INVESTIGATOR CONFLICT OF INTEREST

1. POLICY

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to ensuring the disclosure of potential conflicts of interest, to evaluate the potential impact on the research and research participants, and to manage the conflicts so they do not negatively impact the research or research participants.

This policy establishes written procedures that ensure the identification, management, and minimization of conflicts of interest in research activities conducted by VA investigators (including full-time, part-time and WOC), including but not limited to the investigator(s), Institutional Review Board (IRB) members, Subcommittee on Research Safety (SRS) members, and Research & Development (R&D) Committee members.

2. RESPONSIBILITIES

BVAMC Medical Center Director is the institutional official responsible for the R&D Program, and as such, oversees the facility in issues related to conflict of interest in research and administers the facility’s program related to financial conflict of interest.

Associate Chief of Staff, Research & Development (ACOS/R&D) is responsible for:
- Developing and implementing policies and procedures for identifying, reviewing, eliminating and/or managing conflicts of interest in research.
- Ensuring all potentially significant financial or non-financial conflicts of interest have been either eliminated or minimized to uphold federal and institutional compliance and ethical standards of research at the BVAMC.
- Making final decisions in collaboration with the Director and Chief of Staff (COS) regarding investigator appeals of R&D Committee decisions for identifying and managing conflicts of interest.

Financial Conflict of Interest (FCOI) Committee - a subcommittee of the R&D Committee is responsible for:
- Reviewing Financial Conflict of Interest forms (OGE Form 450 Alternative-VA November 2013)
  1) submitted with initial applications for any research investigators involved in each study,
  2) submitted annually,
3) submitted at any time when an investigator has a change in relevant information that requires them to change an answer on Section I of the form to "yes" or that changes the reason for a "yes" answer, or
4) when an investigator is added to a study protocol.

- When applicable, the FCOI Committee approves plans to manage any identified conflicts of interest. The FCOI Committee may not disapprove research but it has the authority and responsibility to make recommendations to the R&D Committee and any applicable R&D Subcommittee if it determines that reported conflicts of interests cannot be managed sufficiently to best protect the interest of the research participants.

- Ensuring all potentially significant financial conflicts of interest have been either eliminated or minimized to uphold federal and institutional compliance and ethical standards of research at the BVAMC.

- Maintaining written records of its reviews, recommendations and determinations.

**Research Personnel**, including the Principal Investigator, Sub- or Co-investigator(s) involved in the study, are responsible for:

- Disclosing accurately, honestly, and completely all conflicts of interest, financial or non-financial, that they may have with a research project. If a conflict of interest, financial or non-financial, develops or exists at any other time during the conduct of an active research project, it must be reported to the FCOI Committee.

- Adhering to and implementing decisions made by the R&D Committee or the FCOI Committee, regarding minimizing, managing, monitoring, auditing and/or eliminating conflicts of interest financial or non-financial with the research project.

- Maintaining the protection of human research participants’ and the BVAMC’s best interests in conducting studies in which the investigator may have a conflict of interest.

- Disclosing, when appropriate, on the informed consent form that the investigator has a conflict of interest in the research project that may potentially affect the design of, decisions made, and/or actions taken surrounding the study.

- Submitting annual conflict of interest updates as required by the Research & Development Department. (Please see instructions on page 3 for the appropriate month to submit your annual update.)

**Institutional Review Board (IRB)** is responsible for ensuring that risks are minimized and the rights and welfare of research participants are protected through appropriate disclosure and effective management of conflicts of interest. The FCOI Committee will report to the IRB all conflicts reported by investigators conducting human research along with a management plan for the study. The IRB has the final authority to decide (for studies involving human subjects) whether the conflict of interest and its management, if any, allow the research to be approved.

**Research and Development Committee (R&DC)** is responsible for the oversight of all research conducted at the Birmingham VA Medical Center. The Financial Conflict of Interest (FCOI) Committee reports to the R&DC all conflicts reported on the VA FCOI form. The R&DC is responsible for the review of submitted conflict of interest management plans from investigators or any other staff in research.
Institutional Officials, including but not limited to the Director, COS, and ACOS/R&D, AO, R&D do not serve as voting members of the IRB.

3. DEFINITIONS

Non-financial Conflict of Interest: A non-financial conflict of interest may exist for IRB and R&D Committee members or investigators for interests that may affect an investigator’s judgment or IRB/R&D Committee member’s vote, such if their career advancement is based on the outcome (i.e., positive or negative results) of the study. Other non-financial conflicts of the IRB or R&D Committee members is involvement in the design, conduct or reporting of the research, or their immediate families in the design conduct or reporting of the research. Non-financial conflict of interests must also be disclosed either at the meeting or on the conflict of interest form.

Financial Conflict of Interest: Potential for a financial conflict of interest may exist when one or more of the following are present:

- Compensation to the investigator or institute that is affected by the outcome of clinical studies. For example, compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

- Significant equity interest in the sponsor of a covered study, such as ownership interest, stock options, or other financial interest whose value exceeds $10,000 during the time the clinical investigator or institute is carrying out the study and for 1 year following completion of the study.

- Proprietary interest by the investigator or institute in the tested product means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright, or licensing agreement.

- Significant payments of other sorts made by the sponsor of a covered study to the investigator or the institution to support activities of the investigator that have a monetary value of more than $10,000, exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for 1 year following the completion of the study.

