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Mission Statement

The mission of Seattle Institute for Biomedical and Clinical Research is to facilitate the research and educational programs conducted at VA Puget Sound Health Care System, Seattle and American Lake Divisions. SIBCR strives to provide outstanding support to VA staff in their research, education and training endeavors to foster progress in biomedical, clinical, rehabilitative and health care services programs that benefit the nation's veterans and the general public.

General Information

Seattle Institute for Biomedical and Clinical Research (SIBCR) serves the research and education endeavors of the investigators and staff at both divisions of VAPSHCS, for the benefit of the nation's veterans and the general public. SIBCR has been incorporated in the State of Washington as a nonprofit charitable corporation since 1989 and qualified as a 501(c)(3) under the IRS as a federally tax exempt nonprofit in 1990.

SIBCR is a membership organization whose members are staff at the Seattle and American Lake divisions leading scientific projects or educational programs. In order to perform its mission of support to VA research and education, SIBCR receives funds from gifts or grants from federal agencies, voluntary health organizations and other nonprofits, professional societies, for-profit companies and individuals. All funds expended by SIBCR directly or indirectly support its research and education mission. All results from VA-approved research are in the public domain.

SIBCR is governed by a fourteen member Board of Directors, none of whom receive compensation for that service.

SIBCR undergoes an annual financial audit by an independent auditing firm. The auditors annually report the results of the audit and their review of the financial operations to the Board of Directors.

Chapter 1

Membership Policy

Membership in SIBCR may be requested under the research mission or the education and training mission or both.

- SIBCR members are appointed by the SIBCR Board of Directors and hold membership positions at the will of the Board.
- Members are required to adhere to the policy and procedures described in the SIBCR Policy Manual as established by the Board of Directors and administered by the Executive Director.

CRITERIA FOR MEMBERSHIP INITIATION

Following are the general criteria to initiate membership:

A. Research

1. SIBCR members will be investigators of the Department of Veterans Affairs Puget Sound Health Care System (VAPSHCS), Seattle and American Lake Divisions and have staff appointments. Members will be engaged in the conduct of research as approved by the VAPSHCS Research and Development (R&D) Committee.
2. Application for membership is based a) upon R&D Committee approval of a research project on which the candidate is the principal investigator; or b) approval for Intramural Funds (see Chapter 7 of this Policy Manual). The Board of Directors must approve the election of all members. New member accounts may be set up in the interim period between Board meetings, but will not be approved accounts until the Board of Directors has met and voted on the candidate's membership.
3. Members are to conduct their professional activities in keeping with VA and SIBCR policy for ethical conduct of research activities.

B. Education

1. Education and training that may be supported by SIBCR include:
 - a) Work-related instruction or other learning experiences for employees that (i) improve performance of current duties; (ii) assist employees in maintaining or gaining specialized proficiencies; or (iii) expand understanding of advances and changes in patient care, technology, and health care administration.
 - b) For veterans under VHA care, the education and training may include instruction or learning related to improving and maintaining health of veterans and their families and guardians.
2. Members involved in education activities may be: a) individuals with staff appointments who are awarded an education training grant; b) a service chief who receives funds for

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the benefit of the education and training of the service line employees, patients, or caregivers; c) the responsible individual or designee for an education or training initiative or activity at VAPSHCS. Alternatively, if the organizer of an educational activity is not a member, a member may provide oversight for the individual activity.

3. The organizer of the proposed education activity or activities must obtain the approval of the Education Council (EC) for the activity. Please see the VAPSHCS memorandum HR-39, dated September 2001, for the EC policy and the procedures for approval of an education/training activity. This policy memorandum includes the procedures for approval of educational activities with non-VA funding administered by SIBCR. The policy memorandum is also available at www.sibcr.org.
4. To apply for membership in SIBCR, the organizer should obtain request paperwork from SIBCR for approval by the Board. The Board must approve all members.
5. Educational activities, including patient/family oriented education, must be conducted under highest standards and in accordance with all guidelines of VAPSHCS and the policies and procedures of SIBCR.
6. Special guidelines and procedures must be followed for all continuing medical education (CME) programs under VAPSHCS accreditation or under the VA Employee Education System (EES). All education activities that involve such accreditation for CME programs should be reviewed with SIBCR before any funding is sought. Agreements from sponsors of such programs need to be reviewed by either EES or the VAPSHCS Center for Education and Development to ensure all CME requirements are met and the agreement language is acceptable.

Please note that the education and training programs described above do not include educational coursework towards a degree or other academic coursework.

INACTIVE MEMBER

If a member does not use SIBCR funds to support any research or educational activity for three (3) years, membership may be forfeited.

MEMBER RESIGNATION OR RETIREMENT

If a duly elected member resigns or retires from VAPSHCS and no longer has a VAPSHCS appointment, membership in SIBCR is ended.

Chapter 2

Acceptance of Funds

SIBCR accepts funds in support of the research and education mission of VAPSHCS. All funds deposited in the Institute and all equipment purchased with Institute funds are the property of the Institute and are subject to policies and procedures established by the Board of Directors. Such policies and procedures will be consistent with applicable federal and state statutes and regulations.

The Institute may only invest in instruments backed by the full faith and credit of the U.S. Government.

Grantors or donors may send funds by check or electronic transfer. For direct deposits to SIBCR's account, the Controller will provide necessary information.

All checks or other funds directed to SIBCR should be made payable to the Seattle Institute for Biomedical and Clinical Research, Employer Identification Number (EIN) 91-1452438. Checks made payable to other individuals or organizations cannot be accepted. Prospective donors should be given a copy of the document "Information for Donors." This form is provided to all prospective members and is available at www.sibcr.org.

If funds are received in support of a specific research proposal, no funds may be expended until that project has received approval from the VAPSHCS R&D Committee.

If funds are received in support of a specific educational or training activity, no funds may be expended until that activity has received approval from the VAPSHCS Education Committee (EC).

SOURCES OF REVENUE

The general categories for revenue are: (A) voluntary health agency and private foundation grants; (B) corporate sponsored grants or studies or gifts; (C) federally-funded programs; (D) transfer funds and; (E) miscellaneous. SIBCR administration of the funding may vary depending on the stipulations of the funding source.

Funds derived from indirect support provided by the sponsored research or education activities administered by the Institute will be used to support the operation of the Institute. These institutional funds may also be used to respond to the needs for direct or indirect research costs or educational and training support as identified by the SIBCR Intramural Funds Committee, the VAPSHCS R&D Committee, the VAPSHCS EC and the SIBCR Board of Directors. The Board of Directors must approve all support provided.

A. Voluntary Health Agency/Private Foundation Research Studies

Funding in this category is derived from nonprofit entities to support a specific research or education proposal or a career development award. Indirect cost reimbursement rates vary among sponsors. Some sponsors in this category have written policies that either state the organization does not provide overhead costs or that set limits for this support. The

investigator should review the proposal and budget with SIBCR prior to submission to the sponsor. If required by the funder policy, SIBCR may accept and administer these sponsored awards with less than its approved indirect cost rate.

B. Federal Programs

This category consists of grants or contracts from federal agencies, other than VA but including the National Institutes of Health and Department of Defense. An indirect cost rate is negotiated with the relevant agency. For SIBCR, this is the Division of Cost Allocation, Department of Health and Human Services. The indirect costs are provided to the grantee institution in addition to the direct costs provided for support of the studies. The negotiated indirect cost rate is available at www.sibcr.org.

C. Corporate Sponsored Research or Education Grants

Funding in this category is usually provided by pharmaceutical or other commercial sponsors involved in the development of new drugs or devices, or in the support of medical research or education. The studies may be investigator-initiated or sponsored by the pharmaceutical company. Negotiations for this type of award should ensure that the SIBCR indirect cost rate is provided as an additional cost to the funding required for the study. The applicable rate should be reviewed with SIBCR administrative staff.

The Department of Veterans Affairs Office of General Counsel has determined that the appropriate mechanism for industry-sponsored or funded research is a Cooperative Research and Development Agreement (CRADA).

The Veterans Health Administration (VHA) Directive (2007-044) requires the use of a CRADA for industry-funded studies effective March 26, 2008. Clinical research agreements existing at that date will not need to be revised.

SIBCR cannot accept funds where the sponsor will acquire any services or product, other than review of intellectual materials or results, as an outcome of the research being supported.

D. Transfer Funds

Members may transfer to SIBCR funds from accounts at other nonprofit institutions. Indirect costs may have already been deducted or may not have been requested on these funds. Transfer funds will not be subject to SIBCR administrative overhead charges. Such exemption does not extend to funds in support of an active project being transferred; rather, project funds will follow the stipulations or guidelines of the funding agency or institution.

E. Miscellaneous Support

Sources for funding in this category may be broad and may include gifts or other donations from individuals or public or private entities. Single awards or donations or \$2,000 or less will not be charged overhead unless the award represents a portion of a larger contribution. Deposits totaling more than \$2,000 generally will have an overhead rate applied to unrestricted donations that are not related to a specific project or projects.

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SPECIAL CONSIDERATIONS

Ethical considerations: VA investigators sometimes wish to have an honorarium, consulting, or speaker fee directed to a VA-affiliated nonprofit corporation such as SIBCR as a donation in lieu of accepting it personally. Some apparently do this in the belief that donating a fee to a nonprofit relieves them of the need to make sure the subject of their presentation is not related to their official VA duties or the need to take annual leave. However, federal ethics regulations at 5 CFR §2635.807 allow federal employees to earn fees for presentations related to their official duties *only* if they are teaching a course requiring them to make multiple presentations during a program of education or training sponsored and funded by the federal government or by an institution of higher education, an elementary school, or a secondary school. As far as we have been able to determine, this is the only exception; there is no exception for turning the payment into a donation to a nonprofit.

Tax implications: Investigators sometimes also believe they will not be assessed personal income taxes on a speaker fee if they instruct the payer to send the check to a nonprofit. However, the IRS is likely to view as income amounts earned any time there is a *quid pro quo* - an exchange of goods or services for payment - or when an individual exercises control over dispensation of payment. Such payments may be taxable to that individual regardless of whether payment goes to a nonprofit or the individual accepts it personally. Acceptance of such funds may be viewed as tax avoidance by the IRS, affecting both the investigator and the nonprofit.

Personal benefit concerns: Finally, investigators often wish to specify - or simply expect -that their donation of speaking fees, writing fees and consulting payments will be available to support their own research. In some cases, investigators may want to direct a personal donation for their own research program.

In IRS terms, their expectation is that use of the gift is “restricted” to their own research. However, the IRS has asserted that such contributions could provide a prohibited actual or perceived benefit to the donor if the donor subsequently controlled or even influences use of the gift. This jeopardizes the nonprofit’s exempt status because no nonprofit assets may benefit an individual associated with the organization.

The SIBCR Board of Directors has formally determined that gifts from members will be accepted only if completely unrestricted or used for a research program other than the member’s program.

One option is for SIBCR to send a letter to the sponsor requesting an unrestricted donation to SIBCR in lieu of an honorarium. These funds may be deposited into general funds. Use of the funds will be under the control of the Board of Directors. Special requests for use of these funds can be directed to the Board. Members should contact the SIBCR Executive Director if such a donation request is contemplated.

Chapter 3

Transfer of Funds and/or Equipment

All funds are the property of SIBCR and remain under the control of the Board of Directors. All SIBCR-owned equipment is the property of SIBCR and is under the control of the Board.

No funds or equipment may be transferred to for-profit organizations.

Any residual funds and equipment attributable to completed research projects or educational activities must continue to benefit VA research or education. The Board may consider a request to transfer the funds or a portion of the funds to another VA-affiliated nonprofit corporation established under 38 U.S.C §§7361-7368. A request may be made to the Board of Directors that the residual funds not eligible for transfer be used to support another member's research or education activity.

Transfer of Active Projects to Another Institution

If the member is moving to an academic nonprofit or other nonprofit research institution and will continue an ongoing VA-approved research project, funds received by SIBCR attributable to that project may be transferred to that institution at the discretion of the Board of Directors. If such funds retain donor-imposed restrictions, SIBCR may be required to return remaining funds to the donor. Equipment purchases with SIBCR attributable to that project may also be transferred at the discretion of the Board of Directors. Sponsor notification and approval are usually required. The destination institution must request the transfer and agree in writing to accept responsibility for the project, funds and equipment.

Transfer of Active Projects Within Institution

If a member resigns before a project is completed, the member may request that another SIBCR member assume responsibility for research or education activities with SIBCR funding. This request requires either R&D Committee approval or EC approval, the approval of the SIBCR Board of Directors and if necessary, sponsor approval.

The member should submit a written request to the Board of Directors for review. This request should be sent through the Executive Director as soon as possible in order to obtain necessary information for review by the Board.

Chapter 4 Inactive Accounts

After research study closeout or completion of an educational activity, residual funds may remain. Some accounts may have funds remaining from gifts or other unrestricted grants not associated with a specific project.

If there is no activity on any given account for the period of a year, the member will be contacted to determine an appropriate plan for expenditure. The SIBCR bylaws state that accounts inactive for three years are subject to closure.

If there is no plan to spend funds in an inactive account in a timely way, the funds may be used for general research support to the R&D program as determined by the Board of Directors.

If there is sufficient rationale for some or all of the funds to be merged with that of a VAPSHCS collaborator or other member, a formal request should be made to the Board of Directors for their consideration.

Chapter 5 Research Activity Cycle

GRANT SUBMISSION PROCESS

In order to submit a grant to an outside sponsor (including voluntary health organizations, other nonprofits, federal agencies or corporate sponsors), please review the SIBCR Grant Guide for details; information is available on the SIBCR website under Research Grants. The information on the website provides the most complete and up to date information available.

SIBCR must review all grants prior to submission and receive a completed Grant Review Submission form for each project. For projects that require services or subcontracts with other organizations, please submit the materials to SIBCR no less than three weeks or fifteen business days prior to the submission deadline. Shorter times may be acceptable if no other organizations are involved.

For investigator-initiated projects obtaining corporate support, a Cooperative Research and Development Agreement (CRADA) must be established between SIBCR, the corporate partner, and VAPSHCS. Negotiation of CRADAs will be initiated by SIBCR once the investigator has provided necessary information. All such CRADAs must be signed by SIBCR and VAPSHCS. Investigators cannot enter into funding agreements that bind SIBCR or VAPSHCS in any way.

Please note that Veterans Affairs Central Office (VACO) requires that the local VA R&D Committee review proposals being submitted to granting agencies prior to their submission to the sponsor. Principal Investigators submitting grants through SIBCR should submit to the R&D office Pre-Awards Manager the scientific abstract and a completed Grant Review form. For grants submitted through SIBCR, the Grant Review form can be found under the forms section of the SIBCR website.

If an investigator-initiated project is a clinical trial, the investigator must register the trial on the website ClinicalTrials.gov. Please contact the Executive Director for more information.

CLINICAL STUDIES

For clinical studies sponsored by pharmaceutical companies, the investigator should advise SIBCR as soon as the determination to participate is made. Sponsor contact information including name, email, and phone number will be needed. SIBCR will oversee the negotiation and establishment of a CRADA for the project.

SIBCR will also assist with budget review and finalization, including any requirement for human subjects review costs.

