



**Research Education and Training – Standard
Operating Procedures**

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1. Overview

Purpose

The purpose of these procedures is to outline the research education and training requirements for Drexel University faculty, staff members, students, and Drexel University Research Agents engaged in research activities under the oversight of the Office of Research & Innovation (ORI) which may include non-employee associates or volunteers as per [ORI-004 Drexel Research Agent Eligibility and Responsibilities](#). Establishing standardized processes for research training requirements supports compliance with Federal and State laws and University policy to promote ethical conduct of research.

These procedures do not limit a department, office, or unit from developing additional requirements or guidance that supplement these procedures, provided they do not conflict with them. In addition, protocol/project-specific training must also be completed on an individual project basis, i.e., procedures training, investigational product training, etc. Other institutional requirements outside of the purview of the ORI, such as annual Drexel employee training, privacy, and human resources training requirements, Minors Program registration are required per institutional procedures.

Please note that training requirements are separate and distinct from submission requirements such as institutional and research Conflict of Interest (COI) disclosures, Institutional Review Board (IRB) submissions, and Occupational Health evaluations (e.g., physicals). While all are required for compliance, each serves a different purpose and follows its own process and timeline. Completion of training does not substitute for submission of the above documentation, requirements, or processes and vice versa.

2. Definitions

Clinical research is the scientific study of human health and disease to develop new medical treatments, interventions, and health practices. It involves the systematic study of drugs, medical devices, behavioral interventions, and public health strategies to assess their safety, efficacy, and impact on individuals and populations.

Drexel University Research Agents are individuals who act on behalf of the institution, exercise institutional authority or responsibility, or perform institutionally designated activities. Drexel University Research agents include faculty, staff, students, contractors, and volunteers, depending upon their involvement in research, sponsored programs, or projects as determined by the applicable committees (e.g., IRB, IACUC) or ORI offices.

3. Required Institutional Training

3.1 Drexel Enterprise Learning

Drexel University will assign annual Enterprise learning for faculty and staff based on an individual's role. Enterprise learning for all faculty, staff and students includes training on Research Compliance and Regulatory Affairs. ORI expects all agents of Drexel University to complete all training as assigned by the institution, and specifically for research as the following:



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Required Training	Population	Frequency
University Research Compliance and Regulatory Affairs	All faculty, staff, and students	At time of hire or as assigned by the institution

4. Required Research Training

The applicable ORI group (e.g., HRPP/IRB, IACUC, OSP) may accept alternate research training to the required trainings listed below for applicable personnel under the oversight of Drexel University. Alternate research training may be appropriate:

- if CITI modules are not presented in the language for international research personnel,
- for individuals with limited literacy or who may benefit from training that uses plain language, visual aids, or an oral format,
- for individuals without formal academic affiliations, e.g., community advisory members or lived-experience experts who otherwise are unable to complete CITI training modules due to significant burden or barriers to participation.

CITI training courses requiring periodic completion, including courses for human subject protection, responsible conduct of research, and good clinical practice offer “refresher courses” for renewal of the training certification. Refresher courses include a limited core set of modules and additional optional modules which may be selected based on areas of interest.

For questions about engagement in research activities, who qualifies as personnel under the oversight of Drexel University, or alternate training allowances, contact the applicable ORI office, e.g., HRPP/IRB Office for human subjects research, IACUC Office for animal research, etc.

4.1 Conflict of Interest (COI)

Required Training	Population	Frequency
CITI Training: Research Administration COI or Conflict of Interest	Personnel/Investigators affiliated with Drexel or engaged in sponsored projects	At least every 4 years

In addition to the CITI training requirements, investigators and key personnel must complete an annual research conflict of interest disclosure, project-specific disclosures at the time of proposal submission, and a new disclosure when there is a change in conflict of interest.

Separate from research COI, Drexel University also requires institutional training on a periodic basis as well as annual conflict of interest disclosures as assigned by the institution through Enterprise learning.

4.2 Responsible Conduct of Research (RCR)

Required Training	Population	Frequency
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CITI Training: Research Administration RCR	Faculty, staff, students participating in NIH, NSF, or USDA NIFA funded projects	At least every 3 years
Responsible Conduct of Research Face-to-Face Session	Faculty, staff, students conducting research supported by an NIH type D, F, K, R, T or U award	At least every 4 years or at each career phase

Ongoing RCR training of investigators and research personnel is expected and requirements may vary per funder and award terms. Investigators are required to comply with the funder and award terms regarding RCR training requirements and track applicable training completion for applicable personnel.

