Roles & Responsibilities at OHSU
# Table of Contents

**Introduction** .......................................................... 4

**Overarching Principle:** ............................................. 4

**Part 1: Roles & Responsibilities at OHSU** .................................. 4

- **OHSU Members** .................................................. 4
- **Executive Leadership** ............................................ 4
  - *Special Authorities of the Board of Directors:* ................. 5
  - *Obligations of the President and the Chief Financial Officer:* 5
- **Integrity Program Oversight Council** ................................ 5
- **Chief Integrity Officer** ........................................... 5
  - *Special Authorities:* ........................................... 6
- **General Counsel** .................................................. 6
- **Area Administration** ............................................... 7
- **Specific Compliance and Integrity Programs** ....................... 7

**Part 2: Roles & Responsibilities in Research** .............................. 9

- **Institutional Oversight** ............................................. 9
- **Senior Vice President for Research** ................................ 9
  - *Policy Formulation:* ............................................ 9
  - *Responsibilities:* ............................................... 9
  - *Delegation of Authority:* ....................................... 10
- **Area Administration** ............................................... 10
  - *Area Leadership:* ............................................... 10
  - *Unit Leadership:* ................................................ 10
  - *Research Support Staff:* ....................................... 11
- **Principal Investigator** ............................................. 12
  - *Proposal / Protocol / Project:* ................................ 12
  - *Proposed Project Questionnaire (PPQ):* ........................ 13
  - *Acceptance of an Award:* ....................................... 14
  - *Conduct of the Research:* ....................................... 14
  - *Budget Management:* ........................................... 14
  - *Non-Competitive Renewals:* .................................... 15
  - *Project Closure:* ................................................ 15
- **Research Funding & Development Services** ......................... 15
  - *Grant Funding:* .................................................. 15
  - *Research Communications:* .................................... 15
- **Office of Proposal & Award Management** ............................ 16
  - *Proposal Preparation, Assistance, & Review:* .................. 16
  - *Award Receipt & Setup:* ........................................ 16
  - *Award Management and Compliance:* ............................. 17
  - *Award Reporting, Closeout, and Audit:* .......................... 17
- **OHSU Research Integrity Office** .................................. 18
  - *Institutional Animal Care and Use Committee (IACUC):* ....... 18
  - *Institutional Biosafety Committee (IBC):* ........................ 18
  - *Institutional Review Board (IRB):* ................................ 18
  - *Conflict of Interest in Research Committee (CoIRC):* ........... 18
- **Responsibilities:** .................................................. 18
- **Technology Transfer and Business Development** .................... 19
  - *Intellectual Property Management:* .............................. 19
  - *Material Transfer Agreements:* .................................. 19

*Updated: September, 2015*
Element 8. Risk Assessment ................................................................. 20
Element 6. Enforcement and Discipline ........................................... 20
Element 4. Training and communication ........................................... 20
Element 3. Due care .......................................................................... 20
Element 2. Program Governance ...................................................... 20
Element 1. Standards, Policies and Procedures .................................... 20
Clinical Trials Office ........................................................................ 20
  Contract negotiation and execution. .................................................. 20
  Education Activities ...................................................................... 21
Compliance on behalf of investigator ................................................ 21
Other Programs .............................................................................. 21
  Clinical Research Billing Compliance Office: ................................ 21
  Department of Comparative Medicine-Central/Waterfront Campus (DCM-C) & Division of Comparative Medicine-West Campus (DCM-W) ........................................................................... 22
  OHSU Office of Export Controls .................................................... 22
  Research Administration Training & Education (RATE) .................. 22
  Research Core Services ................................................................ 22
  University Shared Resources ........................................................ 22
  Research Oversight Committee ...................................................... 22
  Scientific Integrity Committee (SIC) ............................................... 23

Part 3: Elements of Integrity at OHSU ................................................. 24
Element 1. Standards, Policies and Procedures .................................... 24
  In practice: .................................................................................... 24
Element 2. Program Governance ...................................................... 25
  In practice: .................................................................................... 25
Element 3. Due care .......................................................................... 26
  In practice: .................................................................................... 26
Element 4. Training and communication ........................................... 26
  In practice: .................................................................................... 26
Element 5. Monitoring, Auditing, and Reporting Systems ................. 27
  Auditing and Monitoring .............................................................. 27
  Reporting Systems ...................................................................... 28
Element 6. Enforcement and Discipline ........................................... 28
Element 7. Response and Prevention ................................................ 29
  In practice: .................................................................................... 29
  OHSU responds to integrity concerns by: ..................................... 30
Element 8. Risk Assessment .............................................................. 30
  In practice: .................................................................................... 30
Introduction

This document describes the OHSU’s integrated, system-wide approach to fostering commitment to OHSU’s Code of Conduct, organizational values, and compliance with applicable laws and regulations. The terms integrity and compliance are both used in this document.

*Integrity* is a commitment to a set of values and principles through consistent actions, with unwavering dedication to being upright and honest. It is about conduct that follows ethical and institutional standards regardless of whether a law expressly requires such conduct.

*Compliance* means acting in accordance with applicable laws and regulations. To act with integrity is to engage in conduct that follows institutional standards, values, and expectations, which includes abiding by applicable regulations; thus, compliance is a component of integrity. Like the OHSU Code of Conduct, this document applies to all OHSU Members.

Overarching Principle:

OHSU exercises due diligence to prevent and detect unlawful conduct by promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law. The standards set out in this document are adopted from the Federal Sentencing Guidelines for Organizations, the Office of the Inspector General’s Compliance Program Guidance for Hospitals, the Office of the Inspector General’s Compliance Program Guidance for Third-Party Medical Billing Companies, and the Federal False Claims Act.

These source documents guide the development of compliance and integrity at healthcare institutions to ensure integrity and compliance with federal, state, and local regulations. OHSU believes that these guidelines are essential in promoting its culture of ethical and lawful conduct.

Part 1: Roles & Responsibilities at OHSU

OHSU Members

Every OHSU Member is responsible for adhering to the highest ethical, organizational, and operational standards in the performance of duties and responsibilities at OHSU. This expectation is reinforced by formal line and organizational responsibilities and by the OHSU Integrity Department.

When acting in any capacity for OHSU, all OHSU Members will:

1. Act in accordance with the OHSU Code of Conduct and all applicable OHSU policies.
2. Carry out their responsibilities in an ethical, effective and professional manner.
3. Follow all federal, state, and local laws, regulations and standards that apply to their responsibilities.
4. Report potential integrity concerns through the reporting mechanisms described in the OHSU Code of Conduct.
5. Lead by example.

Executive Leadership

The members of the Board of Directors, President and Executive Vice Presidents are responsible for articulating the values, mission and vision of the institution; fostering high ethical, organizational and operational integrity; and ensuring compliance with policies, laws, regulations and other appropriate standards. Executive leadership is ultimately responsible for integrity at OHSU. These individuals receive regular updates and reports from the Chief Integrity Officer and may be called upon to resolve specific issues or concerns. In some instances, Executive Leadership may need to emphasize or underscore the importance of integrity in certain standards, issues or activities.