When preparing the budget, the investigator and study staff should ensure that all costs for conducting the study will be covered. VAPSHCS must be reimbursed for all services utilized in support of a research project that are in addition to those required for standard patient care. If VAPSHCS services are used (e.g. laboratory, radiology, surgery), the investigator or study coordinator must complete a Research Use Agreement form for each such service line prior to finalizing the study budget, or must obtain an equivalent memorandum of agreement with the relevant service line. By agreement between SIBCR and VAPSHCS, the rate of reimbursement is 90% of the current Medicare charge for a given procedure, unless an exception is formally

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requested and approved. For more information on this, see the section below, "Reimbursing the VA for Clinical Costs".

If the Clinical Research Unit will perform required procedures or otherwise assist in the study, those services should also be included in the budget.

The investigator should ensure that all regulatory and compliance issues are addressed, including possible requirements for an FDA Investigational New Drug application.

POST AWARD

For all research studies, projects cannot be initiated nor any funds expended, prior to VA R&D Committee approval. R&D Committee approval will not be given until all committee and subcommittee reviews and approvals have been secured. This may take up to eight (8) weeks or more if Human Subjects Committee approval is required.

In order to avoid a significant delay in study start up, the approval process should begin as soon as the sponsor notifies the PI and/or SIBCR that a grant or project will be funded.

For studies with corporate funding, generally the CRADA is negotiated at the same time that the project is being reviewed for IRB approval, so that the project will not be delayed. If any other subcommittee approvals are required, they will need to be completed prior to R&D Committee approval.

The following are the relevant committees for approval of research projects as applicable.

- R&D Committee
- Human Subjects Review Subcommittee or Institutional Review Board (IRB)
- R&D Biohazard Committee
- R&D Safety Committee
- Institutional Animal Care and Use Committee (IACUC)
- Recombinant DNA Committee
- Approval of the facility Radiation Safety Officer must be obtained for projects using radioactive compounds or procedures.

After a study has received all required approvals and funding has been received, an SIBCR project account will be opened. The account number will reflect the VA RDIS number assigned after R&D Committee approval.

Funds may be expended from the project account in accordance with the study budget, all relevant guidelines of the sponsor, and SIBCR policy. Financial reports will be provided monthly to members for each project or separate fund.

For all studies that use VAPSHCS clinical resources, the VA Medical Care Appropriation must be reimbursed for any costs incurred for work over and above the standard care required for normal patient care. Study coordinators must ensure that the relevant service lines have current and complete information on actual usage. SIBCR will review projects at least annually to verify that bills of collection have been received for these services in accordance with the Research Use Agreement(s) on file.

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SIBCR will send all required financial reports to sponsors. The principal investigator will be responsible for any scientific progress reports.

REIMBURSING THE VA FOR CLINICAL COSTS

This procedure applies to all extramurally-funded research projects administered by SIBCR, regardless of source (e.g., private industry, voluntary health organizations, NIH or other federal grants). It covers all research projects approved for conduct by VAPSHCS that involve provision of medical care services, such as radiology, cardiology, laboratory medicine, or others as defined by service lines.

Research use of such services consists of:

1. Services provided over and above standard medical care for an eligible veteran;
2. Services provided to a non-veteran participating in a research project (except those provided under 38 CFR §17.85).

Prior to approval of a study, investigators should notify each required service of their intent and seek agreement with them to collaborate in the study. This review and approval will ensure the service has the wherewithal to provide the required study procedures.

At this stage, the investigator or designee should verify the exact CPT or LMIP code for the procedure requested and the charge per procedure. The charge will be the standard rate of reimbursement as set by agreement between SIBCR and VAPSHCS, which is determined to be 90% of the current Medicare rate. Note that Pharmacy and the Clinical Research Unit have separately determined charge schedules that are not encompassed by this procedure.

These written agreements, signed by the service line leader or designee and by the investigator and study coordinator, become a part of the approval packet for the R&D Committee.

After the approved study commences, each providing service must receive a completed Request for Procedure or Test form for each research subject receiving a medical care procedure or test that falls under category 1) or 2) above. On a periodic basis, the service will compile an invoice of charges from research usage and present it to SIBCR for payment.

Rate Exceptions for Medical Service Reimbursement:

Occasionally a research project may be proposed that would significantly further the VA mission but has unusually limited support from its sponsor. If the cost of medical service reimbursement is a specific obstacle to the conduct of such a study, the PI may request a special, project-specific exception to the standard rate.

The PI must prepare a written request for an exception to the rate, describing the particular value of the proposed project to VA patients and VA care, the source of funding and the nature of its limitations, and a justification of the rate that is being requested. The written request will be reviewed by the relevant service line leader, the VAPSHCS Deputy Director or designee, and the SIBCR Executive Director. These individuals will confer with each other and the PI and arrive at a consensus decision as to whether the reduced rate is granted. Such a rate may only be applied to the specific research project for which it was approved, and must be approved prior to the project's submission to the R&D Committee.

STUDY CLOSEOUT

A study account should not be closed in SIBCR prematurely. When the study is completed and all expenditures have been made including for publication costs, the member should inform SIBCR to close the account. Generally, this occurs at the same time as the study is removed from the R&D list of approved projects.

For grants that require final reports to the sponsor, the grant account will not be closed until the final report has been submitted and accepted by the grantor.

Most granting agencies will require return of all unencumbered or unexpended funds. However, requests for no-cost extensions are usually allowed if appropriate scientific rationale is provided. This allows an extension of the grant period and continued use of the project funds.

Sponsors may require requests for no-cost extensions to be received prior to the expiration date of the project. Due dates may vary depending on the sponsor.

If residual funds remain after completion of the project, all expenses have been paid, and there is no requirement by the sponsor to return unexpended funds, these monies may be transferred to a general research account ("zero account"). These funds can be used for general research expenditures within Board-approved policies.

Chapter 6 Education Activity Cycle

INITIATION AND APPROVAL

All educational activities to be administered by SIBCR as described in Chapter 1 must be approved by the VAPSHCS Education Council (EC). Please submit the Request for Review and Approval of Non-Profit Educational Activity form (available on the SIBCR website) to SIBCR. SIBCR will submit it to the EC for review. The EC will base its recommendations for proposed activities on applicable VA Education Manual policies pertaining to conflict of interest and appropriateness to VA's education and training missions as well as the definition of education and training established by PL 106-117, Section 204 (Title 38, §7362). The Council meets in person quarterly and will review proposals on an ad hoc basis by email throughout the quarter.

The activity may be a one-time event or an ongoing series. SIBCR will review the request, request additional information if necessary, and approve it before submitting it to the EC. The request should include an estimated budget for the program(s) with the most inclusive list of types of expenditures that may be made in support of the activity. In this way, once EC approval is received there will be no need to file an amendment for approval of types of expenditures that were not included in the initial budget.

If funds to support the activity must be solicited from outside sources (including individuals, corporations, or other organizations), such solicitations may not be made by VA employees in their official position. SIBCR will make the request. There is a template request letter on the website that is appropriate for most programs. Please provide the necessary details and submit a completed draft letter electronically to the Executive Director. The request letter will be reviewed and sent on SIBCR letterhead over the Executive Director or Assistant Director's signature.

If the template letter is not appropriate for a specific program or request, please provide details to SIBCR so that a letter tailored to the program can be sent.

For programs accredited either through VAPSHCS or the Employee Education System (EES), there are additional guidelines. If the sponsor requires a formal grant agreement, the agreement must meet the requirements of the accredited provider (VAPSHCS or EES).

Corporate sponsors will require formal agreements for educational grants, whether for CME or non-CME.

SIBCR works with both EES and VAPSHCS on accredited programs that have outside sponsors. Most corporate sponsors have agreed to follow certain guidelines for the support of educational programs that meet the standards required for accredited programs. These guidelines were published in 2002 as the "*PhRMA (Pharmaceutical Research and Manufacturers of America) Code on Interactions with Healthcare Professionals.*" Other relevant guidance can be found in the Federal Register dated December 3, 1997 (Volume 62, Number 232) page 64073-64100. The document is called "*Final Guidance on Industry-Supported Scientific and Educational Activities.*"

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In addition to these documents, both VISN 20 and VHA have published guidance on interactions with pharmaceutical sponsors. For VHA, it is the VHA Directive 2003-060, dated October 21, 2003, on "*Business Relationships between VHA Staff and Pharmaceutical Industry Representatives.*" The VA Northwest Network, VISN 20 has also executed a "*Vendor Gratuity Policy Memorandum*" (10N20-2004-003, January 23, 2004).

Again, no educational activity can be initiated until approval of the EC has been received.

POST AWARD

Funds received in support of educational programs usually have explicit restrictions on their use.

Educational grants and activities will be tracked individually by SIBCR and will have a designated fund number and name. Monthly financial reports will be provided to the responsible member or designee.

The EC will require an annual report on ongoing activities. For one-time events, the EC will notify the responsible member or designee for the necessary report. The financial data for the report will be provided by SIBCR.

Funds received in support of an accredited program often have additional restrictions. If some funds remain after the initial approved activity, these remaining funds cannot be used in support of other similar accredited programs unless it is allowed for in the grant agreement.

CLOSEOUT

As indicated above, educational grants are usually received with explicit instructions limiting expenditures to a particular program or activity. Therefore, funds remaining at the end of an activity may have to be returned to the sponsor or used only as allowed for education as in the original donation. If possible, SIBCR will include wording in all requests that will allow as broad usage as possible for educational activities.

Chapter 7

Intramural Funds Policies and Procedures

Purpose

Intramural funds are available for providing grants to start up, develop or retain research investigators. There will be a commitment to flexibility in providing such funding to SIBCR-qualified principal investigators.

Generally, in determining what to fund, the following factors will be considered:

1. Start up funds for new investigators
2. Funds for novel ideas or pilot projects for new/junior investigators
3. Development of new or novel projects within a member's existing program

Overview

All requests for SIBCR Intramural Funds must be accompanied by a specific plan for applying or reapplying for extramural funding, and all remaining sources of support must be provided.

All applications will be reviewed by the Intramural Funds Committee (IFC). The three members of the committee are selected by the Board in order to have clinical and laboratory research expertise and both MD and PhD representation. In addition, a Board liaison and the Executive Director are appointed to the IFC. The Executive Director will be a non-voting member. Either the Board liaison or the Executive Director must be present at all IFC meetings.

Who May Apply:

1. All intramural fund applicants must be SIBCR members or applicants for SIBCR membership.
2. a). New Investigator: Applicants must be individuals who are recently appointed at VA Puget Sound Health Care System (VAPSHCS); or who want to initiate a research program administered by SIBCR; or who have had some career development funding and want to develop novel or pilot project data in order to compete for peer-reviewed funding.
b). Current Investigator: Applicants must be individuals who have experienced a recent reduction in funding due to non-renewal of a grant application or termination of an existing grant or contract. The investigator must have, in total, less than \$50,000 in direct cost extramural grant support at the time of the award.

Note: Recruitment Incentive: If SIBCR funds are to be included as part of a recruitment package, a separate process will be followed. The ad hoc Management Committee of the SIBCR Board will be advised of the potential candidate and the suggested intramural award. If they agree the candidate is important to the future of the VAPSHCS clinical mission and/or to the research enterprise, they will forward the

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request to the IFC. If the IFC agrees the qualifications of the candidate and the benefit to VAPSHCS merit an award, they will approve and forward for a vote of the Board. This vote may be done electronically. The candidate must agree to apply for SIBCR membership as soon as possible.

Application Process and Conditions:

1. Requests for funds should include the following information:
 - a) One page narrative describing the PI's area of research
 - b) List of all outside funding received by the PI during the three years preceding the request (all funding, through any administering institution, must be listed)
 - c) Current CV and publications
 - d) Description of anticipated proposals to be developed, potential funding sources, and timeframes for submission.
 - e) Detailed budget and budget justification for requested funds.
2. The performance site of proposed future research must be within assigned VA space.
3. The applicant may not request support for his/her salary.
4. The upper limit of a request for direct funds should not exceed \$30,000/year.
5. Upon receipt of funding from an outside sponsor, all unused funds awarded by SIBCR in the PI's Intramural Funds account will be returned. Intramural funds may not be added to the sponsored research award.
6. Intramural funds awarded through this process cannot be "banked" for a future lack of support beyond the agreed term of the award. The recipient may make a request to the IFC to carry-over funds within the grant years awarded.

Approval Process

A request for funding should be directed to the IFC via the SIBCR Executive Director. The Executive Director will review the request for accuracy, confirm available funds, and forward it to the IFC. The committee will make its recommendation to the Board of Directors which will make a decision for or against support. Grants will be awarded on a funds available basis. The IFC will meet when requests are received. Requests may be made at any time.

A record of awards by amount and service line will be kept for review by the IFC and the Board in order to evaluate the fairness of the selection process over time.

Chapter 8

Purchasing

GENERAL GUIDANCE

The Executive Director or designee and the Treasurer of the Board are the only officials authorized to commit the expenditure of SIBCR funds.

If it is unclear whether any item or service should be paid for by SIBCR, the Executive Director will determine the appropriateness of the request.

Purchases that provide personal benefit are not allowed, nor are purchases that may give the appearance of a conflict of interest. Please note that some of the IRS rules in this area are not intuitive. SIBCR will provide guidance, but final authorization of payment rests with the Executive Director. Please review this section and whenever appropriate discuss the proposed purchase with SIBCR before ordering.

The following requirements apply for all purchases:

- Sufficient funds must be available in the requester's account to cover costs;
- A research rationale must be provided for each research-related purchase; for education activities the expense must be within the scope of the proposal as approved by the EC;
- All purchases for sponsored research projects must be reasonable and necessary for the performance of the project, as well as allowable and allocable under the terms and conditions set forth in the grant.

SIBCR funds may not be used to pay professional licensure payments. Also, the costs of CME credits cannot be paid for members.

SIBCR is not exempt from state sales and excise taxes and must pay tax on all tangible goods purchased for use in Washington State. If sales tax is not charged, SIBCR is required to pay use tax to the state. See High Technology Sales/Use Tax Deferral under Equipment in this chapter for the sales tax exemption on certain equipment.

No expenditures will be authorized for donations to organizations engaging in general charitable or other philanthropic activities unrelated to research conducted at VAPSHCS.

GENERAL PROCEDURES

Orders must be placed by members or an authorized designee.

An SIBCR purchase order (PO) is required for all purchases made using SIBCR vendor accounts. Forms are available on the SIBCR website or from the accounting office. Please clearly indicate SIBCR as the "bill to" party with the mail stop of 151F included.

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SIBCR maintains accounts with most of the vendors used by the VA and UW. A list of current vendors is available at www.sibcr.org under accounting forms.

The SIBCR accounting office will establish and approve new vendor accounts in advance of the purchase. Please contact the accounting staff with the vendor information. You will be notified once an account has been set up with the new vendor.

Members may give signature authority on their SIBCR accounts to individuals they designate. The authorization may include dollar limits on the purchasing authority. SIBCR will periodically review the signature authority on members' accounts.

An authorized signer on the SIBCR account must sign the PO. The signed PO serves as authorization for payment by SIBCR upon receipt of the invoice from the vendor.

Fax the completed, signed PO to the SIBCR office and mail the original form to Accounts Payable, S-151F.

