



VA Pittsburgh Healthcare System Research Scientific Evaluation Committee (RSEC)

Standard Operating Procedures

VERSION 1.2

Approved: 05/13/14

**VAPHS R&D Committee
Standard Operating Procedures**

TABLE OF CONTENTS

Definitions:	3
I. INTRODUCTION.....	6
II. RSEC Roles and Authorities	6
III. RSEC Committee Responsibilities for the Review of Research	7
IV. RSEC Committee Operations	11
V. RSEC Records.....	15
VI. RSEC Membership	16
VII. Conflict of Interest.....	19

Definitions:

Animal. According to this SOP, the term "animal" is defined as any live or dead vertebrate animals including dog, cat, non-human primate, guinea pig, hamster, rabbit, rat of genus *Rattus* and mouse of genus *Mus* as well as birds that are used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose. The term "animal" also includes any vertebrate animals or birds bred to be used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose. The term excludes horses not used for research purposes and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use in improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

Animal Research. Animal research, as used in this SOP, refers to any use of laboratory animals in research, testing, or training.

Engagement. The VAPHS is considered engaged in any research activity that: 1) is conducted by VAPHS employees (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, 2) utilizes VAPHS resources (such as equipment), and/or 3) is conducted on VAPHS property, including space leased to, or used by VAPHS.

Exempt Research. Research initially reviewed by the VAPHS Institutional Review Board (IRB) and determined to involve human subjects in one or more minimal risk categories defined in VHA Handbook 1200.05.

Institutional Animal Care and Use Committee (IACUC). The IACUC is the local committee charged with ensuring compliance with animal research regulations and guidelines. In the VA system, the IACUC is organized administratively as a subcommittee of the Research and Development Committee.

Human Subject. A human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (38 CFR 16.102(f)). The definition provided in the Common Rule includes investigators, technicians, and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled. As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.

NOTE: The FDA definition of human subject differs according to the applicable regulation. See 21 CFR 812.3(p), 21 CFR 50.3(g), 312.3(b,) and 56.102(e).

Institution. In the context of this SOP, an institution is a VA medical center or integrated VA health care system and its satellite facilities including community-based outpatient clinics.

IRB. An IRB is a board established in accordance with and for the purposes expressed in the Common Rule (38 CFR 16.102(g).) Within VHA, an IRB was formerly known as the Subcommittee on Human Studies. At VA medical centers, the IRB is a subcommittee of the R&D Committee.

Principal Investigator (PI). Within VA, a PI is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The FDA considers a PI and an investigator to be synonymous.

Quorum. A quorum is defined as a majority of the voting members as listed on the RSEC membership. At meetings of the RSEC, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote.

Research. Research is defined as the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question.

Research and Development (R&D) Committee. The R&D Committee is charged with overseeing and approving all research projects at the medical center. In the VA system, committees such as the IACUC, Institutional Biosafety Committee (IBC), the Research Scientific Evaluation Committee (RSEC) and the Institutional Review Board (IRB) are technically subcommittees of the R&D Committee.

Science-Only Research. Research which does not meet the definition of Human Subjects research, as determined by the VAPHS IRB or VA Central IRB.

Science-Safety Protocols. Research which does not meet the definition of Human subjects research, however, does require review by the VAPHS Institutional Biosafety Committee.

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

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. Once a study has been approved by the R&D Committee it becomes VA research.

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, research, 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.

I. INTRODUCTION

This VA Medical Center Research Scientific Evaluation Committee (RSEC) Standard Operating Procedure (SOP) is a reference for members of the VA Pittsburgh Healthcare System (VAPHS) Research Community, including committee members, staff, and investigators. The purpose of the RSEC, a subcommittee of the VA Pittsburgh Healthcare System's Research and Development Committee, is to ensure that the research performed at VAPHS is of appropriate scientific quality and to provide assistance to investigators preparing competitive peer-reviewed grant applications. This SOP details the policies and procedures related to the Committee's functions and oversight.

The SOPs will be reviewed at least annually to incorporate any changes necessary in response to VA and/or Federal regulations.

