



**Department of Veterans Affairs  
Jesse Brown VA Medical Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

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## **SOP: R&D Committee Operations**

### **PURPOSE**

The purpose of this SOP is to establish procedures for R&D Committee Operations and oversight of subcommittee functions at Jesse Brown VA Medical Center (JBVAMC). This SOP enables the R&D Committee to prioritize their deliberations around broad areas of program development, risk management, and quality & performance activities. In addition, the R&D Committee is no longer required to review individual protocols.

### **POLICY**

The JBVAMC is committed to conducting all research activities with integrity and with adherence to scientifically sound practices and ethical principles. To stimulate a high-quality research program that is responsive to investigators and that maintains compliance with all applicable regulations.

### **BACKGROUND**

The research mission of the Department of Veterans Affairs (VA) is conducted within individual VA medical centers according to the highest ethical standards with accountability to all involved stakeholders. Responsibility for oversight and maintaining high standards is assigned to the R&D Committee.

### **DEFINITIONS**

a. **VA Data or VA Information.** VA data or VA information is information owned or in the possession of VA or any entity acting for, or on the behalf of, VA.

b. **VA Research.** VA research is research that is conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), and/or on VA property including space leased to, or used by, VA. The research may be funded by VA, by other sponsors, or be unfunded. Research conducted by non-VA investigators that does not utilize VA resources and that occurs on space or

with equipment, leased from VA or covered under a use agreement between VA and a non-VA entity is not considered VA research.

c. **VA Sensitive Information.** VA sensitive information is all VA data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information (VA Handbook 6500). The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under the Freedom of Information Act (FOIA). Examples of VA sensitive information include:

(1) Individually-identifiable medical, benefits, and personnel information;

(2) Financial, budgetary, certain forms of research information (not all research information is sensitive), quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information;

(3) Information that is confidential and privileged in litigation, such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and

(4) Other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of Federal programs.

## **SCOPE**

A. Every VA facility conducting research must have, or establish, an R&D Committee of record

B. R&D Committee is responsible; through the Chief of Staff (COS) to the medical center Director, for:

(1) Advising and assisting the medical center Director in providing oversight, planning, and execution of the local research Program, and

(2) Assisting the medical center Director in maintaining high standards throughout the R&D Program. Those standards include ensuring the:

(a) Scientific and ethical quality of VA research projects,

(b) Protection of human subjects in research,

(c) Safety of personnel engaged in research,

(d) Welfare of laboratory animals,

(e) Security of VA data, and

(f) Security of VHA research laboratories.

3. R&D Committee is assisted by the Associate Chief of Staff (ACOS) for R&D and the Administrative Officer (AO) for R&D in carrying out its duties.

4. R&D Committee has delegated the responsibility for review of the scientific validity of human subject research to the Collaborative JBVAMC/NU/UIC IRB (IRB#4).

5. Research engaged at the Jesse Brown VA Medical Center may not be undertaken without review and written approval of all appropriate subcommittees of the R&D Committee. The investigator must not initiate a research project until after being notified by the ACOS for R&D that the project has been approved by all relevant committees, subcommittees, or other entities and the R&D Committee has approved the final minutes of its relevant subcommittees.

6. R&D Committee may serve as the R&D Committee of record for another VA facility. In doing so, it must fulfill all R&D Committee responsibilities for that VA facility including oversight of its subcommittees. The R&D Committee may not serve as the R&D Committee of a non-VA institution.

