1 Maintain written policies and guidance to manage Conflicts of Interest (COI).
- 2.2 Post COI policy and additional relevant information on Prisma Health website (www.prismahealth.org).
- 2.3 Educate and inform all team members of their responsibilities toward this policy.
- 2.4 Require Prisma Health personnel and Medical Group covered under this policy (Interested Person) to complete a COI Disclosure Form on an as needed basis, but no less than annually.
- 2.5 The OCI will review all COI Statements and report the findings to the appropriate and designated COI Review Committee(s) to review and manage COI Disclosures.
- 2.6 Resolve disclosed COI and report findings to the Prisma Health Finance, Audit and Compliance Committee and appropriate Medical Staff Leadership Committees.

3. Responsibilities of Prisma Health Investigators

In *addition* to the General Responsibilities described above, For Investigators:

Investigators participating in commercial or Public Health Service (PHS) – Funded Research, Prisma Health Office of Sponsored Programs and Office of Research Compliance (ORCA) will:

- 3.1 Maintain records of disclosures of any and all reported research related Conflicts of Interests.
- 3.2 Review and respond to reported research related Conflicts of Interests.
- 3.3 Establish enforcement mechanisms to ensure COI reporting compliance.
- 3.4 Require researchers and staff to assist and collaborate in any and all COI investigations and resolve potential COI issues that are discovered.
- 3.5 Assure researchers comply with a written research agreement that meets with the requirements of federal and state laws and regulations.

4. Duty to Disclose – In General

Annual Disclosure Statement

- 4.1 All Interested Persons identified as covered by this policy shall submit their individual COI to the OCI in a complete and timely manner.
- 4.2 By being identified as an Interested Person covered by this policy, the Prisma Health team member including physicians and leadership staff attests to the following:
 - 4.2.1 Has received a copy of the Prisma Health COI Policy
 - 4.2.2 Has read and understands the COI Policy
 - 4.2.3 Has agreed to comply with this COI Policy
 - 4.2.4 Understands that Prisma Health is not-for-profit entity and is required to engage in activities which primarily accomplish and support these purposes.

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5. Duty to Disclose – For Investigators/IRB Members

In addition to the General Duties to Disclose as described above, For Investigators:

Investigators participating in Commercial or Public Health System (PHS) – Funded Research, Prisma Health team members, including physicians will:

- 5.1 Disclose any Significant Financial Interest (SFI) to the appropriate Institutional Review Board (IRB) as well as to the OCI, by submitting a completed Prisma Health Investigator and IRB Member Conflict of Interest statement as found on the Prisma Health website on an annual basis or during Continuing Review via the IRB Continuing Review module. In accordance with the Office of Human Research Protection Policy (HRPP) 9.0 Conflicts of Interest in Research and 42 CFR §50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
- 5.2 Require Investigators to disclose known or potential Significant Organizational Interests (SOI) no later than at the time of application; within thirty (30) days of discovering the SOI; and at least annually

6. Management of Conflicts of Interest – In General

- 6.1 If Prisma Health determines that a Prisma Health team member or Medical Group member covered by this policy did not comply with the terms of this Conflict of Interest – Annual Disclosure Policy, or if Prisma Health discovers that one of these individuals had a Significant Financial or Organizational Interest that was not disclosed in a timely manner pursuant to this Policy, Prisma Health will conduct a retrospective review, and if, upon conclusion of the review, the Prisma Health Conflict of Interest Committee finds that a conflict of interest existed that could have affected the decision-making and/or independent judgement of the individual, Prisma Health will take appropriate steps in accordance with this Policy to manage or eliminate the conflict and report its finding to the appropriate Prisma Health administrative body.
- 6.2 Purchasing, Evaluations, Committees and Workgroups: A team member, Investigator, or member of our Medical Staff who has a disclosable financial Interest, must disclose this at the beginning of any meeting as appropriate to the context of that meeting (for example, being paid as a speaker or consultant for medical equipment supplier or pharmaceutical company whose product is being evaluated by the committee). The individual disclosing the Financial Interest may continue to participate in the work of the group or committee evaluating products or services. When discussions are finalized the Chair of the Committee may, based on the significance of the Financial Interest, ask the individual to recuse themselves from the actual purchasing decision.