II. RSEC Roles and Authorities

A. Institutional Authority of the RSEC

The Medical Center Director is responsible for all research activities conducted under medical center auspices. The R&D Committee, which reports to the Director, oversees the RSEC in accordance with VHA Handbook 1200.01 which states that the R&D Committee may establish any subcommittee(s) deemed necessary for the efficient and effective management and oversight of the Research and Development Program.

B. Purpose of the RSEC

The VAPHS RSEC's primary responsibility is to ensure that research performed at this facility is of appropriate scientific quality. The RSEC conducts initial and continuing review of this VA's protocols designated as science-only or science-safety only, as well as continuing reviews of those projects determined by the VAPHS IRB to meet the definition of exempt research. The Committee also conducts reviews of peer review grant applications.

C. The Authority of the RSEC

The Authority of the RSEC is granted by VA Pittsburgh Healthcare System Institutional Official, through the R&D Committee.

The RSEC has the authority to approve, require modifications in, or disapprove projects under its purview and to conduct continuing reviews of research at intervals not less than once per year.

Although the RSEC is a subcommittee of the R&D Committee, neither the Medical

Center Director nor the R&D Committee can approve research that has been disapproved by RSEC. If at the time of initial approval, the R&D Committee raises concerns regarding the project, the R&D Committee must refer those changes back to the RSEC. The R&D Committee may also disapprove a project that has been approved by the RSEC. In that case, the notification of R&D disapproval, along with a written justification for the disapproval will be sent to the RSEC and the investigator.

The RSEC has authority to suspend or terminate research activities related to those projects under its purview.

The R&D Committee serves as a parent committee to all of its subcommittees, including the RSEC, and must review and approve subcommittee actions, minutes, and periodic reports. A list of all protocols approved by the RSEC is forwarded to the R&D Committee for review and approval. Only once all subcommittee approvals, R&D Committee approval, and notification from the ACOS/R&D that the study may be initiated are received by the investigator may a study begin.

III. RSEC Committee Responsibilities for the Review of Research

A. The RSEC Committee is responsible for reviewing the following types of research for scientific quality:

1. Studies deemed “not human subjects” by the IRB, and not involving animal subjects (e.g., “Science-Only” proposals).
2. Studies deemed “not human subjects research” by the IRB, not involving animal subjects, but involving review by the Institutional Biosafety Committee (e.g., “Science-Safety” proposals)
3. Studies meeting the criteria for one or more exempt categories, as determined by the VAPHS IRB or VA Central IRB.
4. Peer-review grant applications (e.g., Competitive Pilot Project Fund (CPPF) applications, VHA Competitive Merit applications, NIH grant applications, etc)

B. Initial Review: Science Only and Science Safety proposals are reviewed and approved initially (‘Initial Review’). Such projects are received by the Research Office and initially sent to the IRB for a “not human subjects’ determination. If the project includes safety information the project is also submitted to the IBC. Once the IRB determination of “Not human subjects research” is made the project will be reviewed by the RSEC.

1. In conducting an initial review, the RSEC Committee evaluates scientific quality, the relevance to both VA's mission and the facility's research program, and the ability of the investigator to perform and complete the research. In addition, the review includes information on the use, storage, and security of VA data and VA sensitive information; the budget; the requirements for space, personnel, equipment, and supplies; the role of the investigator at the facility; the investigator's qualifications; and other information deemed relevant by the RSEC. If Service Lines within the VAPHS will be impacted by the research, investigators are required to obtain a letter of support from each applicable Service Line. Letters of Support will facilitate the Service Line Representative's assessment as to whether or not the impact of the research on the service is acceptable.

2. The initial approval of research may be conducted by the fully convened committee or by expedited means. Reviews conducted by the fully convened committee require a majority vote of the convened quorum. A quorum equals more than half of voting members.

3. The initial approval of research includes a specific approval period, not to exceed 1 year.

C. Continuing Review. Each project initially approved by the RSEC and each study determined by the IRB to meet one or more exempt category) will undergo continuing review at least annually. The RSEC determines continuing review intervals for studies determined exempt by the IRB, as well as studies deemed 'science-only' i.e. not human subject's research..

1. Continuing review of research, which does not meet the criteria for expedited review (See Section IV), requires a review during a convened meeting at which there is a quorum consisting of a majority of voting members. A quorum equals one more than half of the voting members. A quorum must be present during the vote.