The member or designee should verify receipt of the complete order, and inspect for damage, defects or other errors.

Please contact the accounting office immediately with any discrepancies with your items that will affect the invoice. This process will serve as documentation to verify discrepancies between items ordered, items shipped and items invoiced.

The recipient must initial and date the packing slip from received items and send it to the SIBCR accounting office. If a packing slip was not included with the items received, then the Packing Slip Replacement form must be completed. The form can be found at www.sibcr.org under accounting forms. SIBCR will not pay an invoice without first receiving the corresponding packing slip or Packing Slip Replacement form.

SIBCR will issue payment for the order upon receipt of the vendor invoice matching the authorized PO and packing slip.

PURCHASE REIMBURSEMENTS

A completed, signed Check Request Form should be submitted to SIBCR to initiate payments for the occasional purchases made not using an SIBCR PO. These forms are available at www.sibcr.org under accounting forms.

All Check Request Forms must be accompanied with original receipts. Photocopies or facsimiles are not acceptable.

All requests for payment or reimbursement should be made in a timely manner. NOTE: SIBCR reserves the right to deny payment for invoices or receipts held for more than 90 days.

PROFESSIONAL MEMBERSHIPS AND SUBSCRIPTIONS

Subscriptions must indicate a business, not a residential, address for delivery.

Memberships and dues are generally not allowable expenses through SIBCR. There are certain conditions that may allow memberships to be paid/reimbursed through SIBCR.

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Professional societies that are general in nature and not specialty driven are not allowable expenses.

For research oriented memberships, the organization must have a research focus demonstrated by provision of a research journal(s) and/or scientific meetings. Payment of such memberships is predicated on the membership providing a journal or other subscription that would be at a much higher cost to non-members (possibly in excess of the total membership if purchased separately). In some cases, an organization's journals are not available to non-members. Alternatively, a relevant research membership may provide access to the annual research meeting at a significantly reduced rate, and so justify membership as the prudent business decision.

Prior approval of the EC is required for educational memberships/subscriptions without research relevance. Educational subscriptions must show a benefit to VA or SIBCR employees or to VA patients.

If the subscription rate or annual meeting costs are not sufficiently reduced, SIBCR may not pay for the memberships.

GRANT PURCHASES

For all the purchases under the Federal Government Grants Programs, SIBCR abides by Circular A-110 of the Office of Management and Budget of the United States. OMB A-110 requires that we provide a:

- Basis for vendor selection;
- Justification for selected or sole source purchases; and
- Basis for the price of the purchase.

SIBCR maintains accounts with vendors who are competitive and generally offer the lowest price available. SIBCR vendors often match the prices given to the VA (GSA) or University of Washington. Questions and concerns with vendor selection or competitive pricing may be directed to the SIBCR accounting office.

PURCHASING RULES BASED ON COST THRESHOLDS

Funds for payroll costs (including properly executed personnel agreements) are excluded from this policy.

Purchases under \$5,000

SIBCR understands the need to maintain continuity of vendors during the course of research. Also, the volume of purchases under \$5,000 makes it impractical to supply written price comparison documentation for each purchase.

Members and their designees are required to use sound business judgment and to rely on professional experience in making the buying decision. All reasonable effort should be made to use and verify available discounts, check comparable market prices and review past purchase orders for similar items.

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Purchases \$5,000 to \$24,999

When a member or designee must use a single or sole source in the acquisition of a product or service with a cost of \$5,000 or more, a vendor justification form is required.

Single source means other sources are available but the PI chooses to use only one particular source.

Sole source means that no other source than the one recommended is available.

The Vendor Justification Form can be found at www.sibcr.org under accounting forms.

Please contact the SIBCR accounting office in advance of making these types of purchases.

Purchases \$25,000 to \$49,999

Purchase requests greater than \$25,000 must be submitted to the SIBCR accounting office for approval. Members and their designees are strongly encouraged to obtain competitive bids for all purchases over \$25,000.

All purchases over \$25,000 must include documentation of the need for the purchase, the basis of the contractor selection and the price data.

A member's request for an expenditure of funds in amounts between \$25,000 and \$50,000 during any 30-day period shall require 30 days' prior notification and SIBCR approval.

See also the information under Purchases over \$5,000.

Purchases exceeding \$50,000

SIBCR requires three bids on all purchases over \$50,000. Exceptions may be made for professional services and brand or trade name products or proprietary services available only from a sole source, or for those designated to match others in use at a particular qualified institutional location.

The purchase request and competitive bids must be submitted to the SIBCR accounting office prior to placing the order.

A member's request for an expenditure of funds in amounts between \$25,000 and \$50,000 during any 30-day period shall require 30 days' prior notification and SIBCR approval.

A member's request for expenditure of funds for amounts greater than \$50,000 during any 30-day period shall require 60 days' prior notification and SIBCR approval.

Exceptions may be granted in an emergency with the concurrence of the Executive Director and the Treasurer.

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SUPPLIES

Laboratory supplies (including animals) and research office supplies may be purchased with research rationale provided.

Supplies purchased for an educational activity must be within the scope of the activity as approved by the EC.

Laboratory Animals

The Animal Research Facility (ARF) supervisor or the Veterinary Medical Officer (VMO) must approve in advance any animal orders that are to be delivered to the VA. Approval must be obtained before the order is placed with the vendor. This policy is to assure that only animals for which there is an Institutional Animal Care and Use Committee (IACUC) approved protocol are ordered; that an acceptable vendor is used; that space and caging are available; and that, should an expected order not arrive, it can be immediately investigated.

To obtain approval, you may send an email message to the VMO or ARF supervisor. An approval response will be sent back to you. An email message and response will provide confirmation that the order is approved. You may also contact the VMO or ARF supervisor by phone for approval. However, leaving a voice mail message is not sufficient.

The request must include the following information:

Principal Investigator	Protocol Number (IACUC number)
Species of Animal	Strain
Quantity	Age or Weight
Sex	Vendor
Source of Funds (SIBCR)	Any special housing or care instructions
Date of Arrival	Contact person/phone number

Please contact the VMO if you have questions about this policy.

Radioactive Materials

The preferred method for purchasing radioactive substances is to order through VAPSHCS. In those cases where SIBCR is used, the following should be done:

- The RSO must be notified by telephone at ext. 6-1433 whenever radioactive material is ordered. Notification must include the PI's name, isotope, quantity, and expected delivery date.
- The radioactive material must be covered under the site license, have the member's authorization and be approved by the RSO. Check with the Radiation Safety Officer (RSO) prior to ordering any material.
- Every order must clearly specify that delivery should be to the RSO.
- The investigator name should appear as user so the RSO will know where to send the supplies after the material is checked.

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ELECTRONIC DEVICES

Computer and Laptop Purchases

SIBCR funds may be used to purchase desktop and laptop computers for use in or support of VA-approved research. SIBCR funds may not be used to purchase a desktop computer for home use. To purchase a laptop computer, a specific rationale that explains the need for a laptop instead of a desktop computer must be provided.

Purchases in support of an educational activity must be within the scope of the proposal as approved by the EC for all education activities.

Computers purchased with SIBCR funds that are not related to federal awards may later be donated to the VA for use on the VA network if required. Forms for donation can be obtained from the SIBCR accounting office.

SIBCR computers may not be used to store VA sensitive data and may not be linked to the VA network.

All computers and laptops purchased with SIBCR funds are identified with purple tags for inventory and disposal purposes.

Computer Disposal

Principal Investigators are required to return all computers and laptops to the SIBCR Accounting Office for disposal.

It is the responsibility of the Investigator to ensure that all personal programs and information have been erased from the hard drive prior to returning them to SIBCR.

All data held on the computers will be irrevocably erased before disposal by either the SIBCR Controller or VA ADPAC.

These requirements apply to all computers (PCs, Macintosh, UNIX, etc) as well as other items of computer equipment (e.g., printers, scanners)

All computer equipment will be disposed of in an environmentally-friendly manner.

Other Devices

SIBCR funds may not be used for the purchase of cell phone equipment.

Personal Data Assistant (PDA) devices may be purchased, but must include a specific research-related rationale for their use and should reflect reasonable pricing.

Other specialty devices or electronic items such as digital cameras may have a valid research rationale, but due to the potential personal use must be pre-approved before purchase.

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Donation of Animal Purchases and Expendable Supplies to VAPSHCS

The VAPSHCS Institutional Animal Care and Use Committee, established in accordance with Federal law, reviews all studies involving the use of animal subjects. Only studies approved by this committee and its parent VAPSHCS R&D Committee are conducted at VAPSHCS facilities. The animal research program and facilities are accredited by the American Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC); the program is appropriately registered with the US Department of Agriculture; a current assurance is on file with the NIH Office for Laboratory Animal Welfare. SIBCR is included within this assurance.

Within the requirements of the law, and in order to eliminate duplication of registration, review and reporting activities, it is SIBCR policy that any animals purchased by SIBCR for the purposes of research are immediately upon receipt donated to, and become the property of, VAPSHCS.

SIBCR also utilizes VAPSHCS resources for such activities as handling and removal of medical and laboratory waste, including radioactive materials and other hazardous or controlled materials. In order to ensure conformance with requirements of the law and to eliminate duplication of activities, it is SIBCR policy that all expendable supplies purchased by SIBCR that are to be used in VA research laboratories for approved research and educational activities are immediately upon receipt donated to, and become the property of, VAPSHCS.

EQUIPMENT

The acquisition of any equipment requiring space, utilities or other resources not available in the member's assigned research space must be reviewed by VAPSHCS R&D administration prior to placement of the order. Equipment to be purchased as part of an educational activity must be explicitly included in the proposal as approved by the EC.

Members should advise SIBCR of any equipment purchase prior to placing the order to assure sufficient funds are available. Note that SIBCR is not exempt from Washington State sales tax and the appropriate amount must be included in your cost estimate unless the equipment is eligible for the High Technology Sales Tax Deferral (see below).

Equipment purchased with SIBCR funds will be classified according to the depreciation policy as defined below.

EQUIPMENT INVENTORY AND DEPRECIATION

A. Fixed Assets

1. Durable, non-expendable items with an acquisition cost of \$5,000 or more with a useful life of more than a year will be considered equipment. All such equipment, including furniture, will be SIBCR property and listed as a fixed asset.
2. GAAP (Generally Accepted Accounting Principles) require that such fixed assets be depreciated over a reasonable term or the estimated useful life. Therefore, fixed assets will be depreciated using the straight-line method at a term set uniformly at five (5) years.
3. The equipment or furniture listed as part of the Institute's fixed assets will be affixed with an SIBCR property tag and tracked biennially for location and condition.

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4. The acquisition cost will include all reasonable components that allow the equipment to function. The acquisition date will be the date of the invoice.

B. Inventory

1. Durable items (equipment/furniture/computer systems) purchased with SIBCR funds for less than \$5,000, but greater than \$2,000 will be listed on the SIBCR inventory and affixed with an SIBCR property tag in order to maintain an inventory record.
2. These inventory items will be tracked biennially for location or status, but will not be depreciated as fixed assets by SIBCR.
3. Individual components purchased for \$2,000 or more and added to an existing computer system will be tagged as SIBCR inventory, if reasonable to do so.
4. A durable item purchased for less than \$2,000 will not be tagged or listed as inventory.

If a member transfers to another 501(c)(3) research institution, s/he may direct a request to the Board of Directors to transfer fixed assets or inventory items that were purchased with SIBCR funds if the item will continue to benefit VA research or education. Please see Chapter 3: Transfers of Funds and/or Equipment for more information.

A member may request that SIBCR items purchased with non-federal funds be donated to VAPSHCS for research support.

Durable items ordered through SIBCR will ordinarily be delivered to VAPSHCS and will be subject to acceptance based on available facilities and safety policy.

Chapter 9

Subject Payments

Subject payments and reimbursements to patients and volunteers for their participation in a study must be issued in accordance with the Human Subjects Committee and the R&D Committee approvals for the project.

For all such participation payments or reimbursements, appropriate language must be in the human subjects consent form or Health Insurance Portability and Accountability Act (HIPAA) addendum to notify the participant that the individual's Protected Health Information (PHI) will be released to SIBCR in order to process such payments. If the study will require release of PHI to SIBCR in order to pay for diagnostic tests not available at VAPSHCS and obtained from outside vendors for the participant, the consent form should also include this information.

Subject participation payments of \$600 or more in a given calendar year are taxable income and SIBCR is required to report the payment to the IRS and send an IRS 1099-MISC form to each such recipient. SIBCR therefore requires the Social Security Number and permanent mailing address of each individual to whom subject payments are made if it is possible this \$600 threshold will be reached.

NOTE: The \$600 threshold does not include reimbursement of costs (e.g., travel) incurred by study participants.

Chapter 10

Travel

SIBCR may support expenses for travel of authorized individuals to bona fide scientific meetings or for other research or research-related educational purposes. The travel support will be consistent with SIBCR policies and the stipulations of any relevant funding source(s).

The EC must approve travel related to educational or training activities. If the travel reimbursement is for a visiting fellow or scholar, the visa status of the individual must allow such reimbursement. SIBCR must pre-approve travel for foreign fellows or scientists.

Travelers should purchase their own tickets, pay for their costs, and apply for reimbursement after the travel is completed. Cash advances and pre-paid airfare are generally not provided to members or other non-SIBCR employees. Cash advances and pre-paid airfare may be available to employees.

The request should be submitted on the Travel Reimbursement form. Requests for reimbursement should be submitted within 60 days after travel has been completed.

If another organization is providing partial reimbursement for a trip, sufficient information must be provided to SIBCR to show that we are reimbursing appropriately. For example, the VA travel documents showing which items have been reimbursed and the amount.

Documentation of the meeting dates, location, and topic or theme must be provided. A program guide or brochure (a copy of the cover is sufficient if all the information is stated on it); an invitation letter; or other written documentation that includes the dates, location and purpose must be submitted with the reimbursement request.

Individual items \$25 or greater in cost must be accompanied by receipts. Items costing less than \$25 need only be itemized on the Travel Reimbursement form.

NOTE: Original receipts are required for reimbursement.

Registration: Meeting registrations may be pre-paid through SIBCR directly to the meeting organizer. Alternatively, the registration cost will be reimbursed after the meeting along with other travel expenses.

Lodging: Full reimbursement of reasonable hotel expenses with appropriate documentation will be made. The original itemized hotel bill must be submitted with the reimbursement request.

Per Diem: The per diem reimbursement (meal and incidental expenses) will be at the federal per diem rate. These rates are posted on the SIBCR website. Travel days will be paid at 75% of the federal rate, regardless of the time of departure. Travel that begins and ends within the same day (e.g., 7 AM to 7 PM) will not include per diem reimbursement.

If a member plans to host a special dinner meeting with research collaborators, these costs must comply with the policy on "Meeting and Conference Support" (Chapter 11 of this Policy Manual). Such events should be pre-approved with the Executive Director or designee to ensure that reimbursement will be allowable.

Transportation: Reimbursement for travel costs will be based on the most reasonable method of travel to the location, generally coach airfare.

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If the traveler chooses to take an indirect route, interrupt the business travel or utilize a mode of travel that requires additional accommodations en route, any resulting expense will be borne by the traveler.