Executive Leadership:

1. Requires and supports an OHSU Integrity Department that is consistent with the mission, vision and values of OHSU and that ensures integrity and compliance.
2. Appoints and oversees the OHSU Chief Integrity Officer.
3. Ensures appropriate representation on the OHSU Integrity Program Oversight Council.
4. Establishes integrity standards, goals and objectives and ensure that they are met.
5. Ensures that all OHSU Members cooperate with internal and external reviews (audits, investigations, inspections, etc.) to provide honest, accurate and complete responses and information.
6. Provides policy direction concerning integrity issues.
7. Oversees the enforcement of policies and supports an ethical culture across the organization.
8. Appropriately responds to concerns and issues brought to their attention.
9. Ensures the availability of counsel to review and manage integrity matters as appropriate.
10. Ensures that they are appropriately informed regarding the nature and status of the OHSU Integrity Department and integrity issues at OHSU.
11. Leads by example.

**Special Authorities of the Board of Directors:**
In addition to the above responsibilities, the OHSU Board of Directors has special authority in carrying out its oversight of the OHSU Integrity Department. These authorities include:
1. Initiating third-party audits or assessments of the Integrity Department.
2. Retaining outside counsel or consultants to address integrity issues when appropriate.
3. Subject to limits imposed by applicable law, meeting with the Chief Integrity Officer and/or the General Counsel.
4. Requiring receipt of information regarding any governmental investigations or audits.

**Obligations of the President and the Chief Financial Officer:**
1. If an accounting restatement is necessary due to misconduct, the President and Chief Financial Officer will reimburse OHSU for any bonus or other incentive received during the 12-month period following the issuance of the erroneous financial statement.
2. Any incentives provided to the President or Chief Financial Officer related to financial results must be disclosed to the Finance and Audit Committee and to the Integrity Program Oversight Council.
3. The President and Chief Financial Officer will rigorously adhere to the highest ethical behaviors and standards in fiscal accountability.
4. The President and Chief Financial Officer will immediately notify the members of the Finance and Audit Committee of the OHSU Board of Directors and the OHSU Integrity Program Oversight Council of any adverse actions taken against them personally, related to securities, misconduct, exclusion or debarment from federal programs, or similar sanctions.

**Integrity Program Oversight Council**
The Integrity Program Oversight Council (IPOC) provides oversight of OHSU’s Integrity Department. The IPOC consists of three Board members, Executive Vice-Presidents, the Senior Vice President for Research and the General Counsel. Included in its oversight responsibilities are review and management oversight of institutional conflicts of interest, ensuring appropriate resource allocation for integrity and compliance efforts and high level guidance on organizational integrity issues.

**Chief Integrity Officer**
The OHSU Chief Integrity Officer is responsible for the development, coordination, implementation and oversight of the OHSU Integrity Department. The Chief Integrity Officer:
1. Develops, coordinates, implements and oversees the OHSU Integrity Department.
2. Ensures the effectiveness of the OHSU Integrity Department, including overall consistency and integration of integrity activities throughout the organization.
3. Ensures the alignment of the OHSU Integrity Department with OHSU policies and procedures and all applicable laws, standards and regulations.
4. Reviews, revises and develops policy for adoption via institutional processes, as appropriate to complement and reinforce the OHSU Integrity Department.
5. Assesses integrity and compliance risks and ensures that the OHSU Integrity Department is responsive to those risks.
6. Staffs the Integrity Program Oversight Council.
7. Directs the OHSU Audit and Advisory Services Program.
8. Directs a program of Integrity Education and training tailored to the missions and activities of OHSU.
9. Ensures prompt and thorough investigation of matters reported via the OHSU Integrity Hotline.
10. Communicates matters brought to his/her attention that are deemed potentially or actually illegal, unethical or in violation of regulatory standards to appropriate personnel, including legal counsel.
11. Works closely with the General Counsel to ensure that the Integrity Program meets applicable, current legal requirements and that both functions share information necessary to fulfill their responsibilities.
12. Conducts or authorizes independent investigations of integrity matters when appropriate.
13. Serve as a resource to management to determine and implement corrective and preventative action in coordination with those who have authority to make employment or disciplinary decisions.
14. Monitors national, state, and local information to keep current with applicable regulatory and legislative changes, settlements, and federal contractor initiatives to tailor the Integrity Department accordingly.
15. Makes recommendations to the Board of Directors, the Integrity Program Oversight Council, the Finance and Audit Committee and Executive Leadership regarding integrity priorities and resource allocation.
16. Provides periodic reports to the Board of Directors and Executive Leadership regarding the nature, progress and status of the OHSU Integrity Department, any corrective action being taken and any recommended changes.
17. Serves as a knowledgeable resource for organizational and operational matters related to integrity issues.
18. Communicates audit findings and recommendations to the Board of Directors, the Integrity Program Oversight Council, the Finance and Audit Committee and related oversight committees as appropriate.
19. Leads by example.

**Special Authorities:**
The Chief Integrity Officer is provided with special authority to:

1. Communicate any matter deemed potentially illegal or unethical to the appropriate department for review, investigation and follow-up.
2. Notify Executive Leadership if not satisfied that a matter has been adequately addressed.
3. Conduct or authorize an independent investigation of any matter, which, in the Chief Integrity Officer’s judgment, cannot be adequately investigated through the usual means. Normally, such investigations receive prior approval from one or more members of Executive Leadership. If the matter involves Executive Leadership or a member of the Board, the Chief Integrity Officer may conduct the investigation after obtaining prior approval from a member of the Board who is not involved in the matter to be investigated or, if this is not possible, without prior approval. If the Chief Integrity Officer determines that OHSU’s interests cannot be adequately and appropriately represented by the use of OHSU’s Legal Department, as a result of a conflict of interest or other identified issue, the Chief Integrity Officer may retain the services of outside counsel or consultants.

**General Counsel**
OHSU’s General Counsel has primary responsibility for ensuring that OHSU meets the requirements of federal, state and local laws and regulations. In addition, General Counsel is expected to:

1. Assist the Board of Directors in understanding OHSU’s legal risks and the adequacy of operations to address them.
2. Provide the Board of Directors with appropriate and timely information on the organization’s compliance with applicable laws.
3. Assist and advise the Chief Integrity Officer in interpreting government regulations and their policy implications.
4. Advise identified OHSU integrity committees, including the Integrity Program Oversight Council, the Audit and Advisory Services Committee and the Clinical Integrity Committee.
5. Cooperate with internal and external auditors to honestly, accurately and completely provide information that will ensure the integrity of audit processes.
6. Participate with the Chief Integrity Officer in directing OHSU’s response to suspected compliance failures that come to the Chief Integrity Officer’s attention, where such failures may trigger administrative, civil or criminal liability.
7. Report material violations of law up the chain of command.
8. Ensure the availability of counsel to review integrity matters that require Legal Department involvement.
9. Lead by example.

**Area Administration**

Deans, vice presidents, department chairs, division chiefs, directors and managers of schools, institutes, centers and departments are responsible for compliance and integrity in their respective areas. Area administration will:

1. Develop, coordinate, implement and oversee integrity and compliance measures tailored to their area, which may include appointing an integrity/compliance lead for the area or a specific function within the area.
2. Communicate requirements and procedures to personnel in their areas.
3. Determine department-specific training needs and ensure that they are met.
4. Coordinate their efforts with the RDA and/or the Integrity Department, as needed.
5. Investigate and resolve concerns and issues reported or identified in their areas, provide any necessary follow up and ensure non-retaliation.
6. Provide information, when requested, to the Chief Integrity Officer or Integrity Department related to:
   a. The area’s specific integrity measures and performance;
   b. Suggested or needed changes;
   c. Specific integrity objectives; and
   d. Urgent concerns, as appropriate.
7. Provide information, when requested or required, to the Chief Financial Officer, Comptroller, Audit and Advisory Services, the Finance and Audit Committee or the Integrity Department related to:
   a. Financial reports or statements;
   b. Financial reporting and disclosure processes; and
   c. Identified weaknesses or concerns related to the adequacy of controls over financial reporting and disclosures.
8. Cooperate with internal and external reviewers by honestly, accurately and completely providing information that will ensure the integrity of review processes.
9. Lead by example.

