

ROLES AND RESPONSIBILITIES

IN THE

CONDUCT OF RESEARCH

AND

ADMINISTRATION OF SPONSORED PROJECTS

INSTITUTIONAL OVERSIGHT

This policy describes the research-related compliance roles and responsibilities and lines of authority of each component of OHSU that conducts or administers research, whether externally or internally funded. Research Roles & Responsibilities are just one part of the Integrity Program of OHSU, which also includes Institutional Roles & Responsibilities, the Code of Conduct, and the Clinical Compliance Plan. The documents that describe the Integrity Program are adopted by the OHSU Board of Directors and represent highest-level policy (OHSU Board of Directors Resolution 2004-12-20).

Three fundamental principles define the foundation for institutional oversight.

- Responsibility is defined as the authority to make a decision and accountability associated with that decision.
- To the extent possible, responsibility is maintained locally within administrative units (Schools, Institutes, Departments, and Divisions), so that decisions are made by individuals with the best information. In the research context, this means that these administrative units are responsible for compliance with all laws and regulations governing human, animal, basic science, and applied research. Financially, this means if a transaction is approved at the administrative unit or departmental level, the department accepts the fiscal responsibility for that transaction.
- Oversight responsibility is always separate from the administrative unit that makes the decisions
 and exists to ensure compliance with all applicable federal, state, and local regulations and OHSU
 policies.

The roles and responsibilities of the following individuals and offices are described herein:

- Vice President for Research
- Principal Investigator
- Administrative Staff
- Head of Administrative Unit
- Deans and Institute Directors
- Senior Executives
- Research Funding and Development Services
- Research Grants and Contracts
- Sponsored Project Administration
- Research Integrity Office
- Technology Transfer and Business Development
- <u>Clinical Trials Office</u>
- Other Units

VICE PRESIDENT FOR RESEARCH

The Vice President for Research (VPR) is designated as the Institutional Official who has the authority to deal directly with funding agencies, both federal and non-federal, relating to any aspect of externally funded activity at OHSU. The Office of the VPR promotes the creation and maintenance of a University environment that encourages and supports research productivity and compliance. The VPR is responsible for directing and guiding OHSU's research mission and for oversight of Research Development and Administration (RDA) where, among other things, policies, procedures, and business decisions related to research and sponsored project administration are formulated and monitored. RDA ensures that OHSU implements and evaluates Conflict of Interest in Research (CoIR) management and that education on the responsible conduct of research (RCR) is conducted and evaluated. In addition, the VPR is responsible for the patenting and marketing of technology arising from inventions of OHSU personnel. An organizational chart demonstrating authority for units within RDA is provided in Appendix A.

The VPR reports directly to the President of OHSU.

POLICY FORMULATION. The VPR oversees policy formulation for a broad range of research activities at OHSU, including, but not limited to:

- Human and animal subjects
- Research grants and contracts
- Sponsored projects administration
- CoIR disclosure and management
- Disclosures, copyrights, intellectual property, and technology transfer
- Education requirements for researchers and their staff
- Clinical research billing
- rDNA research, stem cell research, infectious agents, select agents, or biological toxins

OVERSIGHT RESPONSIBILITIES. The VPR has ultimate responsibility for oversight for all research activities at OHSU, including, but are not limited to:

- Ethical standards for the conduct of research (including issues of scientific integrity, financial and business conflicts of interest, grant and contract compliance, etc.)
- Financial management of sponsored accounts (including guidelines in OMB Circulars A-21 and A-110)
- Research infrastructure development
- Indirect cost rate (F&A) decisions, reductions, or waivers
- Management of core facilities
- New research initiatives
- Clinical research billing compliance

DELEGATION OF AUTHORITY. The VPR may delegate responsibility to appropriate Associate or Assistant VPs, Directors, or committees.

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PRINCIPAL INVESTIGATOR

The **Principal Investigator** (**PI**) is the individual designated by the grantee (OHSU), responsible for the technical aspects and regulatory compliance of the research or project. The PI is responsible for ensuring compliance with the financial, administrative, and programmatic aspects of the project; for conducting the research in an ethical manner; and for compliance with all applicable laws, <u>policies</u>, guidelines, and regulatory requirements regardless of the source or existence of any sponsorship. PIs must meet the criteria for <u>Principal Investigator Eligibility</u>.

PROPOSAL (PROTOCOL). The PI is responsible for preparing the proposal, unless the project has been initiated by a corporate sponsor or collaborating institution and that party has prepared the proposal or protocol. In this latter instance, the PI is responsible for reviewing the ethical and scientific merit of the protocol and associated terms of participation prior to agreeing to participate as an investigator.

By signing the OHSU **Proposed Project Questionnaire** (**PPQ**) and submitting the application for review and approval, the PI is certifying that:

- The proposal is ethically and scientifically meritorious.
- Institutional reviews and approvals and continuing reviews and approvals will be obtained and maintained, as appropriate.
- The PI and study staff have not been excluded or debarred from participation in federally funded activities.
- Any/all grant/contract terms and conditions, as well as agency rules and regulations, have been read and agreed to.
- The PI is in compliance with appropriate federal and state regulations and OHSU policies governing human or animal subjects, conflict of interest, intellectual property disclosure, RCR education, rDNA, U.S. export control laws, and other compliance requirements that may be promulgated by RDA departments.
- All information in the PPQ is accurate.

PROPOSAL BUDGET. The PI:

- Prepares or directly supervises the preparation of the budget and its justification.
- Requests and/or identifies appropriate cost-sharing/matching funds, subcontracts, financial resources available for direct support of the project, and anticipated program income.
- Assures that proposed expenditures are allowable, reasonable, allocable, and consistent and meet the terms and conditions of the sponsoring agency.
- Identifies sources for covering the costs for the project that are not covered by a grant or contract.
- Cooperates with appropriate RDA departments in negotiating the terms and conditions of a contract with a sponsor.
- In collaboration with SPA and the project sponsor, if necessary, modifies the project budget in line with the award.
- May, under certain circumstances, request the Unit Head and SPA to establish an account prior to receipt of the award in order to initiate work on the project.

REGULATORY REQUIREMENTS. The PI is responsible for the accurate and complete preparation and submission of information for review by the IRB, IACUC, IBC, CoIRC, OSCRO, The Knight Cancer Institute, OCTRI, and other reviewing bodies as appropriate.

The PI is responsible for making certain that all laboratory staff and support personnel are properly trained in the practices and techniques required to ensure safety, for supervising the safe performance of those involved, for providing safe and healthful working conditions for employees, and for fostering environments conducive to high-quality, ethical research.

For NIH-funded projects, the PI is responsible for ensuring that electronic versions of final, peer-reviewed manuscripts are submitted to the National Library of Medicine's PubMed Central, per NIH policy, upon acceptance for publication.

PROPOSED PROJECT QUESTIONNAIRE (PPQ). The PI prepares or directly supervises the preparation of the PPQ. If other universities, entities, or OHSU departments are involved, the PI provides all requested information. By signing the PPQ, the PI is attesting that the submission is accurate and complete, he or she will conduct the protocol in compliance with all RDA policies and guidelines, and he or she has read and agreed to the responsibilities expressed in this Roles & Responsibilities policy.

ACCEPTANCE OF AN AWARD. The PI:

- Reviews the award document which contains the budget and the terms and conditions of the award.
- If applicable, reviews the proposed contract after negotiation by the appropriate office (see RDA Units below) and signs the contract acknowledging the terms.
- Notifies SPA of any discrepancies in the award or SPA acceptance documents or, in the case of a contract, notifies the appropriate pre-award office.
- Ensures that he or she and his or her research staff understand all award terms and conditions and sponsor requirements.