2. A continuing review assesses the research activities that have occurred, the progress of the research, and any issues that may impact on the progress of the research.

3. Continuing approval of research must include a specific period, not to exceed one year. For exempt studies, Science-Only studies, or Science-Safety studies in which the continuing review submission is received by the RSEC before the actual expiration date but not in time for the RSEC to grant continuing approval prior to expiration, then the study is expired and further research activities cannot occur until continuing review and approval occurs. If the study expiration date passes and no continuing review materials are received, the study is administratively terminated and must be re-reviewed and re-approved.

4. In cases of contingently approved continuing reviews, the RSEC will allow the investigators 42 days to respond to the contingencies. If a response is not received within the 42 day time frame the study approval will expire and the project will be administratively suspended. A written letter indicating expiration of the research approval will be sent from the RSEC Chairperson or designee to the investigator. Copies will also be sent to the relevant subcommittees and the the R&D Committee.

D. The RSEC may:

1. Approve with no changes. The research may proceed.
2. Approve with conditions to be reviewed by the Chairperson or his/her designee. Such changes must be clearly delineated by the RSEC so the investigator may simply concur with the RSEC's stipulations. The research may proceed after the required changes are verified and approved by the Chairperson or his/her designee.
3. Table, pending receipt of additional substantive information or substantive changes. The RSEC determines that it lacks sufficient information about the research to proceed with its review or that the changes are so numerous as to require re-review by the full committee. The research may not proceed until the convened RSEC has approved a revised application incorporating all necessary information.
4. Disapprove. The RSEC determines that the research cannot be conducted at the VAPHS or by its employees or agents.

E. A list of all protocols approved by the RSEC is forwarded to the R&D Committee for review and approval. Only once all subcommittee approvals, R&D Committee approval, and notification from the ACOS/R&D that the study may be initiated are received by the investigator may a study begin. Once approved by the R&D Committee, the research becomes VA-approved research.

F. If a research protocol requires review by a facility's non-research committee(s), such as the Radiation Safety Committee (RSC) or another subcommittee, such as the IBC, this review may be conducted at any time, but the research may not be initiated until the non-research committee 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 the ACOS/R&D.

G. Peer-Review Applications

1. Projects that are to be submitted to the VA, other federal agencies, or other entities for funding consideration which will be administered through the VA or the Veterans Research Foundation of Pittsburgh (VFRP) must undergo a preliminary review by the RSEC prior to submission of the protocol for competitive funding review.

- 1.1. Centers of Excellence Projects: Applications originating from one of the VAPHS Centers of Excellence may undergo scientific review using the Center's Review procedures. Under this process, a copy of the Center's written review is provided to the RSEC. The RSEC will ensure that the review performed by the Center has assessed all relevant criteria and provided that it has will accept the Center review as is. No additional review will be conducted by the RSEC. The Chair may expedite approval for submission when Center reviews are highly positive in advance of the next scheduled RSEC meeting. Otherwise, the Committee votes whether or not to approve the application for submission at the next scheduled RSEC meeting.
- 1.2. Projects that are not reviewed by a Center review process will be reviewed by the RSEC. Under this review process, the Principal Investigator is asked to identify two reviewers with appropriate expertise. The RSEC Chair may accept the PI's recommendations or may identify other reviewers. The reviewers are asked to provide the RSEC with written copies of their reviews. The assigned reviewers must provide written copies of their reviews to the RSEC, which are also provided to the applicant. The Chair may expedite approval for submission when both reviews are highly positive in advance of the next scheduled RSEC meeting. Otherwise, the Chair assigns at least one Committee member to present at the next RSEC meeting, summarizing the reviewers' comments. The Committee then votes whether or not to approve the application for submission.

The RSEC assesses the appropriateness of the scientific methodology, the relevance of the research to VA's mission, the investigator's qualification to conduct the research, and adequacy of the resources.

The RSEC may recommend submission to the funding agency or may disapprove the project if the reviewers find that it is not scientifically valid, does not meet the research mission of the VAPHS, or is deemed unworthy due to incompleteness. All decisions are communicated in writing to the Principal Investigator by the RSEC Chairperson/designee.

A list of those merit review/grant applications that the RSEC recommends for submission is communicated to the R&D Committee via RSEC minutes.