**Specific Compliance and Integrity Programs**

Certain programs are responsible for specialized compliance and integrity activities and have professional expertise in these areas. Some of these programs are housed in the Integrity Department, while others exist within other departments and areas throughout the organization. The Integrity Department is composed of:

- Audit and Advisory Services
- Information Privacy and Security
- Environmental Health and Radiation Safety
- Clinical Enterprise Integrity (including Hospital/Clinics Integrity, Professional Billing Integrity and Clinical Trials Billing Compliance)
Roles & Responsibilities at OHSU

Conflicts of Interest
Research Integrity (including the Institutional Review Board, Institutional Animal Care and Use Committee, and the Institutional Biosafety Committee)

Integrity and compliance programs throughout OHSU will:

1. Develop, implement, maintain and oversee a scope of oversight, work plan, policies, procedures and guidance related to the areas, activities, responsibilities and/or subject matters for which they are responsible.
2. Raise awareness of requirements to the appropriate personnel, including any mandatory training or education.
3. Develop, deliver, revise, oversee and monitor training programs, as appropriate.
4. Coordinate as needed with management and compliance representatives across the organization.
5. Serve as a resource to management responsible for or addressing integrity issues.
6. Monitor, investigate, and resolve concerns reported in their areas and provide any necessary follow up.
7. Have a working knowledge of laws, regulations, and policies applicable to their areas.
8. Perform periodic risk analyses to determine risk factors within their areas.
9. Communicate and coordinate with the Chief Integrity Officer regarding concerns or issues in their areas; results of audits and investigations; suggested or needed changes in their areas related to integrity issues, integrity objectives or other topics of concern or as requested.
10. Represent OHSU as authorized in its relationships with regulatory agencies and other internal and external stakeholders.
11. Promote the integration of standards and requirements into OHSU’s business processes in order to mitigate risk to OHSU operations.
12. Promote a culture of shared responsibility for integrity by all OHSU Members.
13. Lead by example.
Part 2: Roles & Responsibilities in Research

Institutional Oversight
This section describes the research-related compliance roles and responsibilities 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 the previous section on Institutional Roles & Responsibilities as well as 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.

Senior Vice President for Research
The Senior Vice President for Research (SVPR) 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 SVPR promotes the creation and maintenance of an organizational environment that encourages and supports research productivity and integrity. The SVPR 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 are formulated and monitored.

Policy Formulation - The SVPR oversees policy formulation for a broad range of research activities at OHSU, including, but not limited to:
- Proposal and award management.
- Human and animal subjects.
- Conflict of Interest in Research disclosure and management.
- Invention disclosures, copyrights, intellectual property and technology transfer.
- Education requirements for researchers and their staff.
- Clinical research billing.
- Recombinant DNA research (rDNA), infectious agent and stem cell research.

Responsibilities - The SVPR has ultimate responsibility for oversight for all research activities at OHSU, including, but 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.).
- Research infrastructure development.
- Indirect cost rate (F&A) decisions, reductions or waivers.
- Management of core facilities.
- New research initiatives.
Delegation of Authority - The SVPR may delegate responsibility to appropriate VPs (all levels), Directors or committees.

Area Administration
Area Administration includes all levels of leadership and staff and is responsible for supporting the advancement of research via fostering an environment where investigators can pursue innovation while maintaining appropriate compliance with OHSU, state and federal policies and regulations.

Area Leadership
Area leadership (Deans, VPs, Directors, Chairs) act in an oversight capacity by supporting the management, promotion and integration of research throughout the organization and in the resolution of issues that are not or cannot be resolved through normal processes. Deans and Center/Institute Directors are academic leaders with programmatic, managerial and fiscal responsibilities for a school, research institute or center and may have responsibility to oversee research activities in the unit and thus are delegated appropriate authority to act in matters relating to research and other sponsored projects, including the appropriate resolution of issues as they arise. Deans’ and Directors’ offices are the administrative center for the School or Institute. These offices may have Associate Deans/Directors as well as Research Support 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. 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. Responsibilities include but are not limited to:

- Review and approve the research project by signing/approving the appropriate routing forms and Proposed Project Questionnaire (PPQ). Approval indicates agreement to comply with all OHSU policies, regardless of funding sources for the proposed project.
- Approve requests for an F&A rate that varies from OHSU’s negotiated rate 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, re-budgeting, 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.

Unit Leadership
Unit Leadership has programmatic, managerial and fiscal responsibilities for a Department, Division, Institute or a Center and provides oversight for compliance with OHSU, state and federal policies and regulations within the unit. Unit Leadership responsibilities include but are not limited to:

Review, approval and management of research

- Attest to the accuracy of all information submitted and indicates agreement with the responsibilities as outlined in the submission.
- Reviews and provides unit approval of PI requests for F&A rate reduction or waiver or cost-sharing, 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 to pay for expenditures should the award not be received.
- Approves resolution of overdrafts on all sponsored accounts.
Roles & Responsibilities at OHSU

- Approves and notifies the Dean/Director of re-budgeting in cases where re-budgeting 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 understanding that these funds must follow the requirements outlined by the sponsored project they relate to.
- 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 Senior Vice President for Research and OPAM).
- Resolves issues related to effort reporting ensuring forms are certified and submitted to OPAM timely, signed by individuals with knowledge of how the employee worked and following sponsor salary limitation requirements.
- Assures that PI will fulfill his/her responsibilities related to the research and take the necessary steps to assure compliance, if needed.
- Accepts responsibility for payment of any fines due to OR-OSHA, DEQ, or other rule violations in the Department/Division.
- Nominates faculty for service on research review committees.
- Ensures that all proposed research has been submitted to the appropriate research 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.
- 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.
- Promptly works to resolve any problems or issues that are brought to his/her attention.
- Provides local oversight for record retention and ownership of scientific data at project closure and attests to adequate systems for data privacy and security.
- Assumption of financial responsibility in the case of projects that go into deficit.
- For an ongoing study or for a study without proper termination where the PI has departed OHSU, Unit Leadership assumes responsibility for the proper conduct or termination of the study or will appropriately delegate responsibility to another eligible PI.

Delegation of Authority - Unit Leadership may delegate authority for grant management tasks, and the Monitoring of CoIR management plans so long as duties are assigned to individuals appropriately trained or certified by standard OHSU procedures.

Research Support Staff
Research Support Staff include department administrators, study coordinators, departmental grants and contracts analysts, research assistants, accounting specialists, office specialists, et al. It is essential that Research Support Staff maintain current knowledge of all requirements, policies and procedures related to the management and conduct of the research, including funding agency requirements.