## **RESPONSIBILITIES**

### **1. RESPONSIBILITIES OF MEDICAL CENTER DIRECTOR**

The medical center Director, acting in the capacity of the Institutional Official, is responsible for:

a. The Jesse Brown VAMC research program, and is assisted by an R&D Committee. The medical center Director serves as the Institutional Official responsible for all aspects of the research program including but not limited to: human subjects protection, animal welfare care and use, privacy and security of VA data, and bio-safety.

b. Retaining institutional responsibility for the research program at the JBVAMC,

c. Ensuring that research in which the facility is engaged is approved by the appropriate R&D Committee subcommittees.

d. Ensuring there are adequate resources and administrative support, including personnel, space, equipment, and training, for the R&D Committee and its subcommittees to fulfill their responsibilities.

e. Ensuring appropriate education and training for members of the R&D Committee, the research administration staff, and other staff involved in research.

f. Ensuring that investigators meet the requirements of Paragraph 8 in VHA handbook 1200.01.

g. Appointing the members of the R&D Committee following the specifications in Paragraph 13 in VHA handbook 1200.01.

h. Ensuring an annual evaluation of the Human Subjects Protection Program (HSPP). This function is delegated to the R&D Committee.

## **2. RESPONSIBILITIES OF THE ASSOCIATE CHIEF OF STAFF (ACOS) AND ADMINISTRATIVE OFFICER (AO) FOR R&D**

The primary responsibilities of the ACOS and AO for R&D are defined in VHA Directive 1200.

Facilities with large, active research programs will establish a position equivalent to Associate Chief of Staff (ACOS) for R&D such as Research Director, or Clinical R&D Executive or equivalent, through the Chief of Staff (COS) and/or the Chief Medical Officer (CMO) and/or the Chief Clinical Executive (CCE), or equivalent. The medical center Director is responsible for implementing the R&D program, policies, and procedures, including establishing and appointing members to the R&D committee and any appropriate subcommittees.

The AO for R&D is the individual responsible for the administrative functions of the research program. The AO for R&D serves as an assistant to the ACOS for R&D.

## **3. RESPONSIBILITIES OF THE ACOS FOR R&D**

ACOS for R&D is the individual with delegated authority for management of the research program at facilities with large, active programs.

ACOS for R&D is responsible for:

a. Notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees, and after the R&D Committee has been appropriately notified of subcommittee approval.

The ACOS for R&D is also responsible for notifying the investigator of approval after continuing review by the R&D Committee and subcommittees.

b. Functioning as Executive Secretary of the R& D Committee.

c. Conducting an annual quality assurance review of publications assessing the acknowledgement of VA support and affiliation.

d. Ensuring that information pertaining to all requests for WOC appointments for research have been appropriately justified and the appointments are in compliance with all applicable research, Human Resource Management, and other VA policies.

e. Providing an annual quality assurance review of research employees involved in human subject research to ensure the employees are working within their scopes of practice and their privileges allowed by the facility's by-laws and granted to them by the facility.

f. Providing an annual quality assurance review of Cooperative Research and Development Agreements (CRADAs) and other agreements in support of the research program or specific research projects and an assessment of the impact of these agreements on the research program, when applicable.

g. Ensuring that all minutes of the R&D Committee and its subcommittees, including those from subcommittees at VA facilities or at the affiliate, are sent to the medical center Director and COS for review and appropriate action.

#### 4. RESPONSIBILITIES OF THE INVESTIGATOR

The investigator is responsible for:

a. Confirming with the applicable service chief that he/she has been awarded the appropriate credentials and privileges at JBVAMC to conduct research at JBVAMC prior to initiating any research.

b. Complying with all applicable personnel and other VA requirements whether the investigator is compensated, WOC, or IPA.

c. Obtaining the complete approval of all appropriate non-research entities and R&D Committee subcommittees, and written notification from the ACOS for R&D prior to initiating a research project.

d. Developing a research plan that is scientifically valid; minimizes risk to human subjects, animals used in research, and personnel; and contains a sufficient description of the research including all procedures and the plan for statistical analysis, to allow the R&D Committee subcommittees to fully review the research project.

e. Developing and implementing plans for data use, storage, and security that are consistent with VA Directive 6500, Information Security Program, and its implementing Handbooks and other legal requirements.

f. Preparing and submitting information, at least annually or as required, on his/her research program(s) and on each project to the appropriate R&D Committee subcommittee for continuing review as required by the respective R&D Committee subcommittees.

g. Ensuring that all research proposals submitted for funding, from any source, support the mission of VHA and enhance the quality of health care delivery to Veterans.

