



OHSU

Integrity Program

**Roles & Responsibilities
and
Program Elements**

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OHSU Integrity Program

Introduction

This document describes the OHSU Integrity Program, an integrated, system-wide approach to fostering commitment to ethical principles and institutional values and compliance with applicable laws and regulations. The terms integrity and compliance are both used in this document. Integrity refers to conduct that follows ethical and institutional standards regardless of whether a law expressly requires such conduct. Compliance means acting in accordance with applicable laws, regulations, and other explicit legal guidelines. To act with integrity is to engage in conduct that follows institutional standards, values, and expectations; thus compliance is a component of integrity.

Part 1 of this document explains the roles and responsibilities for integrity at OHSU. Part 2 describes the seven elements of the OHSU Integrity Program. Related and supporting documents are listed in Appendices A, B and C.

Overarching Principle

OHSU exercises due diligence to prevent and detect unlawful conduct, and promotes an organizational culture that encourages ethical conduct and a commitment to compliance with the law. The guidelines set out in this document are adopted from the Federal Sentencing Guidelines for Organizations (revised and amended, 2010), 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 provide guidance for integrity programs for institutions engaged in health care delivery, research, and education, 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 and Responsibilities for Integrity

Roles and Responsibilities

Employees, Students, Volunteers, and Other OHSU Members

Every OHSU employee, student, volunteer, and other 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 Program.

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.

*The term "OHSU Members" includes all employees (faculty, represented, unclassified administrative and other categories), registered and visiting students, volunteers, members of the OHSU Board and the Doernbecher Children's Hospital Foundation Board of Directors, visiting healthcare practitioners, contracted nonpermanent individuals, vendors while doing business with OHSU, and others who work for or on behalf of OHSU, OHSU Foundation and Doernbecher Children's Hospital Foundation.

Roles and Responsibilities

Directors

Deans, department chairs, division chiefs, directors, and managers (hereafter referred to as “Directors”) are responsible for integrity efforts in their respective areas. This responsibility may involve appointing an Integrity Coordinator, oversight committee, Compliance Officer, several integrity representatives in various areas, or other means. Directors will:

1. Develop, coordinate, implement, and oversee integrity measures tailored to their area.
2. Communicate integrity plan requirements and procedures to personnel in their areas.
3. Determine department-specific integrity training needs and ensure that they are met.
4. Coordinate their efforts with integrity designees in other areas and with the OHSU Chief Integrity Officer as needed.
5. Investigate and resolve integrity concerns and violations 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 related to:
 - a. The area’s specific integrity measures and performance;
 - b. Suggested or needed changes;
 - c. Specific integrity objectives; and
 - d. Urgent integrity concerns as appropriate.
7. Provide information, when requested or required, to the Chief Financial Officer, Comptroller, Audit and Advisory Services Department, the Finance and Audit Committee, or Integrity Specialists (defined below) related to:
 - a. School or unit level financial reports or statements;
 - b. The School’s or unit’s 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 auditors by honestly, accurately, and completely providing information that will ensure the integrity of audit processes.
9. Lead by example.

Roles and Responsibilities

Integrity Specialists

Certain individuals are responsible for specialized integrity activities and have professional expertise in these areas. Examples of such areas include, but are not limited to, Environmental Health and Radiation Safety, human and animal subjects research, clinical compliance, Affirmative Action & Equal Opportunity, and others; these areas are shown in Appendix B. “Integrity Specialists” refers to the individuals responsible for integrity issues in those areas. Integrity Specialists will:

1. Develop, coordinate, implement, and oversee an integrity plan tailored to the areas, activities and/or subject matters for which they are responsible (collectively, “scope”).
2. Communicate integrity requirements and procedures to the appropriate personnel in their areas, including any mandatory training or education.
3. Develop, deliver, revise, oversee, and monitor integrity education and training programs in coordination with the OHSU Integrity Education Manager.
4. Coordinate as needed with Integrity Specialists in other areas.
5. Serve as a resource to directors, managers and others responsible for or addressing integrity issues.
6. Monitor, investigate, and resolve integrity concerns and violations reported in their areas and provide any necessary follow up.
7. Have a working knowledge of laws, regulations, and rules 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 integrity concerns or violations in their areas, results of integrity audit activities, suggested or needed changes in their areas related to integrity issues, integrity objectives, or other topics of concern or as requested.
10. Lead by example.