Responsibilities - Research Support Staff assist the PI in fulfilling his/her responsibilities. Such assistance includes being familiar with all PI responsibilities and ensuring those are met in a timely manner, including but not limited to all of the following:

- **Financial:**
- Prepares documents for budgeting, effort reporting, non-competitive renewals, interim and final financial reports, other closing reports, and coordinates the labor distribution of individuals on sponsored projects.
- Processes financial transaction requests.
- Analyzes financial reports, resolving overdrafts in a timely manner.
- Works with PI and OPAM to submit prior approval requests to sponsor, as needed.
- Assigns correct expenditure types in OGA.
- Reconciles OGA accounts in a timely manner.
- Monitors sponsored project expenditure activity regularly to identify inappropriately assigned costs.
- Initiates requests for cost transfers in a timely manner.
- Processes documents to record program income.
- Gathers information to assist in the establishment of subcontracts and identification of matching funds.
- Documents cost sharing, proposal preparation, and compliance committee reviews.
- Establishes compliant billing and financial processes.
- Notifies the PI of any problems regarding grants or contracts management.

**Regulatory:**
- Prepares, in a timely manner, materials for review by the PI for submission to appropriate research review committees.
- Ensures that reports of non-compliance, safety and other information requiring prompt reporting are completed, reviewed by the PI and submitted to the appropriate research reviewing committee within the required timelines and according to current policy.
- Ensures that CoIR disclosures and mandatory education modules are completed and current for all persons working on a protocol.
- Forwards project modifications along with supporting documents in advance of the PI implementing any modifications or changes to the research to the appropriate research reviewing committee(s).
- Prepares submissions in sufficient time for PI to avoid any lapses in approval and/or funding.
- Notifies OPAM and ORIO of changes in key personnel.

**Other:**
- Processes requests for off-campus space.
- Develops and maintains internal systems ensuring regulatory compliance and preventing compliance approval lapses.
- 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.

**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, policies, guidelines and regulatory requirements regardless of the source or existence of any sponsorship. **PI’s must maintain current knowledge of all requirements, policies and procedures related to the management and conduct of the research, including funding agency requirements.** PIs must meet the criteria for **Principal Investigator Eligibility.**

**Proposal / Protocol / Project** - The PI is responsible for preparing the proposal or protocol, 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 proposal or protocol and associated terms of participation prior to agreeing to participate as an investigator. In addition, the PI is responsible for providing a clear and concise description of the proposed work and disclosing any conflicts or collaborations that may impact the terms of an application or agreement.
By submitting the application for review and approval, the PI is certifying that:

- The proposal is ethically and scientifically meritorious and accurate.
- Institutional reviews and approvals and continuing reviews and approvals will be obtained and maintained, as appropriate.
- There are sufficient and appropriate resources to meet the aims of the research, including, but not limited to space, staff, equipment, training support and ancillary services, for the care, safety, and protection of research participants and staff.
- The PI and study staff have not been excluded or debarred from participation in federally funded activities.
- All grant/contract terms and conditions, as well as agency rules and regulations, have been read and agreed to.
- The PI is and will remain in compliance with appropriate federal and state regulations and OHSU policies governing human or animal subjects, FDA-regulated products, conflict of interest, safety, intellectual property disclosure, training, rDNA, U.S. export control laws, and other compliance requirements applicable to the research.

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 OPAM and the project sponsor, if necessary, modifies the project budget in line with the award.
- When necessary, request Unit Leadership and OPAM establish an account prior to receipt of the award in order to initiate work on the project.

Regulatory requirements -

- Accurate and complete preparation and submission of information for review to the reviewing committees and bodies as appropriate, and for responding promptly to requests for information from compliance committees or boards.
- Ensures and attests to the completion of required training 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.
- Ensures 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/approving the PPQ, the PI is attesting that the submission is accurate and complete, he or she will conduct the research in compliance with all requirements, 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).
- Ensures that all applicable compliance requirements (IRB, IACUC, IBC, CoIR, training) have been met, approved and updated in appropriate systems, which must be completed prior to award set-up.
- Notifies OPAM of any discrepancies in the award or 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 Research - 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 all research staff have completed CoIR disclosures and 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 subcontract agreements prepared by OPAM, TTBD, or CTO, if applicable.
- Completes and files, as appropriate, any required interim programmatic (technical) reports, materials transfer agreements, or intellectual property disclosures.
- Notifies OPAM and ORIO, or others as appropriate, if the PI or other key personnel withdraw from the project entirely, will be disengaged from the project during any consecutive period of three months or more, or reduce their time devoted to the project by a significant amount as determined by sponsor requirements.
- Notifies ORIO if the PI intends to be disengaged (e.g., unable to promptly resolve critical and/or safety matters) from the project for longer than a 5 business days and identifies a responsible and qualified person to act as Interim PI.
- Promptly reports any safety or other reportable information per ORIO policies.
- 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 OPAM when required and reviews them in a timely manner, providing feedback to OPAM as necessary for timely reporting.
- Responds promptly, completely, and cooperatively to requests and recommendations related to internal investigations, audits, and reviews (e.g., OPAM, Integrity, etc.).
Non-Competitive Renewals -
- Completes the progress report timely and accurately including reporting a greater than 25% carry forward or reduction in key personnel, if applicable.
- Prepares the budget request for renewal period if applicable.
- Completes continuing review materials as required for applicable research review committees (IRB, IACUC, IBC) working with ORIO to obtain proper review and approval before expiration.
- Updates CoI disclosures at least annually or as needed to describe additional financial interests.
- Forwards the proposal to be signed by the delegated Institutional Official in OPAM or TTBD, as appropriate.

Project Closure -
- Prepares and submits to the sponsor the final programmatic (technical) narrative report when required and sends copies to OPAM and TTBD.
- Reviews the final financial report provided by OPAM in a timely manner.
- Provides resolution to cost over-runs.
- Provides information on other closing reports, such as for patents or equipment.
- In coordination with OPAM and TTBD, initiates preparation and submission of a final invention statement, if required.
- Completes and submits any required final reports as required for the IRB, IACUC, IBC as applicable.
- Ensures a smooth transition of responsibilities when separating from the organization.

Research Funding & Development Services
Research Funding & Development Services (RFDS) is a program within RDA that provides advice, consultation, and training for OHSU researchers. The group works closely with other RDA units, 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. RFDS assists 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 and prizes and awards for researchers.
- Manages the Presidential Bridge Funding and Emerging Technology programs.
- Administers review competition database and process.
- 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 -
- Works with key OHSU leaders to provide timely and up to date information, strategic advice, and other critical research information functions.
- 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.
• Manages the SciVal university research expertise system.
• Coordinates and provides information about OHSU research for surveys.

Office of Proposal & Award Management

The Office of Proposal and Award Management (OPAM) is responsible for the pre- and post-award management of externally-funded as well as individually-budgeted university funded sponsored projects. OPAM 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. OPAM 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, other key personnel, and the approved budget.

OPAM maintains OHSU's overall financial compliance related to the management of all OHSU sponsored activity, and is responsible for assuring institutional compliance with all sponsor regulations, including 2 CFR 200 “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards” issued by the federal Office of Management and Budget. In resolving issues, OPAM works closely with the other RDA Units, Central Financial Services, the Information Technology Group, Human Resources, the Legal Department, and OHSU Foundation.

