

## **21 Conflict of Interest in Research**

It is University of Virginia policy to preserve public trust in the integrity and quality of research by reducing actual or perceived conflict of interest in the conduct of research.

Conflicts of interest ('COI') in research can be broadly described as any interest that competes with an organization's or individual's obligation to protect the rights and welfare of research subjects, the integrity of a research study, or the credibility of the research program. Conflicts of interest can be financial or non-financial.

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

### **21.1 Researcher Conflicts of Interest**

Pursuant to the Conflict of Interest policy "[RES 005: *Financial Conflicts of Interest for Research Investigators*]", University of Virginia maintains a Conflict of Interest Committee ("COI Committee"). University of Virginia IRB will collaborate with the COI Committee to ensure that COI of researchers and research staff ('researchers') are identified and managed before the IRB completes its review of any research application.

#### **21.1.1 Procedures**

##### **21.1.1.1 Disclosure of Researcher COI**

For IRB purposes, researcher conflict review occurs at the time of new study submission, continuing review, with the addition of a new researcher, and whenever a researcher updates their University of Virginia COI disclosure indicating a new or changed interest. IRB staff notify the COI Chair whenever a submission requiring conflict review is received. The COI Chair reviews the researchers' disclosures and either notifies the IRB staff that no researcher COI was identified or that one or more researchers has an interest that requires evaluation by the COI Committee. In the event a conflict that requires disclosure or management is identified, the COI Chair will provide to the IRB in writing with a summary of conflict and the conflict management plan ('CMP') approved by the COI Committee. If the COI Committee has not completed its review, the IRB will defer the research study review or prohibit participation by the researcher with a potential COI until the COI Committee review process is completed and the results are made available to the IRB.

##### **21.1.1.2 Evaluation of COI**

The IRB will review COI and CMP to determine:

- Whether the COI affects the rights or welfare of research subjects,

- Whether the COI might adversely affect the integrity or credibility of the research or the research program, and
- Whether the CMP effectively protects research subjects and the integrity and credibility of the research and the research program

The IRB will consider:

- How the research is supported or financed,
- The nature and extent of the conflict,
- The role and responsibilities of the conflicted individual in the design, conduct, and reporting of the research, and
- The ability of the conflicted individual to influence the outcome of the research

### **21.1.1.3 Management of COI**

The IRB has final authority to determine whether the research, the COI, and the CMP, if any, allow the research to be approved. With regard to the CMP issued by the COI Committee, the IRB shall either affirm or request changes to strengthen it. The IRB can require additional measures to manage a COI so that the research may be approved. However, the IRB cannot weaken a CMP approved by the COI Committee.

For example, in addition to the CMP, the IRB may require:

1. Disclosure of the COI to subjects through the consent process
2. Modification of the research plan or safety monitoring plan
3. Monitoring of research by a third party
4. Disqualification of the conflicted party from participation in all or a portion of the research
5. Appointment of a non-conflicted PI
6. Divestiture of significant financial interests
7. Severance of relationships that create actual or potential conflicts.

In the event the conflict cannot be effectively managed, the IRB may disapprove the research.

## **21.2 IRB Member Conflict of Interest**

No IRB member or alternate (note: “IRB member” in this section includes IRB staff and consultants) may participate in the review of any research project in which the member has a conflict of interest (COI), except to provide information as requested. It is the responsibility of each IRB member to disclose any COI related to a study submitted for review and recuse him/herself from the deliberations and vote by leaving the room.

All members and alternate members of the IRB complete an “IRB Member Conflict of Interest Statement” when first appointed and annually thereafter.

IRB members, alternates, or consultants may be considered to have a conflicting interest requiring recusal when they, or an immediate member of their family, have any of the following:

1. Involvement in the design, conduct, and reporting of the research,
2. Significant financial interests (See *[IRB Member Conflict of Interest Statement]* for a definition of significant financial interests) related to the research being reviewed,
3. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a study.

The IRB Chair will ask IRB members at the beginning of each convened meeting if any members have a COI regarding any of the items to be reviewed and reminds members that they must recuse themselves by leaving the room during the discussion and vote of the specific research study. If a conflicted member is participating by conference call, videoconference or web meeting, the member's participation (connection) is terminated for discussion and voting.

IRB members with a conflicting interest are excluded from being counted towards quorum. Recusals of members with COIs are recorded in the minutes.

### **21.3 Institutional Conflict of Interest**

The Institutional Conflict of Interest ("ICOI") policy ("University of Virginia Institutional Conflict of Interest Policy") outlines University-wide requirements regarding ICOI. It covers the entire University and applies to both the interests of the Institution itself and the interests of senior university officials. It is a comprehensive policy covering all institutional activities including, but not limited to, research, education, patient care, and professional and business practices. Pursuant to the ICOI policy, the President will appoint an ICOI official who will have responsibility for the implementation of this policy. The University will maintain an Institutional COI Committee, which may be the same as the Research COI Committee. The ICOI official will oversee the monitoring of the financial interests of the Institution and senior university officials and will work with the ICOI Committee to evaluate and manage ICOI.

### **21.4 Recruitment Incentives**

Payment arrangements among sponsors, organizations, investigators, and those referring research participants present a conflict of interest and may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective participants ("finder's fees") is not permitted. Similarly payments designed to accelerate recruitment that is tied to the rate or timing of enrollment ("bonus payments") are also not permitted.