

OFFICE OF UNIVERSITY RESEARCH COMPLIANCE

Mission

The Office of University Research Compliance ensures conformance to governmental and university regulations and policies that affect research using humans, animals, recombinant DNA, infectious agents and toxins, radiological materials and devices, and research lasers; provides oversight to these activities; ensures that conflicts of interest are disclosed and managed, and investigates improprieties and research misconduct.

Vision

The Office of University Research Compliance will achieve national prominence for effective research compliance by creating an environment where compliance is viewed as an integral component in the ethical conduct of research.

Core Values

Excellence -We seek excellence in all our endeavors, and we are committed to continuous improvement.

Intellectual Freedom -We believe in ethical and scholarly questioning in an environment that respects the rights of all to freely pursue knowledge.

Integrity -We are committed to the principles of truth and honesty, and we will be equitable, ethical and professional.

Service - We believe that serving others is a noble and worthy endeavor.

Diversity - We respect others and value diversity of opinion, freedom of expression, and other ethnic and cultural backgrounds.

Stewardship of Resources -We are dedicated to the efficient and effective use of resources. We accept the responsibility of the public's trust and are accountable for our actions.

Goals, Critical Success Factors, Objectives and Strategies

Goal 1. Human Resources and Infrastructure: Provide the infrastructure required for an effective research compliance program that is fully integrated into a centralized research administrative structure.

Critical Success Factors (*measures the degree of success over the next five years*):

- Necessary human and capital resources provided on a recurring funding basis at a level no less than 95% of the projected resources needed over the next five years.

Objectives:

Objective 1.1: The office will identify human and capital resources required for effective research compliance program.

Strategies:

- The office will baseline existing resources allocated to research compliance.
- The office will project research growth over next five years.
- The office will map requirements to existing resource base and project human and capital resources needed for the next five years.

Assessments:

- Initial baseline and projection of resources required are provided to central management
- Adequate resources are provided

Objective 1.2: The office will establish internal and external bases of support.

Strategies:

- The office will obtain support and approval for enhanced research compliance from OSU Board of Regents, President, and central administration for authority and emphasis.
- The office will identify >champions= from within the University and the community to represent each compliance area.
- The office will form alliances with other academic institutions and organizations to stimulate program development, implementation, and continuous improvement, and to seek external funding for these purposes.
- The office will empower faculty, staff, and students to take an active role in research

compliance.

- The office will provide adequate compensation to faculty chairing compliance committees.
- The office will promote importance of serving on compliance committees to university leadership.
- The office will implement recognition programs for serving on compliance committees.

Assessments:

- Publicity from highest administrative levels promoting OSU=s commitment to excellence in research compliance
- Number of active consortia and/or alliances
- Size of internal and external support base
- Extramural funding for research compliance activities
- Nationally-recognized researchers on compliance committees

Objective 1.3: The office will facilitate program development, delivery, and assessment.

Strategies:

- The office will identify essential components of a model research compliance program.
- The office will design and enhance existing curricula for use in multiple delivery mechanisms.
- The office will deliver training in a variety of media to faculty, staff, and students, including compliance committee members.
- The office will implement assessment mechanisms and quality improvement measures, to include best practices from peer institutions, professional organizations, and governmental agencies.
- The office will create a technology infrastructure that streamlines research compliance administration.
- The office will leverage existing technology resources.

Assessments:

- Number of persons trained
- Research compliance included in research methodology and research ethics courses
- Educational programs used by other institutions
- Recognition at professional meetings and in professional publications directed towards research administration and compliance

Goal 2. Risk Management: Minimize Liability and Risk to University from Non-Compliance and Adverse Events.

Critical Success Factors: (*measures success over the next five years*):

- Comprehensive risk assessment and analysis are conducted for 5 major compliance areas in three years
- Significant risks are identified and managed or eliminated
- Appropriate mitigation and/or management plans for low-level risks are implemented
- Non-threatening procedures for reporting non-compliance are implemented
- Written procedures and policies which foster an institutional commitment to compliance are disseminated in year 2
- Number of adverse events are reduced by 25%
- Cybersecurity is provided and supported across all compliance areas by year 3

Objective 2.1: The office will conduct comprehensive risk analysis of research compliance program.