CONDUCT OF THE PROJECT. The PI:

- Is responsible for all actions required to manage and complete the scientific and programmatic aspects of the project.
- Provides appropriate technical and safety training for those working on the project, consulting with the research safety staff for assistance with this training as appropriate.
- Ensures that all research staff has completed mandatory education modules.
- Ensures compliance with all policy, regulatory, and review committee requirements for all personnel working on the project.
- Ensures staff does not exceed 1.0 FTE for all activities combined within the institution, accurately certifying level of effort by personnel working on the project.
- Initiates and approves subcontract agreements prepared by RGC, TTBD, or CTO, if applicable.
- Completes and files, as appropriate, any required interim programmatic (technical) reports, subcontracts, materials transfer agreements, or intellectual property disclosures.
- Notifies RGC, SPA, and ORIO, as appropriate, if the PI or other key personnel withdraw from the project entirely, will be absent from the project during any consecutive period of 3 months or more, or reduce their time devoted to the project by 25% or more.
- Notifies ORIO if the PI intends to be absent for longer than a four-week period and identifies a responsible and qualified person to act as Interim PI.
- Provides a clear and concise description of work and discloses any conflicts or collaborations that may impact the terms of an application or agreement.
- Reports any protocol deviations or adverse events per ORIO policy.

- Promptly works to resolve any problems or issues that are brought to his/her attention by any RDA unit.
- Discloses any inventions to TTBD.

BUDGET MANAGEMENT. If the project is sponsored, the PI:

- Initiates and provides programmatic justification of expenditures of the project budget.
- Attests to the allowability, reasonableness, allocability, and consistency of all expenditures at the time expenditures are requested.
- Initiates the process of documenting cost sharing and/or matching as mandated by the sponsor and institutional procedure.
- Initiates requests for rebudgeting as the sponsor requires.
- Ensures that project accounts are not over-spent and in the cases where they are, identifies and proposes a resolution of any overdraft.
- Approves payments of subcontractor invoices in a timely fashion.
- Uses Oracle Grants Accounting reports to monitor financial progress of sponsored projects, including appropriateness of expenditures, budgeted vs. actual expenditures, and other areas as appropriate.
- Receives interim and final financial reports to be submitted to sponsoring agencies by SPA when
 required and reviews them in a timely manner, providing feedback to SPA as necessary for timely
 reporting.
- Responds promptly, completely, and cooperatively to requests and recommendations from the OHSU Audit & Advisory Services Department.

NON-COMPETITIVE RENEWALS. The PI:

- Completes the progress report, including changes in work scope or key personnel when due.
- If appropriate, notifies the sponsor of significant remaining balances to be carried forward.
- Prepares the budget request for any renewal period.
- Prepares the PPQ for any renewal period.
- Completes continuing review materials for animal, human subjects or rDNA/infectious agent studies, working with ORIO to obtain proper review and approval prior to regulatory deadlines.
- Forwards the proposal to be signed by the delegated Institutional Official in RGC or TTBD, as appropriate.

PROJECT CLOSURE. The PI:

- Prepares and submits to the sponsor the final programmatic (technical) narrative report when required and sends copies to SPA and TTBD.
- Reviews the final financial report provided by SPA in a timely manner.
- Provides information on other closing reports, such as for patents or equipment.
- In coordination with SPA and TTBD, initiates preparation and submission of a final invention statement, if required.
- Completes and submits any required federal final invention statements.
- Provides a financial close-out report that resolves any deficits.

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ADMINISTRATIVE STAFF

Administrative Staff at the School, Department, Division, Institute, Center, or other unit level may provide administrative support for all research and sponsored projects within that unit. Included in the Administrative Staff category are department administrators, study coordinators, grants and contracts analysts, research assistants, accounting specialists, office specialists, et al. It is essential that Administrative Staff maintain current knowledge of sponsor regulations and OHSU policies and procedures related to sponsored projects management and research compliance. Administrative Staff have responsibilities in the areas listed below.

KEY RESPONSIBILITIES. Administrative staff may assist PIs by:

- Prepares documents for the budget, effort reporting, non-competitive renewals, interim and final financial reports, other closing reports, and the appointment of individuals to the project.
- Prepares in a timely manner, initial, continuing, and modification review documents for review by the PI for submission to appropriate compliance committees.
- Ensures that adverse event and protocol deviation reports associated with human and animal subjects research or rDNA/infectious agent research are completed, reviewed by the PI, and filed with ORIO within the required timelines.
- Ensures that CoIR disclosures and mandatory education modules are completed and current for all persons working on a protocol.
- Gathers information to assist in the establishment of subcontracts and identification of matching funds.
- Documents cost sharing, proposal preparation, and compliance committee reviews.
- Works with the CRBO to establish and implement compliant billing documents and processes.
- Processes requests for off-campus space.
- Processes financial transaction requests.
- Analyzes financial reports, resolving overdrafts in a timely manner.
- Assigns correct expenditure codes.
- Reconciles SPA accounts in a timely manner.
- Initiates requests for cost transfers in a timely manner.
- Processes documents to record program income.
- Notifies the PI of any problems regarding grants or contracts management.
- Notifies the PI of any changes in OHSU policies and procedures.
- Develops and maintaining internal systems for insuring regulatory compliance and that prevent compliance approval lapses.
- Forwards project modifications along with supporting documents in advance of the PI implementing any modifications or changes to rDNA, animal, or human research protocols.
- Notifies SPA, RGC, and ORIO of changes in key personnel.
- Performs duties delegated by the PI, including but not limited to data collection and analysis, interaction with study sponsors and external or internal auditors, and preparation and maintenance of study documentation.

HEAD OF ADMINISTRATIVE UNIT

The Head of an Administrative Unit is an academic leader with programmatic, managerial, and fiscal responsibilities for a designated area, such as a Department, an Institute, or a Center. The Unit Head reports to a Dean or Director.

DEPARTMENTS. In general, financial transactions using sponsored funds start at the Department/ Division or Center/Institute level with completion by a PI (or her/his designee) of a purchase request to the person who will complete the purchase transaction in the unit office. Department Chairs or Center Directors authorize the individuals in their departments who have fiscal authority for financial transactions. PIs (or their designees) retain appropriate records to reconcile with purchase transactions. Charges posted to sponsored accounts are monitored by SPA. In this process, transactions that are inappropriate on sponsored accounts are transferred to non-sponsored accounts and any required remediation is accomplished.

REVIEW, APPROVAL, AND MANAGEMENT OF PROPOSALS AND AWARDS. The Head of the Administrative Unit:

- Reviews and provides approval of the project by signing the Proposed Project Questionnaire (PPQ), thus attesting to the accuracy of all information submitted in the PPQ and indicating his/her agreement to the responsibilities as outlined in the PPQ.
- Reviews and provides unit approval of PI requests for F&A rate reduction or waiver or costsharing, taking into account the financial impact such waiver would impose on the unit.
- Reviews and approves proposals to perform research that does not have an external source of funding (i.e., unfunded or internally-funded research).
- Approves pre-award arrangements and provides a non-sponsored account in the department from which expenditures are paid if the award is not received.
- Approves resolution of overdrafts on all sponsored accounts.
- Approves and notifies the Dean/Director of rebudgeting in cases where rebudgeting has an effect on resources in the Unit or Dean's/Director's Office.
- Provides local oversight on disclosure of research support from other sources and assures nonduplication of resources.
- Maintains local oversight for the project budget and the allowability, consistency, allocability, and reasonableness of all expenditures.
- Provides oversight on all aspects of program income.
- Assumes responsibility for informing the Dean/Director and negotiating the space, when successful conduct of the project requires additional space or modification or renovation of existing or other space.
- Resolves issues related to late payments or problems with collection of awarded funds (in conjunction with the Vice President for Research and SPA).

RESEARCH COMPLIANCE RESPONSIBILITIES. The Head of the Administrative Unit:

• Attests to completion of mandatory education in responsible conduct of research for all departmental personnel involved in the project, including export compliance training for staff in the event the project will be controlled under U.S. export laws.

- Accepts responsibility for payment of any fines due to OR-OSHA, DEQ, or other rule violations by faculty members in the Department/Division.
- Makes advanced arrangements for hazardous waste disposal when laboratories are vacated and accepts responsibility for charges to remove and dispose of any hazardous waste left behind.
- Nominates faculty for service on compliance review committees IACUC, IBC, IRB, CoIRC, et.
 al.
- Provides oversight for compliance with OHSU, state, and federal policies and regulations at the departmental level.
- Ensures that all proposed research has been submitted to the appropriate compliance review committees.
- Attests that the PI, co-investigators, and all study personnel have completed and filed annual CoIR disclosure forms.
- Reviews completed CoIR forms and, if desired, recommends a resolution for potential CoIs to the employee and the CoIR Committee.
- Assumes responsibility for monitoring the CoIR management plan prescribed by the CoIRC.
- Attests that the PI, co-investigators, and all study administrative staff have read this Roles & Responsibilities policy and accepted their responsibilities as expressed in it.
- Promptly works to resolve any problems or issues that are brought to his/her attention by any RDA unit.
- Provides local oversight for record retention and ownership of scientific data at project closure and attests to adequate systems for data privacy and security.