4.3 Environmental Health & Radiation Safety (EHRS)

Required Training	Population	Frequency
EHRS BioRAFT	Individuals working or learning in university laboratories and clinical/medical operations, working with biological agents, chemical agents, or radioactive materials	Annually More Information

4.4 Animal Research

Required Training	Population	Frequency
CITI: Working with the IACUC - Investigators, Staff and Students	Faculty, staff and students engaged in the use of animals for research, education and testing	At least every 3 years More Information
CITI: Reducing Pain and Distress in Laboratory Mice and Rats (if working with mice or rats) CITI: Aseptic Technique CITI: Additional Species-Specific Modules as applicable	Faculty, staff and students engaged in the use of animals for research, education and testing	At least once More Information
Animal Facility Tour	Faculty, staff and students engaged in the use of animals	At least once More Information



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	for research, education and testing	
<p>Protocol/Species-Specific (Hands-On) Training</p> <p>The animal research trainings listed above must be completed before the hands-on training.</p> <p>Available trainings include:</p> <ul style="list-style-type: none"> • Lift & Restrain • Intraperitoneal Injection • Subcutaneous Injection • Intravenous Injection • Intramuscular Injection • Gavage • Aseptic Technique • Barrier Technique • Instrument Prep • Operative Tech/Care • Suturing & Wound Care • Euthanasia • Blood Collection • Breeding Techniques <p>If you are rotating to another lab or doing additional techniques not previously covered during the hands-on training, the Trainer MUST be contacted again to receive further technique instruction and an updated training certificate.</p> <p>A prerequisite to the hands-on training is completion of the Occupational Health Services certification.</p>	<p>Faculty, staff and students engaged in the use of animals for research, education and testing</p>	<p>Once per technique; refresher sessions are available upon request</p> <p>More Information</p>



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4.5 Human Subjects Research

Required Training	Population	Frequency
CITI: Human Subjects Research (HSR)	Key research personnel, including for exempt human research, affiliated with Drexel University	At least every 3 years
CITI: Health Information Privacy and Security (HIPS)	Key research personnel affiliated with Drexel University who are handling Protected Health Information (PHI) and Personally Identifiable Information (PII)	At least every 3 years
CITI: Good Clinical Practice (GCP)	Key research personnel affiliated with Drexel University, when required by the project Sponsor or if conducting clinical research	At least every 3 years or per sponsor requirements

5. Recommended Research Training

5.1 Additional Recommended Training

Training	Population	Frequency
CITI: Export Compliance	Drexel agents involved in activities subject to the U.S. export control laws or as required by the project Sponsor	At least once or per sponsor requirements
CITI: Undue Foreign Influence: Risks and Mitigations	Drexel agents involved in international relationships and activities	At least once or per sponsor requirements

6. Responsibilities

6.1 Office of Research & Innovation Responsibilities

The Office of Research & Innovation is responsible for maintaining these procedures, applicable tools, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).



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Different functional groups of ORI (e.g., HRPP/IRB, IACUC, OSP) may verify applicable required training is completed prior to granting approval for the research project to proceed.

6.2 Principal Investigator Responsibilities

The Principal Investigator (and Faculty Mentor, as applicable) is ultimately responsible for the conduct and oversight of the project and personnel. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following this SOP, ensuring appropriate training for research personnel engaged in the project, and submitting the applicable documentation or exceptions to the appropriate ORI groups.

7. Resources

- [National Science Foundation’s \(NSF\) Proposal & Award Policies & Procedures Guide \(PAPPG\)](#)
- [NIH RCR Training Requirements](#)
- [USDA NIFA RCR Training Requirements](#)
- [ORI-002 Principal Investigator Eligibility and Responsibilities](#)
- [ORI-004 Drexel Research Agent Eligibility and Responsibilities](#)
- [ORI-613 Clinical Research Guidelines for Site Initiation](#)
- ORI-005 Supplemental Training Matrix

8. Revision and Workgroup Members

8.1 Revision

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8.2 Workgroup Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup Members:

Workgroup Members	
Martin Bell, MS, CIH, CSP Director of Environmental Compliance Environmental Health & Radiation Safety	Tsz Kwok, EdD Director of Academic Affairs Graduate College
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