Review by this process does not equate with approval to initiate the project. In order to initiate the research, the investigator must obtain the approval of the appropriate R&D subcommittees, other applicable non-research entities, the R&D Committee, and receive a letter indicating the project can be initiated from the ACOS/R&D.

2. Projects that are to be submitted to other federal agencies, or other entities for funding consideration which will be administered through a non-VA or non-VRFP agency (e.g., University of Pittsburgh), but which will engage the VAPHS in research, must receive an administrative review by the Research Office prior to submission. The RSEC cover sheet must be submitted to indicate which VA resources are being requested, and provide documentation of assent by the relevant Service Lines for patient recruitment, and clinical or laboratory services. The RSEC will list in their minutes those applications that have been reviewed by the Research Office.

3. Projects that are a response to brief submission deadlines (e.g., Request for Applications with agency deadlines of less than two months after initial announcement) may require flexibility in the approval process. The RSEC Chair is authorized to adapt the review process for such submissions in collaboration with administrative review by the Research Office.

IV. RSEC Committee Operations

The information below applies to activities of the RSEC.

A. The RSEC Committee meets at least monthly, unless there are no new items on the agenda. Additional meetings may be added at the discretion of the Chairperson.

B. If physical presence at convened meetings is not possible, a member may be 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.

C. Unscheduled meetings may be held in response to ad-hoc issues. There must be a quorum present in person or by teleconference or videoconference for any unscheduled meetings. A quorum must be present to conduct business and must be present for each vote.

D. An agenda is developed prior to each meeting and is distributed to members five (5) business days prior to the meeting date.

For meetings of the fully convened RSEC, the agenda includes the following:

1. Review and approval of RSEC minutes of the previous meeting.
2. Old Business, any issues unresolved from a previous meeting.
3. Announcements, new non-study specific issues that do not require a vote.

4. New business, any issue that has arisen since the last meeting, including Merit/Grant applications.
5. Initial reviews of research projects, with responsible reviewers identified.
6. Continuing reviews of Exempt Studies, Science-Only studies, and Science Safety studies, with responsible reviewers identified.
8. Amendments
9. Study closures

E. For initial reviews, the RSEC Committee Chairperson or designee will make a preliminary review of each research study proposed and assign two reviewers to review the study protocol and any other study-related material for the next meeting, based on the field of study and the reviewers' expertise. Assigned reviewers complete the RSEC Checklist for Initial Review.

If the reviewers determine that the project can be approved with no need for modification, the Chair will conduct a secondary review and if the Chair agrees that the project can be approved with no additional modifications, the project will be approved by expedited means, with no need for review by the fully convened RSEC. In this case, the expedited approval will be included as an acknowledgement on the agenda of the next meeting of the fully convened RSEC.

Should the primary reviewers or the Chair determine that there is a need for additional modifications, the project will be placed on the agenda for review by the fully convened RSEC.

At the convened RSEC meeting, during the initial reviews of research projects, the primary reviewers will provide a brief summary of the research project. RSEC members are provided an opportunity to voice any ethical or scientific concerns that they may have regarding the research project, request clarification and request changes, if needed, as determined by majority vote of the committee.

The entire research file is available to all members prior to and during the convened meeting. All members are afforded full opportunity to discuss each research proposal during the convened meeting.

F. For continuing reviews, the RSEC Committee Chairperson or designee will make a preliminary review of each research study proposed and may approve the review if there are no changes or only minor modifications/amendments. Otherwise, the Chairperson or designee will assign one primary reviewer to review the study protocol and any other study-related material for the next meeting, based on the field of study and the reviewer's expertise. The reviewer will complete the RSEC Checklist for Continuing Review

If the primary reviewer determines that the continuing review can be approved with no need for modification, the Chair will conduct a secondary review and if the Chair agrees that the continuing review can be approved with no additional modifications, it will be approved by expedited means, with no need for review by the fully convened RSEC. In this case, the expedited approval will be included as an acknowledgement on the agenda of the next meeting of the fully convened RSEC.

Should the primary reviewer or the Chair determine that there is a need for additional modifications, the project will be placed on the agenda for review by the fully convened RSEC.