Roles and Responsibilities

OHSU Chief Integrity Officer

The OHSU Chief Integrity Officer is appointed by the Board of Directors and is responsible for the development, coordination, implementation, and oversight of the OHSU Integrity Program. The Chief Integrity Officer:

1. Develops, coordinates, implements, and oversees the OHSU Integrity Program.
2. Ensures the effectiveness of the OHSU Integrity Program, including overall consistency and integration of integrity activities throughout the organization.
3. Ensures the alignment of the OHSU Integrity Program 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 Program.
5. Assesses integrity and compliance risks and ensures that the OHSU Integrity Program 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 integrity concerns and violations 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.
12. Conducts or authorizes independent investigations of integrity matters when appropriate.
13. Assists in the determination and implementation of corrective action for integrity violations in coordination with others 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 and tailors the Integrity Program accordingly.
15. Makes recommendations to the Board of Directors, the Integrity Program Oversight Council, the Finance and Audit Committee, and the OHSU Executive Leadership Team regarding integrity priorities and resource allocation.
16. Provides periodic reports to the Board of Directors and the OHSU Executive Leadership Team regarding the nature, progress, and status of the OHSU Integrity program, 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 audit 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 management (up to the President) and the Board of Directors 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 the OHSU Executive Leadership Team. 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.

Roles and Responsibilities

General Counsel

OHSU's General Counsel has primary responsibility for ensuring that the Integrity Program meets the requirements of federal, state, and local laws and regulations. Operationally, the Chief Integrity Officer reports to General Counsel. In addition, General Counsel is expected to:

1. Assist the Board of Directors in understanding OHSU's legal risks and the adequacy of the Integrity Program and other OHSU offices and programs in addressing 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 Compliance 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.

Roles and Responsibilities

Executives

The members of the Board of Directors, President, and Vice Presidents, (hereinafter referred to as “Executives”) are responsible for articulating the values, mission, and vision of the institution; fostering high ethical, organizational, and operational standards; and ensuring compliance with policies, applicable laws, regulations, and other appropriate standards. Executives are 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, they may be asked to emphasize or underscore the importance of certain integrity issues or activities. Executives:

1. Require and support an OHSU Integrity Program that is consistent with the mission, vision, and values of OHSU and that ensures compliance.
2. Appoint and oversee the OHSU Chief Integrity Officer.
3. Ensure representation on the OHSU Integrity Program Oversight Council.
4. Establish integrity standards, goals, and objectives and ensure that they are met.
5. Ensure that all OHSU Members cooperate with internal and external auditors to provide honest, accurate, and complete responses and information in connection with any audit.
6. Provide policy direction concerning integrity issues.
7. Oversee the enforcement of integrity policies.
8. Appropriately respond to complaints and reported violations brought to their attention.
9. Ensure the availability of counsel to review and manage integrity matters as appropriate.
10. Ensure that they are appropriately informed regarding the nature and status of the OHSU Integrity Program and integrity issues at OHSU.
11. Lead 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 Program. These authorities include:

1. Initiating third-party audits or assessments of the Integrity Program.
2. Retaining outside counsel or consultants to address integrity issues when appropriate.
3. Subjecting 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, criminal conduct, exclusion or debarment from federal programs, or similar sanctions.

Part 2

Elements of the OHSU Integrity Program

Elements of the OHSU Integrity Program

Element 1. Compliance Standards and Procedures

“The organization shall establish standards and procedures to prevent and detect criminal conduct.”

--U.S. Sentencing Guidelines – rev. (2010)

Application:

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 integrity standards and procedures expressed in these documents and with all OHSU policies. By following these standards, OHSU Members support the fundamental belief that organizational success requires honesty, respect, and trust.

Effectiveness Measures:

Designation of a Compliance Officer and a Compliance Committee: The OHSU Integrity Office has articulated a mission and organizational structure for the institutional Integrity Program. This program is directed by a high-level position within the organization and implemented through staff that is dedicated to integrity and compliance activities. The Chief Integrity Officer reports to the OHSU Vice President and General Counsel. The integrity committee structure that supports the Integrity Program includes 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 Clinical Compliance Committee; the Audit and Advisory Services Committee; and multiple other, issue-focused integrity, ethics, or compliance committees.

OHSU Board of Director Resolutions: 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.

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 the Integrity Program and supports other essential initiatives such as hospital accreditation, accreditation of OHSU as an institution of higher education, Institutional Review Board accreditation, and other certifications and accreditations. The

Code is periodically revised and updated and shared on-line at:

<http://www.ohsu.edu/integrity/policies/coc.cfm>

OHSU Integrity Program Roles and Responsibilities: The R&R document (this document) has been reviewed and approved by deans, directors, the Executive Leadership Team, and the OHSU Board of Directors. It is posted to the [OHSU Integrity Office](#) web page. The R&R document was adopted as one of four policy documents that describe the Integrity Program via a 2004 Board of Directors resolution.

