



**Principal Investigator Eligibility and  
Responsibilities-Standard Operating  
Procedures**

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## 1 Overview

### 1.1 Purpose

The purpose of these procedures is to outline the eligibility, responsibilities, and expectations for Principal Investigator (PI) engaged in research activities, funded programs, projects, or related activities under the oversight of Drexel University's Office of Research and Innovation (ORI) (e.g., HRPP-IRB, IACUC, OSP), regardless of collaborators. These procedures apply to all Drexel University faculty, staff members, and otherwise Drexel University Agents.

Please note that if ORI has agreed to provide managed service or regulatory oversight for non-Drexel University collaborators, individuals must also refer to their institutional procedures and requirements for Principal Investigator (e.g., Saint Christopher's Hospital for Children).

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.

## 2 Definitions

**Affiliated Faculty** is an individual who has received an affiliated appointment that may be extended by an academic department or unit (School or College) to a person who meets the professional qualifications of the department or unit but whose primary assignment is outside the department or unit. This definition is subject to the Drexel University Provost Office; please refer to their policies or procedures.

**Courtesy Faculty** is an individual who has received a courtesy appointment that may be extended by an academic department or unit (School or College) to a person who meets the unit's professional qualifications. This definition is subject to the Drexel University Provost Office; please refer to their policies or procedures.

**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.

**Emeriti Faculty** is an individual who has been designated as a retired faculty member, having demonstrated a distinguished professorial career, and as having made significant contributions to the University. This definition is subject to the Drexel University Provost Office; please refer to the Emeriti Faculty Policy.

**Hospital/Clinical Faculty** is an individual who has a clinical appointment or designated hospital privileges that permit an individual to serve as Principal Investigator either by the hospital or clinic's policies or procedures or through an established agreement with Drexel University.



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**Research Faculty Mentor** is an experienced individual who guides, advises, and supports an inexperienced scholar or student to provide oversight for research purposes. Research Faculty Mentors must meet the requirements of the Principal Investigator as outlined in the [“Eligibility Table”](#) per their own employment/faculty status (e.g., Faculty, Full-Time).

**Human Research Protection Program (HRPP)** is responsible for providing administrative and regulatory support to the Drexel University IRB. HRPP provides guidance on the responsible conduct of human research to Drexel's IRB members, faculty, investigators, and the research community.

**Institutional Animal Care and Use Committee (IACUC)** is responsible for oversight of the animal care and use program and its components as described in the Animal Welfare Act, Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, and the Guide for the Care and Use of Laboratory Animals. Its oversight functions include an ongoing assessment of animal care and use and serve an important role in ensuring the ethical and human care of animals.

**Institutional Review Board (IRB)** is an appropriately constituted independent group formally designated to review and monitor research involving human subjects. In accordance with regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group reviews human subjects research and serves an important role in the protection of the rights and welfare of human research subjects. (Per FDA and OHRP consideration)

**Non-Employee Associates (NEA)** is an individual who will not be paid through Drexel's payroll system and is not considered a Drexel Employee; however, they have been given access to Drexel University Services provided they follow the processes and procedures of Drexel University.

**Principal Investigator (PI)** is the individual responsible for preparing, conducting, and administering a protocol, research project, research grant, cooperative agreement, training or public service project, contract, or other sponsored project.

**Faculty (Full-Time or Part-Time)** are full or part-time faculty, including Assistant Professor, Associate Professor or Professor.

**Visiting Faculty** are full-time, non-tenure track appointments and are intended to be temporary engagements, generally for periods for one to two years. This definition is subject to the Drexel University Provost Office; please refer to their policies or procedures.



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### 3 Eligibility

#### 3.1 Eligibility Table

Drexel Employment/Faculty Status	Institutional Animal Care and Use Committee (IACUC)	Institutional Review Board (IRB)	Office of Sponsored Programs
<b><u>Faculty</u></b>			
Faculty (Full Time)	Yes	Yes	Yes
Faculty (Part Time)	No*	Yes	Yes
Adjunct, Affiliated, or Emeriti Faculty	No*	No*	No*
Volunteer & Core Faculty	No	No	No
Hospital/Clinical Faculty	No*	Yes	Yes
Temporary Faculty	No	No	No
Visiting Faculty	Yes with Faculty Mentor	No	No
Casual Faculty	No*	No*	Yes
Courtesy Faculty	No	No	No
<b><u>Staff/Others</u></b>			
Full-Time Professional Staff	No*	Yes	Yes
Part-Time Professional Staff or Hourly Staff	No	No	No
Non-Employee Associate	No	No*	No
<b><u>Students</u></b>			
Post-Doctoral Fellows	Yes with Faculty Mentor(s)	Yes with Faculty Mentor(s)	Yes with Faculty Mentor(s)
Graduate Level Students and above	No	Yes with Faculty Mentor(s)	Yes with Faculty Mentor(s)
Undergraduate Students	No	No	No
*Indicates Section 3.3 PI/Faculty Mentor Exception Process Requirement.			

#### 3.2 Multi-Agent Status

In instances where an individual has both a Drexel University appointment or position and a position or appointment with another entity, institution, or company, the primary institution should be responsible for the oversight (e.g., IACUC, IRB, OSP, Research Compliance) of the project. However, there are instances where ORI will need to determine, given the specifics of the project or proposal (e.g., funding, collaborating institution, research activities, and location of the activities) to determine if Drexel University is engaged and, per regulatory requirements, who is responsible for oversight, additional oversight requirements, and to engage with other entity's, institutions, or companies appropriately.



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As a reminder, if any Drexel Agents receive salary, pay, or any other incentive as outlined in the Institutional COI Policy and Research COI Policy, please ensure this is reported in accordance with these policies to ensure an appropriate management plan.

