RESEARCH AND DEVELOPMENT (R&D) COMMITTEE

Standard Operating Procedures

JAMES H. QUILLEN VA MEDICAL CENTER

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Abbreviations

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
ACOS/R	Associate Chief of Staff for Research & Development
AO/R	Administrative Officer for Research & Development
CDC	Center for Disease Control
CFR	Code of Federal Regulations
CIO	Chief Information Officer
COI	Conflict of Interest
COS	Chief of Staff
CRADA	Cooperative Research and Development Agreement
CRADO	Cooperative Research and Development Officer
CROW	Comprehensive Research Operations Workgroup
CV	Curriculum Vitae
EPA	Environmental Protection Agency
ETSU	East Tennessee State University
FCOI	Financial Conflict of Interest
FWA	Federal Wide Assurance
HRPP	Human Research Protection Program
IACUC	Institutional Animal Care and Use Committee
IPA	Intergovernmental Personnel Agreement
IRB	Institutional Review Board
ISSO	Information Systems Security Officer
JHQVAMC	James H. Quillen VA Medical Center
MCD	Medical Center Director
MOU	Memorandum of Understanding
NIH	National Institutes of Health
NRC	Nuclear Regulatory Commission
ORD	Office of Research and Development (VA, Washington, DC)
OSHA	Occupational Safety and Health Administration
PO	Privacy Officer
RCEP	Research Compliance Education Program
RCO	Research Compliance Officer
RDIS	Research and Development Information System
RDC	Research and Development Committee
RISP	Research Information Security Program
RSAW	Research Safety and Animal Welfare Program
RSO	Research Safety Officer
R&D	Research & Development
SAE	Serious Adverse Event
SRSS	Subcommittee on Research Safety and Security
SOP	Standard Operating Procedures
VHA	Veterans Health Administration
WOC	With-Out Compensation

1. Introduction

a. Standard Operating Procedures (SOP): The SOP for the Research and Development Committee (RDC) are the current policies and procedures in operation at the James H. Quillen VA Medical Center (JHQVAMC). This SOP is based on VA regulations applicable to research activities and will be updated as regulations and policies change.

b. Institutional Authority: Unique to the VA, the RDC consists of members approved by the MCD. It is the responsibility of the MCD to provide the necessary resources, such as staff support, meeting area, filing space, reproduction equipment and computer access. The RDC is established in accordance with VHA Directive 1200.01.

c. VA Research: VA research is research that is conducted by VA Investigators (serving on compensated, WOC, or IPA appointments) while on VA time. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the RDC before it is considered VA research and before it can be initiated. All research data and biological specimens generated during the conduct of a VA-approved research protocol are the property of VA and are not owned by the Investigator, unless there is a valid agreement (e.g., CRADA or other equivalent) that establishes that data collected by VA belong to the sponsor with a copy retained by VA. (VHA Directive 1200.02)

d. VA Investigator: A VA investigator is any individual who conducts research while acting under a VA appointment, including full and part-time employee, Without Compensation (WOC) employee, or employee under the IPA of 1970. Individuals working under a contract with VA cannot conduct research under a WOC appointment.

2. Scope of Authority

The RDC, with administrative support from the Research & Development Office and the Associate Chief of Staff for Research (ACOS/R), is responsible, through the Chief of Staff (COS), to the MCD for assuring the scientific and ethical quality of VA research, protection of human subjects in research, safety of personnel engaged in research, welfare of laboratory animals, security of VA data, and security of VHA research laboratories. The RDC advises the MCD by providing oversight, strategic planning, and execution of the local research program. All R&D activities within the facility, whether funded or unfunded, are within its purview. No research may be undertaken without review of individual research protocols by the appropriate subcommittee(s), Privacy Officer (PO), Information System Security Officer (ISSO), Financial Conflict of Interest (FCOI) administrator, and the Administrative Officer (AO) for Research. Approval for research protocols requires review and approval by appropriate R&D subcommittee(s) and the RDC once subcommittee approvals are granted. A voting member of the RDC will then notify the ACOS/R. Further, the RDC can recommend suspension/termination of any approved research activity and/or investigator(s) and require the implementation of additional safeguards when serious non-compliance, ethical, and/or Conflict of Interest (COI) are brought to its attention.

3. Legal Authority

VHA Directive1200.01 (Research and Development Committee), VHA Directive 1200.02 (Research Business Operations), VHA Directive1200.05 (Requirements for the Protection of Human Subjects in Research), VHA Handbook 1200.07 (Use of Animals in Research), VHA Handbook 1200.08 (Safety of Persons Engaged in Research), and VHA Handbook 1058:03 (Assurance of Protection for Human Subjects in Research).

4. Mission and General Principles

a. Assuring the continuing high quality of the facility's R&D program.

b. Planning and developing broad objectives for the research program so that it supports VA's mission and the JHQVAMC.

c. Determining the extent to which the R&D program has met its objectives.

d. Evaluating critically the quality, design, desirability, and feasibility of each new R&D proposal, continuing R&D protocol, application for funding, or other reporting activity to assure maintenance of high scientific standards, protection of human subjects, safety of VA data and research laboratories, adequate safety measures of personnel, and proper use and protection of experimental animals. This evaluation is delegated to the appropriate R&D subcommittees and individuals (e.g., ISSO, PO, RSO, RCO, etc.).

e. Recommending on the basis of such evaluations and after consideration of other needs, the distribution of R&D funds, space, personnel, equipment, supplies, and use of animal facilities and other shared resources.

f. Annual reviews of written agreements involving research.

g. Oversight and annual review of R&D subcommittees.

5. R&D Subcommittees

a. The RDC may establish subcommittees deemed necessary for the efficient and effective management and oversight of the R&D program and may use consultants or advisors who are selected for specific tasks and who do not have a vote.

NOTE: External committees established by MOUs or other agreements in lieu of required subcommittee(s) are not considered subcommittees and are governed by the agreement (e.g. the VA Central IRB).

b. All studies undergoing initial review, continuing review, or request for changes to the protocol must be approved by the appropriate subcommittee. Initial and any continuing reviews for exempt research protocols, and any approved research not reviewed annually by a sub-committee of the RDC also require review and approval by the RDC.

c. The RDC is the parent Committee within the R&D structure. The following permanent Subcommittees of the RDC have been established at the JHQVAMC.