The Associate Vice President of OPAM is the designated Institutional Official and Fiscal Officer for proposal & award related matters. The Associate Vice President has been delegated authority by the SVPR to sign grant and contract proposals; to receive awards; and to conduct official business on behalf of OHSU with funding agencies, both federal and non-federal, relating to regulatory compliance, award terms & conditions, and the on-going management of sponsored activity at OHSU. The Associate Vice President requests further delegations of authority, as appropriate, from the SVPR for subordinates within OPAM, and provides advice to the SVPR on systemic issues and continuous improvement in the quality of award management. OPAM’s main functions include:

Proposal Preparation, Assistance, & Review.
• Assist PIs and support staff in the accurate completion of grant applications, progress reports, contract proposals, budget preparation and justification, and grant submissions. Review proposals for PI eligibility status and overall completeness and administrative accuracy.
• Review sponsor guidelines and provide feedback on areas where application does not meet those guidelines.
• Review the electronic Proposed Project Questionnaire (ePPQ) for completeness and accuracy and for approval from appropriate parties.
• Provide Institutional Official signature assuring institutional commitment and oversight.

Award Receipt & Setup.
• Assist departments with meeting sponsor “just-in-time requests” prior to the issuance of grant awards.
• Receive, accept, and disseminate, the Notice of Grant Award (NGA)/award agreement, if applicable.
• Complete and provide to Departments 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.
• When required, work with the CoIR office to assure that funding agencies are appropriately notified of potential conflicts of interest prior to award account set-up.
• Confirm that all compliance items have been completed.
• For accepted awards, authorize and establish separately identifiable accounts in the Oracle Grants Accounting (OGA) system.
Award Management and Compliance.

Prior Approval Requests
- In accordance with sponsor requirements, work with departments and PIs to provide proper justification and notification to the sponsor to request prior approval as needed per award terms & conditions. These may include (but are not limited to) reduction in committed effort of key personnel, carry-over of unused funds, no-cost extensions, change in scope, and re-budgeting.

Award Oversight
- Provide high level oversight ensuring that expenditures on sponsored projects are allowable, reasonable, allocable, and consistent in accordance with sponsor terms and conditions as well as incurred within the awarded project period.
- Review Cost Transfer adjustment forms to ensure they follow terms & conditions of the award, are completed accurately, and approved by the appropriate fiscal manager and PI.
- Provide high-level oversight in monitoring overspending and notify departments when overspending occurs.
- Move overdrafts/deficits to non-sponsored accounts as provided by departments. If no direction provided, move overdrafts to departmental general funds.

Effort Reporting
- Manage the federal grant effort certification program including the creation, distribution, and collection of Effort Certification Statements from Departmental Effort Coordinators (DECs).

Consortium Agreements (Outgoing Sub-awards)
- Develop and negotiate outgoing subaward agreements and amendments, in response to PI requests and in accordance with award terms and conditions.
- Receive, review (for consistency with the subaward agreement), and process all subaward invoices.
- Ensure that all sub-recipients under federal awards are appropriately monitored, and obtain copies of their annual Single Audit reports and/or questionnaires in order to provide reasonable assurance of their ability to comply with award terms and conditions.

Cash Management
- Perform and comply with cash management, & reporting requirements on sponsor funding including invoicing (with the exception of invoicing for Industry sponsored clinical trials, which is performed by departments).

Award Reporting, Closeout, and Audit.

Reporting
- Ensure that OHSU adheres to all reporting requirements on all sponsored funding per sponsor terms and conditions.
- Prepare and submit all financial reports and final invoices for concurrence to PIs and fiscal managers, coordinating with PIs and/or fiscal managers to resolve discrepancies noted prior to submission to sponsors.
- Work with TTBD the PIs and department staff to ensure that OHSU adheres to reporting requirements on all sponsored project awards per award terms and conditions or contract.

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.
Audit
- Coordinate all administrative and financial related external audits on sponsored projects including the annual Single Audit, which includes both direct and pass-through federal funding (excluding Medicare and Medicaid funding).

Record Retention
- Maintain overall knowledge and oversight on record retention requirements as indicated in award documents, ensuring that all appropriate documentation is maintained by OPAM.

Oracle Grants Accounting & InfoEd (Systems) Management.
- OPAM is responsible for the maintenance, access to, and development of the OGA and InfoEd Systems.

OHSU Research Integrity Office
The OHSU Research Integrity Office (ORIO) is responsible for overseeing compliance with all requirements that govern human, animal, basic science, and applied science research at OHSU. ORIO is responsible for maintaining appropriate assurances for human and animal subjects research compliance programs, 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 overseeing rDNA and infectious agent research, select agents, stem cell research, and conflict of interest in research are systematic, comprehensive, and current.

ORIO is responsible for the function and oversight of OHSU’s Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), and the Conflict of Interest in Research Committee (CoIRC). The Integrity Program as a whole (including ORIO) organizes and monitors training and conducts internal investigations, audits, inspections, and other reviews related to research conduct. The ORIO consists of the following programs:

Institutional Animal Care and Use Committee (IACUC)
The IACUCs provide institutional oversight for proposals and policies related to live animals used as subjects in research or teaching.

Institutional Biosafety Committee (IBC)
The IBC approves and provides institutional oversight for proposals involving recombinant DNA, synthetic nucleic acids, infectious agents, and 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

Responsibilities:
- Assists PIs and research staff with preparation of submissions to research review committees.
- Facilitates assistance with training, risk assessment, and other guidance for the safe use of biological and chemical hazards in research and general lab safety
• Confirms that study personnel have completed required training and filed CoIR disclosures.

• Ensures that research reviewing committees are compliant, efficient, and timely with communications to research team.

• Establishes policies and procedures to oversee and monitor research integrity, including those addressing safety concerns and 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 appropriate federal agencies, internal entities, the Institutional Official, and other relevant parties of regulatory violations and other required compliance reports or notifications.

• Advises the IO whether there is appropriate expertise and resources to review and oversee the volume and types of research being performed at OHSU and that the research review process has adequate resources to carry out their duties.

• Ensures that the research review process is independent and free from coercion and undue influence. The Chief Integrity Officer will establish policies and procedures to respond to investigator or organizational attempts to unduly influence a review committee. The response may include reporting to the Senior Vice President for Research, the President of OHSU, and the Board of Directors.

• Implements programs to continuously educate the research community in human and animal subjects protections requirements, safety, and all other applicable policies and state and federal laws and regulations.

Technology Transfer and Business Development
OHSU recognizes the importance of transferring technology to the commercial sector where it can benefit the people it serves. Technology Transfer and Business Development (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, material 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. 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 and Collaboration Agreements.
• TTBD is responsible for negotiating, managing, and assuring that the terms of non-clinical SRAs and research collaboration agreements 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.

Business Development/Industry Partnership.
- TTBD works to forge relationships with industry, the investment community, academia and government and serves as one of the liaisons between OHSU and the external industrial community.

Startup Company Formation.
- TTBD helps to support an entrepreneurial culture at OHSU and is responsible for assisting the formation of new startup companies based on the research and technologies at OHSU.

Compliance.
- Reports to sponsors any intellectual property developed in the course of research at OHSU.
- Ensures compliance with the Bayh-Dole Act and the federal regulations under 37 CFR 401.
- 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 Senior Vice President of Research of invention management activities.
- 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.

Clinical Trials Office
The Clinical Trials Office (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 sub-contractees 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.

Contract negotiation and execution.
- 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 OPAM for corporate-sponsored 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.**
- 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 OPAM, requests an OHSU Hospitals and Clinics account.