DELEGATION OF AUTHORITY. The Head of the Administrative Unit may delegate authority for the following activities:

- Grants management tasks so long as this duty is assigned to individuals appropriately trained or certified by standard University procedures.
- Monitoring CoIR management plans.
- For an ongoing study or for a study without proper termination where the PI has departed OHSU, the Head of the Administrative Unit will assume responsibility for the proper conduct or termination of the study or will appropriately delegate responsibility to another eligible PI.
- Assumption of financial responsibility in the case of projects that go into deficit.

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DEANS AND INSTITUTE DIRECTORS

Deans and Center/Institute Directors are academic leaders with programmatic, managerial, and fiscal responsibilities for a school or research institute or center. Deans/Directors report to the President, Provost, or a Vice President.

Deans' and Directors' offices are the administrative center for the School or Institute. These offices may have Associate Deans/Directors as well as Administrative Staff. An Associate Dean/Director may have responsibility to oversee research activities in the unit and thus is delegated appropriate authority to act in matters relating to research and other sponsored projects.

OFFICE OF A DEAN OR INSTITUTE DIRECTOR. The Office of a Dean or Center/Institute Director provides local oversight for research and sponsored projects. Periodic reports from RDA departments are received and reviewed by the Office of the Dean or Institute Director. When such reports reveal problems, the Office of the Dean/Director will facilitate resolution of those issues.

KEY RESPONSIBILITIES. The Office of the Dean/Director:

- Reviews and provides approval of the project by signing the Proposed Project Questionnaire
 (PPQ). Because signature on the PPQ attests to the signers' agreement to comply with all OHSU
 policies, including this Roles & Responsibilities policy, this obligation applies regardless of
 funding sources for the proposed project.
- Approves a request for an F&A rate that varies from OHSU's negotiated and is aware of the financial impact on the department of a reduction in that rate.
- Receives notification of potential inventions and licensing or program income.
- Approves matching funds as necessary, if they come from a source outside the School/Institute.
- Reviews support from other sources, rebudgeting, and cost sharing and attests to their appropriateness.
- Ensures that there is a written agreement between parties engaged in a cost-sharing arrangement.
- Promptly works to resolve any problems or issues that are brought to the attention of the office by any RDA unit.
- Provides local oversight for grant renewals; appropriate academic review and approvals of projects; compliance with all federal, state, and local laws and regulations governing the conduct of research; and CoIR management.

DELEGATION OF AUTHORITY. The Dean/Director may delegate authority to an appropriate person who may accept responsibility and accountability for any of the Key Responsibilities.

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SENIOR EXECUTIVES

Senior executives include the President, Provost, and Vice Presidents whose responsibilities contain few, if any, direct duties in research activities in the University. Vice Presidents who are also Deans are addressed in the preceding section of this document. Senior Executives act in an oversight capacity and in the resolution of issues that do not or cannot occur in normal processes.

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RESEARCH FUNDING & DEVELOPMENT SERVICES

Research Funding & Development Services (RFDS) is a program within the Office of the Vice President for Research that provides advice, consultation, and training for OHSU researchers. The group works closely with other offices in Research Administration, such as Research Grants & Contracts (pre-award) and Sponsored Projects Administration (post-award), as well as the OHSU Foundation. RFDS also serves as the communication hub for information related to grants, research administration, and other key tools for investigators.

The director of RFDS reports to the Assistant VPR. RFDS provides assistance to faculty and staff in the following ways:

GRANT FUNDING.

- Keeps researchers informed about potential funding opportunities via the OHSU Funding Database, Funding Alerts, and other mechanisms.
- Helps researchers strategize about funding approach.
- Coordinates OHSU's Limited Submission process.
- Manages the Presidential Bridge Funding program.

PROPOSAL DEVELOPMENT.

- Meets with investigators one-on-one to make their proposals more competitive.
- Leads workshops and trainings on proposal writing and grantsmanship.
- Assists with institutional proposals.
- Provides boilerplate for grants.
- Offers science and grant writing classes to graduate students, postdoctoral fellows, and faculty.

RESEARCH COMMUNICATIONS.

- Publishes the OHSU Research News blog, which includes the latest information on events, funding opportunities, policy changes, and more.
- Sends targeted emails to faculty, postdoctoral fellows, and other research staff regarding important institutional updates and information.
- Manages the Research homepage and Research Calendar and provides support to Research Administration for web development.

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RESEARCH GRANTS & CONTRACTS

Research Grants & Contracts (RGC) is the only institutional unit legally able to submit proposals to external, non-corporate entities for financial support in the form of a contract, grant, or agreement unless supported by an industry sponsor. It is also legally able to commit OHSU, on behalf of the Board of Directors, in the event an award is made, whether by formal contract, grant agreement, or other arrangement, with respect to the terms and conditions of the award, the scope of work, the period of performance or term of the contract, the identity and commitment of the principal investigator and other key personnel, and the approved budget. The exceptions to this are that TTBD performs these functions for non-clinical trial corporate sponsored research and CTO performs these functions for corporate sponsored clinical trials.

RGC performs the following functions:

- Provides advice to investigators on sponsor guidelines and requirements.
- Reviews, assists with completion of, and approves all grant applications and contract proposals for non-industry funded sponsored projects.
- Negotiates contractual and subcontract agreements with non-corporate sponsors and other entities.
- Negotiates award terms and conditions with non-corporate sponsors and other entities.
- Accepts all non-corporate awards on behalf of OHSU.

RGC has the authority to communicate directly with sponsors on behalf of OHSU on matters related to regulatory compliance, award terms and conditions, and the ongoing non-financial management of grants and contracts.

The Director of RGC is designated as an Institutional Official and has been delegated authority by the VPR to sign grant and contract proposals, to receive awards, and to conduct appropriate pre-award business with federal and private funding agencies. The Director of RGC may request further delegations of signing authority from the VPR for management subordinates within RGC.

The Director of RGC reports to the Assistant VPR. The Grants and Contracts Manager and the Assistant Director report directly to the Director of RGC. The Grants and Contracts Manager leads a team that includes Grants and Contracts Analysts who are assigned a portfolio of departments/units as the first point of contact in RGC. The Assistant Director leads an operations team, including administrative and information systems support staff.

PROPOSAL PREPARATION. The RGC director and RGC team will:

- Assist PIs and their staffs in the accurate completion of grant applications and contract proposals, budget preparation and justification, and electronic grant submissions.
- Confirm PI eligibility status.
- Confirm that matching funds and cost sharing through contributed effort and other commitments
 are identified and approved and that a defined cost-sharing budget has been submitted and
 approved at the time of award.
- Check the PPQ for:
 - Complete and accurate information and accompanying approvals as appropriate;

- Involvement of human or animal subjects, rDNA, infectious agents, radiation, select
 agents, or biological toxins and ascertain that necessary approvals have been obtained or
 have been applied for; and
- Any export control issues.
- Check the final application for completeness and administrative accuracy.
- Screen all industry/commercial sponsors for excluded/debarred status if RGC is managing a contract/grant with an industry/commercial sponsor.
- Provide feedback on grant-writing and match applications with program goals and fundability.
- Obtain the signature of the Institutional Official on behalf of the institution assuring institutional commitment and oversight.
- Complete and provide to the PI and department contact the Department Award Checklist (DAC) outlining all compliance items that must be completed for the program prior to account set up should the grant or contract be awarded.