Also refer to HRPP #24 – HRPP Definitions

4. PROCEDURES
Requirements for Financial Conflict of Interest Form:
In order for the BVAMC HRPP to identify and manage any potential conflicts of interest, ensuring the protection of human research participants is the primary interest of those
engaged in the conduction and reviewing of research, the BVAMC HRPP requires all investigators submit a financial disclosure and conflict of interest disclosure form through the FCOI subcommittee to the appropriate R&D subcommittee at initial submission. Thereafter, the BVAMC HRPP requires all investigators submit a financial disclosure and conflict of interest disclosure form through the FCOI subcommittee to the appropriate R&D subcommittee annually or at any time significant changes emerge during the year. These forms must be submitted by the investigator regardless of the research funding source.

All FCOI forms will be stored electronically on the Research Share Drive in a file named FCOI Forms. Each investigator will have their own sub-file and all of their forms will be sorted by study and year. The RCO will maintain all the documents in this file.

In addition to financial conflicts of interest, a conflict of interest would exist if an IRB member, staff or R&D Committee member were an investigator or co-investigator, research assistant, or spouse of an investigator.

A. Instructions for submitting the FCOI Form for review:

1. Initial Review - Prior to the initial review of a study protocol, the Principal Investigator will submit an electronic copy of the FCOI Form by email to the Research Compliance Officer (RCO) for all investigators listed on the study personnel list.

2. Annual Review – All VA investigators are responsible for providing the FCOI Committee an updated copy of their FCOI Form annually even if there are no changes to the document.

   i. The FCOI Form with a current signature and date should be sent to the RCO by email.

   ii. The RCO will collect the FCOI Form from all investigators on an annual basis. Investigators (or their study staff on behalf of the investigator) should submit the FCOI Form to the RCO once a year according to the first letter of the investigator’s last name. See the table below.

<table>
<thead>
<tr>
<th>Investigators whose last name begins with the letter:</th>
<th>Report by the 15th of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A – F</td>
<td>January</td>
</tr>
<tr>
<td>G – L</td>
<td>April</td>
</tr>
<tr>
<td>M – R</td>
<td>July</td>
</tr>
<tr>
<td>S – Z</td>
<td>October</td>
</tr>
</tbody>
</table>

iii. If an investigator has multiple studies open it MAY NOT be necessary to send a separate FCOI Form for each study annually for review.
* If the investigator is listed on multiple studies and he or she has no conflict to declare with any open study, list each study number separated by commas in the “Name of Study” section on page 2 of 7 on the FCOI Form.

* If the investigator is listed on multiple studies and he or she has a conflict to declare with some but not all of the studies, submit a separate FCOI Form for each study that there is a conflict. Then, for all studies that there is no conflict to declare, follow the instructions above.

3. **Adding Study Personnel** - If a new investigator is being added to a study, email the RCO with a copy of the investigator’s FCOI Form prior to submitting the request to add personnel to the appropriate subcommittee.

4. **Change in Information** – When there is a change in relevant information that requires you to change an answer on Section I of the FCOI Form to “yes” or that changes the reason for a “yes” answer email the RCO with a copy of the updated form immediately.

**B. Review of Financial Conflict of Interest Form:**

The RCO will conduct an initial review of all FCOI Forms submitted. If there are no conflicts of interest declared, the RCO will sign the FCOI Form and maintain an electronic copy of the document.

If an investigator has declared a conflict of interest, the FCOI Committee will hold a convened meeting to review and discuss the declared conflict. All members of the FCOI Committee must be present before a decision regarding the declared conflict of interest can be made. If the FCOI Committee determines the declaration is a true conflict of interest, a management plan will be established if possible and communicated to the investigator by email. Recommendations are based on the FCOI Committee’s examination of 1) the investigators’ financial conflict of interest forms and 2) source of funding for the study. The FCOI Committee will forward their review and proposed management plan to the appropriate R&D subcommittee.

The appropriate R&D subcommittee will review recommendations from the FCOI Committee regarding any investigator’s financial conflict of interest. The IRB, SRS, R&D and/or the FCOI subcommittee may request additional information (i.e. budget, contract) if needed to determine whether the financial interests of parties involved in research could affect the rights and welfare of subjects. For a human research study, the IRB may also request additional information if needed to determine whether an investigator’s financial interests could affect the rights and welfare of subjects.

If the IRB/R&DC/ACOS, R&D cannot determine if a FCOI does exist, legal regional counsel may be contacted for assistance. In the event of a financial conflict of interest, the appropriate R&D subcommittee, in consultation with the FCOI subcommittee and R&D Committee, can specify allowable remedies, but the IRB has the final authority to decide whether or not the research can be approved if a conflict exists with a human research study.
C. **Allowable Remedies for Investigator Conflict of Interest:**

The IRB, SRS, R&D and/or the FCOI subcommittee may place restrictions on the investigator or study, if necessary, or outline allowable remedies. Any restrictions or allowable remedies will be conveyed to the investigator in writing via email. Conflict of interests may be managed by eliminating them or mitigating their potential negative impact. Allowable remedies for an investigator or IRB/R&D Committee member who has a conflict of interest may include, but are not restricted to:

- Reduction of the financial or nonfinancial interest
- Disclosure of the financial or nonfinancial interest to prospective subjects
- Separation of responsibilities for financial decisions and research decisions
- Addition of further oversight or monitoring of the research
- Establishment of independent data and safety monitoring board
- Modification of role(s) of particular research staff (i.e. change the person who seeks consent to a non-biased party or change of investigator)
- Elimination of the financial or non-financial interest

5. **REFERENCES**

VHA Handbook 1200.05

6. **ATTACHMENTS**

Financial Conflict of Interest Form - OGE Form 450 Alternative-VA November 2013

7. **RESCISIONS**


8. **REVIEW DATE**

January 1, 2019

[Signature]

Louis Dell'Italia, MD
ACOS, Research and Development