At the time of continuing review, the RSEC members will review documentation submitted by the Principal Investigator and determine whether appropriate progress has been made and evaluate whether or not the scientific quality of the research project has changed. The entire research file is available to all members prior to and during the convened meeting. All members are afforded full opportunity to discuss each research proposal during the convened meeting.

G. Modifications/Amendments. Modifications to an approved project are categorized as either major or minor changes. Minor changes may be reviewed and approved by expedited means by the RSEC Chairperson/designee.

A minor change is one that does not substantially change the specific aims or design of the study. Examples may include but are not limited to:

- Changes in funding, project title, or study staff
- Small changes in experimental procedures, design, or analysis

Changes that are not minor include:

- Changes in experimental procedures, design or analysis that may have a significant impact on the scientific merit of the project.
- Changes which in the opinion of the Chairperson/designee do not meet the criteria or intent of a minor modification.
- Changes in experimental procedures, design or analysis that may impact the exempt status of the project. In that case, the project should be sent to the IRB for evaluation before being reviewed by the RSEC.

Any modification made to a study that had been previously determined by the IRB to meet one or more categories for exemption must be re-evaluated by the IRB prior to RSEC review. The IRB review will focus only on ensuring that the modification does not change the project's exempt status. Once a determination has been made that the project continues to meet one or more of the exempt categories, it will be forwarded on to the RSEC.

H. Minutes for each meeting are recorded. The minutes 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 indicate this fact and name who the alternate member is replacing.
 2. The presence of a quorum. The quorum determination is verified and recorded by the research office staff member taking the minutes at the meeting.
 3. Actions taken by the committee, to include:
 - a. The type of action.
 - b. The vote on the action, including the number for, against, and abstaining. In addition, any recused member from the vote is named, and whether the person was present during the discussion and the vote must be noted. If the member decides to be recused, the member must not be present for the discussion or vote.
 - c. The basis for requiring changes to a research project, program, or center to obtain approval.
 - d. Any required follow-up and which committee, subcommittee, or person is responsible for the follow-up.
 - e. The basis for disapproving a research project, program, or center when this occurs.
 - f. Action taken on minutes submitted to the Committee if not recorded in other R&D Committee records.
 4. All minutes of the RSEC Committee are sent to the medical center Director through the ACOS for R&D and COS for review and signature.
- I. The Principal Investigator is notified in writing of the RSEC' s decision to approve, approve with conditions (i.e., contingent approval), table, disapprove a proposed research activity, or if modifications are required to secure RSEC approval. The Principal Investigator is notified in writing of the results of the RSEC's annual review of the project.
- J. Once a study has obtained final initial RSEC approval, the RSEC provides written notification of approval to the VAPHS R&D Committee for approval. The R&D Committee then notifies the ACOS/R&D of project approvals via written communication

signed by a voting R&D Committee member. Research cannot be initiated until the ACOS/R&D issues a written notification of project approval and initiation to the Principal Investigator.

K. The ACOS/R&D will notify the investigator in writing of RSEC Continuing Review approval

V. RSEC Records

The adequate documentation of all the activities of the RSEC are maintained, including, but not limited to, the following:

1. Copies of all research proposals undergoing initial or continuing review, all amendments reviewed, and any accompanying materials.

Each research proposal is given a separate file. Protocols are assigned a unique number from MIRB and a unique grant number from Project Management and Information System (PROMISE) for tracking and administrative purposes.

The VAPHS Research Office uses a computerized tracking system, the MIRB computer program/database developed by N-Core Systems, Inc., which is maintained by office staff. MIRB stores information regarding each document received, when it was received, and the results of that review. Additionally, MIRB tracks changes that are needed, when those changes were received and approved, and the date of continuing review.

2. All continuing and final reports.
3. Minutes of the RSEC meetings.
4. Copies of all written correspondence.
5. Membership lists for the RSEC, including all voting, non-voting, and ex-officio members and their roles.
6. Written records documenting actions taken to carry out the RSEC's responsibilities for review of research if not recorded adequately in the minutes.
7. Copies of all communications to and from investigators, other committees, and other entities or individuals.

Records are the property of the VA, and must be retained as outlined in the VHA Records Control Schedule (RCS) 10-1, or longer depending upon other applicable policies and regulations such as the Food and Drug Administration (FDA) regulations or medical record retention policies.