AWARD & PROJECT ADMINISTRATION. RGC provides institutional oversight and assistance in the processing and acceptance of new awards. In addition, RGC:

- Assists PIs and their staff with meeting sponsor "just-in-time requests" prior to the issuance of grant awards.
- Receives the Notice of Grant Award (NGA), if applicable.
- Notifies the PI that the award has been received and sends a copy of the NGA with an updated copy of the DAC to the PI and Unit Administrator.
- Ensures that all compliance approvals have been obtained, including RCR education and CoIR disclosure.
- When required, works with the CoIR office to assure that funding agencies are appropriately notified of potential conflicts of interest with that award prior to account set-up.
- Authorizes establishment of accounts for accepted awards and sends grant information and the NGA to SPA for account set-up.
- Develops and negotiates subcontracts in response to PI requests and in accordance with award terms and conditions.
- Negotiates, approves, and notifies the PI of the project terms and conditions for federal and non-federal sponsors as appropriate.
- Accepts the agreement on behalf of OHSU.
- Approves and expedites pre-award arrangements in coordination with SPA.
- Accepts grants transferred to OHSU from another institution.
- Reviews and approves annual progress reports as required by sponsors.
- Reviews and provides institutional endorsement to the sponsor for requests for programmatic changes initiated by the PI and notifies SPA.
- Prepares, negotiates, and executes agreements for subcontracts from other organizations.
- Prepares amendments for ongoing subcontract arrangements.

EDUCATION AND DEVELOPMENT ACTIVITIES. RGC:

• Provides education to the research community on electronic submission processes, including eSNAP progress report submissions through the NIH Commons, grant submissions through

InfoEd, direct Grants.gov submissions, and other federal and non-federal electronic submission requirements.

- Implements InfoEd in Proposal Tracking and Proposal Development, including initial and continued InfoEd training to the OHSU research community.
- Reviews, interprets, and disseminates policies from federal and non-federal funding agencies.
- Interprets and implements OHSU policies related to non-industry grants and contracts and suggests revisions or new policies as necessary.
- Identifies areas that require additional education and refers them to the appropriate venue.

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TECHNOLOGY TRANSFER AND BUSINESS DEVELOPMENT

TECHNOLOGY TRANSFER AND BUSINESS DEVELOPMENT (TTBD). OHSU recognizes the importance of transferring technology to the commercial sector where it can benefit the people it serves. TTBD is responsible for managing that process. It partners with industry to facilitate research, license promising discoveries, and create new companies. TTBD is authorized to legally bind OHSU to non-clinical agreements, materials transfer agreements, and commercialization agreements (e.g., License Agreements, Option Agreements, Collaboration Agreements, etc.) with corporate or public entities. In addition, TTBD manages obtaining, maintaining, licensing, and commercialization of intellectual property developed at OHSU. The Director of TTBD reports directly to the Vice President for Research and the Vice President for Commercialization Strategies.

TTBD's key areas of responsibility are:

INTELLECTUAL PROPERTY MANAGEMENT

- TTBD is responsible for assessing commercial potential of research and technologies at OHSU.
 This includes assessing intellectual property protections, marketing the technology to industry, and
 negotiating and managing agreements for the development and commercialization of research and
 technology.
- TTBD may accept intellectual property transferred to OHSU from other institutions.

MATERIAL TRANSFER AGREEMENTS

• TTBD is responsible for negotiating and managing MTAs to assure that the terms of an agreement do not jeopardize an investigator's future work or academic freedoms and the institution's ability to fulfill its mission.

INDUSTRY-SPONSORED RESEARCH AGREEMENTS

• TTBD is responsible for negotiating, managing, and assuring that the terms of SRAs protect the investigator and the institution. This includes, but is not limited to, protecting the investigator's intellectual property, performing due diligence, and assuring that projects are within the scope of OHSU's missions.

COMPLIANCE. TTBD:

- Reports to federal and non-federal sponsors any intellectual property.
- Ensures compliance with the Bayh-Dole Act.
- Provides reports of inventions to sponsors.
- Distributes income received from commercialization activities according to institutional and federal guidelines.
- Provides reports to the CoIR program in ORIO to assist in identifying and managing both individual and institutional conflict of interest issues and serves as an ex officio member of the CoIRC.
- Notifies the VPR of invention management activities.
- Reviews, interprets, and disseminates federal and institutional intellectual property and technology transfer policies.
- Interprets and implements OHSU policies related to corporate-sponsored contracts, intellectual property, and technology transfer.

• Ensures all agreements comply with current U.S. export control regulations.

EDUCATION ACTIVITIES. TTBD organizes, manages, provides, and participates in:

- Seminars, workshops, and additional education/training opportunities.
- Referral of staff and faculty to appropriate educational venues.
- Seminars and workshops relating to intellectual property, entrepreneurship, licensing/commercialization issues, transfer and management of biological materials into and out of OHSU, and working and collaborating with industry on industry-sponsored research agreements.

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CLINICAL TRIALS OFFICE

CLINICAL TRIALS OFFICE (CTO). CTO is responsible for negotiating industry-sponsored clinical trial contracts with corporate sponsors. CTO reviews, negotiates, signs, and accepts agreements and associated amendments to agreements and subcontracts with sponsors and subcontractees on behalf of OHSU. CTO also provides clinical research education and training to ensure compliance.

The CTO provides services to investigators during the pre-study start-up phase of industry-sponsored clinical trials. Certain services are provided for non-industry clinical trials also. When providing these services, CTO, acting on behalf of investigators, ensures compliance with applicable policies and regulations governing the conduct of clinical trials.

The CTO is legally able to commit OHSU to corporate-sponsored clinical trial contracts and agreements. The Director of Investigator Support & Integration Services (ISIS) in OCTRI is designated as an Institutional Official and has the authority (or may delegate laterally, if necessary) to sign contracts and agreements with corporate sponsors of clinical trials. Contract language is negotiated by CTO Contract Coordinators. The Director of ISIS reports to the Assistant Vice President for Research.

CONTRACT NEGOTIATION AND EXECUTION. The CTO Contract Coordinator:

- Negotiates terms of confidentiality agreements with corporate sponsors when such agreements require institutional signature.
- Negotiates contract terms with corporate sponsors for clinical trials.
- Obtains the signature of the Institutional Official on behalf of the institution assuring institutional oversight once all required compliance approvals have been obtained.
- Notifies the PI that the contract has been executed and sends a copy of the contract to the PI and Unit Administrator.
- Authorizes establishment of accounts and sends contract information to SPA for corporatesponsored clinical trials.
- Approves and notifies the PI of the project terms and conditions for corporate-sponsored clinical trials.
- Negotiates terms for subsequent amendments to industry-sponsored clinical trial agreements or subcontracts associated with industry-sponsored clinical trial agreements.

EDUCATION ACTIVITIES. CTO:

- Reviews, interprets, and disseminates federal regulations and institutional policies regarding clinical research and clinical trial contracting.
- Interprets and implements federal regulations and OHSU policies related to clinical research conduct and corporate-sponsored clinical trial contracts.
- Conducts regular training regarding clinical research conduct.
- Identifies areas that require additional education/training and refers staff and faculty to the appropriate venue or develops and conducts appropriate training.

COMPLIANCE ON BEHALF OF INVESTIGATOR. If requested by the PI, the CTO:

- Prepares and negotiates, with supervision from the PI, budgets for corporate sponsored clinical trials including approval of all rates for OHSU healthcare system services.
- Prepares, with supervision from the PI, and obtains approval of submissions to the IRB and other appropriate reviewing committees.
- Upon set-up of study account by SPA, requests an OHSU Hospitals and Clinics account.

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OHSU RESEARCH INTEGRITY OFFICE

OHSU RESEARCH INTEGRITY OFFICE (ORIO). ORIO is responsible for assuring compliance with all laws, regulations, and guidelines that govern human, animal, basic science, and applied science research at OHSU. ORIO is responsible for maintaining appropriate assurances and accreditations for human and animal subjects research compliance programs, filing federal Office of Research Integrity reports of scientific misconduct, making necessary reports of conflicts of interest in research, and other federal and state research compliance initiatives. ORIO has the responsibility and authority to ensure that OHSU's human and animal research protection programs and compliance programs overseeing rDNA and infectious agent research, select agents, research safety, stem cell research, and conflict of interest in research are systematic, comprehensive, and current. These programs will comply with all federal, state, and local regulations governing research. The human research protection program will follow the ethical principles set forth in the Belmont Report.