1. Institutional Review Board (IRB)/ HRPP Subcommittee: The RDC has secured the services and delegated the responsibility of the scientific review of all human subject research to the East Tennessee State University (ETSU)/ (VA) IRB. The RDC supports and rigorously abides by the Federal Policy for Protection of Human Subjects of Research (the Common Rule) and the principles outlined in the Belmont Report and the Nuremberg Code. The rights and welfare of all persons participating in research must be vigorously protected. All research involving human subjects must comply with Federal and State regulations and VA requirements that address the protection of human subjects according to the JHQVAMC Human Research Protection Program Policies and Procedures and the ETSU/VA IRB Policies, including Title 38 Code of Federal Regulations (CFR) Part 16 (VA's implementation of the Common Rule, also codified by the Department of Health and Human Services as 45 CFR Part 46, Subpart A), and all related policy and procedural documents issued by the Office of Research and Development (ORD, i.e. VHA Directive 1200.05), Washington, DC. These regulations and requirements must be met before any research involving human subjects is initiated, and adherence must be sustained throughout the conduct of the research. An MOU between the JHQVAMC and ETSU governs the services of the IRB as described in VHA Directive 1200.05.

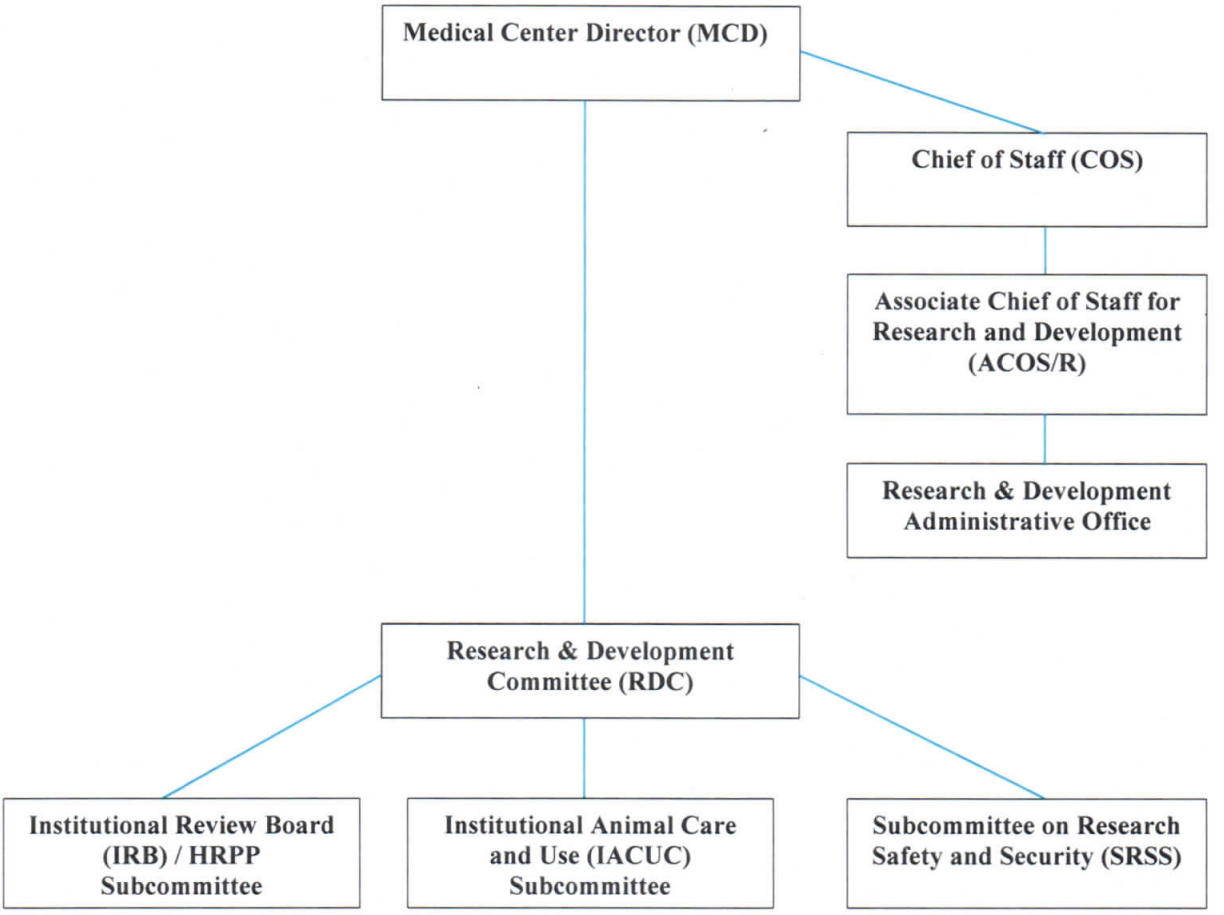
2. Institutional Animal Care and Use Committee (IACUC): Every VA facility conducting research involving the use of live vertebrate animals must establish an IACUC or secure the services of an IACUC as described in VHA Handbook 1200.07. The RDC supports only those animal studies that are designed and performed with the highest degree of attention to the welfare of research animals. Full compliance with VHA Handbook 1200.07, Use of Animals in Research and the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) international guidelines as established in the SOP for the IACUC Subcommittee is maintained. An MOU between the JHQVAMC and ETSU governs the services of the IACUC as described in VHA Handbook 1200.07.

3. Subcommittee on Research Safety and Security (SRSS): The RDC supports a safety program consistent with policies, statutes, and regulations outlined in VHA Handbook 1200.08, Safety of Persons Engaged in Research and issued by the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), Centers for Disease Control and Prevention (CDC), and National Institutes of Health

(NIH). The RDC supports only those studies with the highest standard of protection of personnel against biohazards, chemical hazards, radiation hazards, and physical hazards in the research laboratory setting as established in the SOP of the SRSS.

d. Findings and recommendations of the subcommittees are recorded and reported to the RDC. Meeting minutes for each of the three subcommittees must be presented to the RDC for review, discussion, and approval within sixty (60) days of the subcommittee's finalization of the minutes.