**NOTE:** *Examples of research that may not support the mission of VHA includes research involving children or prisoners.*

## 5. RESPONSIBILITIES OF THE R&D COMMITTEE

### A. R&D COMMITTEE FUNCTIONS:

a. The R&D Committee assists JBVAMC Director in fulfilling responsibilities for the facility's research program. The R&D Committee is responsible for ensuring the effective operation of the research program through oversight of the R&D Committee's subcommittees and making appropriate recommendations, including *space and resource needs*, to the medical center Director based on the Committee's oversight and evaluation of the research program. All R&D Committee functions and proceedings are confidential and information presented during RDC meetings is considered privileged information.

b. The R&D Committee must accomplish its *responsibilities* through the following activities or procedures:

(1) Planning and developing broad objectives for the research program so that it supports VA's mission.

(2) Determining the extent to which the research program has met its objectives.

(3) Overseeing all research activities for each VA facility for which it serves as the R&D Committee of record.

(4) Reviewing all written agreements that establish:

(a) A committee from another VA or non-VA entity in lieu of a required committee or subcommittee for the R&D Committee; and

(b) R&D Committee or one of its subcommittees, as a committee or subcommittee of another VA facility.

(5) Reviewing and evaluating all R&D subcommittees both within the VA facility and at external entities that function in lieu of R&D subcommittees, such as but not limited to Collaborative JBVAMC/Northwestern University (NU)/University of Illinois at Chicago Institutional Review Board (UIC IRB#4), Institutional Animal Care and Use Committees (IACUC), or Bio-Safety committees. ***A summary of these reviews and evaluations must be sent to the medical center Director annually.***

c. In fulfilling its responsibilities of ensuring the effective oversight of the research program and making appropriate recommendations to the medical center Director, including the *suspension* of a research study or *remedial or restrictive* action regarding a principal investigator, the R&D Committee needs to *rely on* a variety of information sources including:

(1) Quality assurance activities, reports to the committee by the ACOS for R&D, AO for R&D, or other research staff members, subcommittee reports, facility reports or activities, and other appropriate sources.

(2) Review of subcommittee activities is ongoing, and is accomplished through review of the monthly subcommittee meeting minutes. [Budget, space, training needs or goals for next year are reviewed by the R&D Advisory Panel, and are presented by the R&D Program Support Assistant for discussion and recorded in the minutes. Review includes the following:

(a) Annual reviews of the Research Safety and Security Program (including planned training, compliance, security issues, etc.),

(b) The Animal Care and Use Program (including inspection reports, IACUC composition, IACUC arrangements, budgets, space, support staff, training, quality improvement activities, compliance issues, and *goals for the next year*)

(c) The Human Research Protection Program (including IRB composition or IRB arrangements, credentialing and training status report, budget, space, support staff, quality improvement activities, compliance issues, and goals for the next year).

d. The R&D Committee is responsible for the evaluation of resources needed for the HSPP, including but not limited to; space, personnel, the HSPP education program, legal counsel, conflict of interest, the quality improvement plan, community outreach, and the IRB. The evaluation conducted annually consists of the following:

(1) Review of IRB physical location for space assessment and staffing. This review is delegated to the R&D administrative HSPP staff.

(2) Review of HSPP training records including any trainee feedback documentation when said training pertains to VA research.

(3) Engagement of VA Legal Counsel as appropriate.

(4) Review of conflict of interest via review of minutes of the appropriate subcommittees including conflicts identified by members of said committee(s).