OHSU Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects: This R&R document addresses research integrity through the cycle of proposal, funding, performance, and termination of protocols. It is distributed (electronically) to all OHSU principal investigations and posted to the [Research Development & Administration](#) web page.

OHSU Clinical Compliance Plan: The OHSU Clinical Compliance 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 integrity-related policies are drafted by Integrity Officers, adopted by the OHSU Policy Advisory Committee, and implemented by the Integrity Office. 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 to integrity issues. These are local level policies and procedures that receive final approval from the Professional Board.

*The term "OHSU Members" is used throughout this document to refer to all employees (faculty, represented, unclassified administrative and other categories), registered and visiting students, volunteers, members of the OHSU Board and the Doernbecher Children's Hospital Foundation Board of Directors, visiting healthcare practitioners, contracted nonpermanent individuals, vendors while doing business with OHSU, and others who work for or on behalf of OHSU, OHSU Foundation and Doernbecher Children's Hospital Foundation. An index of relevant documents is provided in Appendix A.

Elements of the OHSU Integrity Program

Element 2. Oversight Responsibilities/Assignment

“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”

--U.S. Sentencing Guidelines – rev. (2010)

Application:

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. Line responsibilities for integrity are shown on the organizational chart provided in Appendix B. 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 indicated in the Program chart in Appendix C.

Effectiveness Measures:

- 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.
- Integrity Program reports are made to the Board of Directors no less frequently than annually.
- The Integrity Program Oversight Council meets no less frequently than quarterly.
- The Chief Integrity Officer meets with the Finance and Audit Committee periodically.
- The Chief Integrity Officer reports directly to the Vice President and General Counsel.
- The Chief Integrity Officer meets with the President periodically.
- The structure of the Integrity Program allows the Chief Integrity Officer to access the President or the Board of Directors directly to report concerns.

Elements of the OHSU Integrity Program

Element 3. Oversight Responsibility/Due Care

“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.”

--U.S. Sentencing Guidelines – rev. (2010)

Application:

OHSU exercises due care to ensure that discretionary authority is not delegated to people who have a propensity to engage in illegal or unethical 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.

Effectiveness Measures:

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.
- The names of all existing employees are screened twice per year 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.
- Pre-employment criminal background checks are performed for all potential employees.

Elements of the OHSU Integrity Program

Element 4. Education and Training

“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.”

--U.S. Sentencing Guidelines – rev. (2010)

Application:

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

Effectiveness Measures:

Education and training content areas 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
- Integrity standards for vendors and affiliates
- Legal and regulatory issues guiding integrity activity
- Reporting violations or questionable conduct and the routes for making such reports

The following areas participate in the development and delivery of integrity education:

- OHSU Integrity Office
- OHSU Research Integrity Office
- Hospitals Compliance Department

- Faculty Practice Plan Integrity Program
- Affirmative Action/Equal Opportunity
- Human Resources
- Sponsored Projects Administration
- Grants and Contracts Administration
- Clinical Trials Office
- Clinical Research Billing Office
- Operational Units and Departments
- Information Technology Group

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. Integrity education is documented in numerous ways, including automated databases, web registration, and attendance sheets. This documentation is available for review as necessary.

The OHSU Integrity Office devotes appropriate resources to this critical element of the Integrity Program.

All integrity education initiatives are regularly re-evaluated and amended, as changes in law and regulations require. This re-evaluation process considers both content and process of the educational module. Education initiatives are modified according to integrity reports, audits, or other monitoring that reveals trends. User evaluations of educational programs are obtained.

The Chief Integrity Officer participates in or leads many education initiatives and is responsible for providing integrity education and materials to the Board of Directors. Performance on key integrity education programs is monitored and tracked. Some programs set minimum performance requirements for completion of the program. Sanctions are imposed for failure to complete required educational modules.

Elements of the OHSU Integrity Program

Element 5. Monitoring, Auditing, and Reporting Systems

“The organization shall take reasonable steps to ensure that the organization’s compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct; to evaluate periodically the effectiveness of the organization’s compliance and ethics program; and to have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization’s employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.”

