1. **PURPOSE**
   1. This procedure establishes the IRB process to review Investigator financial Conflict of Interest (COI) or institutional financial interest related to the research. The IRB is charged with reviewing the executed management plan to ensure that the rights and welfare of participants are protected and that research objectivity is maintained.
   2. The process begins when Carilion Clinic’s COI Office determines that an Investigator or research staff has reported a financial interest Related to the Research or an institution financial interest Related to the Research has been identified.
   3. The process ends when the IRB makes the final decision as to whether the financial interest and its management, if any sufficiently protects the rights and welfare of participants and allows the research to be approved.
2. **POLICY**
   1. Carilion Clinic’s Policy on Conflict of Interest and Conflict of Commitment establishes the University’s compliance framework to promote objectivity in research.
   2. The Carilion Clinic’s Conflict of Interest Committee has been established by the organization to consider matters in accordance with the organization’s Conflict of Interest policies.
   3. If a conflict exists, a management plan must be provided to the IRB.
   4. The IRB will consider the COI Management Plan during review to determine whether the investigator’s relationship to the research creates a bias that might affect the rights and welfare of the human subject or the reliability of the data.
3. **RESPONSIBILITIES**
   1. The COI Office, IRB Office staff and IRB Members will carry out these procedures:
4. **PROCEDURE**
   1. The COI Office will conduct a review of all new projects, continuing reviews, and modifications where there is a change of Principal Investigator.
   2. The COI Office will provide the IRB Office with the written management plan so that the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.
   3. The IRB will review any identified conflict of interest and the management plan and determine whether the plan appropriately maintains objectivity, disclosure, and measures to protect the rights and welfare of participants. The IRB analysis of the COI may place additional restrictions on the conflicted individuals or the research in its entirety, up to and including disapproving participation of a conflicted individual or disapproving the research. IRBs have final authority to determine whether any disclosed interest and its management allows the research to be approved
   4. If a management plan involves more than a simple disclosure, the HRPO Director will consider whether it should be returned to the convened IRB for review.
   5. The meeting minutes should document whether a conflict of interest exists, any management plans, and the convened IRB determination of the plan.
   6. For Non-Committee Review, the Designated Reviewer will document when a conflict of interest exists, any management plans, and their determination in the designated review within the IRB system.
5. **MATERIALS**
6. **REFERENCES**
   1. 42 CFR §50
   2. CFR §94
7. **PREVIOUS VERSIONS**
   1. None