



# Stratton VA Medical Center IRB Standard Operating Procedure: Conflict of Interest

## **POLICY**

It is Stratton VA Medical Center's policy to comply with all applicable federal, state, and local regulations, and guidelines in the conduct of human subject research studies. Nationally, conflicts of interest have increased as the relationships of investigators with private corporations, pharmaceutical companies, and outside institutions have become more complex. Written procedures are required for addressing conflicts of interest in research.

## **PROCEDURE**

### **Initial Submission of Research Protocols**

All initial human subject research proposals submitted to the Stratton VA must contain a Stratton VA Medical Center "Conflict of Interest Disclosure Form" for each member of the research team.

The form must be completed fully. If the form(s) is missing or information is incomplete, the IRB staff will contact the Principal Investigator to submit the form(s) or the missing information. Final approval for the research will not be issued until the document is completely reviewed and approved by all appropriate signatory officials.

### **Conflict of Interest Administrator Role and Responsibilities**

The Conflict of Interest Administrator has the lead role in reviewing potential conflicts of interest. At Stratton VAMC, the role of the Conflict of Interest Administrator (COIA) is filled by the Associate Chief of Staff for Research (ACOS/R); when the ACOS/R is the Principal Investigator on a study, the Chairperson of the Research and Development Committee (R&DC) assumes the role of COIA.

The COIA conducts a preliminary review of the disclosure statement(s) in the "Conflict of Interest Disclosure Form" from each member of the research team and determines whether there is an actual or potential conflict of interest that could impact an investigator's proposed or current research.

If satisfied, the COIA approves the disclosure statement(s). The COIA contacts the research team member if there are questions concerning the information in the disclosure.

Identified conflicts of interest may affect the design, conduct, or reporting of the research. The determination of the effect of potential COI should evaluate whether identified conflicts influence the following:

- risks to subjects
- anticipated benefits, if any, to subjects
- the scientific or scholarly integrity of the research

- the selection of subjects
- the possibility of coercion or undue influence during the consent process
- the information provided to the participant

Once a conflict of interest is determined to be of concern to the COIA, s/he must:

- Determine, with the assistance of VA regional counsel as needed, what conditions or restrictions, if any, should be imposed to manage, reduce, or eliminate the conflict.
- Report findings and identify steps to manage the conflict of interest to the appropriate institutional official, the IRB, the R&D Committee, and the researcher/s
- When necessary, as determined by the COIA and/or the IRB, establish, with the assistance of VA regional counsel, a process to allow the research team member to appeal a decision restricting the conduct of research and requiring specific steps to manage, reduce, or eliminate the conflict of interest.
- Establish criteria for evaluating a research team member's appeal.
  - Criteria may include the nature of the research, the unique experience or qualifications required to conduct the research, the number of other investigators that may possess these qualifications, the nature and magnitude of the conflict of interest, as well as any substantial effect of the research on the conflict of interest such as increasing financial gains for the investigator.
- The COIA will maintain records of all disclosures and all actions taken by the medical center with respect to each conflicting interest for the period that the protocol records are maintained.

### **Role of the IRB**

The IRB is responsible for identifying, reviewing, and requiring appropriate changes in protocols affected by COI for research involving human subjects.

The IRB may determine that, based on the actions and recommendations of the COIA and the research team member's COI Disclosure statement, that the research protocol should not be conducted at the institution.

The IRB should be aware of the funding arrangements and determine if the protocol addresses any COI and the management of the COI.

At the time of initial or continuing review of research, the IRB will consider the impact of the COI on the subject, the risk to the subject, the subject's willingness to participate in the research after disclosure of the conflict, and the impact on the research and the research results.

The IRB will determine if actions in addition to those required by the COIA should be taken to manage, reduce, or eliminate the COI.

### **Disclosure to Subjects**

The IRB may determine that the Principal Investigator must disclose to the research subject financial arrangements with the research sponsor.

The disclosure to the subjects may be in discussion in the consent regarding the source of funding, the payment arrangements for the Principal investigator, and if there is a COI, the nature of the COI, how the COI is being managed, and the additional protections that have been put in place.

- The additional protections may include special measures to modify the consent process,
- having a non-biased third party obtain the consent, and recruit subjects,

- or having the investigator recuse him or herself from decision making that may influence the outcome or reporting of the research results.

### **Research & Development Committee (R&DC) Role**

The Research & Development (R&D) Committee is responsible for reviewing the actions taken by the IRB, and may approve the IRB's actions and add other stipulations or changes to the proposal, but may not disallow any of the IRB's stipulations or required changes regarding the COI.

### **Conflicts of Interest of IRB or R&DC Members**

IRB and R&DC members must recuse themselves from review of protocols for which the conflict exists. The IRB or R&DC conflicts of interest are to be self-reported at the start of each respective committee meeting upon solicitation of the matter by the chairperson of the committee. IRB members with a conflict of interest in the research are expected to declare the reasons for the conflict to the IRB prior to the review of research. At that time, the COIA will consider whether the self-disclosed COI is in fact a conflict.

Committee members with a confirmed COI may not participate in the review of any research in which the member has a conflict of interest, except to provide information requested by the IRB.

The research will not be voted upon should quorum be lost due to the absence of the member(s) with a conflict of interest.

### **Managing COI Findings**

When conflicts of interest are confirmed, the findings of the COI Administrator, IRB, and R&D are reported to the research team member and the Medical Center Director. Also, any recommended actions, consequences or stipulations are also reported.

The Medical Center Director may add to the actions, consequences and/or stipulations but may not lessen them.

### **Appeals of COI Findings**

In situations where the COI cannot be resolved, the Medical Center Director will make the final binding decision regarding the COI.

Any member of the research team may appeal the recommendations of the COIA, IRB and/or R&D Committees in accordance with VA and medical center policies and procedures.

### **Actions, Consequences and/or Stipulations**

The research team member must comply with the final decision of the Medical Center Director and/or COIA in managing the COI.

The medical center Director or COIA may take the following actions to manage, reduce, or eliminate COI:

- Public disclosure of significant financial interests;
- Monitoring of research by independent reviewers or consultants;
- Modification of the research plan and/or the informed consent documents;
- Disqualification from participation in all or a portion of the research;
- Divestiture of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.

### **Post Protocol-Approval Determinations of COI**

If a COI is identified after a research protocol has been approved or initiated, the COIA, along with the IRB and R&D, will identify the impact of the conflict on the protocol and the research subjects, if applicable, and corrective actions to be taken to decrease the impact. Corrective actions may include:

- modifying the protocol and consent form;
- re-consenting subjects or
- removing the research team member from a role in subject selection;
- Supervision of the protocol by independent reviewers or consultant;
- and/or requiring that the COI must be disclosed in all publications or presentation resulting from the research.

### **Modification of Informed Consent Forms**

When a significant COI exists and cannot be eliminated, the consent form must contain a discussion of the financial arrangement, and how the conflict of interest is being managed and the additional protections that have been put in place. The inability to resolve a significant COI will be reported to the Medical Center Director through the appropriate committees.

### **Failure to Comply with COIA, Director or Committee Determinations**

If a research team member fails to comply with the COI policy or with corrective actions, the COIA will report the failure to comply to the Medical Center Director and this failure may result in the following conditions or restrictions:

- Termination of the research protocol;
- Removal of the investigator from the research team; or
- Revocation of the privilege to conduct research within the VA.

The research team member may also face negative consequences from the Public Health Service, Food and Drug Administration, or other applicable entities depending on the seriousness of the non-compliance and the determination of the research sponsor.