**Other Programs**

**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 the research community and the clinical enterprise to develop policies and procedures for compliant billing. In addition, the CRBO monitors and audits research billing to ensure compliance with regulations.

**The CRBO is responsible for:**
- Developing clinical research billing schedules that discriminate between research and standard care services.
- Identifying research subjects and protocol encounters and discriminate services for clinical trials in such encounters from standard care services.
- Reviewing charges for protocol encounters.
- Ensuring compliance with federal/state laws, regulations, and with the Medicare National Coverage Determination.
- Identifying study services that are routine costs and that require appropriate code modifiers.
- Training on policies, processes and procedures related to billing for clinical research services.
- Coordinating with Epic (Electronic Medical Record) training on research related functionality.
Department of Comparative Medicine-Central/Waterfront Campus (DCM-C) & Division of Comparative Medicine-West Campus (DCM-W)
The DCM-C and DCM-W 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
The OHSU Office of Export Controls 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.

Research Administration Training & Education (RATE)
The Research Administration Training & Education Program (RATE) collaborates with departments within RDA 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 Core Services
Cores, or Scientific Service Centers are Advanced Technology Centers dedicated to meeting scientists’ research needs. Cores help investigators reach their scientific goals through access to state-of-the-art technology and consultation with top-level scientific expertise. While the cores’ primary mission is to serve the OHSU campus investigators, most cores welcome users from outside of OHSU, both academic and commercial.

University Shared Resources
The University Shared Resources (USR) program assists cores in maintaining optimal scientific and financial operations to benefit the OHSU investigators and research. A subset of cores on campus that meet the specific USR criteria and offer services to a wide variety of campus investigators may apply for membership in the USR. Membership offers various benefits to the core, including financial assistance. New USR core applications are evaluated by a variety of OHSU stakeholders, including members of the Research Oversight Committee.

The Program Manager leads the strategic oversight and long-range planning of the USR, is the central contact for shared resources at OHSU, and serves as a strategic liaison for scientific and financial operations between research cores and Central Financial Services. The Program Manager acts as an advocate for cores within the university and the community and will guide decisions regarding current research cores and establishment of new core services. The Program Manager works in close collaboration with the Senior Vice President of Research, the Research Oversight Committee and the Core Directors on decisions regarding maintenance, establishment, and support of University Shared Resources.

Research Oversight Committee
The Research Oversight Committee (ROC) is the deliberative body that assists and advises the Program Manager and the Senior Vice President of Research in the development of policies regarding University Shared Resources. It is comprised of various research stakeholders, including core resource users. The Committee evaluates current core facilities and assesses the need for new campus cores. Evaluations ensure that cores meet both scientific and fiscal expectations and continue to add value to the OHSU research community. The ROC assists in decisions regarding financial support of shared resources.
Scientific Integrity Committee (SIC).
The SIC reviews and acts on allegations of scientific misconduct, which is defined by federal law as falsification, fabrication, or plagiarism in the conduct of science.
Part 3: Elements of Integrity at OHSU

Every organization, its programs, and workforce have standards to meet. The definition of a standard according to Webster.com is:

- A level of quality, achievement, etc., that is considered acceptable or desirable.
- Something that is very good and that is used to make judgments about the quality of other things.
- Something set up and established by authority as a rule for the measure of quantity, weight, extent, value, or quality.

There are standards established for the structure of an effective compliance and ethics programs that are outlined in the U.S. Sentencing Commission’s (USSC) Federal Sentencing Guidelines (FSG) Manual, Chapter Eight for Effective Compliance and Ethics Programs. These standards are established to strengthen the importance of promoting a culture that complies with all laws and regulations and to create “an ethical culture woven within the fabric of the organization from top to bottom.” The elements are often referred to as the “eight elements of a compliance program,” and are broken down below to highlight each aspect addressed in the FSG.

<table>
<thead>
<tr>
<th>CHAPTER 8 FSG REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>To have an effective compliance and ethics program, an organization shall—(1) exercise due diligence to prevent and detect misconduct; and (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law. Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting misconduct.</td>
</tr>
</tbody>
</table>

Meeting the operational day-to-day responsibilities and standards and meeting integrity standards are related. To implement an effective integrity program, it’s important that the leadership, the OHSU community, and the integrity officer collaborate to properly identify and evaluate risks and lessen or eliminate the risks through well-designed internal controls. An effective program will be established when everyone works together as a TEAM (Together Everyone Accomplishes More).

Element 1. Standards, Policies and Procedures

<table>
<thead>
<tr>
<th>CHAPTER 8 FSG REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization shall establish standards and procedures to prevent and detect misconduct.</td>
</tr>
</tbody>
</table>

OHSU integrity standards, policies, and procedures are statements of institutional values and expectations. Integrity guidance is contained in institution level documents and in documents specific to schools, units, groups, and divisions. OHSU Members are required to be familiar with, understand, and comply with all OHSU policies relevant to their responsibilities and employment at OHSU. In doing so, OHSU Members support the fundamental belief that organizational success requires honesty, respect, and trust.

In practice:

- **Code of Conduct:** The Code is electronically distributed to all new employees within 30 days of initial employment and to new students, first term during orientations. The Code is an essential component of integrity and compliance at OHSU and supports other essential initiatives such as hospital accreditation, accreditation of OHSU as an institution of higher education, and other certifications and accreditations. The Code is periodically revised and updated and available on O2.
- **Roles and Responsibilities at OHSU:** This Roles & Responsibilities document was adopted as one of four policy documents that describe the Integrity Program via a 2004 Board of Directors resolution. It describes some of the overarching roles and responsibilities related to compliance and integrity for all levels of OHSU Members. In
addition, it describes responsibilities associated with the management and conduct of research, including the cycle of proposal, funding, performance, and termination of protocols.

- **OHSU Clinical Compliance Plan:** The OHSU Clinical Integrity Committee has approved a plan that follows guidance from the Office of the Inspector General for hospitals and clinics, professional fee billing, clinical laboratory compliance, and other appropriate clinical functions and areas. This Plan describes the implementation of integrity efforts that ensure compliance with federal, state, and local regulations related to clinical compliance. The Plan is periodically revised in response to pertinent guidance from the Office of the Inspector General.

- **OHSU Policy Manual:** New and revised policies are drafted by operational areas and adopted by the OHSU Policy Advisory Committee. The Chief Integrity Officer sits on the Policy Advisory Committee (ex officio). These policies are enacted following an open comment period and are then publicized to the OHSU community. All policies are available on-line. Re-evaluation of policies is a continual process occurring via monthly Policy Advisory Committee meetings and via issue-driven initiatives.

- **OHSU Health Care System policies:** The Health System policy manual includes a large number of policies related specifically to the clinical enterprise. These policies and procedures receive final approval from the Professional Board and the Healthcare Administration Team.

**Element 2. Program Governance**

<table>
<thead>
<tr>
<th>CHAPTER 8 FSG REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization’s governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.</td>
</tr>
</tbody>
</table>

*High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program, as described in this guideline. Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program.)*

Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.