The cost of a rental automobile may be allowable under certain circumstances. For example, if rooms are unavailable at the conference hotel, a shuttle service is not available, or cab fare is prohibitively expensive. However, car rental is allowable only as an exception. Specialty vehicles such as convertibles and SUVs are not allowable.

Please note:

- Reimbursement for ground transport is limited to travel between the home or place of business and the airport; the airport and meeting site and return.
- Mileage expenses for private automobile use will be at published government rates. Reimbursements for travel using a private automobile will not exceed the cost of roundtrip coach airfare or the most reasonable travel method.
- Coach airfare will be reimbursed. Any exceptions require prior approval from the Executive Director or designated authority.
- SIBCR recognizes the particular requirements of persons with disabilities and will make every effort to accommodate those needs. Please contact the SIBCR administrative office for further information.

VA Requirements: If you are a VA employee seeking reimbursement from SIBCR for travel related to your research or education programs, there are additional procedures you must follow. As a government employee going on domestic or foreign travel, you are responsible for complying with the requirements of your employer.

Chapter 11

Meeting and Conference Support

Meetings, conferences, workshops, seminars, grand rounds, town halls, symposia, and other similar meetings are all accepted features of conducting research and education. Additionally, certain events, such as retreats and board meetings as well as fundraising and public relations, are necessary for the conduct of business. Meals and refreshments may be considered for support only if they are incidental to the business purpose of such meetings.

POLICY FOR SUPPORT

Various laws and regulations, the federal ethics standards, and the statute that authorizes SIBCR control the extent to which expenditures related to such events are appropriate for SIBCR support. Consequently, in order for such costs to be considered for direct payment or reimbursement by SIBCR, the following policy has been established.

1. In order to be eligible for SIBCR support, a meeting must have a documented research, education or SIBCR business purpose. SIBCR will not support "entertainment" expenses such as social activities, parties, ceremonial occasions or those that provide amusement.
 - For a research-related meeting: A request for SIBCR support must include an explicit statement about the research rationale for the event; that is, its research related purpose and how it will further VA research. Accompanying documentation should include the program, agenda or topic of discussion, and a roster of attendees. When appropriate, the request should tie the meeting to an approved research project.
 - For an educational program not related to research: The education activity itself must first be approved by the VAPSHCS Education Council (EC). Documentation should include an explicit statement of the purpose and how the program will further the VA's education and training mission. Please complete the Education Approval Request form to submit for EC review.
 - For other SIBCR business events: A request must include an explicit statement of how the meeting will further SIBCR's ability to facilitate research and education. Appropriate events include, but are not limited to, retreats, board meetings, annual membership meetings and investigator meetings, as well as fundraising and public relations events. Documentation should include the purpose, agenda, program or topic of discussion, and a roster of attendees.
2. Factors that SIBCR will consider when evaluating a meeting for support include:
 - Whether at least one speaker makes a research presentation or presents educational instruction.
 - Whether there is a non-VA and or non-VAPSHCS speaker or non-VA or non-VAPSHCS personnel are among the expected attendees.
 - The frequency of similar meetings that may involve the same personnel. Irregularly scheduled meetings and those that occur no more than monthly may be eligible for support; weekly meetings will not.
 - Whether the meeting involves at least one individual who is being recruited to conduct research or education at the VAPSHCS.
 - Whether the meeting lasts more than two hours or extends through a normal mealtime.

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Regardless of the type of meeting, the documentation required in section 1 above is a prerequisite for SIBCR support.

3. Requests for SIBCR support will be reviewed and approved by the individual designated by the Board, generally the Executive Director or the Executive Director's designee. SIBCR will provide direct payment for reasonable meeting costs, or reimbursement based on submission of original receipts. In the event of disagreement, the request may be referred to a designated member of the Board of Directors or to the full Board as appropriate.
4. SIBCR encourages meeting organizers to obtain pre-approval of SIBCR support for meetings. Such approval is not mandatory, but events lacking pre-approval may be denied support or may receive only partial support. For meetings of significant size or cost, prior discussion and authorization by SIBCR management is highly recommended.

Additional Factors

- Only actual, reasonable costs will qualify for reimbursement.
- SIBCR does not pay for alcoholic beverages.
- Refreshments may be paid as part of a non-routine research or education meeting if incidental to the meeting. SIBCR will not pay for refreshments for regular staff meetings.
- Lunch or dinner expenses for a meeting with only VA staff cannot be reimbursed.
- Please note that luncheon or dinner meetings with invited speakers or research collaborators may be an appropriate expense for reimbursement through SIBCR. However, such an event should be reviewed prior to the event to make sure it is eligible for reimbursement.

GUEST LECTURER INFORMATION

When members are providing honoraria, speaker fees, or travel reimbursement to invited guest lecturers, the following apply:

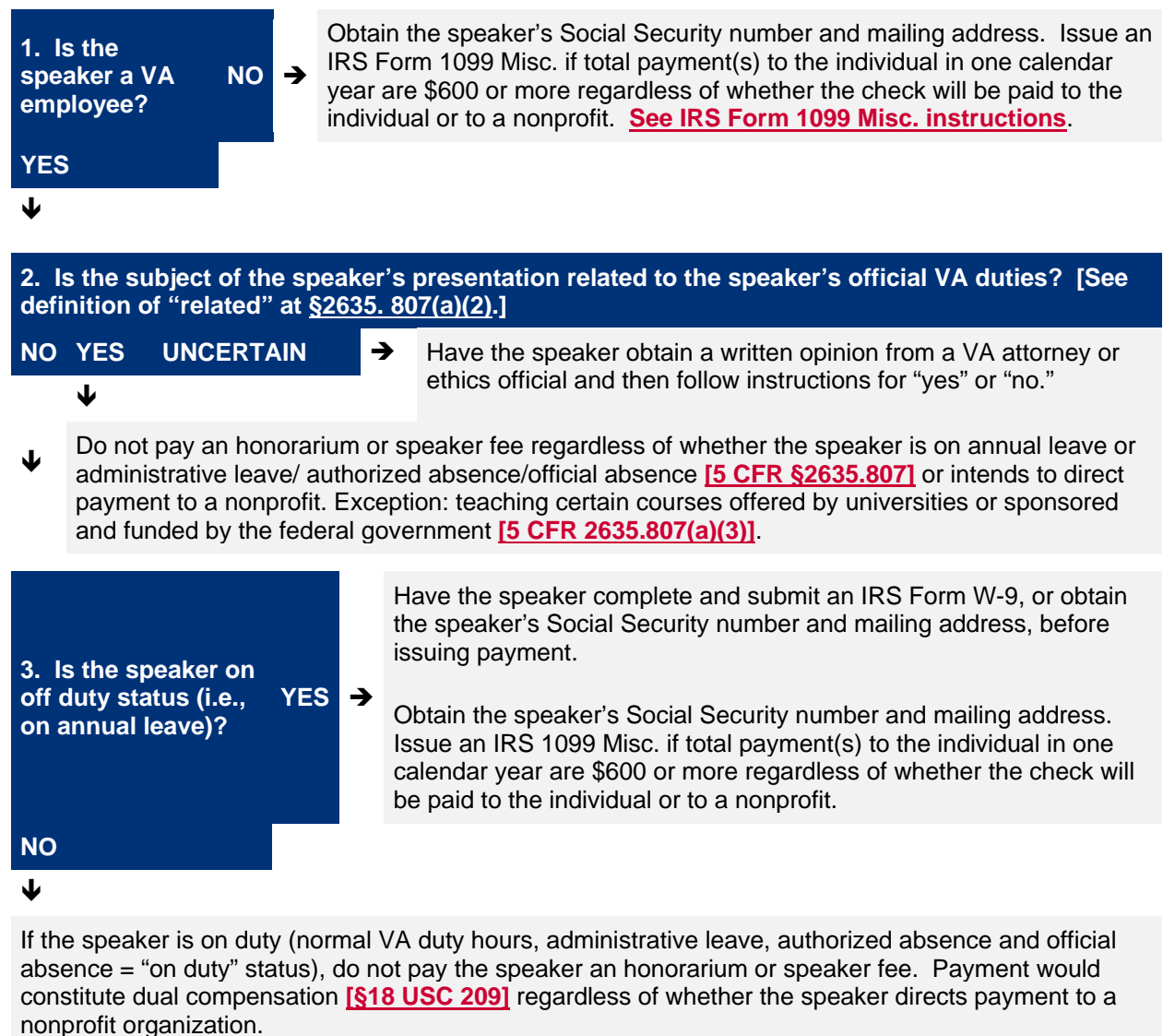
- Check Request Form must include the Social Security or Tax Identification Number and the address of the guest lecturer.
- Sufficient credentials should be provided to show the expertise of the speaker as the basis for providing an honorarium. For example, part or all of the speaker's CV.
- If the speaker is a VA employee, the decision tree in the following section must be filled out and provided to SIBCR before an honorarium can be paid.
- If the invited speaker is a non-resident alien SIBCR must be advised in advance in order to determine if an honorarium can be provided.
- SIBCR must file IRS 1099 Misc forms for speaker fees and honoraria payments totaling \$600 or more in a single tax year.
- The payment of travel expenses associated with this category follows the same policy as for general travel by members (see Chapter 10 of this Policy Manual for more information on travel).

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HONORARIA AND SPEAKER FEES

VA-affiliated nonprofits such as SIBCR are often asked to pay honoraria and speaker fees or to accept donations of honoraria. To assist the nonprofits to work through the sometimes complex issues related to compensation for outside speaking, writing and teaching, NAVREF offers the following decision tree in determining when honoraria and speaker fees may be paid to VA employees without putting the employee at risk of violating federal ethics regulations.

Payment of Honoraria Decision Tree



Chapter 12

Consultant and Professional Services

In order to distinguish consultant and professional services from work performed as an employee, these services must be based on self-directed work towards an objective determined by the SIBCR member. Such services will be arranged by contractual agreement with SIBCR.

Certain IRS criteria distinguish an employee relationship from a contractor relationship. A member considering establishing an agreement for a consultant or other professional services should review the criteria with SIBCR staff. For informational purposes, the 20-point test that the IRS has promulgated to distinguish an employee from an independent contractor is available at www.sibcr.org under human resources forms.

If the consultant or independent contractor is a non-resident alien, payment may be prohibited or subject to tax withholding based on INS or IRS rules.

Acquisition and payment for any service to be provided by technical, consultative or professional individuals or groups in support of member research programs or educational activities must be authorized by SIBCR administration in advance of receipt of such services. The Executive Director's signed approval of the standard professional services agreement will provide authorization. Members may not commit the Institute to pay for such services without approval.

Members or their designees will certify such services have been received before reimbursement or payment to the vendor by SIBCR is initiated.

Additional details of the SIBCR policy and the template for a professional services agreement can be found below. The template is available on the web site www.sibcr.org under accounting forms.

Contractual Services Detail Information

In order to obtain the written purchase agreement for individual professional/technical contractual services, a request to SIBCR administration should be submitted in writing and should contain sufficient information for review and processing. The following list highlights the details needed to complete a service or contractor agreement. The agreement form or an equivalent one covering all the pertinent information should be completed before services are initiated.

1. Contractor's name, address and phone number.
2. Contractor's social security number.
3. Contractor's State of Washington UBI or other relevant licenses.
4. Description of contractor's qualifications (a CV or resume may be used where appropriate).
5. Period of the agreement.
6. Cost basis and rate of pay (cost reimbursement basis or fixed fee), for example: \$___ per hour x ___ hours = \$___ total cost, or 1 job @ \$___.
7. A "not to exceed" amount, if other than the total cost above. This is particularly important if estimates are involved.
8. Description of work to be performed. This should be specific and should include end results or product desired; where work is to be performed; any technical requirements; a

description of what measures will be used to determine the degree of completion by the contractor. A statement indicating that "the contractor's work will be self-directed to meet the goals and objectives as set by the Principal Investigator" should be included.

9. Justification of the use of the contractor, including (a) a certification by the member that such services are not available through existing R&D Cores, and (b) how this work is related to the principal investigator's VA-approved R&D program, citing specific studies by title and RDIS number where possible.
10. Delivery and invoice/payment schedule. The requesting member must certify invoices before payment will be made.

The independent consultant/professional service agreement can be found at www.sibcr.org under accounting forms.

Chapter 13

Cost Transfer Policies and Procedures

To comply with the requirements of OMB Circular A-122, NIH policy, and the requirements of other federal sponsors, SIBCR has established the following policy and procedures for the processing of cost transfers.

It is necessary to explain and justify transfers of charges into federal awards from other federal accounts, non-federal accounts or residual accounts. Timeliness and completeness of explanation of transfer are important factors in supporting allowability and allocability in accordance with the principles of the Circular.

NIH Grants Policy Statement (12/01/03, pp.83-84)

"Cost transfers to NIH grants by grantees should be accomplished within 90 days. Transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the grantee. An explanation merely stating that the transfer was made 'to correct error' or 'to transfer to correct project' is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable. Grantees must maintain documentation of cost transfers, pursuant to 45 CFR 74.53 or 92.42 [record retention requirements] and must make it available for audit or other review. Frequent errors in recording costs may indicate the need for accounting system improvements and/or enhanced internal controls. NIH also may require a grantee to take corrective action by imposing additional terms and conditions on an award(s)."

All SIBCR members, their staff and SIBCR employees must comply with the cost transfer policies.

Responsibilities

The Principal Investigator (PI) is responsible for ensuring that their staff and administrators abide by this policy and accompanying procedures when requesting cost transfers.

SIBCR is responsible for maintaining the policy and for answering questions regarding the policy. Individuals requesting cost transfers are asked to first contact SIBCR with questions on this policy, to ensure the grants management and accounting offices are aware of cost transfer questions and to ensure consistent guidance is provided.

PROCEDURES

A cost transfer is a transfer to a federally funded sponsored account of a charge previously recorded elsewhere. Examples:

- * Transfer pre-award costs from a holding account;
- * Correct clerical error
- * Reallocate staff time and effort; or
- * Reallocate shared services that were previously charged elsewhere.

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If more than 90 calendar days have passed since the date of the original charge, an explanation for the lateness of the cost transfer (question 3 on the Cost Transfer Explanation & Justification Form) is required in addition to questions 1 and 2.

Cost Transfers after the 90-day period need the approval of the SIBCR Executive Director and/or Controller. Documentation justifying the lateness of the cost transfer should be attached to the form.

1. Approval for cost transfers submitted later than 90 calendar days (as defined above) *will only be granted in extenuating circumstances*; examples are given below. They DO NOT include absences of PI or responsible administrator, nor shortage or lack of experience of staff. It is the responsibility of the grantee and the PI to ensure the availability of qualified staff to administer and exercise stewardship over federally-funded projects in accordance with federal policies and regulations, including those relating to regular monitoring of expenditures and timely correction of errors and reallocation of expenses.

Examples of Acceptable Extenuating Circumstances for Cost Transfers over 90 Days

- Late issuance of a notice of grant award or full execution of a subcontract subsequent to the start of the budget year or other period of performance; supporting documentation required.
 - Failure of another department or service to take action, e.g. on a properly submitted payroll distribution change request; supporting documentation required.
2. Federally funded accounts should never be used for expenses which will subsequently be transferred elsewhere. This includes continuations of the same project for which the notice of award or the new account number has not yet been received.
 3. Requestors are advised to submit explanations for lateness (i.e. over 90 calendar days) to SIBCR for review before completing the form and assembling backup documentation. SIBCR is available to assist departments in all aspects of cost transfer explanation and preparation of documentation, both for transfers within the 90-day time limit and for those beyond.