Ordinarily, access to the records is limited to the members of the Research Office administrative staff, R&D Committee and subcommittee Chairperson(s) authorized VA representatives, and officials of federal and state regulatory agencies, including the Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP) and the FDA. Research records are accessible to office staff, R&D Committee chairs and members. Research investigators shall be provided reasonable access to files related to their research. Other authorized individuals, such as officials of federal and state regulatory agencies, including the ORO, OHRP, and FDA, will have access to research office records for inspection and copying upon determination of appropriateness and necessity at reasonable times and in a reasonable manner.

The research office staff keeps a log of such individuals who access the research office records, other than the R&D Committee and subcommittee members, Chairs, and research office staff.

VI. RSEC Membership

The RSEC will have a minimum of five members. The membership is selected to assure appropriate diversity, including representation by multiple professions, multiple ethnic backgrounds, both genders, knowledge of institutional commitments, and inclusion of scientific members.

A. Appointment of Chairperson and Vice Chairperson, Length of Service and Duties

The Chairperson and Vice-Chairperson(s) of the Research Scientific Evaluation Committee shall be voting members who have a significant physical presence at the VAPHS and is involved with the research program.

Appointment: The RSEC Chairperson and Vice Chairperson shall be appointed by the Medical Center Director based on the recommendations of the R&D Committee for a term of one year and may be re-appointed without any lapse in time. The Chairpersons shall have the right to resign from the position of Chairperson upon notifying both the ACOS/R&D and the RSEC with three months advance notice whenever possible to allow for an orderly transition.

The RSEC Chairperson, by virtue of his/her position is appointed as an ex-officio, voting member of the R&D Committee, provided that his/her employment status allows such. If the RSEC Chairperson does not satisfy the requirements for voting status on the R&D Committee, he/she will be appointed as an ex-officio, non-voting member. The RSEC Vice Chairperson will serve as the alternate to the Chairperson. His/ her status as a voting or non-voting, ex-officio member will depend upon his/her employment status.

The RSEC Chairperson/Vice-Chairperson shall not simultaneously serve as chair of the R&D Committee.

Qualifications: The RSEC Chairperson and RSEC Vice-Chairperson will have earned the M.D., Ph.D. or equivalent degree and will be nominated to the R&D Committee by the ACOS/R&D for appointment.

Authority: The RSEC Chairperson and Vice Chairperson have the authority to approve the agendas of the RSEC meetings as presented by the Research Office. The RSEC Chairs will represent, or appoint other members to represent, the RSEC to the institutional administration, and the research staff. The RSEC Chairperson or Vice Chairperson also has the authority to call an ad-hoc meeting of the RSEC as necessary.

Duties:

1. To convene, conduct and ensure the documentation of all the meetings and official business of the RSEC, as well as to assure timely distribution of the monthly meeting agenda.
2. To assign reviewers for initial and continuing reviews consistent with protocol content and reviewer expertise.
3. To evaluate each protocol to determine if additional expertise is required from a consultant.
4. To evaluate and, if appropriate, approve all requests for minor modifications.
5. To determine immediate actions to be taken in cases of serious or continuing non-compliance of ongoing research, as well as to meet the reporting requirements of federal agencies.
6. To assure all RSEC members and consultants provide a financial conflict of interest statement.

The RSEC Chairperson or the Vice Chairperson may designate any one of the voting members of the RSEC to carry out any of these duties provided that the RSEC designee completes the required documentation on behalf of the Chairperson. The RSEC designee shall be an experienced member. A member is considered "experienced" once he/she has served on the RSEC for a minimum of six months. Assignments will also be made based on the expertise and type of member appropriate for the item to be reviewed.

The RSEC Chairperson may also choose to send any requests for expedited review, and minor modifications to the fully convened RSEC. The Chairperson cannot disapprove any proposals by expedited mechanisms and must forward requests that may potentially be disapproved, to the full RSEC. The Chairperson must seek the opinion of the Vice Chairperson or another RSEC member or forward the matter to the full board when he/she is a PI or co-investigator or a consultant for any proposal being considered for approval by expedited review.