RESEARCH & DEVELOPMENT COMMITTEE ORGANIZATIONAL STRUCTURE



6. RDC and Subcommittees Communications

a. Appropriate communication between the RDC and its subcommittees and external committees is imperative to the JHQVAMC R&D Program. The communications between these entities should be collaborative and clearly documented.

b. Communication from the subcommittees and external committees to the parent RDC, rely on the RDC review of the Subcommittees' minutes, reports from common committee members, and written communications. Findings and recommendations of the subcommittees are recorded and reported to the RDC. Subcommittees provide notice to the RDC that a research protocol has been approved and a brief written summary of the research to be conducted.

c. Communications from the RDC to the subcommittees and external committees is accomplished through both written exchanges and common committee members.

7. RDC Membership

a. Qualified potential RDC members will be identified by voting members of the Committee and recommended through the ACOS/R and COS, then presented to the MCD for official appointment.

b. The RDC will have at least five (5) voting members with varying backgrounds to perform complete and adequate reviews of the research activities conducted at the JHQVAMC. Voting members of the RDC will be asked to appoint an alternate member in writing or recorded as part of the meeting minutes. The alternate member's qualifications shall be comparable to those of the primary member. The RDC will meet the following elements of composition:

c. At least one member from the affiliated institution (ETSU).

d. At least two members from the staff of the JHQVAMC selected because they have major patient care or management responsibilities.

e. At least two members who are VA employees and actively engaged in one of four major R&D programs or who can provide R&D expertise. This expertise will reflect the types of research being conducted at the JMQVAMC. All four VA programs including: (1) Biomedical Laboratory Research & Development, (2) Clinical Science Research & Development, (3) Health Services Research and Development, and (4) Rehabilitation Research and Development should be represented, when active programs are ongoing in these areas. Similarly, nursing and allied health professionals should be represented whenever there is research activity in these areas. If applicable, a representative of a facility Research Enhancement Award Program or Center of Excellence should be a member.

f. When possible, one member of the Committee selected according to the criteria listed above should have expertise in biostatistics and research design.

g. One voting member of the Committee selected according to the criteria listed above should have pharmaceutical or research pharmaceutical experience.

h. Membership should reflect diversity including consideration of race, gender, and cultural background.

i. Ex-officio (non-voting) members include the MCD, COS, ACOS/R, Administrative Officer for Research (AO/R&D), Research Safety Officer (RSO), ISSO, and PO. They are considered ex officio, non-voting members of the R&D Committee by virtue of their position and no appointment letter is required. The ACOS/R functions as Executive Secretary of the Committee. The RCO can be invited by the RDC to attend the meetings as a non-voting consultant.

j. Voting members must hold a VA appointment (permanent, term, IPA, WOC). Committee members who are VA employees will serve on the RDC as part of their VA assignments and will not receive additional compensation.

k. The Chairperson of the RDC is approved by the MCD, following election by the voting members of the RDC. The Chairperson serves a term of 1 or 2 years and may be re-appointed without any lapse in time. The Chairperson shall not simultaneously chair a subcommittee of the RDC.

l. Voting members serve three-year terms and may be reappointed without any lapse in time. The terms shall be staggered to provide partial change in membership annually. Standard re-appointment of a voting member is managed by the R&D Office without the requirement of a committee review and vote.

m. Regular attendance at meetings of the RDC is required, and a member may be removed because of unexcused absences. Members may be removed from office at the discretion of the MCD upon consultation with the COS and ACOS/R.

n. All committee members and alternates must complete the educational requirements specified by ORD.

o. Each Committee member is required to submit a copy of his or her Curriculum Vitae (CV) to the R&D office prior to appointment. The CV must show the version date and current VA appointment.

p. Alternate voting members must be appointed by the facility Director. The roster must identify the primary voting member(s) for whom each alternate voting member may substitute. The alternate member's qualifications must be comparable to those of the primary member(s) to be replaced. The alternate member can only vote in the absence of the primary member.

8. **Responsibilities of the Institutional Official (IO), ACOS/R, RDC Chairperson, RDC, Privacy Officer (PO), Information System Security Officer (ISSO), Research Safety Officer (RSO), Research Compliance Officer (RCO), and the R&D Office.**

a. Institutional Official:

1. The MCD serves as the Institutional Official (IO) and is 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, biosecurity and biosafety

2. The IO ensures that research in which the facility is engaged is approved by the appropriate subcommittees and RDC.

3. The IO suspends or terminates research that has been approved by the RDC when concerns are raised and substantiated about the conduct of the research.

4. Federal Wide Assurance (FWA). The VA MCD must obtain an FWA in accordance with VHA Handbook 1058.03 prior to conducting any human subject's research. The MCD must serve as the institutional official (IO) listed on the FWA for the local VA facility. Renewal is required every 5 years, or whenever the IO changes at the facility.

a) Institutional Culture. The MCD is responsible for fostering an institutional culture that supports the ethical conduct of all research involving human subjects.

b) FWA Signatory Authority. The MCD is responsible for serving as signatory authority for the FWA, and thereby making a written commitment to protect human subjects participating in research at the local VA facility and to comply with the requirements of 38 CFR Part 16.

c) Assurance Training. The MCD is responsible for completing assurance training required in VHA Handbook 1058.03 prior to signing the FWA initially, and every 3 years after that.

d) The VA Facility's HRPP. The MCD is responsible for overseeing the creation and implementation of an HRPP for research involving human subjects or human biological specimens. The exact composition of the HRPP depends on the specific facility, the resources of the facility, and the size and complexity of the research program at the facility. The VA MCD's responsibilities for the facility's HRPP include, but are not limited to:

- Overseeing the IRB, RDC, research office, and all investigators and research team members who perform human research at that facility.

- Appointing a RCO who reports directly to the Director and is responsible for developing and implementing a research compliance program (VHA Directive 1200 and VHA Handbook 1058.01).
- Delegating authority in writing for all respective roles and responsibilities within the local VA facility's HRPP. This delegation of authority must provide the organizational structure and ensure accountable leadership for compliance oversight activities for all human subject research conducted at the facility.
- Oversight of creating and implementing continuing education programs.

e) Signing the MOU. The MCD is responsible for signing the MOU with the organization(s) providing the subcommittee. This MOU is an agreement delineating the respective roles, responsibilities, and authorities of the VA facility and the external organization providing the subcommittee (see VHA Handbook 1058.03), including, but not limited to, the external organization's providing un-redacted subcommittee minutes and other relevant documents to the VA facility, and the responsibility for both parties to comply with all applicable VA and other Federal requirements. Written agreements that commit the VA medical facility's research program and another entity to specific programmatic responsibilities must be submitted to ORD for review/approval prior to IO signature.