The Board of Directors enacted OHSU's Corporate Compliance Program by resolution in 1999. Since that time, the Board of Directors has been an active participant in institutional integrity development and oversight. Board participation on the Integrity Program Oversight Council has established direct liaison with and regular oversight of the Integrity Program. In addition, the Board has adopted resolutions specifically addressing key integrity initiatives, such as the adoption of policies related to institutional conflicts of interest and outside business relationships of OHSU executives. In a 2004 resolution, the Board adopted four documents as policy describing the Integrity Program and gave the Chief Integrity Officer the authority and responsibility to periodically update and revise the documents. Those documents represent Board-level policy and are: (i.) The OHSU Code of Conduct; (ii.) OHSU Integrity Program Roles and Responsibilities; (iii.) OHSU Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects; and (iv.) OHSU Clinical Compliance Plan. Note that in 2015, the two Roles and Responsibilities documents were combined into one document entitle “Roles and Responsibilities at OHSU”.

OHSU recognizes that integrity is driven by involvement and responsibility at the highest organizational levels. To ensure the implementation and effectiveness of the OHSU Integrity Program, OHSU has delegated responsibility to the Board of Directors, President, General Counsel, and the Chief Integrity Officer. Individuals within OHSU who are delegated day-to-day operational responsibility for the Integrity Program report periodically to the Board of Directors and the Executive
Leadership Team, as appropriate, on the effectiveness of the Integrity Program. The Chief Integrity Officer has direct access to the Board of Directors and President as needed.

The Integrity Program is supported by: the Integrity Program Oversight Council, which includes one or more members of the Board of Directors and several members of the OHSU Executive Leadership Team; the Finance and Audit Committee of the Board of Directors; the Clinical Integrity Committee; and multiple other, issue-focused integrity, ethics, or compliance committees.

In practice:
- The Code of Conduct, Integrity Program Roles and Responsibilities document, and key policies are distributed to and discussed with the Board of Directors and OHSU executives.
- The Integrity Program Oversight Council meets routinely throughout the year.
- The Chief Integrity Officer meets with the Finance and Audit Committee periodically.
- The Chief Integrity Officer reports directly to the Executive Vice President and Provost.
- The structure of the Integrity Program allows the Chief Integrity Officer to access the President or the Board of Directors directly to report concerns.

Element 3. Due care

\textit{CHAPTER 8 FSG REFERENCE}

\textbf{The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization, any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.}

OHSU exercises due care to ensure that discretionary authority is not delegated to people who have engaged in illegal acts. Institutional and local-level policies and procedures have been implemented to address any conduct inconsistent with federal, state, or local law or with ethical behavior. The OHSU Integrity Program facilitates and supports the hiring and promotion of individuals so as to ensure that all individuals within OHSU’s leadership perform their assigned duties in a manner consistent with the promotion of an organizational culture that encourages a commitment to compliance with ethics and the law. Moreover, the Integrity Program applies this same cultural expectation to all of its associates.

OHSU monitors all employees, volunteers, contractors and vendors on a daily basis to ensure they are not in the excluded or debarred database. Employees and volunteers may be terminated if they are on the exclusion list. Vendors and contractors who have been excluded or debarred are not permitted to transact business with OHSU. OHSU’s contracts with vendors allow for immediate termination upon exclusion or debarment from participation in federal programs.

In practice:
- Background checks are conducted on potential employees, students, volunteers, and other affiliates who have access to OHSU patients, research subjects, information, information systems, or resources. Prior to employment, applicants selected for hire are required to disclose whether they are excluded, debarred, or otherwise ineligible for participation in federal programs. Potential employees who are listed as excluded or debarred (as defined in 42 USC 1320a & c-5) are denied employment at OHSU. Human Resources verifies that each potential employee is not excluded or debarred by querying the CMS/GAO databases.
- Applicants selected for hire in certain classifications are required to pass a pre-employment drug-screening exam. Pre-employment criminal background checks are performed for all potential employees.
- The names of all existing employees are routinely screened to ensure they have not become excluded or debarred from participation in federal programs. Employees who are found to be excluded or debarred are subject to termination.

Element 4. Training and communication

\textit{CHAPTER 8 FSG REFERENCE}
The organization shall take reasonable steps to communicate periodically and in a practical manner, its standards and procedures, and other aspects of the compliance and ethics program, to members of the organization’s governing authority, high-level personnel, substantial authority personnel, employees, and, as appropriate, the organization’s agents. This communication shall occur by conducting effective training programs and otherwise disseminating information appropriate to such individuals’ respective roles and responsibilities.

OHSU provides training to communicate policies, procedures, and organizational standards in a practical and understandable manner. These programs cover a variety of content areas and occur at both institutional and departmental levels. Both one-time and continuing training and educational programs are provided. Specific areas of training are required according to an OHSU Member’s role and responsibilities and this requirement extends to the Executive Leadership Team and Board of Directors. Training is continuous and employs a variety of formats for initial and continuing education initiatives.

Various instructional methods, materials, and tools are used to foster appropriate standards of knowledge, awareness, and conduct for OHSU Members. Delivery methods include computer-based courses, print media, live presentations, and web-based technologies. The OHSU Integrity Program is responsible for two training initiatives that are required by all OHSU Members: Integrity Foundations (for new OHSU Members) and the annual Integrity Booster (for all OHSU Members). Content for the annual Integrity Booster is regularly re-evaluated and updated and provides an opportunity for OHSU Members to refresh their understanding of core requirements as well as become aware of emerging issues and requirements. Sanctions are imposed for failure to complete required educational modules.

In practice:
Training may include both general and specific topics, such as:

- OHSU Code of Conduct
- Individual responsibility for knowledge of and compliance with applicable laws
- OHSU policies, procedures, and standards and local-level policies
- Consequences for violations of law, OHSU policies, procedures, and standards
- Information security and privacy (including patient confidentiality)
- Affirmative action, equal opportunity, and respect at OHSU
- Departmental processes, policies, and procedures
- Research laws and policies
- Conflicts of interest
- Standards for vendors and affiliates
- Reporting violations or questionable conduct and the routes for making such reports

Element 5. Monitoring, Auditing, and Reporting Systems

Auditing and Monitoring
Audit and Advisory Services (A&AS) performs audit and advisory services for OHSU to improve operational controls around detection of misconduct. A&AS promulgates a program that performs objective and systematic evaluations of OHSU financial, operational, control, and integrity processes using risk-based audits and application of Institute of Internal Auditor standards. The Program provides oversight at the highest level. Summary information is provided to the Finance and Audit Committee of the OHSU Board of Directors. The results of an internal audit, including audit findings, significant deficiencies, conclusions, and recommendations are communicated to the appropriate executive through an
official report. This executive is responsible for working with the A&AS staff to determine and implement action plans and remediation as appropriate. Departments, divisions, schools, and units are also responsible for ongoing monitoring, periodic quality assessments, and improvement efforts within their areas.

The A&AS has seven general objectives:
1. To identify and thoroughly analyze financial, operational, and compliance risk factors.
2. To assist the institution in implementing risk management strategies, effective internal controls, and process improvements responsive to identified risk factors.
3. To provide financial, managerial, and operational information to ensure that internal audit resources are deployed in an accurate and timely fashion.
4. To monitor the actions of employees, students, visiting scientists, vendors, and other OHSU Members for compliance with laws, policies, regulations, standards, and guidance.
5. To monitor the responsible and appropriate use of OHSU resources.
6. To assist the institution in continuous quality improvement.
7. To monitor the effectiveness of the institution’s policies, procedures, and programs for compliance and to periodically measure, benchmark, and re-evaluate these controls.

