This policy only applies to research that is not funded by Public Health Service (PHS). If the research is PHS funded, see the ABHS policy, Financial Conflict of Interest for PHS Funded Research.

1 PURPOSE
1.1 The purpose of this policy is to establish standards for the management, reduction or elimination of disclosed financial conflicts of interest in research activities conducted within AMITA Health. In order to ensure the design, conduct or reporting of research will not be biased by any conflicting interest of the investigator(s) or any other member of the research team responsible for the research, researchers submitting protocols involving human subjects must disclose all financial interests that could be perceived as a potential conflict-of-interest to the IRB at the time of review of the study.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 A potential conflict of interest exists in any situation in which a financial interest related to a research study or other considerations may compromise or have the appearance of compromising a member of the research team's professional judgment in designing, conducting or reporting research. AMITA Health researchers are expected to perform their duties without having their loyalty divided or compromised.

4 RESPONSIBILITIES
4.1 Investigators, IRB Members, & Staff

5 PROCEDURE
5.1 The principal investigator (PI) will certify to the following at the time of initial and each continuing review period on behalf of himself/herself as well as all research team members who may be in a position to influence the design, conduct or reporting of the research ("covered individuals"):

We have read and understand AMITA Health’s Financial Conflicts-of-Interest policy for Non-PHS Funded Research; have made all financial disclosures required by it, if any; and will comply with any conditions or restrictions imposed by the IRB or AMITA Health to manage, reduce or eliminate actual or potential conflicts of interest.

5.2 The PI will also complete an AMITA Health IRB “Disclosure of Financial Interest Form for Non-PHS Funded Research” on behalf of himself/herself and all covered individuals of the research team. If there is a conflict or potential conflict, the PI will identify the conflicted member of the research team and attach any supporting documentation that further defines and/or explains the conflict or potential conflict.

5.3 If the PI or another covered individual of the research team acquires an equity or intellectual property interest or receives compensation that must be disclosed under the terms of this policy during the IRB approval period, the disclosure should be made as soon as is practicable and not wait until the time of next review.

5.4 IRB administrative staff will review all Disclosure forms to determine if a conflict or potential conflict has been disclosed. The IRB will review all disclosures to evaluate the extent of the potential conflict and determine whether the covered individual will be able to continue with the...
study or recommend other appropriate measures for reducing or managing the conflict. The IRB may also determine that the probability of the financial interest affecting the design, conduct or reporting of the research is too remote to warrant any specific conditions or restrictions or it may determine that monitoring procedures to be performed by external organizations are adequate to protect human subjects and the integrity and objectivity of the research.

5.5 The IRB will be authorized to request other information that it deems necessary to assist in its determination.

5.6 If the covered individual with the conflict is also a voting member of the IRB, he or she will physically leave the room during the discussion.

5.7 The covered individual, and the PI if he or she is not the covered individual, will be notified of the outcome of the review and restrictions or conditions imposed, if any.

5.8 Every effort will be made to maintain the privacy of the information gathered in the IRB’s deliberations, within the limits imposed by applicable laws and regulations. Supporting documentation for disclosed conflicts or potential conflicts will not be maintained as part of the IRB study file. Such documentation will be maintained in a separate file until such time as the IRB study file is no longer required to be maintained. [See related AMITA Health SOP: IRB Recordkeeping” (PP-207)]

6 MATERIALS
6.1 Initial (HRPP-211) and Continuing Review (HRPP-212) Application forms
6.2 HUD Initial (HRPP-218) and Continuing Review (HRPP-219) Application forms
6.3 Disclosure of Financial Interest Form for Non-PHS Funded Research

7 OTHER RELATED POLICY/PROCEDURES
7.1 IRB Recordkeeping (PP-207)
7.2 ABHS policy, Financial Conflict of Interest for PHS Funded Research

8 REFERENCES
8.1 PHS 42 CFR Part 50 Subpart F
8.2 45 CFR Part 94