--U.S. Sentencing Guidelines – rev. (2010)

Application:

OHSU provides audit and monitoring services through the Audit and Advisory Services Program (A&ASP) to prevent and detect unethical, non-compliant, or illegal operations and behaviors. Audit and monitoring activities are conducted as described in the A&ASP Manual and the annual Work Plan. The A&ASP 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 enjoys oversight at the highest level. Summary audit reports are provided to the members of the Finance and Audit Committee of the OHSU Board of Directors and to the OHSU Integrity Program Oversight Council. Departments, divisions, schools, and units are also responsible for quality assessments and improvement efforts and for monitoring integrity procedures. Risk assessment is an integral part of the audit and monitoring planning process. The A&AS Committee is responsible for determining audit priorities based on a risk assessment report developed by the Audit Manager. The risk assessment drives the development of the internal audit plan, schedule, scope, timing, and frequency.

Auditing and Monitoring Systems

OHSU’s A&ASP conducts internal audits, monitoring, and follow-up of:

- Healthcare operations
- Human Resources
- Financial operations
- Research (human, animal, basic, applied)
- Information Privacy and Security
- Environmental health and radiation safety
- Academic programs

The A&ASP 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 to planned and supplemental audit activities, the A&ASP performs investigations and provides advisory services to assist operational units in establishing best practices.

Reporting Systems

OHSU fosters and supports a safe, non-threatening environment where individuals may ask questions about integrity issues and report concerns. The OHSU Code of Conduct describes several ways to report integrity concerns. Concerns may be submitted:

- Anonymously (the caller's identity is not revealed and the caller is assigned a code number);
- Confidentially (the reporter reveals his/her identity but requests limited disclosure of it. Such requests are honored to the extent allowed by law); or
- Identified (the reporter reveals his/her identity and allows it to be used as needed).

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. The Chief Integrity Officer assigns Hotline reports for review and resolution to appropriate OHSU personnel. The Integrity Office maintains a log reflecting all integrity issues reported via the Hotline and the resolution of those issues.

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.

Effectiveness Measures:

Monitoring and Auditing: OHSU monitors all contractors and vendors on a semi-annual basis to ensure they are not excluded or debarred. 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.

- The A&AS plan and program are continuously evaluated. The members of the Finance & Audit Committee evaluate the external audit plan annually.
- 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 and auditors to determine and implement remediation as appropriate.
- High-risk areas such as billing, coding, cash handling, human and animal subjects safety, radiation safety, hazardous waste disposal, select agent use, and many others are reviewed no less than annually. Such areas are subject to unscheduled reviews and monitoring based upon credible reports.
- The roles of internal and external auditors are clearly expressed in charters or work plans.
- Error or non-compliance rates are determined in key areas as part of the A&AS risk assessment and used to make audit priority decisions.

Reporting Systems: 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.

Elements of the OHSU Integrity Program

Element 6. Enforcement and Discipline

“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 criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.”

--U.S. Sentencing Guidelines – rev. (2010)

Application:

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 integrity 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 or the OHSU Integrity Program 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?

Effectiveness Measures:

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.

Elements of the OHSU Integrity Program

Element 7. Response and Prevention

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

--U.S. Sentencing Guidelines – rev. (2010)

Application:

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 integrity concerns and to address occurrences that may be part of a pattern of conduct.

Effectiveness Measures:

OHSU prevents integrity violations by:

- Screening and hiring applicants selectively.
- 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.
- Investigating and responding to integrity concerns as described below.
- Conducting risk-based audits and monitoring.
- Monitoring applicable laws and rules 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 and procedures and reporting relationships as indicated.
- Alerting levels of management as appropriate to address integrity concerns.
- Revising the OHSU Integrity Program as appropriate.

Appendix A

Related and Supporting Documents

OHSU integrity standards, policies, and procedures are statements of institutional values and expectations. These are expressed in documents that apply to all of OHSU as well as area-specific documents. See below for further information.