In addition, the Clinical Enterprise Integrity Office performs similar audit and advisory functions, though limited to the clinical activities of OHSU and focused on the federal program regulatory compliance requirements. A risk based audit plan is developed and implemented annually based on evaluation of industry and entity risks. Results are reported to the Clinical Integrity Committee and to the Integrity Program Oversight Council. Advisory services are also provided in response to specific questions related to clinical regulatory compliance, along with education and updates resulting from industry activities and regulatory updates.

**Reporting Systems**

OHSU fosters and supports a safe, non-threatening environment where individuals may ask questions and raise concerns. The OHSU Code of Conduct describes several ways to report integrity concerns. OHSU has a Hotline that may be used to report integrity issues. The Hotline is provided by an outside, independent company and is available 24 hours per day, seven days per week. All Hotline reports are forwarded to the OHSU Integrity Office and all callers are provided with a response. Anonymous callers are given a code number and advised to re-contact the Hotline number to receive updates.

OHSU Members who report integrity concerns in good faith are not subject to retaliation or harassment as a result of the report. Concerns about possible retaliation or harassment stemming from an integrity report may be reported to any Integrity Officer, the Affirmative Action/Equal Employment Department, or Human Resources.

All reports raising an integrity concern receive an initial inquiry. When an inquiry reveals a *bona fide* concern or issue, an investigation occurs and resolution is sought. If a violation of law or policy has occurred, appropriate discipline, disclosure, and corrective action occur in a timely fashion. At the conclusion of the investigation, a report is completed. If the initial inquiry does not reveal a violation or other legitimate concern, the reporter is advised of this and given the opportunity to rebut this finding.

Centralization of the reporting process enables the Integrity Program to monitor for patterns of noncompliance, failures or other problems. When such patterns appear, further investigation occurs and processes, procedures, policies, or controls are implemented as appropriate to prevent and detect any further non-compliance.

**Element 6. Enforcement and Discipline**

<table>
<thead>
<tr>
<th>CHAPTER 8 FSG REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization’s compliance and ethics program shall be promoted and enforced consistently throughout the organization through appropriate incentives to perform in accordance with the compliance and ethics program; and appropriate disciplinary measures for engaging in misconduct and for failing to take reasonable steps to prevent or detect misconduct.</td>
</tr>
</tbody>
</table>

OHSU Members are expected to conduct themselves with integrity. Individuals are responsible for their actions and are accountable if they knew or should have known that their conduct involved a violation of law, regulation, or policy. OHSU consistently enforces
integrity standards through appropriate disciplinary mechanisms. Any OHSU Member who violates federal, state, or local laws, regulations, or OHSU policy is subject to disciplinary action. Disciplinary action is determined according to the type of violation, case-specific considerations, and the individual’s history. OHSU policies specify disciplinary processes, outcomes, and appeal mechanisms for unclassified employees and students. Classified employees have collective bargaining agreements that describe disciplinary procedures. Depending on the nature of the violation, disciplinary action may include required education/training, additional monitoring, changes in work activities, and reduction in salary, written reprimand, and suspension without pay, demotion, or discharge. Some activities prohibited by OHSU policy may also violate the laws and regulations of the State of Oregon or the United States. Such activities can lead to individual criminal prosecution, significant fines, imprisonment, and exclusion from participation in federally sponsored programs.

While there are broad categories of disciplinary actions, each instance of discipline is case-specific. The following factors may be considered:

- What was the violation and how did it affect OHSU and those who interact with OHSU?
- Was the individual directly or indirectly involved in the violation?
- Was the violation willful or unintentional?
- Has this individual been disciplined previously for similar violations? If so, what were the individual’s past violations?
- Was the violation an isolated occurrence or part of a pattern of conduct?
- Did the individual self-report the violation?
- Did the individual withhold relevant or material information?
- Did the violation occur due to failure to supervise another individual who, in turn, committed the violation?
- If the violation consisted of retaliation against another person who reported a violation or cooperated with an investigation, what was the nature of the retaliation?

Corrective action plans for employees are designed and implemented to ensure that specific violations are appropriately addressed and resolved. Supervisors develop and implement a corrective action plan and monitor it as needed to resolve concerns. In the course of determining appropriate discipline, supervisors may consult with additional OHSU resource experts, such as the Integrity Office, Legal Department, Risk Management, Human Resources and Affirmative Action. Supervisors or other designated individuals provide status reports to the individual responsible for investigating the concern. Response teams, responsible committees or persons are identified to respond to specific problems. Prompt inquiry and appropriate levels of investigation follow all reports or identified problems.

- Periodic re-reviews of past problem areas are performed.
- Required notifications to and appropriate actions with regulatory agencies occur.

**Element 7. Response and Prevention**

**CHAPTER 8 FSG REFERENCE**

*After misconduct has been detected, the organization shall take reasonable steps to respond appropriately to the misconduct and to prevent further similar misconduct, including making any necessary modifications to the organization’s compliance and ethics program.*

OHSU is committed to achieving and maintaining the highest ethical, organizational, and operational standards. The OHSU Integrity Program is designed to prevent and respond to concerns and to address occurrences that may be part of a pattern of conduct.

**In practice:**

OHSU prevents integrity violations by:

- Screening and hiring applicants selectively.
- Screening active employees and volunteers daily against the exclusion database.
- Communicating expected standards of behavior.
- Providing on-going training and education.
- Providing performance oversight.
- Rewarding and encouraging high standards of conduct.
- Implementing appropriate corrective and disciplinary actions.
- Providing several avenues to report integrity concerns.
Roles & Responsibilities at OHSU

- Investigating and responding to integrity concerns as described below.
- Conducting risk-based audits and monitoring.
- Monitoring applicable laws and conforming policies and procedures.

OHSU responds to integrity concerns by:
- Reviewing concerns to determine if a violation of law or policy has occurred.
- Monitoring violations for patterns of conduct.
- Investigating alleged violations and consulting resources, including outside professional advisors, as appropriate.
- Developing and implementing corrective action plans to address concerns.
- Reporting to outside agencies, as appropriate.
- Revising policies, procedures, and reporting relationships as indicated.
- Alerting levels of management as appropriate to address concerns.
- Revising the OHSU Integrity Program as appropriate.

Element 8. Risk Assessment

<table>
<thead>
<tr>
<th>CHAPTER 8 FSG REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization shall periodically assess the risk of misconduct and shall take appropriate steps to design, implement, or modify each program element to reduce the risk of misconduct identified through this process.</td>
</tr>
</tbody>
</table>

Risk assessment is an integral part of the audit planning and monitoring processes at OHSU. The A&AS Director is responsible for conducting the risk assessment process and determining audit priorities while the A&AS Committee provides guidance and oversight to the A&AS function and annual audit plan. The risk assessment process will be conducted on a continuous basis and will be formalized at least annually to support the prioritization of the A&AS and Integrity Office work planning process.

In practice:
- A&AS will facilitate and manage the risk assessment process and related activities to identify and elevate awareness of organizational risk areas.
- Management will provide risk area information and understanding to properly assess and measure against substantive impact criteria, likelihood of occurrence, and existing control and monitoring practices.
- Risk assessment results will support the development of risk based work plans to address and review the identified risk areas.
- Integrity programs provide risk based monitoring and compliance support for the organization.
- Management, as the risk owners, will ultimately be responsible for managing the risk area.
- A&AS includes a fraud risk assessment as part of each review.