ORIO is responsible for the function and oversight of OHSU's multiple Institutional Review Boards (IRB), the Institutional Animal Care and Use Committees (IACUC), the Institutional Biosafety Committee (IBC), the OHSU Stem Cell Research Oversight Committee (OSCRO), and the Conflict of Interest in Research Committee (CoIRC). In addition, ORIO oversees the Clinical Research Billing Compliance Office (CRBO) to ensure compliance with OHSU policy and all federal regulations pertaining to billing for clinical research services. ORIO also organizes and monitors the Responsible Conduct of Research (RCR) education and safety training education programs and conducts internal audits related to research compliance.

The Director of ORIO reports to the VPR. Reporting to the Director of ORIO are the Associate & Assistant Directors, the IRB Chair and co-chairs, the IACUC Chair and co-chairs, and the Research Integrity Officers. The Director of the CRBO reports to the Chief Integrity Officer. There are several IRB, IBC, CoIR, OSCRO, and IACUC analysts; a Regulatory Specialist; and administrative support staff who report to appropriate supervisors.

PROJECT MANAGEMENT & COMPLIANCE. The ORIO:

- Assists PIs and study personnel with preparation of submissions for initial, continuing, and modification reviews; unanticipated problem and protocol deviation reports; and other compliance related materials for appropriate levels of review.
- Provides assistance with training, risk assessment, and other guidance for the safe use of biological and chemical hazards in research and general lab safety.
- Through the oversight of the Responsible Officials, maintains select agent documentation for projects using Select Agents and Toxins.
- Through the oversight and authority of the Responsible Officials, ensures that the Select Agent Program complies with federal and state regulations.
- Confirms that study personnel have completed RCR, HIPAA, and other education modules as applicable, and filed CoIR disclosures.
- Schedules protocols and CoIR disclosures for timely review by qualified IRB, IACUC, IBC, OSCRO, or CoIRC members.
- Prepares written communications from compliance committees to PIs, Department Heads, Deans, and Directors when appropriate.
- Accurately enters and maintains study status information into electronic and paper copy files.
- Establishes policies and procedures for addressing allegations and findings of non-compliance with research protection program requirements including, but not limited to:

- Urgent situations
- Unanticipated problems
- Specific or general noncompliance
- Termination or suspension of research
- Human subject complaints
- Unapproved change in research protocol
- Undue influence on ORIO or review committees
- Failure to submit or appropriately update CoIR disclosures
- Notifies the compliance committee chairs of protocol violations, study lapses, and other regulatory violations.
- Notifies the appropriate federal oversight bodies of regulatory violations and other required compliance reports or notifications.
- Ensures that there are sufficient compliance committees with appropriate expertise to review and
 oversee the volume and types of research being performed at OHSU and that the compliance
 committees have adequate resources to carry out their duties.
- Ensures that all IRBs, IACUCs, IBCs, OSCRO, and CoIR committees, as well as ORIO, function
 independently and free from coercion and undue influence. The Director of ORIO will establish
 policies and procedures to respond to investigator or organizational attempts to unduly influence a
 review committee. The response will include reporting to the Vice President for Research, the
 President of OHSU, and the Board of Directors.
- Implements programs to continuously educate PIs and their staff and compliance committee
 members in human and animal subjects protections requirements, lab safety, and all other
 applicable policies and state and federal laws and regulations.
- In coordination with other RDA departments, assures that research studies have sufficient and appropriate resources, including, but not limited to space, staff, and ancillary services, for the care, safety, and protection of research participants and staff.
- Monitors research compliance and safety of ongoing projects.
- Maintains appropriate federal assurances, accreditations, and registrations.
- Works with the Policy Advisory Committee to develop appropriate policies regarding compliance
 with regulations related to human and animal subjects, CoIR, rDNA, viral vectors, biological
 toxins, infectious agents, select agents, stem cells, and lab safety.
- Works with OHSU Legal Counsel when research questions or issues involve matters of law or interpretation of regulations or regulatory guidance. ORIO has the responsibility and authority to access outside legal counsel if the Director of ORIO determines that internal counsel may have a conflict of interest in providing legal advice.

CLINICAL RESEARCH BILLING COMPLIANCE OFFICE: The Clinical Research Billing Compliance Office (CRBO) implements and directs a program to ensure compliant billing of clinical treatment (according to federal rules and third party payer contracts) delivered within the context of clinical research. The CRBO works with PIs, study coordinators, Patient Billing Services, the Faculty Practice Plan, and others to develop processes and procedures for compliant billing. In addition, this program works with Audit & Advisory Services to monitor and audit research billing to ensure compliance with regulations.

Roles & Responsibilities Page 23 of 37

Compliance Responsibilities

The CRBO is responsible for policies and procedures to:

- Develop clinical research billing schedules that discriminate between research and standard care services.
- Identify research subjects and protocol encounters and discriminate such encounters from standard care visits.
- Review charges for protocol encounters.
- Review and reconcile Oregon law with the National Coverage Decision.
- Identify study services that are routine costs and that require appropriate code modifiers.
- Coordinate denials management.

Education Responsibilities

The CRBO works with department administrators and research coordinators to implement compliant billing practices at the local level. These education responsibilities include:

- Department level training on policies, processes and procedures related to billing for clinical research services.
- Coordinating with Epic (Electronic Medical Record) training on research related functionality.
- Developing, implementing and providing training on the Clinical Research Management System (CRMS).

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SPONSORED PROJECT ADMINISTRATION (POST-AWARD)

SPONSORED PROJECTS ADMINISTRATION (SPA). SPA is the unit responsible for all post-award management of externally-funded as well as individually-budgeted, University funded, sponsored projects. SPA has responsibility for maintaining OHSU's overall financial compliance related to management of all OHSU sponsored projects. SPA is responsible for assuring institutional compliance with all sponsor regulations, including the Federal Office of Management and Budget (OMB) Circular A-21, "Cost Principals for Institutions of Higher Education" and 2 CFR 215 (formerly OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

The Director of SPA reports to the Assistant Vice President for Research and is the designated Institutional Fiscal Officer for sponsored projects related matters. This position has the authority to conduct official business with funding agencies, both federal and non-federal, relating to post-award aspects of externally funded activity at OHSU. The Director of SPA works closely with the other RDA leaders, Central Financial Services, Information Technology Group, Human Resources, the Legal Department, and the OHSU Foundation in resolving problems; maintains current knowledge of federal, state, and OHSU policies; and provides advice to the VPR on systemic and continuous improvement in the quality of grants management.

SPA has the following specific responsibilities:

AWARD SETUP

IDENTIFY AND ACCOUNT FOR SPONSORED PROJECTS AND FEDERAL FUNDING. Ensure that sponsored funds are properly identified and maintained in separate accounts in the Oracle Grants Accounting (OGA) system. Ensure that all federal funds received by OHSU are identified and tracked by SPA as well as reported via OHSU's annual federal grant audit (A133). This includes both direct and pass-through funds (but excludes Medicare and Medicaid funding).

SUSPENSION AND DEBARMENT. Work with other administrative units to ensure that OHSU does not enter into any agreements with individuals or organizations that have been suspended or debarred from doing business with the federal government.

AWARD SETUP RECEIPT, PROCESSING, AND NOTIFICATION. Ensure that all sponsored project funding is set up in accounts in OGA within five business days of receipt in SPA, provided all necessary documentation is included. Notify the PI and department of account setup and account number.

AWARD TERMS AND CONDITIONS. Assist the PI and department staff in understanding and complying with award terms and conditions. Ensure that administrative and financial terms and conditions of project are met.

PRE AWARD ACCOUNT SETUP. Create new account upon receipt of approved <u>Pre-Award Account Setup</u> form and notify the PI and department of new account setup. Track pre-award accounts to ensure that award document is ultimately received and that the account is then fully set up. Transfer expenses to non-sponsored accounts, as necessary, when pre-awarded sponsored projects fail to get awarded.