(5) Review of the HSPP QA/QI program via surveys, focus groups, interviews or other methods including quarterly telephone audits as outlined in the SOP: Assurance of Compliance and Quality Improvement for the Human Research Protection Program At Jesse Brown VA Medical Center.

e. The R&D Committee is responsible for fulfilling such other functions as may be specified by the medical center Director and VHA procedures. These functions may include review and approval of individual research projects. *NOTE: The R&D Committee may not approve human subjects' research if it has not been approved by an IRB (see Title 38 Code of Federal Regulations section 16.112).*

## **B. R&D COMMITTEE REVIEW OF RESEARCH**

a. R&D Committee is responsible for establishing policy to ensure that all research in which JBVAMC is to be engaged has been reviewed and approved for the ethical use of human subjects, animals, and biohazards. This review must promote:

(1) Maintenance of high standards of protocol review, and relevance to the mission of VA;

- (2) Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel;
- (3) Welfare and appropriate use of animals in research;
- (4) Safety of personnel engaged in research;
- (5) Security of research laboratories where hazardous agents are stored or utilized and of all Bio-safety Level 3 (BSL-3) research laboratories; and
- (6) Security of VA data and VA sensitive information.

b. If a research protocol requires review by a facility's non-research entities, such as the Radiation Safety Committee, this review may be conducted at any time, but the research may not be initiated until: the non-research entity has approved the project, and the project has been approved by all applicable R&D Committee subcommittees, and the investigator has been notified in writing by R&D Office. Radiation Safety authorization issued by affiliate Radiation Safety Committees will be reviewed by the SRS, and subsequently reviewed by the RDC through the SRS minutes.

c. For protocols not meeting criteria for assignment to any subcommittee, the R&D Committee is the review and approving committee of record.

d. Concurrence of the R&D Committee or subcommittee under a Just-in-Time (JIT) review process does not represent approval to conduct the research. The investigator must submit the protocol to all applicable R&D Committee subcommittees and any other relevant committees or entities, and have written approval before initiating the research.

### **C. R&D COMMITTEE OPERATIONS**

a. R&D Committee must meet at least monthly, except for 1 month during the year, if it appears that a quorum (i.e. a majority of voting members) cannot be obtained. , A member is considered present if participating through teleconferencing or videoconferencing. In that case, the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.

b. R&D Committee Meeting Minutes for each meeting must be recorded. The minutes need to include the following information:

- (1) A list of all voting members and non-voting members, including ex officio members, indicating the category of their membership and whether they are present or absent. If an alternate is present in place of a voting member, the minutes need to indicate this fact and name who the alternate member is replacing.

- (2) The presence of a quorum.

- (3) Actions taken by the Committee, to include:

(a) The type of action.

(b) The vote on the action, including the number voting for, against, and abstaining. In addition, any recused member from the vote must be named, and whether the person was present during the discussion. **NOTE:** *If the member is recused, the member must not be present for the vote, and may not be counted toward the quorum.*

c. RDC approves protocols based on review of written correspondence from the appropriate subcommittee, and may include final or draft minutes, or a written list of subcommittee approved protocols signed by a member of the subcommittee RDC minutes will reflect the basis of approval.

d. All minutes of the R&D Committee and its subcommittees, including those from “in lieu of” subcommittees at JBVAMC or at the affiliates, must be sent to the medical center Director through the ACOS for R&D and COS for review and appropriate action. They are also sent to and presented at the JBVAMC Executive Leadership Committee meeting

e. Standard operating procedures or other written procedures must be maintained for all recurring processes. These processes include, but are not limited to, communication with the medical center Director, the COS, investigators, and committees or subcommittees. The R&D Committee is notified of subcommittee approval by written correspondence that may be memoranda, minutes, or other written documents. Determinations of non-compliance, suspensions, terminations or corrective actions are reported to the R&DC by the subcommittees via memorandum.

f. Review of R&D Committee subcommittee operations must be conducted as an ongoing function of the R&D Committee. The review must be conducted at least annually and must be accomplished in part by: reviewing the minutes of each subcommittee that reviews VA research protocols (whether those of the VA or non-VA institutions when allowed); by close communication with the subcommittees; and through Quality Assurance and Quality Improvement activities by the R&D Advisory Panel. All R&DC members review the subcommittee minutes on a monthly basis. QA/QI activities are reviewed by R&D administrative staff and reported to the R&DC on a quarterly basis by the R&D Program Support Assistant.

