Guidelines for Researcher Training:
Transparency, Best Practices, and Regulatory Requirements

Reason for Guidance
The conduct of research is subject to federal and state laws, sponsor requirements, award terms and conditions, and University policies. Harvard University is committed to providing training on best practices and resources to facilitate insightful research that is rigorous in its conduct and its compliance with regulatory requirements. Research compliance training should be:
  • Streamlined, clear, and accessible
  • Targeted to research roles and research activities
  • Easy to assign and track

The goal of these guidelines is to promote collaboration amongst faculty, researchers, laboratory managers, staff, and other constituents in the design and delivery of in-person or online research compliance training as well as to establish a process for the approval, uploading, and integration of research compliance training content into the Harvard Training Portal.

Applicability
This guidance is applicable to individuals involved in the development and dissemination of formal University or School/Tub level research compliance programming provided for the researcher community (e.g., faculty, lab managers, postdoctoral researchers)—that includes all administrators at Harvard University within all schools, units, divisions, University-wide initiatives, labs, and centers. Research compliance areas include the following:
  o Human subjects research
  o Special issues regarding biospecimens/human material use
  o Animal care and use
  o Conflict of interest
  o Export controls
  o Lab safety (including biological and biosecurity, radiological, chemical)
  o Rigor and transparency
  o Data management and security

Roles and Responsibilities
Responsibilities for the analysis, design, development, review, and delivery of research compliance training are shared among the following:
Central and School/Tub research compliance subject matter experts (SMEs) are responsible for the following:

- Work with University Research Compliance Training Committee to analyze/assess the need for training on a particular subject, including relevant audience, learner needs and desired outcomes, and objectives
- Design, develop and deliver in-person or online research compliance training offerings based on academic, administrative, regulatory, and resource-based subject-matter expertise
- Request review of research compliance training offerings from the researcher community, including faculty, lab managers, graduate students, research assistants, and/or postdoctoral researchers
- Submit completed Research Compliance Training Checklist for review by the Office of the Vice Provost for Research (OVPR) prior to in-person delivery and/or offering being listed in the Harvard Training Portal

University Research Compliance Training Committee

- Review formal University or School/Tub level research compliance training offerings
- Ensure users from the researcher community have reviewed the training
- Provide resources for administrators developing compliance training content
- Coordinate and/or consolidate duplicate training offerings to be uploaded into the Harvard Training Portal
- Coordinate with the University Research Administration Training Team charged with the coordination and delivery of training related to research administration topics

Harvard University Information Technology/Harvard Training Portal

- Ensure research compliance training offerings have been reviewed by OVPR
- Work with RCTC to ensure consistency with regard to overall research compliance training program strategy and use of the Portal

Researcher Community

- Review content for clarity
- Beta test research compliance training modules

Procedures

The following procedures outline the process for the analysis, design, development, review, and delivery of research compliance training.

1. **Developing a Research Compliance Training Course or Program**
   Administrators planning to develop a University or School/Tub-level research compliance training course or program should:
   - Identify the relevant audience (who should take the training?)
   - Analyze the learner needs, desired outcomes, and objectives related to the subject of the training
   - Consult with the University Research Compliance Training Committee for resources regarding training content and modes of delivery
   - Identify and encourage collaboration amongst academic, regulatory, and resource/support SMEs to partner with on content development
   - Identify the related University policies associated with the training
   - Design and develop the content in collaboration with SMEs
• Review the content with SMEs as well as potential users in the research community and any other stakeholders
• Submit completed Research Compliance Training Checklist to OVPR for review
• Submit to the Harvard Training Portal upon approval of the OVPR

2. **Design and develop content in collaboration with subject-matter experts**
   Subject matter experts may consult with the user community, relevant resource/support staff, and University adult learning education experts as appropriate. Content should be developed to be streamlined, clear, and targeted to research roles and research activities.

3. **Review by researcher community**
   Researcher feedback should be obtained prior to submission of final training materials to the OVPR for review and approval.

4. **Review by Office of the Vice Provost for Research**
   Final review of University or School/Tub level research compliance programming offered to the researcher community should be completed by the OVPR prior to delivering in-person or listing the offering in the Harvard Training Portal. The Research Compliance Training Committee may provide training developers further advice on content prior to final delivery.

**Resources**

Research Compliance Training Checklist

*Principles of Adult Learning & Instructional Systems Design*

*Association for Talent Development Broad Principles for Guiding and Facilitating Adult Learning*

**University Research Compliance Training Committee**

University Research Compliance Training Committee (under Sponsored Administration Leadership Council):

  - **Melissa Lopes** (OVPR), Co-Chair
  - **Denise Moody** (Faculty of Arts and Sciences), Co-Chair
  - **Marissa Cardwell** (Environmental Health and Safety)
  - **Kristen Elwell** (Faculty of Arts and Sciences)
  - **Suzanne Higgins** (Harvard Medical School)
  - **Amy Maltzan** (Center for Workplace Development)
  - **Eileen Nielsen** (Harvard T. H. Chan School of Public Health)
  - **Rachel Talentino** (Office for Sponsored Programs)
  - **Daniel Wainstock** (Harvard Medical School)

**Revision History**

12/2017 – New guidelines released

9/2018 – Added new Research Compliance Training Checklist requirement for new course or program offerings