ACCELERATED SPENDING REQUESTS. Enable account spending upon receipt of approved <u>Accelerated Spending Request Form</u> and notify the PI and department. Ensure that accounts that are activated for

spending prior to receipt of award notice are set up to not bill sponsors. Maintain information on level of accelerated spending and escalate variances as appropriate.

AWARD REVISIONS

PROJECT EXTENSIONS / NO COST EXTENSIONS. Upon notification of approval of extension, update end-dates in Oracle Grants Accounting and notify the PI/department of approved end-date changes.

BUDGET ADJUSTMENTS. Receive prepared request letters addressed to sponsors for budget adjustments and process these in a timely manner and ensure that any re-budgeting is in accordance with sponsor requirements. If sponsor prior approval is required, co-sign on request and assist in communication with sponsor, as needed. If re-budgeting involves change of scope, work with pre-award.

CARRYOVERS. Approve and process automatic carryovers to continuation years, review and approve any carry over requests to sponsors, and work with department to ensure that proper justification and notification to sponsor takes place.

OGA DATA CHANGE REQUESTS (AWARD ATTRIBUTE CHANGES). Maintain current award/project data and roles within OGA. Maintain current organizational structure and contacts within OGA. Process all OGA data changes as requested by departments in a timely fashion.

AWARD FINANCIAL MANAGEMENT

PERIODS. Provide high level oversight in ensuring that expenditures on sponsored projects are allowable, reasonable, allocable, and consistent and in accordance with sponsor terms and conditions as well as occurring within the awarded project period. Ensure, in particular, that expenses normally included in OHSU's F&A rate proposal are not included as direct costs to sponsored projects.

COST TRANSFERS/PERSONNEL ADJUSTMENTS. Receive and process all labor distribution adjustments that fail the validation rules in Oracle in a timely manner. Review labor adjustments for completeness and appropriateness. Contact PI and/or department, as necessary, for additional information or if the adjustment will not be able to be processed.

COST TRANSFERS/NON PERSONNEL ADJUSTMENTS (ACCOUNTS PAYABLE AND INTERNAL BILLING SYSTEM). Receive and process <u>University Adjustment Form</u> in a timely fashion, ensuring that adjustment is appropriate and properly justified and supported. When appropriate, process adjustments by preapproved batch (PAB).

SPONSOR PRIOR APPROVALS. Provide high-level oversight to assist PIs in ensuring that all sponsor prior approvals are requested when appropriate. Receive and process sponsor prior approval requests in a timely fashion.

OVERSPENDING AND DEFICIT RESOLUTION. Provide high-level oversight in monitoring overspending and notify PIs, divisions, departments, and schools/units when overspending occurs. Process transfer of overspending to non-sponsored accounts as provided by departments and move deficits to department general funds if departments do not respond in 10 business days.

BUDGETING AND BUDGET CHANGES. Provide high-level oversight of project spending in relation to awarded budget, helping ensure that proper approval is requested when changes in budget take place.

Process budget adjustments as requested and approved in a timely fashion. Assist PIs and departments in understanding their roles related to budgeting and re-budgeting, with particular focus on spending within the awarded total cost budget.

SUB AWARD INVOICE PROCESSING. Maintain sub award documentation. Receive and process all sub award invoices. Review administrative and financial information provided on sub award invoices for consistency with sub award agreement and budget. Communicate with the PI and/or department administrative staff and sub awardee, as appropriate, for clarification or resolution of discrepancies in information on the invoice.

PROGRAM DEVELOPMENT ACCOUNTS (PDA). Receive, approve, and process, as appropriate, requests for new PDA accounts and for transfers of residual balances into PDA accounts in a timely fashion. Monitor all PDA accounts for adherence to PDA guidelines and notify PIs and departments when non-adherence has taken place. Coordinate with PIs and departments for resolution of non-adherence or other issues. Transfer unresolved deficits on PDAs to department general funds.

INDUSTRY SPONSORED CLINICAL TRIALS. Assist PIs and departments, as needed, related to study invoicing during the life of the study. Receive clinical trial cash receipts and deposit to appropriate accounts and provide copy of check and associated documentation to the PI and department. Monitor clinical trial deficits, notifying PIs and departments when deficits have exceeded \$15,000 and coordinate resolution, as needed. Process Balance Transfer Form received in SPA, including deficit transfers, residual balance transfers, and study account closeout.

VA INTERGOVERNMENTAL PERSONNEL AGREEMENTS (IPA's). Receive, review, approve, and process, as appropriate, all VA IPAs in a timely fashion. Communicate with the PI, VA employee, VA Research Services, and/or department to discuss any issues or discrepancies with IPAs. Process IPA invoices to the VA in a timely fashion and assist in ensuring that timely payments are made on IPA accounts. Monitor IPA accounts and notify PIs and departments if overspending occurs. Process necessary actions for overspending resolution.

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AWARD REPORTING, CLOSEOUT AND AUDIT

AWARD CLOSEOUT. Monitor accounts for necessary closeout actions and coordinate, as appropriate, with PIs and departments to ensure that any closeout reports are submitted in a timely fashion.

FINANCIAL REPORTING. Ensure that OHSU adheres to all reporting requirements on all sponsored project awards per award terms and conditions or contract. Prepare and submit all financial reports for concurrence to PIs and fiscal managers. Allow five business days for concurring review and coordinate with the PI and/or fiscal manager to resolve any discrepancies noted within this timeframe. If no response is received, submit financial report to sponsor by due date.

TECHNICAL, PROPERTY, AND INVENTION REPORTING. Work with the PI and department staff to ensure that OHSU adheres to reporting requirements on all sponsored project awards per award terms and conditions or contract.

AUDIT. Coordinate all administrative and financial related external audits on sponsored projects including the annual A-133 audit.

RECORD RETENTION. Maintain overall knowledge and oversight on record retention requirements as indicated in award documents, ensuring that all appropriate documentation is maintained by SPA.

OVERALL AWARD OVERSIGHT

PROGRAM INCOME. Receive information from RGC related to program income requirements on projects. Report to sponsor on handling of program income as part of award financial report.

COST SHARING. Oversee OHSU's cost sharing procedure and associated guideline documents by ensuring department/unit compliance with University policies and procedures, agency guidelines, and applicable federal regulations. Setup cost sharing accounts, as required or requested. Receive and maintain all documentation related to cost sharing in the official accounting records of OHSU in accordance with audit standards, including documentation of third-party and in-kind donated cost sharing. Be involved with and approve, if necessary, any reductions or changes in an award's budget and any associated cost sharing commitments that take place after the award has been accepted or contract signed and during the conduct of the sponsored project. As needed, review cost sharing expenditures to ensure compliance with award terms and conditions and report to sponsor on Cost Sharing funds as part of award financial report.

EFFORT REPORTING. SPA is responsible for the creation, distribution, and collection of the Effort Certification Statements from the Departmental Effort Coordinators (DECs), as well as the maintenance of the Effort Certification Process as a whole.

SUB RECIPIENT MONITORING. Ensure that contract payments are appropriately burdened and facilitate payment process. Ensure that all sub-recipients under federal awards provide copies of their annual A-133 audit reports and/or audited financial statements in order to provide assurance of financial health and internal controls of the sub-recipient organization.

EQUIPMENT OWNERSHIP. Adhere to Capital Accounting Policy and award terms and conditions related to any equipment purchased on sponsored projects. Notify Fixed Assets of appropriate ownership classification for all equipment purchased on sponsored projects. Coordinate with Fixed Assets and departments related to any disposition or transfer of any equipment purchased on sponsored projects.

CASH MANAGEMENT

INVOICING: COST AND EVENT BASED. Ensure that terms and conditions of award related to invoicing are met. Provide the PI and department with copies of final invoices for concurrence. Submit cost based invoices according to timelines in award documents.

FEDERAL CASH DRAWS AND FEDERAL CASH TRANSACTION REPORTS. Ensure that cash is drawn against federal letter of credit accounts on a weekly basis for all applicable expenses incurred. Apply cash received to accounts, as appropriate. Ensure that quarterly or, as needed, federal cash transaction reports are submitted on time.

CASH RECEIPTS AND APPLICATION. Ensure that all cash (checks and wire transfers) is deposited and applied in a timely and accurate basis into correct OGA Awards based on information provided with checks or wire transfers or from communications with the PI or department, as required. Research appropriate OGA Award information for cash receipts as appropriate and resolve discrepancies noted in a timely fashion.