Cost transfers that require an explanation in writing only (such as an email to the SIBCR Controller or Grants Manager) are those made within the accounting period (month) of the original charge.

ROLES AND RESPONSIBILITIES

It is the responsibility of each SIBCR member and their staff to:

- Ensure compliance with the SIBCR Cost Transfer Policy;
- Retain hard copies of all documentation related to cost transfers in accordance with applicable record retention regulations; and
- Ensure that all personnel engaged in the financial administration of federally funded awards are familiar with the SIBCR Cost Transfer Policy.

The cost transfer explanation and justification form can be found at www.sibcr.org.

Chapter 14

Personnel and Personnel Agreements

SIBCR may directly employ management, technical and administrative staff to support the research, educational and training programs and the administrative functions of the Institute. SIBCR may also enter into agreements with private and public institutions to cover salary costs of personnel conducting SIBCR business. The Executive Director will have discretion to modify all such employment agreements to correspond with available funds in member accounts.

SIBCR will verify the availability of sufficient funds for scheduled salary payments.

Payroll obligations are the primary responsibility of the member and must be met before any other payments will be made. SIBCR policy does not allow for overdrafts.

SIBCR is an equal opportunity employer. We do not discriminate against any person in any matter of employment on the basis of race, color, creed, religion, national origin, sex, age, disability, marital status, sexual orientation or status as a disabled veteran or a veteran of the Vietnam era.

This equal opportunity policy applies to all staff levels within the organization and includes (but is not limited to) the following: (1) recruiting and solicitation for employment; (2) hiring, placement, promotion, transfer, and demotion; (3) employment training or selection for training; (4) pay rates, compensation, and benefits; (5) layoffs and termination.

DIRECT EMPLOYMENT BY SIBCR

SIBCR may employ full and part-time persons for support of the administrative, research and educational activities of the Institute. The length of employment for such individuals shall be indefinite, with no time commitments made. SIBCR maintains an employment relationship with employees that is "at will" of the employer and the employee. The hiring, termination, assignment of duties, and the determination of reasonable salary levels shall be upon the recommendation of the member and subject to SIBCR approval.

An Employee Request Form must be completed and submitted to the SIBCR office prior to employment by SIBCR. The requisite personnel forms for SIBCR employment are available in the SIBCR office. Completed forms must be submitted to the SIBCR office before the employee can be hired.

No offer for employment through SIBCR shall be made without prior consultation with the Executive Director or the Assistant Director.

All SIBCR employees must obtain WOC (without compensation from the VA) status.

Employees are paid on a monthly basis. All employees must complete a time sheet and submit it to SIBCR, signed by the employee and supervisor, on the last working day of the month.

Employees certify by signing their timesheets that the hours worked for SIBCR do not conflict or overlap with hours worked for any other employer.

Specific work schedules will be set by the direct supervisor, but full-time shall mean 40 hours per week.

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The following is a brief description of benefits.

Medical, dental, and vision insurance plans are available to eligible employees (an appointment of at least 50% effort and expected to continue for at least a year). Long and short-term disability is available to employees with appointments of 30 hours/week or greater expected to continue for at least a year.

TIAA-CREF is offered as the group retirement plan. For eligibility, an employee must work 1,000 hours in a 12-month period from the date of hire, and must work for six months before contributions may be made. All employees are eligible to participate in a supplemental retirement plan offered by TIAA-CREF with no waiting period.

All employees are entitled to Social Security coverage, Workmen's Unemployment Compensation, and Washington State Industrial Coverage.

Employees with appointments of more than three months accrue sick and annual leave at the same rate as permitted by VA policy. Limitations on carryover differ from the VA policy. Holidays will be paid for employees whose regularly scheduled tours of duty fall on these dates. The ten paid holidays will be the same as observed by the VA.

Please refer to the SIBCR Personnel Policy for more detailed information on all personnel policies, procedures and benefits.

If you intend to hire staff, more detailed information is provided in the section Employment Basics for Supervisors.

PERSONNEL AGREEMENTS

SIBCR may enter into agreements with eligible institutions, for example, VAPSHCS or UW for repayment of personnel salaries. All personnel agreements should be executed prior to start date with the approval of the Executive Director of the Institute and the appropriate official of the participating institution. A Request Form for an IPA must be reviewed and signed by the Executive Director prior to initiating an agreement.

These agreements may be used when an SIBCR employee will be temporarily assigned to a grant administered by another organization, e.g., a VA merit review award. However, all such mechanisms are temporary assignments. The employee is expected to return to an SIBCR paid appointment. Alternatively, an SIBCR administered award may fund an employee of another institution and require a personnel agreement.

Personnel agreements include the Interagency Personnel Agreement (IPA), the Memorandum of Understanding (MOU), the Joint Personnel Agreement (JPA) or the subgrant or subcontract. In some cases, the reimbursement to the employing institution may be done via a purchase order. The preferred agreement between SIBCR and VAPSHCS is an IPA. An MOU may be used only if SIBCR is reimbursing VAPSHCS for a VA employee appointment.

There are specific requirements and review processes for each type of personnel agreement. SIBCR staff will review the options with the requesting party to make sure the appropriate mechanism is executed.

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All grants that may require a personnel agreement must be reviewed with SIBCR staff prior to submission to a sponsoring agency.

In some cases, the participating institution may apply indirect costs and the proposed budget should reflect these costs. This will be the norm on subgrants/subcontracts between SIBCR and the UW. A JPA between UW and SIBCR will normally carry a 10% fee up to \$5,000 per annum unless it is specifically waived (see below for details).

An IPA agreement can only be instituted for professional or technical personnel that have regular, continuing appointments. Temporary or intermittent personnel are not eligible for any personnel agreement.

Reimbursement payment schedules will be part of the personnel agreements.

Reimbursement for salary support will not be made in the absence of a formal, executed personnel agreement.

The member will attest invoices or time keeping records are accurate and in support of a VA approved research project or education activity before SIBCR will initiate payment to the participating institution.

SIBCR will track effort as required by a funding agency.

Specifics on UW Personnel Agreements

The SIBCR Board of Directors understands that staff on sponsored projects including federal awards should generally be employed by the administering entity. Wherever possible this will be the rule followed by SIBCR so that SIBCR will be credible as the appropriate grantee.

Generally, dual-appointment faculty will not be paid directly from SIBCR administered awards. Instead the standard procedure will be for SIBCR to reimburse UW for VA-based faculty effort on grants whether federal or non-federal. Any exceptions to the standard will not be approved from SIBCR funds unless authorized by UW.

In addition, long term UW staff may be allowed to stay as UW employees because of the loss in state retirement funds if such employees made a switch to SIBCR employ.

A staff person with 10 years status as a UW/state employee will be considered a long term employee.

Staff with less than 10 years as UW/state employee will be considered for SIBCR employment on a grant administered by SIBCR.

Exceptions will be made in hardship cases at the discretion of the SIBCR Board management committee.

It is understood that SIBCR cannot in any way require a UW employee to switch to SIBCR employ. However, if the employee meets the criteria (<10 years as UW/state employee), is funded by grant or grants administered by SIBCR and does not qualify for an exception, SIBCR will not implement a salary reimbursement agreement (referred to as a joint personnel agreement) with UW.

Applying the JPA Fee

The 10% fee is charged to all joint personnel agreements (JPAs) unless the sponsor does not provide any indirect costs or if there is a clear hardship rationale.

In order to cover this cost on a grant with other than the full indirect cost rate, the grant must include sufficient funds in the direct costs of the budget. Alternatively, the PI can cover this fee from unrestricted funds in SIBCR.

SIBCR has negotiated this charge into the DHHS-negotiated indirect cost rate. Therefore for SIBCR-administered federal awards with full negotiated rate, the fee will be covered. Please discuss with SIBCR staff for details on the application of the fee.

Chapter 15

Employment Basics for Supervisors

Employment Requirements

Applicants for employment by SIBCR will not be hired without a completed employment packet. This packet should be completed *prior* to the date of hire but not later than the first day of employment.

- All SIBCR employees must also secure status as a Without Compensation (WOC) employee to work at VAPSHCS. Fingerprinting is required.
- Employees who work with patients or patient identifiable research data must complete training in Human Subjects and Good Clinical Practices. They must have their credentials verified and a scope of work in their personnel file.
- If the SIBCR employee is to engage in direct patient care activities, the securing of WOC status requires verification of professional credentials for nurses and the obtaining of clinical privileges from VAPSHCS for physicians, physician assistants and ARNPs.
- No patient contact is allowed until license verification is complete or clinical privileges are granted by VAPSHCS. Equivalent permission and/or clinical privileging must be obtained from other institutions if such work is to be performed at these sites (i.e., UW Medical Center, Harborview Medical Center, etc.).
- It is your responsibility as an SIBCR member to ensure your study personnel are properly credentialed to perform work on your research projects. DO NOT allow anyone to work on your research projects before completing this essential process.

Separate Employers

Work policies of VAPSHCS and UW differ slightly from SIBCR policies. If questions arise in the course of your staff's employment because of differences in personnel policies, please refer these questions to the SIBCR administrative office. SIBCR employment policies will apply to SIBCR employees, not the policies of VAPSHCS or UW.

Classifications of Employees

1. *Regular Employee*: An employee who is hired to work at least 30 hours per week and whose appointment is expected to exceed 1000 hours per year. Regular employees with an appointment expected to continue for a year are eligible for all SIBCR benefits.
2. *Part-Time Employee*: An employee who is hired to work less than 30 hours per week and whose appointment is expected to exceed 1000 hours per year. Part-time employees are eligible for all or some SIBCR benefits.
3. *Intermittent Employee*: An employee who is hired to work on an intermittent or as-needed basis. These employees are not eligible for any SIBCR benefits.
4. *Temporary Employee*: An employee who is hired with the expectation that he or she will be needed for a specified period of time of less than 12 months and less than 1000 hours. Temporary employees are not eligible for most SIBCR benefits, but may be eligible for leave accrual (see benefits section).

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In addition, employees will be either exempt or nonexempt as defined by the Fair Labor Standards Act (FLSA).

Exempt Employee: Employees who are paid on a salaried basis and who regularly work in certain executive, administrative, or professional positions are exempt employees. Exempt employees are paid on a salary basis for completion of their job and are not eligible for overtime.

Nonexempt Employee: An employee, whether paid on a salaried or hourly basis, who is covered under FLSA. Nonexempt employees are eligible for overtime pay and certain rest and meal breaks (see below).

Most SIBCR employees are nonexempt. Each employee's status under FLSA will be determined upon hiring. See SIBCR for any questions regarding FLSA status.

Workweek and Scheduling

For payroll and accounting purposes, the workweek normally begins at 12:01 a.m. Monday and ends at midnight the following Sunday. You may establish other workdays or workweeks for individual employees or certain positions. Please send SIBCR notification of this change for the personnel file and payroll purposes.

Rest and Meal Periods

All nonexempt employees must receive a 10 minute paid rest break for each four hours of working time. Ideally, a break will occur near the midpoint of each four-hour work period, but scheduling will be approved by you. Break periods for your employees should not be used to extend a lunch period, work overtime, arrive or leave early.

Nonexempt employees working more than five hours in a day are required to take a meal break two to five hours into their shift. However, they may waive this by signing a Lunch Waiver form, signed by both you and the employee and filed in the employee's personnel file. The normal meal break is a 30 minute unpaid period. Employees who work three or more hours beyond an 8-hour shift should have an additional unpaid meal period before or during the overtime period.

Overtime and Time Reporting

Nonexempt employees will be paid at an overtime rate when they work in excess of forty hours per week for SIBCR. Comp time is not legal for non-governmental employees and may not be used for SIBCR employees. Any overtime work must be authorized by you in advance. All overtime should be calculated prior to you signing the time sheet and before turning the time sheet into SIBCR.

The overtime rate is one and one-half times the regular rate of pay. Overtime is paid for all hours over 40 hours worked plus holiday hours in one workweek. Vacation and sick leave hours are not included as hours worked for the purpose of determining overtime.

All hours worked must be paid. "Off the clock" work is strictly prohibited and any violations could lead to disciplinary action. DO NOT instruct any nonexempt employee to work without putting hours on their timesheet.

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Each employee must fill out and sign a time sheet for the actual hours worked, and submit it with a valid signature (not a stamp) from you or your designee. *Supervisors' signatures on timesheets must be by a VAPSHCS employee.*

Equal Employment Opportunity

SIBCR is an equal opportunity employer. Every employee has the right to work in surroundings that are free from all forms of unlawful discrimination. SIBCR will not engage in nor tolerate unlawful discrimination on any basis prohibited by local, state or federal law. Specifically, SIBCR does not discriminate against any person in any matter of employment on the basis of race, color, creed, religion, national origin, gender, age, physical or mental disability, marital status, sexual orientation, military or veteran status or status as a disabled veteran or a veteran of the Vietnam era.

This policy applies to staff of all levels within the organization and includes (but is not limited to) the following: (1) recruiting and soliciting for employment; (2) hiring, placement, promotion, transfer, and demotion; (3) employment training or selection for training; (4) pay rates, compensation, and benefits; and (5) termination. All selection methods and criteria shall be based on job-related criteria and individual merit.

SIBCR encourages men and women of minority status to apply for positions at all scientific and administrative levels.

Employees should speak to either the Executive Director or Human Resources if he or she has any related questions, complaints or comments on this policy.

SIBCR recognizes that employees with physical or mental conditions which significantly limit their major life activities may need reasonable accommodations to enable them to perform their essential job functions. Any employee who believes he or she needs reasonable accommodation should notify Human Resources. Although the need for accommodations is determined on a case-by-case basis, generally SIBCR and the employee engage in an interactive process with the employee's healthcare provider(s). The employee has an obligation to cooperate with SIBCR in this process, which may include authorizing SIBCR to communicate with the employee's healthcare providers concerning the employee's condition, its limitations, and possible reasonable accommodations.

Sexual and Other Harassment

SIBCR expects all supervisors and employees to accomplish their work in a professional and businesslike manner. Harassment of employees by supervisors, fellow employees, or non-employees in the workplace is a form of unlawful discriminatory behavior and is not permitted. Specifically forbidden is harassment based on gender, sexual orientation, race, color, religion, national origin, age, disability, or engagement in protected activities, e.g., opposition to prohibited discrimination.

Harassment includes unsolicited remarks, gestures, or physical contact, display or circulation of written materials, e-mail or pictures derogatory to either gender or to racial, ethnic, or religious groups; or basing personnel decisions on an employee's response to sexually-oriented requests.

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Engaging in any act which discriminates on the basis of race, color, national origin, sex, religion, creed, marital or veteran status, age, the presence of a disability or any other basis prohibited by local, state, or federal laws will not be tolerated. Harassment is improper and illegal and is grounds for disciplinary action up to and including immediate termination.