All actions of the RSEC Chairperson and Vice-Chairperson(s) shall be documented in writing

Evaluation: The RSEC Chairperson and Vice-Chairperson(s) will be evaluated annually by the chairperson of the R&D Committee and ACOS. The evaluation will be based on qualifications, fulfillment of education and training requirements, and attendance at required meetings.

B. Appointment of RSEC Members, Length of Service and Duties

Appointment: RSEC members are nominated by the R&D Committee and their names are forwarded to the VAPHS Director. The Medical Center Director shall officially notify members in writing of their appointment to the RSEC for a period not to exceed three years. Members may be reappointed without any lapse in time. The RSEC member appointments shall be staggered so that approximately 1/3 of the RSEC members' terms shall be up for renewal each year. All RSEC members must have at least a without compensation (WOC) appointment at the VAPHS in order to serve on the board.

Qualifications of Members/ Composition of Boards: In the appointment of RSEC members, equal consideration shall be given to qualified persons of both genders. No appointment to the RSEC shall be made solely on the basis of gender. Every effort will be made to ensure that the RSEC membership does not consist entirely of men or entirely of women. The RSEC members will not consist entirely of members of one profession. The RSEC members shall be sufficiently qualified to review the research through their experience, expertise and diversity, including consideration of race, gender, cultural backgrounds, and sensitivity to community issues and/or attitudes. Each RSEC shall include:

- (1) at least one member whose primary expertise is in scientific areas;
- (2) at least one member whose primary expertise is in statistics or epidemiology.

Duties: Each RSEC member is expected to attend monthly meetings of the RSEC. Members are also expected to provide a complete, detailed and written review of assigned protocols as primary or secondary reviewers when they are assigned a review. Each assigned reviewer is also expected to complete appropriate reviewer checklist(s) and to provide the written review and completed checklist(s) to the RSEC coordinator prior to the meeting. Reviewers who are assigned a review but who are not able to participate in a meeting shall forward a complete written review along with a completed checklist to the RSEC coordinator no less than 24 hours prior to the meeting time.

The RSEC Chairperson has the authority to declare the position of any RSEC member vacant if the RSEC member misses more than two consecutive RSEC meetings or more than five meetings during the course of a 12 month period or fails to consistently provide written reviews when requested. In this case a nomination for a replacement will be requested from the R&D Committee for consideration by the Director of the VAPHS.

Evaluation: RSEC members will be evaluated annually by the RSEC chairperson and the vice chair. The evaluation will be based on qualifications and attendance at required meetings.

Ad Hoc Members, and Consultants: If there is not one person on the RSEC with the expertise to conduct an in depth review and answer specific questions which may arise during review of a protocol, the RSEC will: (1) defer consideration of the protocol to another meeting; or, (2) invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the RSEC. Such individuals may not vote with the RSEC, or contribute to its quorum.

Ex-Officio Members: Representatives of the Research Office or the Institutional Administration may be appointed to the RSEC as consultants and advisors on administrative matters. They take part in deliberations but do not vote, and they provide administrative support for the RSEC

Ex-Officio Non-Voting Members: Ex officio non-voting members of the RSEC include the medical center Director, the COS, the ACOS for R&D, the Deputy ACOS for R&D, the AO for R&D and the Research Compliance Officer(s).

C. Alternate Members.

Alternate members may substitute for regular members and are formally appointed as alternate members by the director of the VAPHS. Alternate members may be nominated by the R&D Committee and appointed by the Director. These alternates replace voting RSEC members who are, on occasion, unable to attend convened meetings of the RSEC. The RSEC roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member's qualifications shall be comparable to those of the primary member(s) to be replaced.- When an alternate member replaces a primary member, the alternate member shall have received and reviewed the same material that the primary member would have received. In addition, the RSEC minutes shall document when an alternate member replaces a primary member.

VII. Conflict of Interest

A. Like all VA employees, VA investigators and RSEC members 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 IPA's conducting VA research or participating on a RSEC Committee. RSEC Committee members and VA investigators must also comply with future VA procedure(s) on 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/or other administrative punishment.

B. RSEC 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.

C. When conducting the initial or subsequent review of research programs or projects, RSEC members must be cognizant of any financial conflicts of interest related to the Principal Investigator, others working on the research project, or others that may influence the conduct of, and the reporting on the research, such as a sponsor). Such conflicts must be resolved prior to the approval of VA research projects.