NOTE: *The Affiliation Agreement between a VA facility and its academic affiliate does not delineate the IRB/IACUC-related respective roles, responsibilities, and authorities of VA and academic affiliate providing the IRB/IACUC. That information is contained in a separate document, an MOU specific for the subcommittee arrangement. The VA facility must have an Affiliation Agreement with its academic affiliate before entering into an MOU specific for the subcommittee arrangement.*

f) Ensuring Compliance by the Affiliate subcommittees. The MCD is responsible for ensuring the external subcommittees of record complies with all applicable VA and other Federal requirements including, but not limited to, the provisions of Handbook 1058.03 when reviewing VA research. If the terms of the MOU are not met, then the VA facility must make alternative subcommittee arrangements.

g) Appointing VA Representatives to the Affiliate subcommittees. The MCD is responsible, in accordance with existing MOU(s), for appointing VA-compensated employees who hold a minimum of 5/8th appointment as representatives to serve as voting members of each affiliate's subcommittee or other local VA facility subcommittee when that subcommittee serves as the subcommittee of record, unless a waiver for such representation is obtained from the CRADO.

- These representatives may not include WOCs from the VA facility, or those with IPA appointments.

- At least one of these representatives must have scientific expertise.

h) Establish and fund research positions including (VHA Directive 1200.02):

1. Research Compliance Officer (8/8th)
2. ACOS/R&D or Coordinator for R&D (5/8th)
3. AO/R&D (8/8th)

i) Ensure that VA research space is not used for non-VA research unless there is an appropriate legal authority to do so and the parties enter into a valid real property agreement that complies with applicable law and VA policy. Questions involving proposed use of VA space should be directed to VA's Real Property Service, which will engage OGC's Real Property Law Group as necessary.

b. ACOS/R: The ACOS/R&D serves as the Executive Secretary of the RDC and provides administrative support, including correspondence, scheduling meetings, and responding to questions about the Committee The primary responsibilities of the ACOS/R include the following:

1. Notifying the investigator when research can be initiated; or continued for exempt research (with approval period), only after all subcommittee approvals have been obtained. The process for ensuring the issuance of the ACOS/R initial and continuing review approval letters is as follows:

   a) For animal research, IACUC initial and continuing review approval letters will be forwarded to the R&D Office via email to ensure the ACOS/R issues either the initial or continuing review approval letter to the PI of record. A copy will be maintained by the R&D Office.

   b) For human subject research, Initial and Continuing review ACOS/R letters will be generated by the R&D Office and a copy will be issued to the PI of record. A copy will be maintained in IRB Manager and by the R&D Office.

   c) The SRS Committee will forward a copy of the signed approved VA 10-0398 to the R&D Office for listing on the RDC Agenda for all initial protocol approvals. A copy will be provided to the PI of record and maintained in IRB Manager and at the R&D Office.

2. Ensuring justification of WOC research appointments and review of associated documentation;

3. Ensure all research personnel hold an official VA appointment.

4. Ensuring that RDC and subcommittee minutes are forwarded to the COS and MCD for review and appropriate action;

5. Conduct and report to the RDC the results of an annual evaluation of the R&D subcommittees;

6. Conducting annual quality reviews of research employee scope of practices, CRADA, and other research agreements; and

7. Communicating results of external reviews to the RDC.

c. RDC Chairperson: The Chairperson is responsible for the following:

1. Supervising the preparation of RDC agendas,

2. Chairing the RDC meetings,

3. Requesting disclosure of any conflict interest from committee members,

4. Reviewing, approving, and signing the RDC minutes, and

5. Interacting with the Chairpersons of other Committees/Subcommittees and the R&D office to maintain uniform policies and procedures.

d. RDC:

1. The overarching responsibilities of the RDC are to ensure that all research is consistent with the VA mission and complies with all applicable statutory and regulatory requirements. Committee responsibilities include, but are not limited to the following:

a) Plan and develop broad objectives of JHQVAMC research program;

b) Determine the extent to which the research program has met its objectives and VA mission annually;

c) Review and vote on all subcommittee (IRB, IACUC, and SRS) reports, SOPs, and minutes (within 60 days of finalization);

d) Review and recommend actions based on quality assurance activities and reports provided by ACOS/R, AO/R&D, facility, or other appropriate sources;

e) Annual review and recommended actions for subcommittee activities based on review of subcommittee annual reports. Subcommittee annual report requests will be sent by the R&D Office to the subcommittee chairpersons via email during the first quarter of each fiscal year. If applicable, then research subcommittee accreditation reports or inspection reports that include the required elements defined in VHA Directive 1200.01 can be used "in-lieu" of the subcommittee annual report. The RDC review of the subcommittee annual reports will occur within the first quarter of each fiscal year and will be documented in the RDC minutes. A

summary of the RDC review and approval of the subcommittee annual reports will be provided to the MCD for concurrence;

f) Recommend based on annual evaluations and after consideration of other needs, the distribution of R&D funds, space, personnel, equipment and supplies, and use of animal facilities and other common resources;

g) Review all written agreements between the RDC and subcommittees within VA and with external entities as required by VHA Directive 1200.05 prior to using an external IRB when a study is reviewed by an IRB of another Federal agency or non-VA IRB serving as the multi-site IRB for a study;

h) Review and ensure prompt reporting if non-compliance is discovered by the Committee, in accordance with VHA Office of Research and Development (ORD), VISN 9 Director, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), VHA Office of Research Oversight (ORO), and IRB Policies and Procedures Reporting Requirements of:

- Unanticipated problems or risks to human research subjects, animals, or staff.
- Serious or continuing noncompliance with regulations.
- All non-compliance issues.

i) Ensure that all research is engaged only after review and approval for the ethical use of human subjects including privacy and data security, animals, biohazards, and all applicable non-research entities. If Collaborative Research is reviewed, then the R&DC ensures that only VA Research activities are reviewed and approved. The RDC is responsible for the approval or disapproval of individual protocols as approved by the IRB/IACUC for both initial and continuing review. Minor modifications and study closures will be reported to the RDC after the appropriate approval by RDC subcommittee minutes. The review and approval of individual protocols will occur as follows:

- The R&D Office, AO/R&D, ISSO, PO, RCO, and RSO will provide an up-front administrative review of initial and continuing review, study modification requests, if applicable, before sending the application to the appropriate subcommittees for review and approval.
- Any reviewer who has a conflict of interest with a study will be recused from the review process and an appropriate alternate will be sought for the particular review.
- RDC and its subcommittees must ensure that research reviews include:

  - Relevance of the research to VA's mission and the care of Veterans;
  - Protection of human subjects
  - Welfare of animals in research

- Safety and security of VA research laboratories
- Security of VA data and VA sensitive information
- Scientific merit
- Availability of resources, investigators time, and appropriate location to conduct research
- Availability of qualified research team members and successful completion of all relevant research-related training requirements.
- PI justification for inclusion of non-Veterans and provide specific approval for recruitment of non-Veterans (when applicable)

j) Remaining current on ethical, legal, information security/privacy and regulatory issues related to the standards of the research program;

k) Comply with educational requirements;

l) Maintain the integrity of the review process. Members must avoid discussing RDC protocols with investigators outside of a convened RDC meeting;

m) Review of all documents submitted to the RDC (e.g., including subcommittee minutes, annual reports and SOPs, etc.) prior to committee meetings;

n) Examine/Evaluate the Informed Consent process to determine areas in need of improvement;

o) Monitor/Evaluate responsiveness and reporting related to participant concerns, withdrawals, and complaints;

p) Fulfill other functions as specified by the MCD;

e. General Operation of the RDC

1. The operation of the RDC is administratively supported by the R&D office according to the Research and Development Service Policies and Standard Operating Procedures.

2. The following process will be followed:

a) Meetings will be scheduled monthly. Additional out-of-schedule special meetings may be arranged when deemed necessary. When possible, the meetings will be held in a regular location and at a regular time. Deviations will be announced to all committee members. A quorum, either in person or via telephone/video conference, must be present.

b) At least two business days prior to the meeting, members and alternates will receive electronically an agenda with embedded copies of all documentation to be reviewed at the meeting. Hard copies will be provided for the RDC chairperson and ACOS/R only.

c) Minutes of each meeting must be recorded and include list of members, their category of membership and whether they are present or absent, presence of a quorum, and actions taken by the committee (type and vote on the action).

f. RDC Records

1. The R&D office will prepare and maintain adequate documentation of RDC activities, including but not limited to the following:

a) All written documentation and correspondences considered for review;

b) RDC meeting agenda;

c) RDC and subcommittee meeting minutes, SOPs, MOUs, reports, and agreements;

d) RDC and all subcommittee membership rosters, including alternate voting members;

e) All correspondences to and from investigators, other committees, subcommittees, RDC, other entities, and individuals;

f) All correspondences between ACOS/R and investigators regarding approval of initial and continuing reviews;

g) Records reflecting training and personnel documentation required of all committee members, investigators, study staff, and R&D staff;

h) Required documentation for all individual study files. These records will be retained in a locked file in accordance with the VA Records Retention Schedule (RCS 10-1). The primary location of these files is in ETSU/VA IRB Manager under MOU with the affiliate university. Physical copies are maintained in Building 5, R&D Administrative Office for events through June 27, 2018. The RDC approved electronic only copies for all events thereafter at the June 2018 meeting, with access limited to R&D office staff maintained on the protected VA network.

g. Privacy Officer: The PO is responsible for:

1. Reviewing individual protocols, prior to RDC approval, to ensure compliance with VA privacy regulations,

2. Ensures the HIPAA Authorization contains all required elements;

3. Providing the RDC with guidance on privacy issues related to research,

4. Serving as the alternate for the ISSO, and;

5. Being current on regulatory policies on privacy and data security.

h. Information Systems Security Officer: The ISSO is responsible for:

1. Reviewing individual protocols, prior to RDC approval, to ensure compliance with VA data security regulations, to include locations where the data is to be stored, accessed, or used including servers, desktop personal computers, laptops, non-VA locations, or portable media;

2. Providing the RDC with guidance on data security issues related to research;

3. Serving as the alternate for the PO, and;

4. Being current on regulatory policies on privacy and data security.

i. Research Safety Officer: The RSO (fulfilled by the SRS Chair) is responsible for:

1. Reviewing individual protocols to determine whether the study needs full SRS committee review;

2. Calling SRS meetings outside of regularly scheduled meetings to ensure timely review of individual protocols with bio-safety issues;

3. Providing the RDC with guidance on bio-safety issues related to research, and;

4. Being current on regulatory policies on bio-safety.

j. Research Compliance Officer: The RCO is responsible for:

1. Reviewing individual protocols to ensure compliance with Federal and VA laws/regulations;

2. Providing the RDC with guidance on compliance issues related to research at JHQVAMC;

3. Reporting instances of non-compliance to the RDC and/or other regulatory organizations as needed;

4. Assisting the AO/R&D in educational programs for research personnel.

5. Conducting required audits of individual research protocols and reporting the results to the RDC;

6. Conducting required audits of RDC and subcommittees minutes and reporting the results to the RDC, and;

7. Being current on regulatory policies on research compliance.

k. The responsibilities of the AO/R&D and R&D Office include, but are not limited to the following:

1. Provide administrative support to subcommittees, RDC or designee, and ACOS/R;

2. Report monthly to the RDC any initial or continuing reviews, and study closures approved during the previous month;

3. Track and verify that all training requirements (CITI and personnel documentation) are current for RDC members and research personnel. CITI training is considered expired outside 1095 calendar days of current training.

a) Specifically, the R&D office will send reminder email notifications regarding training expiration 30 days prior to the date of expiration. These notifications will go to RDC members, Principal Investigators (PI), and research personnel for action;

b) The R&D office will reject all Initial Protocol Submissions, Continuing Reviews, and Minor Modifications involving the addition of personnel if said personnel have a CITI training expiration that will occur within 30 days of the submission date;

c) RDC members: If the RDC member does not complete the training within 30 days from the date of notification, then he/she will not be allowed to participate as a voting member (observer only) at the following RDC meeting. If the RDC member does not complete the training within 30 days from the expiration date, then the RDC may vote to remove the member from the RDC;

d) PIs and research personnel: In accordance with VHA Handbook 1200.05 CITI training is required every 3 years. The JHQVAMC will implement this requirement and defines "every 3 years" as within 1095 days after the previous training. Training is considered expired if it lapses outside of 1095 days of current training. The PI will be required to immediately remove the personnel with lapsed training from the study by completing an IRB modification request. If the modification is not completed and submitted to the R&D Office, through IRB Manager, within 5 working days from the expired training notification, then the ACOS/R has the following options until all training requirements are met.