EDUCATION/COMMUNICATION

Collaborate with the Research Administration Training & Education Manager (RATE) to maintain an effective training and education program in all the elements of grants management. Collaborate with RATE to maintain ongoing standard communication mechanisms to relay important and up-to-date information to the OHSU research community.

ORACLE GRANTS ACCOUNTING (OGS SYSTEM)

SYSTEM MAINTENANCE AND DEVELOPMENT. Maintain Oracle Grants Accounting system on a day-to-day basis to ensure ongoing use by OHSU. Provide ongoing development of Oracle Grants Accounting system to implement new or enhanced functionality to better serve the OHSU community.

SYSTEM ACCESS AND ROLES. Receive and process any requests for OGA Inquiry access in a timely manner; maintain records of all requests for OGA access. Enter, maintain, and update (as needed) all award and project roles in OGA.

INSTITUTIONAL REPORTS/SURVEYS

Publish institutional sponsored projects related information and reports on the SPA website. Receive and respond to <u>requests for information</u>. SPA will respond to requestors by providing an estimated completion date for the request or by requesting further information about the request.

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OTHER OVERSIGHT

CORPORATE FINANCIAL SERVICES

Corporate Financial Services is responsible for establishing policies and procedures that ensure the accuracy and timeliness of all financial transactions posting to the general ledger.

AUDIT & ADVISORY SERVICES

OHSU's internal audit responsibility resides within the OHSU Integrity Office (OIO). The Audit & Advisory Services (A&AS) Program conducts audits in areas across OHSU, provides reports to those areas and executive levels, and uses results to prepare recommendations for compliance and best practices. A&AS considers risks broadly, monitors OHSU activities, and recommends actions to reduce risks to a reasonable level and promote compliance with OHSU policies and applicable laws and regulations.

DEPARTMENT OF ENVIRONMENTAL HEALTH & RADIATION SAFETY (EHRS)

The Department of Environmental Health & Radiation Safety (EHRS) provides technical guidance and core safety services (e.g., ergonomics, fire/life safety, air contaminant monitoring, fume hood certification) to all OHSU operations. For safety services related to lab safety, this function is provided by ORIO through the Research Safety Program. However, EHRS provides institutional oversight and oversees policy formulation for research proposals which involve radioactive materials and/or ionizing or non-ionizing radiation producing equipment. EHRS also provides institutional oversight for off-campus space used as a laboratory or clinic.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

The IACUCs approve and provide institutional oversight for proposals involving and policies related to live animals as subjects.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The IBC approves and provides institutional oversight for proposals involving recombinant DNA, infectious agents, other select agents, or biological toxins.

INSTITUTIONAL REVIEW BOARD (IRB)

The IRBs approve and provide institutional oversight for research proposals involving human subjects.

IRB Chairs' Advisory Council (ICAC)

The ICAC reviews policies, processes, and procedures related to human subjects research and advises the IRB chairs.

CONFLICT OF INTEREST IN RESEARCH COMMITTEE (COIRC)

The CoIRC reviews and provides institutional oversight for potential or real conflicts of interest in research as defined by institutional policy. The CoIRC determines what conditions or restrictions, if any, should be imposed to manage, reduce, or eliminate potential conflicts of interest in research. Appendix C provides electronic links to CoIR policy, disclosure forms, and management guidelines.

OHSU STEM CELL OVERSIGHT COMMITTEE (OSCRO)

The OSCRO provides oversight of issues related to the derivation and research use of human stem cell lines at OHSU regardless of the source of funding and reviews all stem cell research proposals submitted by OHSU investigators.

OHSU IACUC Advisory Council (OIAC)

The OIAC drafts policies and procedures related to the animal research program for eventual approval by the IACUCs. The OIAC is advisory to the VPR, IACUC chairs, the Research Integrity Officers, and the Director of ORIO.

OHSU Integrity Office (OIO)

This office reports to the OHSU Vice President and General Counsel and coordinates, integrates, and facilitates all integrity and compliance oversight functions of the institution in all mission areas.

INTEGRITY PROGRAM OVERSIGHT COUNCIL (IPOC)

The IPOC is a Board of Directors oversight council for OHSU's Integrity Program. The IPOC consists of two Board members, various VPs, and General Counsel. It is chaired by a Board of Directors member and staffed by the Chief Integrity Officer. Included in its oversight responsibilities are review and management of institutional conflicts of interest, ensuring appropriate resource allocation for research compliance efforts, and high level guidance on research mission issues.

RECORDS RETENTION COMMITTEE

The Records Retention Committee, with approval by the VPR, oversees policy formulation for retention and ownership of scientific data and all other research related records. The Records Retention Committee, with OIO, oversees policy formulation for retention and secure data storage of Protected Health Information.

DEPARTMENT OF COMPARATIVE MEDICINE (DCM) & DIVISION OF ANIMAL RESOURCES (DAR)

The DCM and DAR are responsible for the health and well-being of all laboratory animals used at OHSU. The Attending Veterinarians oversee other aspects of animal care and use (e.g., husbandry, housing, etc.) to ensure that the laboratory animal program complies with applicable federal and state regulations and guidelines.

OHSU OFFICE OF EXPORT CONTROLS

This office reports to the OHSU Provost or designee and coordinates, integrates, and facilitates all export compliance oversight functions of the institution in all mission areas. This includes the education of staff on export compliance requirements and the review of research projects, international staffing, and any international collaboration agreements to address any compliance issues. Information is available at www.ohsu.edu/export.

RESEARCH ADMINISTRATION TRAINING & EDUCATION (RATE)

The Research Administration Training & Education Program reports to the Assistant Vice President for

Research and collaborates with departments within Research Development and Administration as well as Central Financial Services and other relevant departments to coordinate training and education for research administration at OHSU. The RDA Education Coordinator collaborates with RDA departments to:

- Provide resources for education to the research community.
- Maintain ongoing standard communication mechanisms to relay important and up-to-date information to OHSU community.
- Maintain effective training and education program in all the elements of grants management.
- Refer staff and faculty to appropriate educational venues.

RESEARCH HUMAN RESOURCES (HR)

The main goals of Research HR at OHSU are to:

- Recruit and retain a happy, energized, motivated, qualified, and cooperative workforce.
- Create and maintain a safe and supportive work environment.
- Offer training and development to all employees at all levels to increase their skills as necessary or when desired.
- Guide and coach management at all levels through each employee's "seasons of employment."
- Partner with others across mission areas in meeting the overall goals of the organization, ultimately resulting in an increase of organizational success and efficiency.

For fiscal year 2012, the focus of Research HR is on cultural readiness. Research is expected to grow, change, and become more efficient and effective over the next five years. The culture must be ready for the changes that accompany growth and to attract and retain diverse and excellent researchers and faculty.

Research HR oversees all HR-related programs for the Research mission and the Basic Sciences departments in the School of Medicine as well as Research and Academic Volunteer Services. Research & Academic Volunteer Services connects potential volunteers to various opportunities, orients them to the complex OHSU environment, and guides them through the volunteer registration process. This program also links Research, Academic, and Central Services departments to interested volunteers.

The Director of Human Resources, Research, reports to the Assistant Vice President for Research. The Director of Human Resources, Research, manages an HR Business Partner and a Program Coordinator.

RESEARCH FINANCE

The Director of Finance is the chief financial officer for the OHSU Research Mission. This position reports directly to the Vice President for Research. The Director is responsible for strategy, cost analysis, and reporting for the research mission. The Director is also responsible for the annual budget of Research Administration, Independent Research Centers and Institutes, and the University Shared Resources Program.

The Director works in a team with the Chief Financial Officer of OHSU and the other mission finance officers, as well as with Central Financial Services.