Strategies:

- The office will inventory risks in each compliance area, and determine the significance of each to the function, process or activity.
- The office will determine the probability of occurrence and relative impact to the unit(s) and the university.
- The office will consolidate and prioritize risk assessment from each compliance areas.
- The office will implement risk assessment and management plan.
- The office will implement procedures for reporting non-compliance.
- The office will approximate costs of compliance and costs to the university from adverse events.

Assessments:

- Costs of compliance (and non-compliance) quantified
- Significant risks eliminated or reduced to manageable levels

- Procedures for managing existing low-level risks implemented
- Technology infrastructure is in place and supported by information technology professionals

Objective 2.2: The office will implement Research Protocol Monitoring and Oversight Procedures.

Strategies:

- Using best practices from peer institutions and federal oversight agencies, the office will establish written procedures and implement practices to monitor approved research protocols to ensure compliance.
- The office will publicize procedures for reporting non-compliance without fear of reprisal.
- The office will establish, implement, and publicize policies and procedures for investigating research improprieties.
- Using best practices from peer institutions, the office will establish written procedures and practices for disclosing financial or institutional conflicts of interest and mechanisms for managing these conflicts.

Assessments:

- Number of reported instances of non-compliance
- Number of cases investigated for non compliance or scientific misconduct
- Number of conflict of interest disclosures and management plans

Goal 3. Continuous Quality Improvement: Requirements to Ensure Best Practices and Program Improvement.

Critical Success Factors (*measures the degree of success over the next five years*):

- Resources provided to maintain or obtain appropriate licenses, federal approvals, and accreditation are provided in the year the accreditation is being sought and is recurring as required.
- Contiguous office space is provided to compliance field officers that provides a high-quality work environment and offers economies of scale by year 5
- All field officers, administrative staff, and compliance committee members are engaged in professional development programs and activities effective in year 1
- Conflict of interest disclosures

Objective 3.1: The office will obtain accreditation for animal program.

Strategies:

- The office will provide resources for site visits in preparation for seeking accreditation for the animal care and use program from the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).
- The office will complete application process for AAALAC accreditation.
- The office will provide resources for infrastructure enhancement in preparation for AAALAC accreditation.

Assessments:

- AAALAC accreditation obtained
- Increase in external funding in programs using animals in research projects
- Federal and state inspections receive positive ratings

Objective 3.2: The office will obtain accreditation for the Institutional Review Board.

Strategies:

- The office will strengthen centralized services that support the Institutional Review Board.
- The office will seek professional certification for staff dedicated to monitoring

research activities using human subjects.

- The office will complete application process for accreditation of the Institutional Review Board.

Assessments:

- Appropriate administrative staff are certified
- Accreditation obtained
- Federal Assurance License with Department of Health and Human Services renewed
- Federal and state inspections receive positive ratings

Objective 3.3: The office will conduct program assessments at regular intervals.

Strategies:

- Each research compliance area will institute a regular schedule for conducting partial and full-scale program audits.
- Procedures for procuring resources and correcting deficiencies will be revealed in implemented program audits.

Assessments:

- Deficiencies identified and corrective actions taken
- Revenue stream to correct deficiencies procured

Objective 3.4: The office will initiate an aggressive training program in research ethics and research compliance.

Strategies:

- The office will leverage existing training, both internally on externally.
- The office will establish a mechanism to continually update content based on changing federal, state, and university regulations and policies.
- The office will implement training records management system that leverages existing systems and information technology.
- The office will provide assistance to departments and other units to implement this training in existing curricula.

Assessments:

- Number of people taking the training
- Feedback from persons taking the training
- Relative ease in obtaining appropriate training