



**ROLES AND RESPONSIBILITIES**

**IN THE**

**CONDUCT OF RESEARCH**

**AND**

**ADMINISTRATION OF SPONSORED PROJECTS**

## INSTITUTIONAL OVERSIGHT

This policy provides a description of 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 total 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.

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 Grants and Contracts](#)
- [Sponsored Project Administration](#)
- [Research Integrity Office](#)
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## 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; and
- 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; and
- New research initiatives; and
- 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 laws, policies, guidelines, and regulatory requirements regardless of the source or existence of any sponsorship. PIs must meet the criteria for Principal Investigator Eligibility listed at <http://www.ohsu.edu/xd/research/administration/research-grants-contracts/policies-procedures/index.cfmh>.

**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, 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; and
- 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, and other compliance requirements that may be promulgated by RDA departments.

**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; and
- 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, 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 safety 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 insuring that an electronic version of any final, peer-reviewed manuscript(s) is/are submitted to the National Library of Medicine's PubMed Central upon acceptance for publication.

**PROPOSED PROJECT QUESTIONNAIRE (PPQ).** The PI prepares, or directly supervises the preparation of the PPQ. If other universities, entities, and/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/she will conduct the protocol in compliance with all RDA policies and guidelines, and he/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; and
- Ensures that he/she and his/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 training for those working on the project;
- Ensures compliance with all policy, regulatory, and review committee requirements for all personnel working on the project;
- Ensures staff do 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;
- Promptly works to resolve any problems or issues that are brought to his/her attention by any RDA unit; and
- 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; and
- Responds promptly, completely, and cooperatively to requests and recommendations from the OHSU Audit & Advisory Services Program.

**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; and
- 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; and
- Completes and submits any required final reports for animal and human subjects studies, including responding promptly to requests for information from compliance committees or boards.

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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 following areas:

**KEY RESPONSIBILITIES.** Administrative Staff may assist PIs by:

- Preparing 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;
- Preparing in a timely manner, initial and continuing review documents for review by the PI for submission to appropriate compliance committees;
- Insuring 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 the ORIO within the required timelines;
- Insuring that CoIR disclosures are completed and current for all persons working on a protocol;
- Gathering information to assist in the establishment of subcontracts and identification of matching funds;
- Documenting cost sharing, proposal preparation, and compliance committee reviews;
- Working with the CRBO to establish and implement compliant billing documents and processes;
- Processing requests for off-campus space;
- Processing financial transaction requests;
- Analyzing financial reports and resolving overdrafts in a timely manner;
- Assigning correct expenditure codes;
- Reconciling SPA accounts in a timely manner;
- Initiating requests for cost transfers in a timely manner;
- Processing documents to record program income;
- Notifying the PI of any problems regarding grants or contracts management;
- Notifying the PI of any changes in OHSU policies and procedures;
- Developing and maintaining internal systems for insuring regulatory compliance and that prevent compliance approval lapses;
- Forwarding project modifications along with supporting documents in advance of the PI implementing any modifications or changes to rDNA, animal, or human research protocols;
- Notifying SPA, RGC, and ORIO of changes in key personnel; and
- Performing duties delegated by the PI, including but not limited to data collection and analysis, interaction with study sponsors and external 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 PI requests for F&A rate reduction or waiver;
- 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 non-duplication 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; and
- 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 appropriate education in responsible conduct of research and HIPAA training for all departmental personnel;
- Accepts responsibility for payment of any fines due to OR-OSHA, DEQ, etc. rule violations by faculty members in the Department/Division;
- Nominates faculty for service on compliance review committees - IACUC, IBC, IRB, CoIRC, et.al;
- Provides oversight on 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 and have completed RCR education;
- Reviews the completed CoIR form(s) and, if desired, recommends a resolution 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; and
- 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 and/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; and
- 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 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), thus attesting to the accuracy of all information submitted in the PPQ and acceptance of responsibilities in regard to the project;
- Receives notification of potential inventions and licensing or program income;
- Approves matching funds as necessary, if they come from a source(s) outside the School/Institute;
- Reviews support from other sources, rebudgeting, and cost sharing and attests to their appropriateness;
- Promptly works to resolve any problems or issues that are brought to the attention of the office by any RDA unit; and
- 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 Associate Dean or Associate Director 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 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; and
- 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 directly to the VPR. The Grants and Contracts Manager and the RGC Operations Manager report directly to the Director of RGC. The Grants and Contracts Manager leads a team that includes Grants and Contracts Assistant Manager at the West Campus and Grants and Contracts Administrators at both campuses. The Operations Manager 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; and
- 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;
- 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; and
- 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 staffs 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 NGA to SPA for account set-up;
- Develops and negotiates subcontracts in response to PI request 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; and
- 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; and
- 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 the 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 manager 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; and
- Interprets and implements OHSU policies related to corporate-sponsored contracts, intellectual property, and technology transfer.