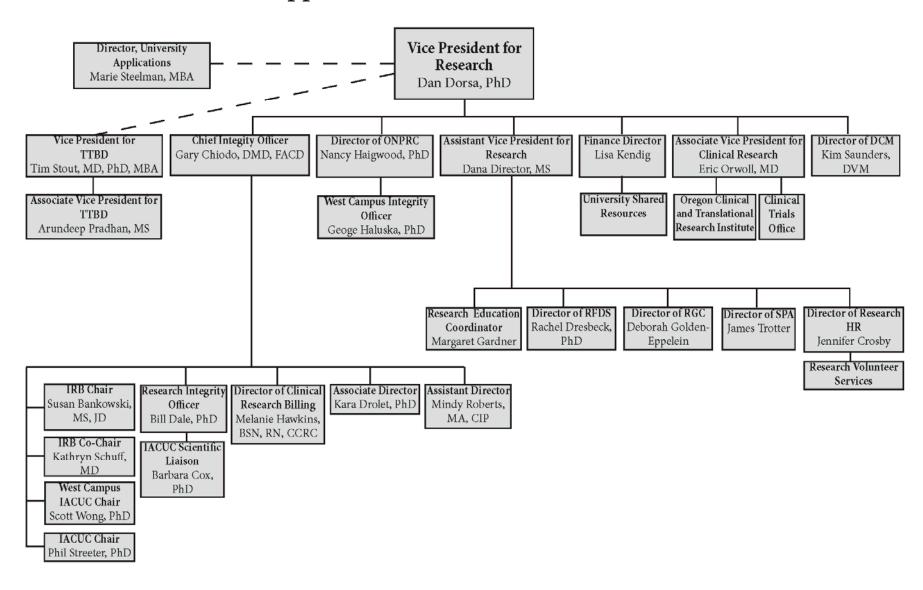
RESEARCH CORE SERVICES

OHSU has an innovative core resources program. At OHSU, University Shared Resources provide services to all OHSU investigators that have primarily an academic research focus, a service center account, and are subject to oversight by the OHSU Core Oversight Committee, including regular reviews. View a list of the <u>Core Services</u>

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Appendix A: OHSU Research Administration



APPENDIX B

LIST OF CONTACTS

| N AME | TITLE | DEPARTMENT | MAIL CODE | Рнопе (503) | E-MAIL |
|--------------------------------|--|---|--------------|----------------|-------------------|
| Susan Bankowski, M.S., J.D. | Chair Chair | Institutional Review Board Stem Cell Research Oversight | L106 RI | 494-3036 | bankowsk@ohsu.edu |
| Janet Billups, J.D. | Policy | Office of the Vice President for Research/Research Development | L585 | 494-5222 | billupsj@ohsu.edu |
| · | Advisor | & Administration Environmental Health & Radiation | | | |
| John Burnham, Ph.D. | Director Chief | Safety OHSU Integrity Office | PP236 | 494-8837 | burnhamj@ohsu.edu |
| Gary Chiodo, D.M.D. | Integrity Officer Director | OHSU Research Integrity Office | L106 RI | 494-8837 | chiodoga@ohsu.edu |
| Jennifer Crosby | Director | Research Human Resources | L335 | 494-7456 | crosbyme@ohsu.edu |
| William E Dale, Ph.D. | Chair Research Integrity Officer | Institutional Animal Care & Use Committee (IACUC) – Main Campus | L106 RI | 494-9644 | daleb@ohsu.edu |
| Dana Director, M.S. | Assistant VP for CWC Research Administrati on & Operations | Office of the Vice President for Research/Research Development & Administration | MAC 2170 | 494-1083 | director@ohsu.edu |
| Daniel Dorsa, Ph.D. | Vice President | Office of the Vice President for Research/Research Development & Administration | MAC 2170 | 494-1085 | dorsad@ohsu.edu |
| Rachel Dresbeck, PhD | Director | Research Communications and Development Services | L335 | 494-3124 | dresbeck@ohsu.edu |
| Kara Manning Drolet, Ph.D. | Associate Director | Research Integrity Office | L106 RI | 494-6727 | manningk@ohsu.edu |
| Margaret Gardner | RDA Education Coordinator | Research Administration Training & Education (RATE) | L106TE | 494-8990 | rate@ohsu.edu |

| Deborah Golden-Eppelien | Director | Research Grants & Contracts | L106R GC | 494-4853 | goldenep@ohsu.edu |
|--------------------------------|-------------------------------|---|---------------|----------|-------------------|
| George Haluska, Ph.D. | West Campus Integrity Officer | Oregon National Primate Research Center (ONPRC) | ORPRC L584 | 690-5289 | haluskag@ohsu.edu |
| Melanie Hawkins | Director | Clinical Research Billing Compliance Office | L460 | 494-8586 | hawkinsm@ohsu.edu |
| Lisa Kendig | Director | Research Finance | L335 | 494-2068 | kendigl@ohsu.edu |
| Darlene Kitterman, M.B.A. | Director | Investigator Support and Integration Services (OCTRI) | CR113 | 494-6263 | kitterma@ohsu.edu |
| Eric Orwoll, M.D. | Asst. Vice President | Clinical Research Program Director, Oregon Clinical and Translational Research Institute | CR113 | 494-0225 | orwoll@ohsu.edu |
| Arundeep Pradhan, M.S. | Director | Technology & Research Collaborations | L106TT BD | 494-4186 | pradhana@ohsu.edu |
| Mindy Roberts, MA, CIP | Assistant Director | OHSU Research Integrity Office - Institutional Review Board (IRB) | L106 RI | 494-9337 | robertmi@ohsu.edu |
| Kathryn Schuff, M.D. M.C.R. | IRB Co- Chair | Institutional Review Board | L106 RI | 494-1685 | schuffk@ohsu.edu |
| Phillip Streeter, Ph.D. | Chair | Institutional Animal Care & Use Committee (IACUC) – Main Campus | 07/L321 | 494-1762 | streetep@ohsu.edu |
| James Trotter | Director | Sponsored Projects Administration | L106SP A | 494-3211 | trotter@ohsu.edu |
| Scott Wong, Ph.D. | Chair | Institutional Animal Care & Use Committee (IACUC) – West Campus | 0104/V GTI | 690-5285 | wongs@ohsu.edu |

APPENDIX C

LINKS TO HELPFUL, FURTHER INFORMATION, POLICIES, CONTACT INFO, ETC.

CONFLICT OF INTEREST IN RESEARCH (COIR) (www.ohsu.edu/xd/research/about/integrity/coi)

- ✓ Instructions
 - ➤ Who must complete
 - Where to send completed disclosure
- ✓ Process
- ✓ Disclosure Form

OHSU INTEGRITY OFFICE (www.ohsu.edu/cc)

- ✓ Conflicts of Interest/Outside Activities/Gifts
 - Policy links
 - ➤ Who must disclose
 - ➤ Where to file
 - > Forms
- ✓ OHSU Code of Conduct
- ✓ HIPAA Compliance page link
- ✓ Compliance in OHSU publications
- ✓ Compliance Program and Roles & Responsibilities document
- ✓ Integrity Education

OHSU RESEARCH INTEGRITY OFFICE (http://www.ohsu.edu/xd/research/about/integrity/)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

(http://www.ohsu.edu/xd/research/about/integrity/iacuc/index.cfm)

- ✓ Process
- ✓ Forms
- ✓ Samples and Boilerplates
- ✓ Schedules
- ✓ Other external resources and guidance

OHSU STEM CELL RESEARCH OVERSIGHT COMMITTEE (OSCRO)

Institutional BioSafety Committee (IBC) (<u>www.ohsu.edu/research/rda/ibc</u>)

- ✓ Process
- ✓ Forms
- ✓ Schedules
- ✓ Federal rules and guidelines

INSTITUTIONAL REVIEW BOARD (IRB) (http://www.ohsu.edu/xd/research/about/integrity/irb/index.cfm)

- ✓ Roles and Responsibilities document
 - ✓ Policies and Procedures
- ✓ Forms, Samples and Boilerplates
 - ✓ eIRB
- ✓ Board Information & Schedules
- ✓ Whom to contact
- ✓ Federal rules and guidelines

OHSU POLICY MANUAL (http://ozone.ohsu.edu/policy/pac)

- ✓ Full on-line OHSU Policy Manual
- ✓ Proposed policies
- ✓ Proposed revisions

RESEARCH SAFETY (HTTP://www.ohsu.edu/xd/research/about/integrity/ibc/research-safety-team.cfm)