If you are aware of conduct of this sort, or feel that the employee's work environment has become a hostile or offensive place to work, you should immediately bring the matter to the attention of the Assistant Director, the President of the Board of Directors or the Executive Director at SIBCR. Do not wait for the harassment to become severe or pervasive. SIBCR will protect the confidentiality of any complainant to the extent possible. It is important to our organization that all claims of discrimination or sexual harassment be thoroughly reviewed and investigated so appropriate steps are taken.

As an SIBCR employee's supervisor at VAPSHCS you should take anti-sexual harassment training through VAPSHCS at least once every two years.

Attendance and Tardiness

If an employee will be unable to report to work or will be late, they must let you know as soon as possible, and always before their scheduled starting time. If you are unavailable, the employee should leave a message for you on your voice mail, stating their reason for being late or absent and a telephone number where you can call back.

If the employee's absence or tardiness is due to an emergency, they should call in as soon as possible, or they may have someone call in for them.

If an employee fails to report to work for three consecutive days without notification to you, the employee will be deemed to have voluntarily resigned their position.

Attendance or tardiness problems, including failure to call in, may result in discipline up to and including termination.

Conflict of Interest

SIBCR expects members and employees to avoid situations that might cause their personal interests to conflict with the interests of our Institute or to compromise its reputation or integrity. A conflict of interest, or the appearance of one, occurs when an employee or a member of their immediate family uses their position with SIBCR for personal benefit through an investment, association, or business relationship that interferes with their ability to exercise independent judgment on our behalf.

Employees are discouraged from accepting meals or other gifts of more than a nominal value from salespeople, vendors, suppliers, or any other solicitors. Also refer to Standards of Conduct and Discipline in the following section.

Employment of Relatives (Nepotism)

Employment of relatives is permitted, except in circumstances where an appointment places related people in supervisory and subordinate roles, or in a situation where influence could be exerted, directly or indirectly, on future decisions concerning the status of employment, promotion, or compensation.

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Alcohol and Drugs

SIBCR has adopted a drug-free workplace policy. All employees of SIBCR are expected to comply with this policy as a condition of their employment.

The unlawful manufacture, distribution, dispensing, possession or use of a controlled substance or alcohol is prohibited in the workplace. Violators are subject to disciplinary action, up to and including termination.

Employees should determine with their physician or pharmacist whether any prescription drugs being taken might impair their ability to perform their jobs safely and effectively. If the employee performance might be so impaired, he/she should not report to work and should discuss the issue with you to determine whether some accommodation may allow them to perform the essential functions of the position safely and effectively.

Any employee convicted of a violation of a criminal drug statute, which occurred in the workplace, must notify you and the Executive Director of SIBCR in writing within five days of the conviction. SIBCR is then required by law to notify all federal agencies providing funds to SIBCR of the infraction within ten days after receiving notice from an employee.

Standards of Conduct and Discipline

SIBCR expects each employee to contribute to the quality and reliability of the Institute within the scope of his or her job responsibilities. Failure to meet this standard of performance may be the basis for adjustment in compensation or disciplinary action, up to and including termination.

We will take appropriate action based on the seriousness of the situation and the circumstances. The evaluation of the facts will be made by you in consultation with the Executive Director and or the Assistant Director.

In addition, 38 USC § 7366 (c)(2) requires that each employee must certify that he or she will comply with the federal laws and regulations applicable to Federal employees with respect to conflicts of interest. The Standards of Ethical Conduct are codified in 5 CFR Part 2635.

Termination

The employment relationship with SIBCR is "at will." It can be terminated, with or without cause, at any time by either employer or employee. The provision of benefits does not constitute a promise that employment will last one year or longer. No agreement inconsistent with this policy is valid, unless it is in writing and signed by the Executive Director. The Employment Request Form does not constitute an exception to the at will policy.

Communications

On occasion you will receive memos about your employees. Most notices are sent to keep you informed about your employee's status, renewal of employment, salary and compliance requirements. It is important that you keep SIBCR well informed of updates and changes that need to be made in the personnel file. It is also important for you to make sure employees follow through with their compliance requirements and other important paperwork pertaining to their employment.

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Safety and Security

SIBCR functions within VAPSHCS facilities. As an SIBCR supervisor, you are expected to take an active part in maintaining the safety of this environment. Please ensure that the R&D Laboratory Safety Manual and Radiation Safety Plan are available in your laboratory and that each employee is aware of and has read these documents. Attendance to the annual safety meeting and other mandatory trainings are required for all SIBCR employees.

No minors (under 18) are allowed in the laboratories of VAPSHCS. This includes in Seattle the 6th and 7th floors of Building 1, Buildings 8, 11, 13, 23, 34; at American Lake Buildings 18N, 18S, 72, and any other space that is designated a laboratory.

Report any accidents or injuries - including any breaches of safety - and report any unsafe equipment, working condition, process or procedure, at once to the R&D Safety Officer.

Your employees may report safety violations or injuries anonymously to the R&D Safety Officer, if they are not the injured or violating party. *No employee will be punished or reprimanded for reporting safety violations or hazards.* However, any deliberate or ongoing safety violation, or creation of hazard, by an employee will be dealt with through disciplinary action by SIBCR, up to and including termination.

Accidents and Accident Reports

An employee must notify you immediately if he/she is injured on the job. It is your responsibility to help them evaluate the situation and assist them in obtaining appropriate medical assistance, should that be necessary.

SIBCR employees are insured under Washington State Industrial Insurance. Please see the Assistant Director for more information.

As soon as practical, but in no case later than 24 hours following the employee's injury or suspected injury, he/she must complete a VAPSHCS accident report, online on the VA intranet, describing the circumstances surrounding the incident. Failure to report the accident to SIBCR may result in a claim denial.

This report will permit us to better assist the employee in obtaining insurance benefits if he/she qualifies for them. Please note that this accident report form is an internal requirement of working at a VAPSHCS facility, and does not register a claim for workmen's compensation.

Snow/Inclement Weather

If there is snow or other inclement weather SIBCR will follow the closure decisions of VAPSHCS. Please have your employees listen to local radio or TV broadcast to find out if VAPSHCS will be closed for all but essential personnel. Employees are to use their best judgment in their decisions to come to work and not put themselves at risk. They should call you or an SIBCR administrator to confirm or leave a message regarding their absence.

Holidays

SIBCR observes the same paid holidays as VAPSHCS. Part-time employees receive pay only for those holidays falling on work days in their scheduled tour of duty, and only for the number of

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hours which they would have been scheduled to work had the holiday not fallen on that date. Intermittent employees and those who work on an unscheduled number of hours per week or month will receive no holiday pay.

Annual Leave

Annual leave should be approved by you at least a week in advance. However, you may grant leave with shorter notice. You may consider workplace coverage in approving leave. Annual leave must be approved by you; unauthorized time off will not be paid.

Sick Leave

A maximum of 240 hours sick leave may be accrued. If an employee who is at the maximum accrual of sick leave uses some of this leave, accrual will restart until the 240 hour cap is reached again. At termination of employment, unused sick leave will not be paid to the employee. For an absence of more than three consecutive days due to illness, the employee may be asked to confirm the illness with a supporting statement from the personal physician of the employee.

Bereavement Leave

An employee is permitted to use a reasonable amount of accrued sick or annual leave when an employee is absent due to the death of a family member.

Military Leave

Employees who are required to attend annual military reserve training or other active military duty are granted leave with regular pay for up to 15 working days per year. Leave for additional military service may be taken as regular vacation or as unpaid leave. *Employees who take military leave are entitled to return to their jobs as provided under federal and state laws.* A copy of the orders must be supplied to the SIBCR administrative office.

Leave for Spouses of Persons in Military Conflict

Any employee who works more than 20 hours per week and whose spouse is deployed or about to be deployed or is on leave from deployment in a military conflict declared by Congress or the President is entitled to up to fifteen (15) days of leave of absence per deployment. The leave is unpaid except that the employee may use their annual leave or sick leave at the same time. An employee wishing to take this leave must notify you within five business days of receiving official notice that the spouse is being deployed or will be on leave from deployment. Upon conclusion of the leave, the employee will return to their position unless the position was eliminated or the employee would otherwise have been terminated during the leave.

Jury Duty

Unless an employee's job responsibilities require it, we will not ask or encourage them to request to be excused from or postpone a call to jury duty. If they are required to perform jury duty, they will be paid their regular pay up to a maximum of 10 days for regular - or part-time employees. The employee will be expected to work their regular schedule on any day they are not required to be present in court. In order to receive compensation during jury duty, they must

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provide SIBCR with a letter or other confirmation from the court clerk indicating the time they served.

Court Appearances

An employee may take annual leave to appear in court as a witness. He/she is responsible for notifying you immediately after receiving the summons to appear for a court appearance during scheduled work hours. A copy of this notice should be given to the Assistant Director attached with their timesheet.

Voting

In most situations, a person should be able to vote before or after work or by absentee ballot. If they are unable to vote during these times due to their work schedule, they may take up to two hours off work with pay to vote. The employee must request this time off in advance from you, and must have a valid reason why they cannot vote by absentee ballot or during non-working hours. They will be expected to take the time off at the time of day which will require the least time missed from work, usually at the beginning or end of the workday.

Family Medical Leave Act (FMLA)

To qualify for Family and Medical Leave, an employee must have worked for SIBCR for a total of at least 12 months, and have worked at least 1250 hours of service during the 12-month period immediately preceding the leave.

An employee must provide notice to you and the SIBCR administrative staff of the need for leave at least 30 days (14 days for a leave due to a child's terminal illness) before the leave is to begin, or if such notice is not feasible, then as soon as is practical. This notice should be in writing.

FMLA Leave Entitlement

Eligible employees are entitled to take up to 12 weeks leave during any 12-month leave period for any of the following reasons: (1) for the birth, adoption or placement for foster care of a child; (2) to care for the employee's spouse, child or parent with a serious health condition; (3) a serious health condition that makes the employee unable to perform at least one of the essential functions of their job. The 12 month leave year or period will be measured backward from the date an employee uses any FMLA leave. For example, for leave requested to start March 1, 2009, SIBCR would look at the previous 12 months (March 1, 2007 - February 29, 2008) to determine the amount of FMLA leave already used. Leave may be taken on an intermittent basis. Please see SIBCR's Assistant Director for more information.

When an employee returns from their leave generally they will be given their former position or an equivalent position with equivalent pay and benefits, unless their position would have been eliminated had they not been on leave or their leave extended beyond their entitlement under the FMLA or applicable state law.

Failure to return from leave as agreed may be treated as a resignation of employment.

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When an Employee is Requesting Family and/or Medical Leave

- Request must be in writing 30 days before the leave is to begin; if such notice is not feasible, then as soon as possible. The dates of leave must be included in the notice.
- If they make contributions to the group benefit plan, arrangements to continue making contributions must be made before the leave begins.
- FMLA and paid leave run concurrently, not in addition to one another (i.e., taking vacation and sick leave at the beginning of FMLA leave does not extend the 12 weeks of FMLA leave by the length of the vacation/sick leave).
- The employee is required to take all accrued sick leave and all accrued annual leave (except in the case of pregnancy).
- During leave for the birth or placement for foster care of a child, the employee must notify SIBCR if they intend to take additional disability leave allowed under Washington state law.
- FMLA leave may be taken intermittently under some circumstances. This will be determined on a pro rata basis, relative to the employee's normal workweek. This intermittent leave must be arranged with Human Resources at SIBCR.

Servicemember Family and Medical Leave Act (FMLA)

The Federal Family and Medical Leave Act (FMLA) entitles employees to take leave for a covered family member's service in the Armed Forces ("Servicemember FMLA"). This policy supplements our FMLA policy and provides general notice of employee rights to such leave. Except as mentioned below, an employee's rights and obligations to Servicemember FMLA Leave are governed by our existing FMLA policy.

Servicemember FMLA provides eligible employees unpaid leave for any one, or for a combination, of the following reasons:

- A "qualifying exigency" arising out of a spouse, son, daughter or parent's active duty or call to active duty in the Armed Forces in support of a contingency operation; and/or
- To care for a spouse, child, parent or other relative for whom the employee is the next of kin who is a member of the Armed Forces, including the National Guard or Reserves, who is undergoing medical treatment, recuperation or therapy, is otherwise in outpatient status, or is otherwise on the temporary disability list for a serious injury or illness.

Duration of Servicemember FMLA

- When leave is due to a "qualifying exigency": An eligible employee may take up to 12 workweeks of leave during any 12-month period.
- When leave is to care for an injured or ill servicemember: An eligible employee may take up to 26 workweeks of leave during a single 12-month period to care for the servicemember. Leave to care for an injured or ill servicemember, when combined with other FMLA-qualifying leave, may not exceed 26 weeks in a single 12-month period.
- Servicemember FMLA runs concurrent with other leave entitlements provided under federal, state and local law.

Any questions regarding Servicemember FMLA leave should be directed to Human Resources.

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Maternity/Parental Leave

Employees are entitled to leave for the actual period of disability associated with pregnancy and childbirth. If the employee is eligible for family leave under the FMLA, described above, FMLA leave will run concurrently with the period of maternity disability. Once the maternity disability period has concluded, an eligible employee may take up to twelve weeks of unpaid leave under the Washington Parental Leave law. The leave is unpaid unless the employee has unused sick and/or annual leave. Sick leave must be used during this leave. This policy will be administered according to the federal FMLA and the regulations interpreting it and any applicable state law. Employees should contact Human Resources with questions about these benefits.

Other Unpaid Leaves of Absence

Unpaid leave of absence for reasons other than those covered under FMLA may be granted under certain conditions, for a specified period of time. Requests for personal leave will be evaluated based on an employee's work record, the department's staffing needs, and the employee's reason for requesting the leave. Circumstances will determine the length of leave granted. During an unpaid leave of absence, the employee may be required to pay their full group health premiums. Employees returning from a personal leave are not guaranteed a return to their former job.

As a supervisor, *all unpaid leaves of absence, including FMLA, must* be approved by you. Employees taking leave without your approval may be considered to have abandoned and resigned their job.

**PLEASE SEE THE FULL PERSONNEL POLICY MANUAL FOR MORE INFORMATION OR
CONTACT THE ASSISTANT DIRECTOR.**

Chapter 16

Financial Conflict of Interest/Objectivity in Research

The purpose of this policy to promote objectivity in research by establishing standards that ensure a reasonable expectation that the design, conduct, or reporting of research is not biased by any conflicting financial interest of an investigator.

A conflict of interest (actual or perceived) occurs when any financial or other arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results or reporting of research activities or findings. Conflicts may be related to financial gain, reputation, promotion, or to the role of research investigator vs. health care provider, among others.

An investigator is required to disclose a conflict of interest when he or she, any of his or her family, or any associated entity possesses a significant financial interest in a research activity which involves his or her responsibilities as a member of SIBCR, VA Puget Sound Health Care System (VAPSHCS), and/or University of Washington (UW).

This policy covers not only SIBCR research sponsored by government grants (e.g., NIH), nonprofit foundations (e.g. American Diabetes Association), or private industry, but also subcontracts, subawards, or subgrants issued by SIBCR in support of an investigator's research project. Furthermore, SIBCR is subject to the requirements of 42 CFR Part 50, Subpart F and 45 CFR Part 94, which govern applicants and recipients of Public Health Service (PHS) funding.