**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; and
- 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 Associate 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 corporate-sponsored clinical trials;
- Approves and notifies the PI of the project terms and conditions for corporate-sponsored clinical trials; and
- 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; and

- 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; and
- Upon set-up of study account by SPA, requests an OHSU Hospitals and Clinics account.

**Clinical Research Billing Office.** The Clinical Research Billing 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 University Medical Group, 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.

### **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; and
- 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:

- Developing complete billing schedules at the department level;
- Applying billing rules to initial billing schedules;
- Synchronizing billing schedules with approved study documents;

- Utilizing Epic research functions; and
- Utilizing a clinical trials management system.

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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 assurances for human and animal subjects research, federal Office of Research Integrity reports of scientific misconduct, and animal and human subjects protections programs, assurances, and accreditations. 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, 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.

The 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 Stem Cell Research Oversight Committee (OSCRO), and the Conflict of Interest in Research Committee (CoIRC). In addition, the ORIO organizes and monitors the Responsible Conduct of Research (RCR) education program 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-chair(s), the IACUC Chair and co-chair(s), and the Research Integrity Officer(s). There are several IRB, IBC, CoIR and IACUC analysts 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 medication reviews, unanticipated problem, protocol deviation reports, and other compliance related materials for appropriate levels of review;
- Confirms that study personnel have completed RCR and HIPAA education 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 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 and all other applicable policies and state and federal laws and regulations;
- In coordination with RGC, CTO, and TTBD, 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 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;
- 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.

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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 Principles for Institutions of Higher Education".

The Director of SPA reports to the Vice President for Research (VPR) 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 Director of RGC and the Comptroller 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

- **IDENTIFYING AND ACCOUNTING 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 5 business days of receipt in SPA, provided all necessary documentation is included. Notify PI and department of account setup and account number.
- **AWARD TERMS AND CONDITIONS** – Assist 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 [Pre-Award Account Setup form](#) and notify 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 [Accelerated Spending Request Form](#) and notify 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** – Review and approve [no cost extension](#) requests working with PI and department to ensure proper justification and notification to sponsor. When sponsor prior approval is required, receive, review, and co-sign request letter. Notify 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; 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

- **EXPENDITURE MONITORING: ALLOWED COSTS, TERMS AND CONDITIONS, AND SPENDING WITHIN PROJECT 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 including those that require the [Labor Cost Transfer Approval Form](#) 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 [University Adjustment Form](#) in a timely fashion, ensuring that adjustment is appropriate and properly justified and supported. When appropriate, process adjustments by pre-approved batch (PAB).

- **SPONSOR PRIOR APPROVALS** – Provide high-level oversight to assist PI's 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 PI's, 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 a timely fashion.
- **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 PI's 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 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 PI's and departments when non-adherence has taken place. Coordinate with PI's and departments for resolution of non-adherence or other issues. Transfer unresolved deficits on PDA's to department general funds.
- **INDUSTRY SPONSORED CLINICAL TRIALS** – Assist PI's 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 PI and department. Monitor clinical trial deficits, notifying PI's and departments when deficits have exceeded \$15,000, and coordinate resolution, as needed. Process [Project Status Forms](#) received in SPA, including deficit transfers, residual balance transfers, and study account closeout.
- **VA INTERGOVERNMENTAL PERSONNEL AGREEMENTS (IPA's)** – Maintain VA IPA documentation. Receive, review, approve and process, as appropriate, all VA IPA's in a timely fashion. Communicate with PI, VA employee, VA Research Services and/or the department to discuss any issues or discrepancies with IPA's. 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 for appropriate spending and notify PI's and departments if overspending occurs. Process necessary actions for overspending resolution.

## **AWARD REPORTING, CLOSEOUT AND AUDIT**

- **AWARD CLOSEOUT** – Monitor accounts for necessary closeout actions and coordinate, as appropriate, with PI's 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 PI's and fiscal managers. Allow 5 business days for concurring review and coordinate with 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 AND INVENTION REPORTING** – Work with PI and department staff to ensure that OHSU adheres to all reporting requirements on all sponsored project awards per award terms and conditions or contract.
- **PROPERTY AND OTHER REPORTING** – Work with PI and department staff to ensure that OHSU adheres to all 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. Set up program income accounts as needed; review expenditures to ensure compliance with award terms and conditions; 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. 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 Fixed Assets 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 PI and dept with copies of 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** – Maintain effective training and education program in all the elements of grants management. Maintain ongoing standard communication mechanisms to relay important and up-to-date information to OHSU community.

## **ORACLE GRANTS ACCOUNTING (OGA) 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, including PI, Award and Project Department Fiscal Managers, SPA Analyst, et.al.

**INSTITUTIONAL REPORTS/SURVEYS** – Publish institutional sponsored projects related information and reports on the SPA website. Receive and respond to [requests for information](#). SPA will respond to requestors by providing an estimated completion date for the request or by requesting further information about the request. SPA has limited resources available to complete requests for information; however, all efforts will be made to produce reports as requested. If a report request cannot be completed, the requestor will be notified.