7. Management of Conflicts of Interest – For Investigators

- 7.1 If Prisma Health determines that an Investigator did not comply with the Conflict of Interest – Annual Disclosure Policy, or if Prisma Health discovers that the investigator had a Significant Financial or Organizational Interest that was not disclosed in a timely manner pursuant to this Policy, Prisma Health will conduct a retrospective review, and if, upon conclusion of the review, the Prisma Health Research Conflict of Interest Committee finds that a conflict of interest existed that could have affected the design, conduct or reporting of the research, Prisma Health will take appropriate steps in accordance with this Policy to manage or eliminate the conflict and report its findings to the funding agency, if required by law. The Prisma Health report will address the conflict’s impact on the research project, and the actions that Prisma Health took or will take to eliminate or mitigate the harm.
- 7.2 Retrospective Review: In the event of failure to meet the requirements of the PHS Financial Conflict of Interest (FCOI) regulations, including failure by the Investigator

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to timely disclose a Conflict of Interest that is determined to constitute an FCOI, Prisma Health's failure to review or manage such an FCOI, or Investigator failure to comply with an FCOI management plan, Prisma Health will, within sixty (60) days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine any bias in the design, conduct or reporting of Research during the time period of the noncompliance. Prisma Health will document the retrospective review in accordance with its Conflict of Interest Policy and applicable PHS regulations.

8. Posting Financial Conflict of Interest Information – Research

- 8.1 For each research related Financial Conflict of Interest that is found to exist by the Prisma Health Research Conflict of Interest Committee, Prisma Health will make the following information available on the Prisma Health Web Site of each individual identified with the aforementioned conflict:
 - 8.1.1 The individual's name
 - 8.1.2 The individual's title and role with respect to the research
 - 8.1.3 The name of the entity in which the SFI is held
 - 8.1.4 The nature of the SFI
 - 8.1.5 The approximate value of the significant financial interest
- 8.2 Prisma Health Research Compliance Office will update the information required by this section annually. In addition, for any financial conflict of the interest not previously available or identified, Prisma Health will make the information required by this section available not later than the sixtieth (60th) day after the financial conflict of interest is identified.
- 8.3 The information must note that it is current as of the date listed and is subject to updates.
- 8.4 The information required by this section must remain available for three (3) years after its most recent update.
- 8.5 For PHS-funded research, in regards to project directors, principal investigators, and other senior or key personnel, this information must be available BEFORE expending PHS funds.

9. Final Determination Regarding Conflict of Interest (Review of Disclosures)

- 9.1 Any disclosure of an interest of \$5,000 or greater will be reviewed by the Prisma Health Conflict of Interest Committee.
- 9.2 The appropriate Prisma Health Conflict of Interest Committee has the responsibility and authority to approve the acceptability of a management plan for conflicts of interest.
- 9.3 The appropriate Prisma Health Conflict of Interest Committee will notify the Discloser in writing of its decision.
- 9.4 All payments to physicians will be reviewed and compared in light of the CMS Open Payments web site portal. When required the OCI will work with individual physicians to reconcile payment information between the disclosure and the Open Payment listing.
- 9.5 Depending on the outcome of this process, disclosures may be listed on the physician profile page through the Kyruus webpage.

10. Record Retention

- 10.1 Records regarding Conflict of Interest, including those required by the PHS regulations, shall be maintained for a period of at least three (3) years from the date when the final expenditure report, final annual report, or disclosure occurred, whichever is later as required by the 42 CFR §50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period.

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The records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

11. Sanctions

11.1 Failure to comply with this Policy will be grounds for disciplinary action pursuant to the relevant Prisma Health Policy.

In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of Prisma Health policy. Prisma Health may require mandatory education, monitoring of research, suspension of research privileges, suspension or termination of research or enacting other sanctions as appropriate. In addition, sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and manage Significant Financial Interest related to federally sponsored projects.

12. Administration of Conflict of Interest Policy

12.1 The OCI will administer this Conflict of Interest Policy, including the administration and monitoring the Annual Individual Conflict of Interest Statements.

References:

N/A

Appendices:

Conflict of Interest Annual Disclosure – Appendix A: Definitions (S-015-03.A1)

Conflict of Interest Annual Disclosure – Appendix B: Specific Activity (S-015-03.B1)