DEFINITIONS

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Investigator means the principal investigator (PI), co-investigators, and other individuals who are responsible for the design, conduct, or reporting of research. For purposes of this policy, it also extends to members of those individuals' immediate families (spouses and dependent children), and to any trust, organization, or enterprise over which an investigator, alone or together with his or her family, exercises a controlling interest. It is not intended to apply to individuals who provide primarily technical support or who are purely advisory and without direct access to the data (e.g., control over its collection or analysis), unless they are in a position to influence the study's results or have privileged information as to the outcome.

Significant financial interest means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria), compensation and reimbursements, royalties, equity interests (e.g., stocks, stock options or other ownership interests), and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

In the case of clinical trials, **any** financial interest is considered significant, regardless of amount or source.

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Where projects other than clinical trials are concerned, the “significant financial interest” does *not* include:

- Salary and other forms of non-royalty and non-equity remuneration from SIBCR, VAPSHCS, or UW;
- Reasonable compensation paid by a public or nonprofit entity in exchange for seminars, lectures, or service on advisory committees or peer review panels;
- An equity interest that when aggregated for the investigator and the investigator's spouse and dependent children does not represent more than a 5% ownership interest in any single entity;
- For research involving human subjects that is not a clinical trial, salary, royalties or other non-equity payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$5,000;
- For research not involving human subjects, salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

IDENTIFICATION OF CONFLICT OF INTEREST

SIBCR reviews potential conflict of interest through the Conflict of Interest Subcommittee, in which VA and University of Washington are also represented. This subcommittee of the Research and Development Committee reviews proposed research and makes recommendations regarding management of conflicts of interest. The Conflict of Interest Subcommittee consists of five voting members:

- A representative of the management of SIBCR;
- The Associate Chief of Staff for R&D, in his/her capacity as a non-Chairing, R&D Committee member;
- An attorney of the VA Regional Counsel's Office;
- A representative of the UW's Office of the Associate Vice Provost for Research; and
- An experienced clinical or biomedical research scientist not currently serving on the R&D Committee.

The subcommittee meets on an ad hoc basis. Its membership is reviewed and authorized on a federal fiscal year basis. The subcommittee reports to the R&D Committee in the form of minutes of the meeting. These minutes include recommendations regarding management of the real or potential conflict of interest disclosed by the PI. Persons appointed to the subcommittee are required to disclose their own potential conflicts of interest to the subcommittee and recuse themselves from reviewing and voting on any matter in which they may have an interest.

The subcommittee retains information submitted by investigators, its minutes, and all related records for a period of at least three years from the date of submission or the project's final expenditure report or close-out date, whichever is later.

SIBCR investigators are also subject to the conflict of interest policies of affiliated institutions such as VAPSHCS and UW, and are responsible for disclosing financial interest in research partners to both institutions. VA employees are furthermore subject to the criminal conflict of

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interest statutes at 18 USC Chapter 11, and the Executive Branch Standards of Conduct at 5 CFR Part 2635.

The instruments used to disclose financial conflict of interest for SIBCR include:

Request for R&D Committee Review form, submitted by the PI to the VAPSHCS R&D Committee for review of any proposed research project performed at VAPSHCS or using VA resources (including VA salary, facilities, personnel, datasets or data warehouses, and/or patients). An indication on this form that the PI or any member of the research team has a financial relationship with the study sponsor requires disclosure to and review by the Conflict of Interest Subcommittee as a condition of approval.

SIBCR Significant Financial Interest Disclosure form must be completed and signed for each study being submitted to a sponsor for which there is a conflict of interest. Information disclosed on this form and related communications will be treated as confidential.

When there is no financial interest to be disclosed, the question on the SIBCR Grant Review form should be marked accordingly and the application can be forwarded to the sponsor.

MANAGEMENT OF CONFLICT OF INTEREST

The subcommittee will consider all information obtained from SIBCR, VA and UW in deciding how best to address conflicts of interest. Options for managing conflict of interest include, but are not limited to:

- Disclosure of significant financial interests to the public, human subjects, researchers and other participants, publishers and/or conference organizers;
- Requiring additional disclosures or actions with respect to IRB or IACUC applications or materials;
- Monitoring of research by disinterested co-researchers or independent reviewers or committees;
- Disqualification from participation in activity affecting or affected by a technology transfer transaction;
- Requiring that investigator participation in the recruitment or consent of subjects be prohibited or restricted;
- Requiring that the significant financial interest be divested, restructured or placed in a blind trust;
- Modification or severance of relationships that create potential conflicts of interest;
- Changing terms of the grant agreement or CRADA relating to the research;
- Requiring non-participation in any business transactions between the parties to agreements involving the research in question.

Investigators are responsible for disclosing new or changed financial relationships with study sponsors or collaborators as they occur. The subcommittee will review these disclosures in the same manner as original disclosures.

Conditions imposed by the Conflict of Interest Subcommittee or the R&D Committee must be met by the researcher in order to receive approval to conduct the proposed research project. SIBCR will not expend funds in support of a research project until that project has been

reviewed by the Conflict of Interest Subcommittee and any conflict of interest satisfactorily managed.

In the case of research supported by a grant from a PHS awarding component, such as NIH, the Department of Health and Human Services may inspect the subcommittee's records regarding that project. For any such research project, the subcommittee will also report to PHS its findings and management of conflict of interest, and any violations of the conflict of interest policy if they are later discovered. Failure to disclose a financial interest or to meet conditions of approval, or other violation of this policy, may result in (a) disapproval of the proposed research; (b) suspension of an ongoing research project; (c) restriction of the researcher's authority to conduct other research activity; and/or (d) disciplinary action against the researcher. In the case of research supported by PHS funding, any violation of this policy will be reported to the awarding PHS agency. Violations of 18 USC Chapter 11 and 5 CFR Part 2635 may be sanctioned by civil and criminal penalties as well.

Chapter 17

Policy on Research Misconduct

INTRODUCTION

A. General policy

The Seattle Institute for Biomedical and Clinical Research (SIBCR) is committed to supporting the performance of scientific research with integrity and high ethical standards. SIBCR personnel are expected to exercise their integrity in carrying out their scientific activities and to provide reasonable supervision of those under their direction to ensure the integrity of the research being conducted. SIBCR has established the following policies and procedures to investigate and resolve alleged or apparent instances of misconduct in research.

B. Joint Jurisdiction

SIBCR shares jurisdiction over all SIBCR research activities with VAPSHCS. SIBCR will coordinate its response to allegations of research misconduct with VAPSHCS in order to maximize procedural uniformity and minimize duplication, while recognizing institutional autonomy.

SIBCR and VAPSHCS will make a good faith effort to conduct a joint inquiry and wherever possible a joint investigation in response to any allegation of research misconduct. VAPSHCS may take the lead in conducting the response to an allegation of research misconduct. SIBCR will, in such an event, designate at least one representative to participate in the inquiry and investigation. If a mutual determination is made that SIBCR shall be the lead agency in an inquiry and investigation, VAPSHCS will designate at least one VAPSHCS employee with research experience and at least 5/8ths status to be a full participant in the inquiry and investigation.

Each inquiry and investigation will result in a single set of recommendations, though a minority opinion may be included. After review by its Board of Directors, SIBCR will accept the findings and recommendations of VAPSHCS-led joint inquiries, investigations, and adjudications.

For investigators with VA and University of Washington (UW) faculty appointments (dual-appointment personnel), UW may exercise concurrent jurisdiction over research misconduct. As necessary, the UW Vice-Dean, Graduate Research and Education will be notified of scientific misconduct issues that arise. In addition, other agencies or entities that co-sponsor or otherwise support the research effort may also exert concurrent jurisdiction. Examples include, but are not limited to, the Public Health Service (PHS) of the Department of Health and Human Services (DHHS), in particular its Office of Research Integrity (ORI), the Department of Veterans' Affairs Office of Research Oversight (ORO), and the Food and Drug Administration (FDA). The Research Integrity Officer (RIO) appointed by SIBCR and VAPSHCS to address allegations of research misconduct must notify all agencies and entities that have joint jurisdiction over a research project of any allegation of misconduct regarding that research.

C. Scope of SIBCR Policy

This policy is applicable to allegations of research misconduct by SIBCR personnel in respect to a research project that is supported by or through SIBCR. In other cases, for example an allegation regarding VA-funded research and VAPSHCS staff alone, the handling of allegations of research misconduct is governed by the policy and procedures in VHA Handbook 1058.2 (“Research Misconduct”) and VHA Handbook 0700 (“Administrative Investigations”).

D. Other Forms of Impropriety

This policy addresses allegations of research misconduct, defined as fabrication, falsification, and plagiarism of research proposals, data, or results. Authorship disputes other than plagiarism are not covered in this policy. It does not deal with ethical lapses or other types of professional misconduct, such as misallocation of funds, harassment or discrimination, violation of laws or regulations established for the protection of human or animal subjects, or violations of other SIBCR or VAPSHCS policies, even if the alleged behavior involves or occurs in connection with research activity.

E. Confidentiality

To the extent allowed by law, SIBCR shall maintain the identity of respondents and whistleblowers securely and confidentially and shall not disclose any identifying information, except to:

1. Those who need to know it in order to carry out a thorough, competent, objective and fair research misconduct proceeding;
2. PHS’s ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings;
3. VA’s ORO as it conducts its oversight of the proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need access to it in order to carry out the research misconduct proceeding.

DEFINITIONS

- A. *Allegation* means any written statement or other indication of possible scientific misconduct received by the RIO, whether directly or referred from the potential respondent’s superior, SIBCR’s Executive Director, or another source.
- B. *Conflict of interest* means the real or apparent interference of one person’s interests with the interests of another person, where potential bias may occur due to prior or existing personal, professional, or financial relationships. Any such conflict that a reasonable person would consider to demonstrate potential bias will disqualify a person for selection to serve in research misconduct proceedings.
- C. *Good faith allegation* means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

- D. *Inquiry* means gathering information and initial fact-finding solely to determine whether an allegation or other readily available evidence of scientific misconduct warrants an investigation.
- E. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person(s) and the seriousness of the misconduct.
- F. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.
- G. *ORO* means the Office of Research Oversight, the office within the U.S. Department of Veterans Affairs that is responsible for scientific misconduct policies and activities within the VA health care system.
- H. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.
- I. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."
- J. *PHS support* means PHS grants, contracts, or cooperative agreements or applications for the same.
- K. *Research Integrity Officer (RIO)* means the SIBCR and VAPSHCS official responsible for receiving allegations of scientific misconduct, determining when such allegations warrant inquiries, and overseeing inquiries and investigations.
- L. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.
- M. *Respondent* means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.
- N. *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. "Fabrication" is making up data or results and recording or reporting them. "Falsification" is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. "Plagiarism" is the

appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences in opinion or interpretation of data.

ORI has a broader definition of research misconduct that includes other practices that seriously deviate from those commonly accepted within the scientific community (see 42 CFR §93.102(b)). If an institutional proceeding does not find sufficient evidence of research misconduct as defined here, ORI may choose to independently review the case based on its own standard of research misconduct.

- O. *Retaliation* means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.
- P. *SIBCR Personnel* means any person who is employed by SIBCR, is an SIBCR member, or serves as an officer of SIBCR.
- Q. *Whistleblower* means a person who makes an allegation of scientific misconduct.

RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer (RIO)

SIBCR will appoint the Research Integrity Officer for the Institute who will have primary responsibility for implementing the procedures set forth in this document. The RIO will be an SIBCR member, officer, or employee who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith. Whenever feasible, SIBCR will appoint the VAPSHCS Research Integrity Officer as its own RIO.

The RIO will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will attempt to ensure that confidentiality is maintained. The RIO will consult and cooperate with those SIBCR and VAPSHCS officers charged with responding to allegations of scientific misconduct in order to conduct a joint inquiry and investigation into such allegations.

The RIO will assist inquiry and investigation committees and all SIBCR and VAPSHCS personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The RIO is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of those files.

The RIO will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

B. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to their allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the RIO has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower for comment.

The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified of the final determinations and resulting actions. All such notices will be in written form. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of legal counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation. If the respondent is found guilty of scientific misconduct, he or she has the right to appeal that finding and any proposed corrective measures.

D. Board of Directors

The SIBCR Board of Directors appoints the RIO, supports the conduct of any inquiries and investigations, and determines corrective measures to be applied to SIBCR personnel in the event of a finding of research misconduct. Respondents may appeal findings of research misconduct or proposed corrective measures to the Board of Directors. The Board of Directors may also direct SIBCR to take actions to restore a respondent's reputation or to protect a whistleblower from possible retaliation.

E. VAPSHCS Director

The Director of VAPSHCS will receive the inquiry report and any written comments made by the respondent or whistleblower on the draft report, and determine based on those materials whether to proceed to conduct an investigation of the allegation.

The VAPSHCS Director is also *ex officio* a member of the SIBCR Board of Directors.

F. VISN Director

The VISN Director will receive the investigation report and any written comments made by the respondent or the whistleblower on the draft report. The VISN Director will consult with the RIO or other appropriate officials and will determine if misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

GENERAL POLICIES AND PRINCIPLES

A. Responsibility to Report Misconduct

All SIBCR personnel should report observed, suspected, or apparent misconduct in science to the RIO. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the RIO to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, SIBCR personnel may have confidential discussions and consultations about concerns of possible misconduct with the Executive Director or the RIO and will be counseled about appropriate procedures for reporting allegations.

Any formal allegation of research misconduct that is received by an SIBCR member, officer, or employee must be referred to the RIO.

B. Protecting the Whistleblower and Others

The RIO will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in good faith with inquiries or investigations. The RIO will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status and will review instances of alleged retaliation for appropriate action.

SIBCR personnel should immediately report any alleged or apparent retaliation to the RIO.

SIBCR will also protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the whistleblower requests anonymity, SIBCR will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an investigation committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed. SIBCR will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or the thoroughness of the inquiry or investigation.

SIBCR personnel accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. The counsel or advisor may not speak for or on behalf of the respondent during the inquiry or investigation.

D. Cooperation with Inquiries and Investigations

SIBCR personnel will cooperate with the RIO and other officials in the review of allegations and the conduct of inquiries and investigations. SIBCR personnel have an obligation to provide relevant evidence to the RIO and other designated officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether PHS support, PHS applications for funding, or research records as defined in 42 CFR §93.102(b) are involved, and whether the allegation falls under SIBCR and/or VA definitions of scientific misconduct. If the allegation fails to meet any of these threshold requirements, the RIO will notify the whistleblower that a research misconduct case will not be opened and provide an explanation of which threshold requirement was not met and to what other, if any, jurisdiction or procedure it is appropriate to direct the allegation.

CONDUCTING THE INQUIRY

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the RIO determines that the allegation provides sufficient information to allow specific follow-up and falls under the definition of scientific misconduct provided above, he or she will immediately initiate the inquiry process. In initiating the inquiry, the RIO will clearly identify the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

The following persons will be provided written notification of the misconduct allegation and the opening of an inquiry: the respondent(s), the whistleblower, the VAPSHCS Director, ORO, the Executive Director of SIBCR, and any other entity with joint jurisdiction, such as ORI.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science, the RIO will take all reasonable and practical steps to ensure that all original research records and materials relevant to the allegation are immediately inventoried and secured. The RIO may consult with ORI for advice and assistance in this regard.