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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 AND RADIATION SAFETY (EH&RS)**

- Provides institutional oversight and oversees policy formulation for proposals which involve:
  - Human blood or body fluids; or
  - Radioactive materials and/or ionizing or non-ionizing radiation producing equipment;
- Collaborates with ORIO to oversee policy formulation for research involving recombinant DNA, infectious agents, biological toxins, or select agents;
- Provides institutional oversight for off-campus space used as a laboratory or clinic; and
- Provides institutional oversight for adherence to chemical, biological, physical, and radiation safety requirements during the conduct of research.

### **INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**

The IACUCs approve and provide institutional oversight for proposals involving 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.

### **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 shall review all stem cell research proposals submitted by OHSU investigators.

## **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)**

DCM, with the IACUC, provides institutional oversight for adherence to protocols and policies for research involving live animals as subjects.

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**APPENDIX A**

**RDA ORGANIZATIONAL CHART**



## APPENDIX B

### LIST OF CONTACTS

NAME	TITLE	DEPARTMENT	MAIL CODE	PHONE (503)	E-MAIL
Susan Bankowski, M.S., J.D.	Chair	Institutional Review Board	L106-RI	494-3036	<a href="mailto:bankowsk@ohsu.edu">bankowsk@ohsu.edu</a>
Janet Billups, J.D.	Legal Counsel	OHSU Legal Department	L585	494-5222	<a href="mailto:billupsj@ohsu.edu">billupsj@ohsu.edu</a>
John Burnham, Ph.D.	Director	Environmental Health & Radiation Safety	PP236	494-8837	<a href="mailto:burnhamj@ohsu.edu">burnhamj@ohsu.edu</a>
Gary Chiodo, D.M.D.	Director Director	OHSU Integrity Program OHSU Research Integrity Office	AD140	494-8837	<a href="mailto:chiodoga@ohsu.edu">chiodoga@ohsu.edu</a>
Daniel Dorsa, Ph.D.	Vice President	Research Development & Administration	L336	494-1085	<a href="mailto:dorsad@ohsu.edu">dorsad@ohsu.edu</a>
Deborah Golden-Eppelien	Director	Research Grants & Contracts	L106	494-4853	<a href="mailto:goldenep@ohsu.edu">goldenep@ohsu.edu</a>
George Haluska, Ph.D.	West Campus Integrity Officer	Oregon National Primate Research Center (ONPRC)	ORPRC L584	690-5289	<a href="mailto:haluskag@ohsu.edu">haluskag@ohsu.edu</a>
Melanie Hawkins	Director	Clinical Research Billing Office	AD140	494-8586	<a href="mailto:hawkinsm@ohsu.edu">hawkinsm@ohsu.edu</a>
Darlene Kitterman, M.B.A.	Director	Oregon Clinical & Translational Research Institute (OCTRI)	CR113	494-6263	<a href="mailto:kitterma@ohsu.edu">kitterma@ohsu.edu</a>
Kara Manning Drolet, Ph.D.	Associate Director Chair	OHSU Research Integrity Office Conflict of Interest in Research Committee Chair	L106-RI	494-6727	<a href="mailto:manningk@ohsu.edu">manningk@ohsu.edu</a>
Eric Orwoll, M.D.	Asst. Vice President	Clinical Research Program	CR113	494-0225	<a href="mailto:orwoll@ohsu.edu">orwoll@ohsu.edu</a>
Arundeeep Pradhan, Ph.D.	Director	Technology Transfer and Business Development	AD 120	494-4186	<a href="mailto:pradhana@ohsu.edu">pradhana@ohsu.edu</a>

TBD	CWC Research Integrity Officer				
TBD	Chair	Institutional Animal Care & Use Committee (IACUC) – Main Campus			
James Trotter	Director	Sponsored Projects Administration	AD 220	494-3211	<a href="mailto:trotter@ohsu.edu">trotter@ohsu.edu</a>
Mindy Roberts, MA, CIP	Assistant Director	Research Integrity Office - Institutional Review Board (IRB) and Institutional Animal Care & Use Committee (IACUC)	L106-RI	494-9337	<a href="mailto:robertmi@ohsu.edu">robertmi@ohsu.edu</a>
Scott Wong, Ph.D.	Chair	Institutional Animal Care & Use Committee (IACUC) – West Campus			

## APPENDIX C

### LINKS TO HELPFUL, FURTHER INFORMATION

#### **CONFLICT OF INTEREST IN RESEARCH (COIR)** ([www.ohsu.edu/xd/research/about/integrity/coi](http://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](http://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

#### **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

#### **INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)** ([www.ohsu.edu/research/rda/ibc](http://www.ohsu.edu/research/rda/ibc))

- ✓ 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
- ✓ Process
- ✓ Forms
- ✓ Samples and Boilerplates
- ✓ 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