OHSU

OHSU Code of Conduct

<http://www.ohsu.edu/xd/about/services/integrity/policies/coc.cfm>

OHSU Policy Manual

<http://ozone.ohsu.edu/policy/pac/>

Environmental Health and Radiation Safety Policies

<http://www.ohsu.edu/xd/about/services/integrity/policies/d-environmentalhealth-policies.cfm>

Audit and Advisory Services Information

<http://www.ohsu.edu/xd/about/services/integrity/audit/index.cfm>

Health System/Professional

Health Care System Administrative Policies

<http://ozone.ohsu.edu/healthsystem/policy/index.cfm>

Health Care System Clinical Policy and Procedure Index

<http://ozone.ohsu.edu/healthsystem/policy/index.cfm>

OHSU Clinical Compliance Plan

<http://www.ohsu.edu/xd/health/integrity/index.cfm>

Research

Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects

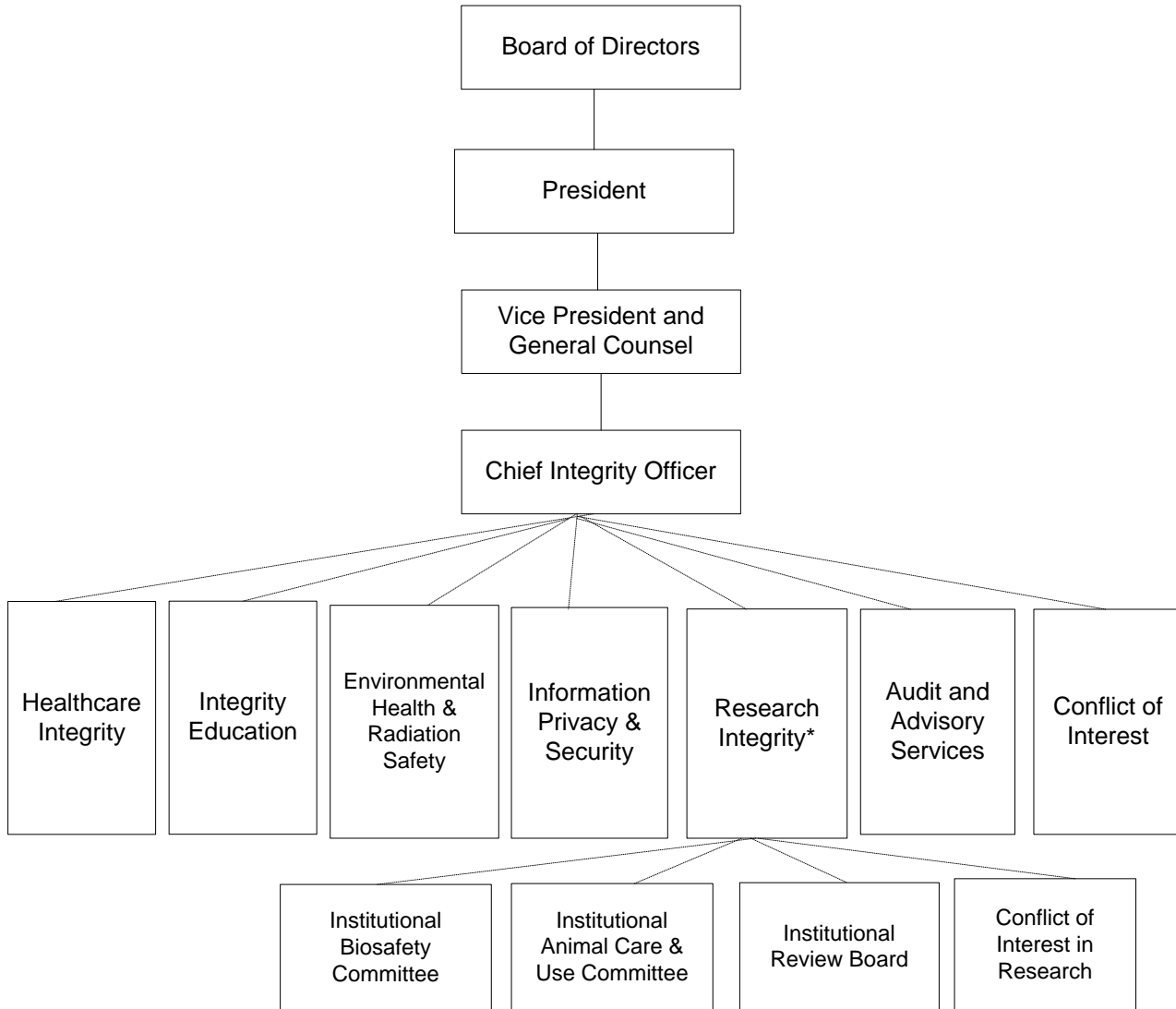
<http://www.ohsu.edu/xd/about/services/integrity/>

Research Development & Administration Policies

<http://www.ohsu.edu/xd/research/administration/rda-policies.cfm>

Appendix B

OHSU Integrity Office Organizational Chart



*Research Integrity reports operationally to the Vice President for Research Development and Administration

Appendix C

OHSU Integrity Program Chart