#### **D. R&D COMMITTEE RECORDS**

a. The adequate documentation of all of the activities of the R&D Committee must be maintained, including, but not limited to, the following:

(1) Minutes of the R&D Committee and R&D Committee subcommittees.

(2) Copies of all written correspondence.

(3) Membership lists for the R&D Committee and all R&D Committee subcommittees.

b. Written records documenting actions taken to carry out the committees' responsibilities for review of research as listed in paragraph 10, and for oversight of the research program as listed in paragraph 9, if not recorded adequately in the R&D

Committee minutes. **NOTE:** Records are the property of VA and the policy for record retention is outlined in VHA Records Control Schedule (RCS) 10-1. Record retention may be longer depending upon other policies and regulations such as Food and Drug Administration (FDA) regulations or medical record retention policies.

## **E. R&D COMMITTEE MEMBERSHIP**

a. **Appointment of Members.** The members of the R&D Committee are appointed in writing by the medical center Director and must reflect the types and amount of research being conducted at JBVAMC. Nominations for membership may be from current R&D Committee members, subcommittee members, and JBVAMC facility's staff.

b. **Number of Members.** The R&D Committee must consist of at least five voting members.

(1) Whenever possible, one member of the Committee needs to have expertise in biostatistics and research design.

(2) If JBVAMC were to have any Centers, such as Centers of Excellence, (e.g., Health Services Research and Development (HSR&D), Rehabilitation Research and Development (RR&D), or Cooperative Studies Program (CSP) Centers), it is recommended, but not required, that at least one voting member of the R&D Committee be chosen from the Center.

(3) Members need to have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise.

### **c. Voting Members**

(1) Voting members of the R&D Committee must include:

(a) At least two members from the JBVAMC facility's staff who have major patient care or management responsibilities (MD).

(b) At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise (VA Funded).

(c) At least one member who holds an academic appointment at one of the affiliates (UIC or NU), and is either a full-time Federal employee or a part-time permanent Federal employee.

(2) All voting members must be compensated full-time or permanent part-time Federal employees.

(3) A voting member may fill more than one criterion for required membership, for example, the member may have both major patient care or management responsibilities and be actively engaged in major R&D programs.

(4) Since JBVAMC conducts research involving the use of investigational drugs, membership includes a representative from the investigational pharmacy or Pharmacy Service as a voting member (VA Research Pharmacist).

(5) If JBVAMC R&D Committee has alternate members, they must be appointed by the facility Director. The roster must identify the primary member(s) for whom each alternate member may substitute. The alternate member's qualifications must be comparable to those of the primary member to be replaced. The alternate member can only vote in the absence of the primary member.

(6) All members of the R&D Committee must fulfill the educational requirements specified by VHA's ORD and other applicable requirements found on ORD's web site at: <http://www.research.va.gov/programs/PRIDE/>.

(7) The R&D Committee may require attendance by R&D subcommittee members, but subcommittee members who are not also members of the R&D committee must recuse themselves (i.e., leave the room or hang up from a conference call) before an R&D Committee vote is taken.

d. **Terms of Members**

(1) Voting members are appointed by the medical center Director in writing and serve terms of at least 3 years with possibility for extensions. Members may be reappointed without any lapse in time if it is deemed in the Committee's best interest.

(2) The terms of members must be staggered to provide partial change in membership annually.

e. **Election of Chairperson.** Committee members, exclusive of ex officio members, must elect a Chairperson every year.

(1) The Chairperson must be approved and officially appointed, in writing, by the medical center Director for a term of 1 year.