- The ACOS/R can suspend the individual from conducting research.
- The ACOS/R can work with the ISSO to suspend all computer rights for the individual to ensure compliance.
- The ACOS/R can suspend the entire protocol.

- The ACOS/R can place the study in an "Administrative Hold" status as long as there is no risk to the enrolled subjects and study staff members rights, welfare or safety.
- The ACOS/R can restrict access to facilities for laboratory or animal research if the training is not completed in the required timeframe.
- The IRB should consider the actions of the ACOS/R but make an independent decision based on the IRB deliberations.
- Actions taken by the ACOS/R will be reported to the RDC at the next scheduled meeting.

e) Identifies and disseminates reference materials (e.g., VA handbooks, etc.) to committee members to optimize R&D function, and;

f) Works with RCO on providing educational opportunities for research personnel on research regulations, compliance, etc.

9. Responsibilities of VA Investigators.

a. Each VA investigator is responsible for:

1. Developing a research plan that is scientifically valid; minimizes risk to human and animal subjects used in research and to research personnel; and contains a sufficient description of the research, including all procedures and the plan for statistical analysis, to allow the RDC and its subcommittees to fully review the research project.

2. Obtaining approval by all appropriate non-research entities and RDC subcommittees, and written notification from the ACOS/R prior to initiating a research project.

3. Submitting a completed, signed and dated OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement), for review by the R&D Conflict of Interest Administrator prior to:

a) Initial review of a study protocol in which the employee is listed as Investigator;

b) Continuing review of a study protocol in which the employee is listed as Investigator;

c) The employee being added as an Investigator to a study protocol, and;

d) When a change in relevant information requires that the investigator change an answer in Section I of an earlier-filed OGE Form 450 Alternative – VA to "yes" or that changes the reason for a "yes" answer.

e) Submitting and implementing plans for data use, storage, and security to the PO and ISSO that are consistent with the Federal Information Security Management Act, HIPAA, Office of Management and Budget Guidance,

National Institute of Standards and Technology Standards, VHA Directive 1605.01, VA Directive 6500, implementing handbooks, and other legal requirements and agency policy.

f) Preparing and submitting information, at least annually or as otherwise required, on all research projects to the appropriate RDC subcommittee or to the RDC for continuing review.

g) Ensuring that research proposals support the mission of VHA and enhance the quality of health care for Veterans.

h) Conducting VA research only within their area of expertise/experience that is consistent with their job description, and where applicable, holding all required credentials and privileges prior to initiating any VA research or research activities. NOTE: Certain procedures can only be performed by practitioners with specific privileges to do so. If specific privileges are required in the clinical setting, then specific privileges are also required in the research setting.

i) Complying with all applicable personnel, applicable law, and VA requirements whether the Investigator is compensated, WOC, or IPA.

j) Developing a protocol that:

- Is scientifically valid and uses methodology that is appropriate for addressing the goals of the protocol;
- Minimizes risk to human subjects, animals used in research, and research personnel;
- Contains sufficient description of the research to allow the RDC and/or its subcommittees to fully review the research protocol, including all procedures, plans for statistical analysis of the data, plans for the confidentiality and security of the data, and plans for maintaining confidentiality of the information, where appropriate, and;
- Is congruent with the funding application/grant for which the Investigator was funded.

k) Ensuring that all research proposals, from any source, support VHA's mission.

l) Sending the protocol and/or proposal to the Research Office to ensure the Research Office is aware of the submission. This allows the Research Office to act upon the submission as needed, enter the protocol/proposal into the Research Office tracking system, and forward the protocol/proposal to the funding institution, if applicable.

m) Ensuring that, when serving as the PI, all research staff are qualified (including but not limited to appropriate training, education, expertise, and credentials) to perform procedures assigned to them.

n) Initiating research, including collecting data, only after receiving notification that the protocol has been approved by all required committees and subcommittees.

o) Assuming full responsibility for all aspects in conducting the research. If responsibility for all aspects of the research cannot be fulfilled, then the research may need to be amended, suspended, or terminated. These responsibilities include ensuring:

- The research is ethical and scientifically meritorious;
- That sufficient resources (personnel, funding, space, etc.) are available to conduct the research;
- The rights, safety, and welfare of VA research subjects;
- The humane care and use of animals used in research;
- The appropriate biosafety/biosecurity practices and laboratory techniques are used for the research, and;
- The integrity of the data.

p) All research data and biological specimens generated during the conduct of a VA-approved research protocol are the property of VA and are not owned by the Investigator, unless there is a valid agreement (e.g. CRADA or other equivalent) that establishes that data collected by VA belong to the sponsor with a copy retained by VA. The original research data, unless collected under a CRADA, are part of the Federal record for the study and must be maintained by VA.

q) All data developed, used, or shared must comply with all VA and Federal regulations.

r) Research data collected for VA-approved research must comply with all applicable Federal regulations and VA policies.

s) VA Investigators must only conduct VA research in VHA medical facility space and/or in third party space that VA has the legal authority to use for the intended purpose, and for which the parties have entered into an appropriate agreement such as a real property agreement that complies with applicable law and VA policy. Examples of these include, but are not limited to, a revocable license, lease, or permit.

t) VA resources must not be used for non-VA research unless there is specific authority allowing such use. If the Investigator holds a compensated appointment at the university affiliate or other entity, the Investigator must ensure that the Investigator's protocols submitted for review do not specifically require that any contract or the scientific integrity of the protocol involve the academic affiliate or the other entity in a way that would violate any financial conflict of interests statutes, including those violations that can be criminal, such as 18 U.S.C. 208.

u) All publications and presentations resulting from an Investigator's research at VA must appropriately acknowledge VA support and VA employment as required by VHA Handbook 1200.19. They must also include the disclaimer stating that the contents do not represent the views of VA or the United States Government.

v) When the research is conducted at another VA medical facility or other institution, permission must be obtained from the VA medical facility/institution's Director or equivalent individual.