Reasonable, supervised access to, or copies of, the original data may be provided to the respondent so that he or she can continue the research prior to the completion of a misconduct proceeding.

C. Appointment of the Inquiry Committee

The RIO, in consultation with other SIBCR and VAPSHCS officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee will consist of individuals who do not have real or apparent conflicts of interest with the respondent, whistleblower, potential witnesses, or others involved in the matter, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside SIBCR and VAPSHCS. The inquiry committee will include representatives of both SIBCR and VAPSHCS.

The RIO will notify the respondent of the proposed committee membership in 10 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

The RIO will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible. At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The inquiry committee will normally interview the whistleblower, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

The resources and advice of ORI are available to the RIO and committee members in formulating and conducting the inquiry process.

THE INQUIRY REPORT

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the source(s) of research support and the identity of sponsors (for example, NIH or another federal agency, nonprofit foundations, voluntary health organizations such as the American Heart Association, or others); a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether and investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Whistleblower

The RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with a summary of the inquiry findings or portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation, so that the whistleblower may comment thereon.

1) Confidentiality

The RIO may establish reasonable conditions for review to protect the confidentiality of the draft report.

2) Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1) Decision by VAPSHCS Director

The RIO will transmit the final report and any comments to the VAPSHCS Director, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. If the RIO, inquiry committee, and/or the VAPSHCS Director find that there available evidence is sufficient to justify opening an investigation, an investigation must be opened. The inquiry is completed when the VAPSHCS Director makes this determination, which will be made within 30 days of the first meeting of the inquiry committee.

2) Notification

The RIO will notify both the respondent and the whistleblower in writing of the decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The RIO will also notify SIBCR's Executive Director and other appropriate SIBCR and VAPSHCS officials of the VAPSHCS Director's decision.

The RIO will also provide ORI with the final report and a copy of SIBCR and VAPSHCS's institutional policies and procedures for research misconduct. If the inquiry committee's decision is not to investigate the allegation, ORI may perform

an oversight review of the determination not to investigate, and will be provided access to all relevant materials to conduct its review.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing no more than 30 calendar days following its first meeting, unless the RIO and ORO approve an extension for good cause. If an extension is approved, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

CONDUCTING THE INVESTIGATION

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public, or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The RIO will immediately take all reasonable and practical efforts to take custody of any additional pertinent research records and evidence that was not previously sequestered during the inquiry. This sequestration will occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including a decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

Reasonable, supervised access to, or copies of, the original data may be provided to the respondent so that he or she can continue the research prior to the completion of a misconduct proceeding.

C. Appointment of the Investigation Committee

The RIO, in consultation with other officials of SIBCR and VAPSHCS as appropriate, will appoint an investigation committee and the committee chair within 10 days of the recommendation to open an investigation. The investigation committee will consist of at least three individuals who do not have real or apparent conflicts of interest with the respondent, whistleblower, potential witnesses, or others involved in the matter, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the Institute.

The inquiry committee will include representatives of both SIBCR and VAPSHCS. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The RIO will notify the respondent and whistleblower of the proposed committee membership within 5 days. If either the respondent or whistleblower submits a written objection to any appointed member of the investigation committee or expert on the basis of conflict of interest, the RIO and VAPSHCS Director will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1) Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the RIO, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2) The First Meeting

The RIO, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, PHS regulations and procedures.

E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. The committee will interview each respondent, whistleblower, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent. All interviews will be transcribed or recorded. Transcripts or recordings will be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

The burden of proof of research misconduct is on the Institute: a preponderance of evidence must be found to be present in order to arrive at a conclusion of research misconduct. The committee must decide by consensus whether research misconduct occurred and, if so, the type and extent of misconduct, who is responsible, and appropriate corrective actions. If a

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consensus cannot be reached on one or more of these questions, the Investigation Report must note the area(s) of disagreement, the arguments supporting and opposing the various viewpoints, and the majority opinion, if any.

The resources and advice of ORI are available to the RIO and committee members in formulating and conducting the inquiry process.

THE INVESTIGATION REPORT

A. Elements of the Investigation Report

The final report will:

- 1) Describe the nature of the allegations of research misconduct and the specific allegations considered in the investigation
- 2) Describe and document all grantor support related to the allegation of research misconduct, e.g., grant numbers, grant applications, contracts, or publications listing the grantor's support;
- 3) Describe the policies and procedures under which the investigation was conducted;
- 4) Identify and summarize the evidence and research records reviewed, including any relevant records and evidence either taken into custody but not reviewed or not taken into custody;
- 5) State and explain the findings as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found:
 - i. Identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard;
 - ii. Summarize the facts and analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations;
 - iii. Identify the specific source of support, whether PHS, a different federal agency, or other;
 - iv. Identify any publications that require correction or retraction;
 - v. Identify the person(s) responsible for the misconduct;
 - vi. List any current or known applications or proposals for support that the respondent(s) has pending with federal agencies other than PHS;
- 6) Include and consider any comments made by the respondent and whistleblower on the draft investigation report;
- 7) Describe any sanctions imposed and administrative actions taken by SIBCR or VAPSHCS.

B. Comments on the Draft Report

The draft report will be provided for comment as provided in this policy, VAPSHCS policy and procedures, and 42 CFR §93.312.

1) Respondent

The RIO will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 7 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The

findings of the final report will take into account the respondent's comments in addition to all the other evidence.

2) Whistleblower

The RIO will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report may be modified, as appropriate, based on the whistleblower's comments.

3) Institutional Counsel

The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments will be incorporated into the report as appropriate.

4) Confidentiality

In distributing the draft report, or portions thereof, to the respondent and whistleblower, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

Within 7 days of receiving the final report, the VAPSHCS Director must certify completion of the joint SIBCR-VAPSHCS investigation and transmit the final investigation report, with all supporting documents, to the VISN Director. The VAPSHC Director may include additional recommendations when he forwards the final investigation report from the RIO to the VISN Director for adjudication.

C. Institutional Review and Decision

Based on a preponderance of the evidence, the VISN Director will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the VISN Director will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI. The VISN Director's explanation will be consistent with SIBCR and VA definitions of scientific misconduct, the Institute's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The VISN Director may also return the report to the investigation committee with a request for further fact-finding or analysis. The VISN Director's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the RIO will notify both the respondent and the whistleblower in writing. In addition, the VISN Director will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. The RIO will also ensure the Executive Director of SIBCR is notified of the VISN Director's conclusions.

D. Appeal by the Respondent

Respondents against whom a finding of research misconduct is made have the opportunity to appeal that finding, and corrective measures proposed by the VA, to the Under Secretary

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of Health. Such appeals are governed by the procedures laid out in VHA Handbook 1058.2 Section 19.

Respondents have the opportunity to appeal corrective measures proposed by SIBCR to the SIBCR Board of Directors.

E. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the RIO will transmit the final report with attachments, including the respondent's and whistleblower's comments and the VISN Director's adjudication, to ORI. ORI will conduct its own oversight review of the results of the proceeding. ORI may accept the findings and conclusions in part or in whole; request additional information or investigation; reject the report and conduct its own investigation; impose administrative sanctions on the respondent beyond those identified by the VISN Director; or take other actions within its authority. SIBCR and the RIO, with the advice of counsel, will cooperate with ORI requests in such an event.

F. Time Limit for Completing the Investigation Report

An investigation will ordinarily be completed within 90 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the VISN Director for approval, and submitting the report to ORI. An extension to this period may be granted by ORO.

If the investigation will not be completed within 120 days, the RIO must notify ORI and request an extension (see section below).

REQUIREMENTS FOR REPORTING TO ORI

The decision to initiate an investigation must be reported in writing to the Director of ORI, on or before the date the investigation begins. At a minimum, the notification will include the name of the person(s) against whom the allegations have been made, a copy of the inquiry report containing the information required by 42 CFR §93.309(a), and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of SIBCR or VAPSHCS policies and procedures will be explained in any reports submitted to ORI.

If it is decided to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the RIO will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

If the investigation committee, SIBCR, or VAPSHCS determines that it will not be able to complete the investigation in 120 days, the RIO will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by the ORI.

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If SIBCR and VAPSHCS plan to terminate an inquiry or investigation prior to the completion of all steps laid out in this policy, the RIO will notify ORI of the planned termination and the reasons for the decision. ORI will review the information provided and advise whether further steps should be undertaken.

When an admission of scientific misconduct is made, the RIO will contact the sponsor(s) providing financial or other support for the research in question for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the Institute cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

The RIO will notify ORI at any stage of the inquiry or investigation if:

- 1) There is an immediate health or safety hazard involved, including an immediate need to protect human or animal subjects;
- 2) There is an immediate need to protect Federal funds or equipment;
- 3) There is an interim decision that research activities should be suspended;
- 4) There is an immediate need to protect the interests of those involved in the research misconduct proceeding;
- 5) It is probable that the alleged research misconduct or the research misconduct proceeding will prematurely be made public;
- 6) There is a determination by SIBCR and VAPSHCS that the research community or the public should be informed; or
- 7) There is reasonable indication of a possible criminal violation. In this instance, the Institute must inform ORI within 24 hours of obtaining that information.

INSTITUTIONAL ACTIONS

SIBCR and VAPSHCS will take administrative actions against individuals and other appropriate corrective actions when an allegation of misconduct has been substantiated.

If the VISN Director determines that the alleged misconduct is substantiated by the findings, the Board of Directors of SIBCR will, after consultation with the VISN Director, RIO, and the SIBCR Executive Director as appropriate, decide on the appropriate actions to be taken with regard to SIBCR membership or employment, SIBCR-supported research, and other SIBCR resources. These actions may include, but are not limited to: withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found, removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible termination of employment, or restitution of funds as appropriate.

Any such actions are separately determined and may be in addition to those taken by VAPSHCS in the course of its adjudication. VAPSHCS procedures for determining and applying appropriate disciplinary actions are treated in VHA Handbook 5021.

DHHS may impose administrative actions as a result of its own finding of research misconduct, as set forth in 42 CFR § 93. Such actions are separate from and additional to those imposed by SIBCR and VAPSHCS. SIBCR and VAPSHCS will cooperate with and

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assist ORI and DHHS as needed to carry out any actions imposed as a result of a final finding of research misconduct by DHHS.

OTHER CONSIDERATIONS

A. Termination of Membership or Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's SIBCR employment or membership, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry but after an allegation has been reported or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, SIBCR and VAPSHCS will undertake all reasonable, practical, and appropriate efforts to restore the respondent's reputation. Depending on the particular circumstances, the RIO will consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any actions on the part of SIBCR to restore the respondent's reputation must first be approved by the Board of Directors.

C. Protection of the Whistleblower and Others

Regardless of whether the institution or ORI determines that scientific misconduct occurred, SIBCR and VAPSHCS will undertake all reasonable and practical efforts to protect whistleblowers who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the VISN Director will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. If the whistleblower is SIBCR personnel, he or she may also consult with SIBCR's Executive Director and/or Board of Directors to determine what steps, if any, are needed to restore his or her position and reputation. The RIO is responsible for implementing any steps the Board of Directors or the VISN Director approves.

The RIO and Executive Director will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

D. Allegations Not Made in Good Faith

If relevant, the VISN Director will determine whether the whistleblower's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith,

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the VISN Director will determine whether any administrative action will be taken against the whistleblower.

E. Interim Protective Actions

At any time during a research misconduct proceeding, SIBCR and VAPSHCS will take appropriate interim actions to protect public health, Federal funds and equipment, and the integrity of the research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

F. Referral of Other Misconduct

An inquiry or investigation may find evidence of misconduct or impropriety that does not fall under the heading of research misconduct defined in this policy. In such cases and where PHS support is involved, the RIO and any inquiry or investigative committee is obligated to refer the allegation as follows:

- 1) In case of possible criminal activity, to the Office of the Inspector General at DHHS;
- 2) In case of possible violation of human subjects protection regulations, to the Office of Human Research Protection at DHHS;
- 3) In case of possible violation of animal subjects protection regulations, to the Office of Laboratory Animal Welfare at NIH;
- 4) In case of possible violation of FDA regulations, to the Office of Regulatory Affairs at FDA;
- 5) In case of possible fiscal irregularities or improprieties, to the Office of Management Assessment at NIH (where NIH grants or contracts are concerned) or the Office of Grants and Contracts at PHS (where non-NIH resources of PHS are concerned).

RECORD RETENTION

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will keep the file for seven years after completion of the proceeding or of any ORI or DHHS proceeding under Subparts D and E of 42 CFR Part 93, whichever is later, unless custody of said file or records has been transferred to DHHS or ORI has advised that the records no longer need be retained.

In addition, upon notice to VAPSHCS or SIBCR, the ORO has the right to inspect or sequester research records related to a misconduct allegation, inquiry, or investigation.

Chapter 18 Required Reports

SIBCR was established under 38 USC §§7361-7368. Section 7366 requires that each VA-affiliated institution submit an annual report to the VA with specific information provided. The report includes information for both research and education revenue and expenditures. The report also includes copies of the Institute's IRS 990 form and annual audited financial statements.

SIBCR also assists the VAPSHCS R&D office in submitting the annual Research and Development Information System (RDIS) Report on Expenditures, which is due for the government fiscal year October 1 through September 30. This report lists expenditure data for all projects.

UW School of Medicine requests an annual report of expenditures by project for all University faculty. The report includes the sponsoring organization.

SIBCR also has to maintain its status as a state-incorporated nonprofit and files a report annually with the Washington Secretary of State for the Nonprofit Corporation Registration.

The state also requires an annual filing with the Charities Division of the Secretary of State to maintain the registration as a state charitable trust and separately, another annual registration for Charitable Solicitations.

Chapter 19

Institutional Support of Research Educational Activities

The Seattle Institute for Biomedical and Clinical Research is committed to supporting the research-related educational endeavors of its members in conjunction with the VAPSHCS R&D Committee for the benefit of the research community and the public. To this end, the Institute may sponsor or provide support, on request, for events such as seminars, retreats, lectures and conferences, as funds permit. The Board of Directors will designate funding for such activities.

Requests for SIBCR support will be reviewed under the following guidelines:

1. The event should be relevant to the R&D mission of the VA.
2. The event will usually be proposed or sponsored by a current member of SIBCR.
3. The scope of the activity should be of interest and use to more than a single individual or small group.
4. A draft of the program, list of potential participants, and description of audience to be invited must be submitted as a written request. This should be done sufficiently in advance of the activity to reach the Board for consideration at its regular, quarterly meetings. In exceptional cases, the Board empowers the President to approve or disapprove requests based on the review and unanimous recommendation of the Vice President, Secretary and Executive Director.
5. Funding support for any one event will usually be limited to \$1,000. Collateral funding from other sources is encouraged. The identities of other sources should be specified in the request.
6. If funding support is approved, a statement acknowledging support provided by SIBCR must appear in brochures, letters of invitation, announcements, or other literature created for the event. The full name of the Institute, not its acronym, should be used for these acknowledgments.
7. Funding support provided by SIBCR does not constitute endorsement of the theories, practices, data, policies or beliefs presented at such events.