(2) The Chairperson may be reappointed without any lapse in time.

(3) The Chairperson must not simultaneously chair a subcommittee of the R&D Committee.

f. **Ex officio Members**

(1) Ex officio (non-voting) members include the medical center Director, the COS, the ACOS for R&D, the AO for R&D, and Research Compliance Officers (or those who are responsible for compliance) of the facility. The ACOS for R&D functions as Executive Secretary of the R&D Committee.

(2) Other ex officio members, such as the Information Security Officer (ISO), and Privacy Officer may be appointed to the Committee if their appointments assist the R&D Committee in fulfilling its responsibilities.

(3) Others may be invited to assist the R&D Committee because of their competence in special areas in the review of issues requiring expertise beyond, or in addition to, that available on the Committee. These individuals may not contribute to a quorum or deliberate or vote with the Committee.

## **F. SUBCOMMITTEES OF THE R&D COMMITTEE**

a. R&D Committee may establish any subcommittee(s) deemed necessary for the efficient and effective management and oversight of the R&D Program.

(1) Findings and recommendations of the subcommittees are recorded and reported to the R&D Committee.

(2). R&D Committee must approve subcommittee minutes. R&D Committee approval of all relevant R&D Committee subcommittee minutes (in draft or final form) reflects an en bloc R&D Committee approval of the projects approved by the subcommittees.

***(3) R&D Committee, through the VA IACUC, must receive and review the Semi-Annual VMU inspections from the affiliates (University of Illinois at Chicago/Northwestern University)***

4) Continuing review requires approval by relevant non-research committees and R&D Committee subcommittees (such as the IRB), and ACOS for R&D notification of the investigator that the approvals have been obtained.

(5) ***The R&D Committee does not perform a continuing review.***

b. The subcommittees of the R&D Committee are:

(1) **Institutional Review Board.** There are two IRBs of record for Jesse Brown: Collaborative JBVAMC/NU/UIC IRB (i.e., UIC IRB#4) and the VA Central IRB. The Chair and Co-Chair of the Collaborative IRB #4 - must be salaried JBVAMC employees, holding academic appointments at one or the other affiliate.

(2) **Institutional Animal Care and Use Committee (IACUC).** As per VHA Handbook 1200.7, the Jesse Brown VAMC has its own IACUC. Reciprocity agreements with the affiliate IACUCs will be obtained.

(2) **Subcommittee on Research Safety (SRS).** The Jesse Brown VAMC has its own SRS, however JBVAMC has entered into a MOU for use of the IBC at both NU and UIC for studies pertaining to rDNA. This alternative committee must deal with different aspects of research safety and security of all VHA research laboratories, as required in VHA Handbook 1200.8, and other applicable regulations and policies. ***NOTE: Biosecurity issues may be assigned by the R&D Committee to another subcommittee or retained by the R&D Committee. If biosecurity issues are retained by the R&D Committee, a separate subcommittee for biosecurity may not be required.*** Per stipulations in the MOU, the RDC will receive monthly

minutes through the SRS from the affiliate IBCs when VA research is discussed at the meeting.

(3) Audit Subcommittee. The Audit subcommittee is responsible for conducting peer-to-peer review of research investigators. The Audit Subcommittee review process is a means to assess and track the adherence to research regulations rendered by individual Research Principal Investigators. The Audit Subcommittee purview includes open Human Subjects protocols, and documentation related to aforementioned protocols.

(4) Space and Common Resource Subcommittee. This subcommittee is responsible for insuring that research laboratory and office space allocations are made appropriately, and that the purchase and maintenance of common use equipment benefits the majority of investigators.

d. Each subcommittee must maintain adequate records, and retain such records according to VHA Directive 6300. These records must include the following:

(1) Copies of all research proposals and their amendments reviewed by the R&D Committee subcommittees and any accompanying materials.