10. Conflicts of Interest

a. VA investigators and RDC 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 RDC. RDC members and VA investigators must comply with VA requirements on financial conflicts of interest in research. If criminal ethics statutes are violated, then 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. RDC 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. If an Investigator holds a compensated appointment at the university affiliate or other entity, then the Investigator must ensure that the Investigator's protocols submitted for review do not specifically require that any contract or the scientific integrity of the protocol involve the academic affiliate or the other entity in a way that would violate any financial conflict of interests statutes, including those violations that can be criminal, such as 18 U.S.C.208

11. Research and Space Allocations

a. Space allocations for the R&D Office are recommended by the Institutional Space Committee to the MCD for assignment.

b. Space assigned to the R&D Office by the MCD is reported to VA Central Office through the R&D Informational System (RDIS) Annual Report Part I (as required) and is reviewed by the RDC.

NOTE: *VA space cannot be used by a VA Investigator or other third party for non-VA research unless there is appropriate legal authority to do so, and the parties enter into an appropriate real property agreement that complies with applicable law and VA policy, such as a Revocable License or lease. Questions*

involving proposed use of VA space should be directed to VA's Office of Real Property.

Owen D. Murnane, Ph.D.
ACOS/Research and Development

Recission Date: April 30, 2024

Appendix A

Research Compliance Reporting Requirements

VHA Handbook 1058.01 describes the requirements for reporting compliance events in VA research to research review committees, VHA officials, and ORO. These requirements do not alter or replace any additional requirements for reporting such events to other internal or external entities as mandated by law, regulation, policy, or agreement.

All VA research personnel will report compliance events following the specific reporting requirements listed in sections (6) Human Research, (7) Animal Research, (8) Research Safety, (9) Research Laboratory Security and (10) Research Information Security. The summary table below does not list all examples of apparent serious and/or continuing noncompliance, but is a reference tool for research personnel. The IRB (423-439-6054) and RCO (423-979-4325) are available for consultation for any questions research personnel may have.

SUMMARY OF REQUIREMENTS FOR REPORTING RESEARCH INCIDENTS UNDER VHA HANDBOOK 1058.01

Reports should be directed to ORO as specified on the ORO SharePoint and Web sites at https://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx and http://www1.va.gov/oro/

Note: This Table provides a CONDENSED SUMMARY of reporting requirements. See VHA Handbook 1058.01 for complete details.

Unless otherwise indicated,

#1. VA employees (including WOC and IPA employees) must notify the relevant research review committee in writing within 5 BUSINESS DAYS (BD) after becoming aware of reportable incidents.

#2. Research review committee must notify the Facility Director (FD) and Associate Chief of Staff for Research (ACOS/R) within 5 BUSINESS after making certain required determinations (DTMs).

#3. FD must report to ORO within 5 BUSINESS DAYS after receiving notification.

HUMAN RESEARCH – Report to ORO Regional Office (or ORO RCEP[1] where indicated)	LABORATORY ANIMAL WELFARE – Report to ORO RSAW[2]	RESEARCH SAFETY – Report to ORO RSAW[2]	RESEARCH LABORATORY SECURITY – Report to ORO RSAW[2]	RESEARCH INFORMATION SECURITY – Report to ORO RISP[3]
§6a. Local Research Deaths that are unanticipated and related to the research. •Immediate oral notice to IRB. •IRB alert to ORO, FD, and ACOS/R within 2 BD. •Written notice to IRB per #1. •IRB Chair DTMs within 5 BD of written notice. •Convened IRB DTMs. •IRB notice of all DTMs to FD and ACOS/R per #2. •FD report to ORO per #3. **§6b-d. Local SAEs and Serious Problems that are both unanticipated and related to the research.** •Written notice to IRB per #1. •IRB Chair DTMs within 5 BD of written notice. •Convened IRB DTMs. •IRB notice of DTMs to FD and ACOS/R per #2. •FD report to ORO per #3. **§6f. Apparent Serious or Continuing Noncompliance.** •Written notice to IRB per #1. •Convened IRB DTMs. •IRB notice of DTMs to FD AND ACOS/R per #2. •FD report to ORO per #3. •Notification of, and tracking by RCO, if from RCO audit. •IRB tracking for Facility Director Certification. **§6h. Suspension/Termination by VA.** •Notice to FD, ACOS/R, & RCO within 5 BD. •FD report to ORO per #3. **§6i. Suspension/Termination by External Entity.** •Written notice to IRB per #1. •Convened IRB DTMs. •IRB notice of DTMs to FD AND ACOS/R per #2. •FD report to ORO per #3. **§6j. Program Changes.** •FD report to ORO per #3.	**§7c. Human Deaths.** •Immediate oral notice to IACUC. •IACUC alert to ORO, FD, and ACOS/R within 2 BD. •Written notice to IACUC per #1. **§7a. Unanticipated Deaths of Research Animals.** **§7b. Animal Theft, Escape, or Unexplained Disappearance.** **§7d. Human Accident, Injury, Illness, or Exposure.** **§7e. Reportable Incidents Under Federal Standards.** •Written notice to IACUC per #1. **§7f. IACUC Review of Incidents Reported under §§7a-7e.** • DTMs by convened IACUC. •Notice of IACUC DTMs to FD AND ACOS/R per #2. •Notice to FD of DTMs by other officials of a reportable event. •FD report to ORO per #3. **§7h. Delayed Determinations.** **§7i. Memoranda of Understanding.** **§7j. Public Health Service Assurances.** **§7k. Accreditation Status Change.** •FD report to ORO per #3.	**§8a. Human Deaths.** •Immediate oral notice to SRS. •SRS alert to ORO, FD, and ACOS/R within 2 BD. •Written notice to SRS per #1. **§8b. Human Accident, Injury, Illness, or Exposure.** **§8c. Reportable Incidents Under Federal Standards.** •Written notice to SRS per #1. **§8d. Review of Incidents.** •DTMs by convened SRS. •Notice of SRS DTMs to FD AND ACOS/R per #2. •Notice to FD of DTMs by other officials of a reportable event. •FD report to ORO per #3. **§8e. Delayed Determinations.** **§8g. Memoranda of Understanding.** •FD report to ORO per #3. **§8h. Lab Decommissions and Reassignments.** •Written request to SRS and ACOS/R 1 month prior to implementation •SRS DTMs. •Notice to facility Safety Officer from ACOS/R. •Notice to FD from ACOS/R of unauthorized decommissions or reassignments within 5 BD. •FD report to ORO of unauthorized decommissions or reassignments per #3.	**§9a. Research Laboratory Security Incidents.** (1) Intrusion, physical security breach, break-in, or other security violations in dedicated research areas. (2) Noncompliance findings by any entity other than ORO. (3) Unplanned suspensions or terminations of research due to security concerns. (4) Other deficiencies that substantively compromise the research laboratory security program. •Written notice to ACOS/R within 5 BD. •Immediate notice to VA Police Service. **§9b. Reporting.** •Notice to FD and VA Police Service from ACOS/R within 5 BD. •FD report to ORO per #3.	**§10a. Research Information Security Incidents.** •Immediate notice to ACOS/R, ISSO, and PO of information security incidents related to research including inappropriate access, loss, theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; theft, loss, noncompliant destruction of equipment containing PHI. •Immediate ACOS/R&D notice to relevant research review committee(s). •Immediate ACOS/R&D notice to Records Management Officer if VA records destroyed. •Written notice to ACOS/R within 5 BD. **§10b. Review of Incidents Reported under §10a.** •Review and DTMs by relevant research review committee(s) within 30 BD. •Notice of serious problem DTM to FD AND ACOS/R per #2. •FD report to ORO of serious problem DTM per #3 **§10c. FD report to ORO within 5 business days of:** •An Issue Brief on the incident for VA central office •An NSOC requirement to notify individuals of an information breach or to provide credit monitoring •Breach notification required under the Health Information Technology for Economic and Clinical Health (HITECH) Act •Notification to or from the OIG regarding the incident.

