INSTITUTIONAL CONFLICT OF INTEREST

1. PURPOSE

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to ensuring that the welfare of human subjects and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations. Although the Department of Veterans Affairs (VA) has separated technology transfer functions (see VHA Handbook 1200.18 Intellectual Property) from research administration, circumstances may exist in which separation of function is not sufficient to avoid the appearance of institutional conflict of interest.

This policy describes the relationships that may produce a real or perceived institutional conflict of interest (COI) for the research being conducted at the BVAMC.

This policy establishes written procedures that ensure the identification, management, and minimization of institutional COI in human subject research.

2. RESPONSIBILITIES

BVAMC Medical Center Director is the institutional official responsible for the Research & Development Program, and as such, oversees the facility in issues related to institutional 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 institutional COI in research.
- Ensuring all potentially significant financial or non-financial institutional COI have been either eliminated or minimized to uphold federal and institutional compliance and ethical standards of human research at the BVAMC.
- Making final decisions in collaboration with the Director, Chief of Staff (COS), R&D Committee and the IRB regarding decisions for identifying and managing institutional COI.

The Financial Conflict of Interest Subcommittee (FCOI) a subcommittee of the R&D Committee is responsible for:
- Reviewing Financial Conflict of Interest forms, VA form (OGE Form 450 Alternative-VA November 2013), submitted with Initial IRB applications for investigators involved in each study and then annually for each investigator or at the time there is a change in the investigator’s conflict of interest.
- Ensuring all potentially significant financial conflicts of interest have been either eliminated
owned invention and may be entered into in cooperation with a license agreement. CRADAs are negotiated by the VA medical center and regional counsel attorneys. Following review and approval by the Office of General Counsel (OGC), they are returned to the medical center for execution.

Royalties
Royalty income to a VA facility is accepted, monitored, and distributed by the TTP. Centralized handling of royalty income allows compilation of data for evaluating and reporting on the TTP’s effectiveness, and ensures compliance with applicable laws; e.g., the current Federal royalty income cap of $150,000 per year per employee. Note: Royalties paid to employees from non-Federal sources such as universities are not subject to this ceiling.

Review
The R&D Committee (and IRB if human subjects are involved) will review protocols to assure that any conflict of interest associated with the research is identified and managed. If a VA researcher has an intellectual property interest, the above arrangements must be in place. The R&D Committee also has a responsibility to review the potential for institutional conflict of interest, including intellectual property agreements, and to evaluate whether the potential conflict is managed adequately for the protection of human participants. After reviewing a significant financial interest in research, the R&D Committee is responsible for communicating its conclusions, along with any management arrangements to be imposed, to the IRB. All relevant conflicts will be disclosed to research participants in a form to be determined by the IRB. The R&D Committee also will communicate conclusions and COI management strategies to the Institutional Official and the Principal Investigator.

b. Management of Conflict of Interest

Assumption of conflict of interest
If the VA facility retains a significant financial interest, or if an institutional official with direct responsibility for the HRPP (including the IRB members) holds a significant financial interest in the invention, then the R&D Committee must assess the potential conflict of interest and weigh the magnitude of any risk to human participants. When reviewing potential institutional conflict of interest, the R&D Committee will assume an inclination against the conduct of human participants research at, or under the auspices, of the institution where a COI appear to exist. However, the assumption may be overturned by the Committee when the circumstances are compelling and the R&D Committee has approved an effective conflict management plan.

Decision making
A key aspect in decision-making is to analyze when it would be appropriate and in the public interest to accept and manage a COI, rather than require that the COI be eliminated. In some cases, the benefits of conducting a proposed research activity at the institution will be potentially high, and the risks will be low. In other cases, the scientific advantages of conducting the research may be speculative and the risks may be great, in these latter instances, the conflict should be avoided by disapproving the research application.

Evaluation of risk
Each case should be evaluated based upon the following:

1. the nature of the science;
2. the nature of the interest;
3. how closely the interest is related to the research;
4. the degree of risk that the research poses to human participants; and
5. the degree to which the interest may be affect by the research.

The R&D Committee will consider whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved, this decision will be reported to the IRB.

Potential actions
Potential actions to be considered to better protect subjects are any (or a combination) of the following:

- Disclosure of the financial interest to potential subjects;
- Not conducting proposed research each at that institution, or halting it if it has commenced;
- Reducing or otherwise modifying the financial (equity or royalty) stake involved;
- Increasing the segregation between the decision-making regarding the financial and the research activities;
- Requiring an independent data and safety monitoring committee or similar monitoring body;
- Modifying of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change in investigator; or
- Establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work and of the VA.

5. REFERENCES

- VHA Handbook 1200.05 Requirements for the Protection of Humans in Research

6. ATTACHMENTS

- Financial Disclosure and Conflict of Interest Form
- Conflict of Interest form
7. **RESCISSIONS**


8. **REVIEW DATE**

January 1, 2020

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