(2) All continuing or final reports.

(3) Minutes of its meetings.

(4) Copies of all written correspondence.

(5) A membership list of all voting, non-voting, and ex-officio members including their appointed roles.

(6) Written records documenting actions taken to carry out the subcommittee's responsibilities.

(7) Standard Operating Procedures (SOPs).

(8) All communications to and from investigators, other committees, subcommittees, and other entities or individuals.

e. Each subcommittee must make available to the R&D Committee a complete, unredacted final set of minutes prior to the R&D Committee meeting.

**NOTE:** *Research records may be electronic or paper. When original signatures are required on documents, either a paper copy of the signature sheet must be maintained or an electronic signature may be used. If an electronic signature is used, it must meet all of the requirements of VA, the Department of Health and Human Services (HHS), Office of Human Research Protection, the Food and Drug Administration (FDA), and any other relevant requirements.*

f. The Collaborative IRB will maintain the master files for human research protocols. The JBVA R&D office will maintain a copy of the original protocol, initial IRB approval

letter, initial ACOS approval letter, and copies of subsequent continuing review and amendment approval letters issued by Collaborative IRB #4.

g. The IACUC Coordinator/VMU Manager will maintain the master files for animal research protocols within the VMU. The JBVA R&D office will maintain a cross-reference list in conjunction with the safety protocols associated with the aforementioned animal protocols.

### **VA INVESTIGATORS AND R&D COMMITTEE MEMBERS FINANCIAL CONFLICT OF INTEREST**

The mission of ORD is to discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for the Nation and its Veterans. In order to fulfill this mission, VHA must preserve public trust in the integrity and quality of research carried out by its investigators and in its facilities. One way to maintain public trust and safeguard the integrity and quality of VA research is to ensure that VA investigators and members of R&D Committees avoid actual or perceived financial conflicts of interest in the research they conduct or review.

a. JBVA investigators and R&D Committee members must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. The obligation to follow applicable ethics laws and regulations also applies to WOC employees and IPAs conducting VA research or participating on a R&D Committee. R&D Committee members and VA investigators must comply with VA requirements on (FCOI) financial conflicts of interest in research. **Failure to follow these ethics laws and regulations can have serious consequences.** If criminal ethics statutes are violated, civil fines and imprisonment can result. Severe administrative disciplinary action can result from violating ethics regulations, including suspension from employment, termination of employment, and other administrative punishment.

b. R&D Committee members with outside consulting, employment, or royalty payment opportunities must ensure that these activities do not present any actual or perceived financial conflict of interest, and must recuse themselves from the review of proposals for which any conflict of interest may exist. Such members may not be present during the deliberations or the vote on such research proposals.

**NOTE:** *To obtain assistance in any matter concerning government ethics, individual researchers and R&D Committee members can contact the Regional Counsel at JBVAMC.*

### **REFERENCES**

Title 38 CFR §16.  
VHA Handbook 1200.05  
VHA Handbook 1200.06  
VHA Handbook 1200.7  
VHA Handbook 1200.08  
VA Directive 6500 and its implementing handbooks in the 6500 series

VHA Handbook 1605.1  
 VA Directive and Handbook 6102  
 VA Directive 6502  
 VA Handbook 6502.1  
 VA Handbook 6502.2.  
 VHA Directive 6300  
 VHA policy concerning Research Financial Conflict of Interest Statement  
 VHA Handbook 1200.13  
 VHA Handbook 1100.19  
 VHA policies concerning Credentialing of Health Care Professionals  
 VHA Directive 1200

**REVISION LOG:**  
**SOP: R&D Committee Operations**

Version (#, date)	Replaces (#, date)	Summary of changes
1.0; May 25, 2010		
1.1; July 13, 2011	1.0; May 25, 2010	Delegation of ensuring an annual evaluation of HSPP to RDC; Description of the evaluation of resources for the HSPP; Delegation of scientific validity review to IRB