REVISED 06.15.2015

Appendix B

Site-Monitor Visit Reporting Requirements

In CRADO Memorandum dated October 14, 2004, Subject: Reporting of All Study Site-Monitoring Visit Results, the following guidance is applicable for each study that is monitored by a pharmaceutical company or CRO.

a. The ACOS/R&D or his/her designee is to be notified of all monitoring visits by pharmaceutical companies or CROs as soon as possible. This is the responsibility of the research staff person who schedules or confirms the monitoring visit. If the monitoring visit is unscheduled, the ACOS/R&D is to be notified as soon as the study personnel are aware of the visit.

b. The CRO or study monitor must sign in as a visitor at the research office as required of all visitors to research areas.

c. The Principal Investigator or other responsible investigator is to meet with the study monitor(s) prior to the monitors' beginning their work. During each visit by a monitor, the role of the monitor should be reviewed, including the new requirement that any potential or actual serious findings be conveyed to the investigator and the ACOS/R&D, Administrative Officer for Research (AO/R&D) or his/her designee during an exit interview. Findings that require an exit interview include but are not limited to:

(1) Any suspicions or concerns that serious non-compliance may exist, and

(2) All findings of serious non-compliance with the study protocol, Institutional Review Board (IRB) requirements or applicable regulations and policies (e.g., failure to consent subjects, entering subjects who do not meet entrance criteria into protocols, failure to report serious or unexpected adverse events).

d. If the monitor records no serious findings or concerns as listed above, the study investigator or research coordinator must notify the research office in writing that there were no such findings identified by the monitor.

Department of Veterans Affairs

Memorandum

Date: OCT 14 2004

From: Acting Chief Research and Development Officer (12)

Subj: Reporting of All Study Site-Monitoring Visit Results

To: Network Directors (10N1-23)

Thru: Acting Deputy Under Secretary for Health (10A)

Thru: Deputy Under Secretary for Health for Operations and Management (10N)

1. Many of the research studies conducted at VA facilities are monitored by entities external to that facility, e.g., pharmaceutical companies and Contract Research Organizations (CROs) through site visits. These site visits may be routine or conducted for specific causes. It is imperative that the appropriate research staff is notified of these visits and informed of any serious findings or issues of concern that result from the monitoring visits. To ensure that this occurs, this memorandum outlines issues that must be addressed and procedures that must be implemented. Please share the following information with your Associate Chiefs of Staff for Research and Development (ACOS/R&D).

2. The following guidance is applicable for each study that is monitored by a pharmaceutical company or CRO.

a. The ACOS/R&D or his/her designee is to be notified of all monitoring visits by pharmaceutical companies or CROs as soon as possible. This is the responsibility of the research staff person who schedules or confirms the monitoring visit. If the monitoring visit is unscheduled, the ACOS/R&D is to be notified as soon as the study personnel are aware of the visit.

b. The CRO or study monitor must sign in as a visitor at the research office as required of all visitors to research areas.

c. The Principal Investigator or other responsible investigator is to meet with the study monitor(s) prior to the monitors' beginning their work. During each visit by a monitor, the role of the monitor should be reviewed, including the new requirement that any potential or actual serious findings be conveyed to the investigator and the ACOS/R&D, Administrative Officer for Research (AO/R&D) or his/her designee during an exit interview. Findings that require an exit interview include but are not limited to:

(1) Any suspicions or concerns that serious non-compliance may exist, and

(2) All findings of serious non-compliance with the study protocol, Institutional Review Board (IRB) requirements or applicable regulations and policies (e.g., failure to consent subjects, entering subjects who do not meet entrance criteria into protocols, failure to report serious or unexpected adverse events).

d. If the monitor records no serious findings or concerns as listed above, the study investigator or research coordinator must notify the research office in writing that there were no such findings identified by the monitor.

3. Each research office must develop procedures that will ensure all serious findings and concerns found during the monitoring visit are appropriately addressed and the appropriate facility officials and committees are notified as required by facility policy. These procedures must also require that monitoring reports be submitted to the IRB at the time of continuing review.

4. Contracts with pharmaceutical companies must define the role of study monitors that is consistent with the requirements of this memo.

5. If you have any questions concerning this policy, please contact Brenda Cuccherini, Ph.D. in the Office of Research and Development at (202) 254-0277.

Stephan D. Fihn, MD, MPH

cc: ACOS for Research (151)
Medical Center Directors (00)