1. PURPOSE
   1. This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest Related to the Research.
   2. The process begins when the COI Office determines that an investigator or research staff has reported a financial interest Related to the Research or the IRB staff have detected an institutional financial interest Related to the Research.
   3. The process ends when the COI Office has evaluated the reported interest and communicated the results of this evaluation to the IRB.
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. The Assistant Vice President for Enterprise Risk and Policy Oversight serves as the COI Officer.
   2. For any or all steps of this procedure, the COI Officer may have a committee follow the procedure whenever the COI Officer believes that institutional consensus is needed to make a decision.
   3. This organization adopts the presumption that, in the absence of a compelling rebuttal, an investigator with a conflict of interest may not conduct human research. However, an investigator will have the opportunity to present compelling reasons and circumstances to justify an exception. Compelling circumstances may include, but are not limited to:
      1. The nature of the research;
      2. The magnitude of the interest or the degree to which it is related to the research;
      3. The extent to which the interest could affect the research;
      4. The fact that the specific individual is unique in her/his clinical or scientific qualifications to conduct the research; and/or
      5. The degree of risk to the human participants involved that is inherent in the research protocol.
   4. IRB and Organizational Official approval will not be granted where an investigator or study staff’s conflict of interests are neither eliminated nor managed.
4. RESPONSIBILITIES
   1. The COI Officer carries out these procedures or ensures that a committee follows these procedures.
5. PROCEDURE
   1. The process to obtain financial disclosures from investigators and investigator staff requires at minimum an annual disclosure. This is done through the E-Disclose electronic system.
   2. Review the reported financial interest and the research protocol.
      1. If the financial interest and research protocol have already been reviewed, and if needed, managed, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
   3. Ensure committee members do not participate in the review of any conflict of interests in which the member has Conflicting Interest
   4. Determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting of the Human Research*.*
      1. If there is no conflict of interests, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
   5. If a conflict of interests exists, require elimination of the conflict unless the investigator has presented compelling reasons and circumstances to justify an exception.
   6. Determine under what circumstances, if any, a conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) should be allowed to participate in:
      1. Subject recruitment?
      2. Prescreening for inclusion/exclusion criteria?
      3. The consent process?
      4. The treatment of subjects, separate from the research interventions or procedures?
      5. Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting?
   7. Create a written management plan, considering the following options:
      1. Public disclosure of the financial interests.
      2. Monitoring of research by independent reviewers.
      3. Modification of the research plan.
      4. Disqualification from participation in all or a portion of the Human Research*.*
      5. Divestiture of financial interests.
      6. Severance of relationships that create the conflict of interests.
      7. Involvement of external individuals in key portions of the protocol
      8. Use of an external IRB.
   8. If the conflict of interests appears to be difficult to manage, or not manageable, make recommendations to the Conflict of Interest Advisory Committee or the VA Maryland Health Care System (VA) according to University policies.
   9. Provide the written management plan to the involved individual and office for comment and review.
   10. Finalize the written management plan.
   11. Provide the IRB staff of the reviewing IRB with the written management plan.
   12. When required, provide the final determination to the funding or regulatory agencies.
   13. Maintain records related to disclosures and management of financial conflicts of interest for at least three years from completion of the research.
6. MATERIALS
   1. None
7. REFERENCES
   1. None