### 3.3 PI Exception Process

In very exceptional circumstances, part-time faculty, professor emeritus, and others, as indicated by the asterisks in the [3.1 Eligibility Table](#), may serve as PI with a PI Exception Form on an individual project basis as completed and certified by their dean, director, or departmental head, and as evaluated and permitted by the Institutional Official, who may consult with relevant offices. In the case of research that requires oversight by the IACUC or IRB, they will have final authority to approve an individual as PI per the regulatory requirements to ensure appropriate expertise and oversight and may have additional submission requirements.

The PI Exception Form should be prepared and attached to applicable submissions. The form includes written confirmation that the appropriate administrative and fiscal support staff and services are available to support the applicant as PI throughout each project stage.

### 3.4 Transfers to Drexel University

Deans, directors, or departmental heads may submit proposals to ORI on behalf of a PI transferring from a different institution to Drexel University. Once the PI has transferred to the University, a PI transfer may be initiated in each ORI area as applicable. However, please note any activities that occur before the PI change will be under the oversight of the dean, director, or departmental head, who initially certified and is responsible for the conduct until the PI change has been approved or acknowledged.

### 3.5 Co-Principal Investigators

In some instances, a sponsor or funder may recognize a Co-principal Investigator; in these instances, a single individual must be designated as the “Principal Investigator” who individually assumes institutional responsibility for the overall project with each applicable ORI office. Please note the PI listed on the OSP application is not required to be the same PI as on the IRB or IACUC submission, and often, there may be multiple IRB or IACUC submissions within a single OSP submission or vice versa, which would permit a division of responsibilities of the PI role based on skills, experience, and expertise. This division of responsibilities should be a collaborative decision between engaged parties and relevant departments.

### 3.6 PI Funder/Sponsor Restrictions

When a funding agency or a sponsor has restrictions on who may serve as PI on a project or program that is more stringent than these procedures, the sponsor’s or funder’s requirements will take precedence over institutional procedures for that specific project. If a funding agency or sponsor requires an individual to serve as a PI who otherwise, under these procedures, may be ineligible, the individual will submit a [PI Exception Form as described in 3.3](#). In these instances, additional time should be provided to the Departmental Approver and ORI offices to facilitate the process accordingly.



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### 3.7 Faculty Mentor

Students may only be designated as a PI, [as noted in 3.1](#), with a Faculty Mentor for funded programs when a funding agency's program guidelines require the student to be listed as the PI on the proposal application. Only those who otherwise meet the requirements of a PI [as identified in 3.1](#) will be allowed to serve as a Faculty Mentor, this includes exceptions. Faculty Mentor's responsibilities are the same as the Principal Investigator's, [as outlined in 4.3](#).

Regardless of funding, if a student is permitted to conduct research with a Faculty Mentor as [noted in 3.1](#), the student's Faculty Mentor is also required to certify they ultimately will be responsible for the overall conduct and oversight of the project and failure to provide adequate oversight could impact the Faculty Mentor's ability to conduct research at Drexel University.

### 3.8 Student-Principal Investigator

[As noted in section 3.1](#), if a student is permitted to serve as PI and conduct research with a Faculty Mentor, the student is required to certify they will adhere to the responsibilities [defined in section 4.3](#) as well as ensure complete transparency and collaboration with the Faculty Mentor as the Faculty Mentor is responsible for all aspects of the work and to provide adequate oversight. Failure to adhere to these responsibilities could impact the Student-Principal Investigators' ability to conduct research at Drexel University.

The Faculty Mentor and Student Principal Investigator both hold responsibility for the conduct of the research. Therefore, all publications or authorship decisions must be agreed to by the Principal Investigator and Faculty Mentor following the terms and conditions of the sponsor as applicable and standard authorship best practice (e.g., HHS-ORI).

## 4 Responsibilities

### 4.1 Office for Research & Innovation Responsibilities

The Institution assumes responsibility for the performance of the stated project, fiscal management of the funds received, and accountability to the sponsor, human participants, and animals used for research purposes, as applicable. These responsibilities are provided oversight by the Institutional Official and may be designated to others as permitted by the regulations and formally documented.

The Office for Research & Innovation maintains these procedures, applicable tools, training, granting exceptions, and monitoring. ORI is also responsible for ensuring that the PI and Department have appropriately certified and given permission to proceed throughout the submission routing process for all programs or projects as defined in the "Overview" section.

Specifically, different areas of ORI (e.g., HRPP/IRB, IACUC, Export Control, OSP) have additional responsibilities as designated compliance offices, which are outlined per their individual guidance. 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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### **4.2 PI Department Responsibilities**

The Principal Investigator's department is responsible for three primary areas as documented by the approval routing process as certified by the Department, submitted to ORI, and include the following:

1. The proposed PI's Drexel University status, expertise, experience, and credentials are appropriate to ensure this individual can fulfill their responsibilities as a Principal Investigator.
2. The department will support the proposed project fiscally to ensure obligations are met, including any commitment to human subjects and animals for research use.
3. If the PI's Drexel University status changes, or their expertise, experience, or credentials are no longer adequate to fulfill their responsibilities as a Principal Investigator, the department will notify the applicable ORI offices and support any required follow-up or management.
  - a. Please note that in addition to status changes, departures, or changes in expertise, this also includes if a PI takes an extended leave of absence, sabbatical, or is unable for any length of time, commensurate with the risk of the research, where the PI is unable to provide oversight.
  - b. Required follow-up and management may include, identifying and being responsible for an appropriate transition plan, storing and retention of documents or data in accordance with Drexel University policies and procedures, as well as federal requirements (e.g., HIPAA, FERPA, FDA), and responding to inquiries or requests from institutional offices, sponsors, or funding and regulatory agencies.

Please note as the Department is responsible for assessing the PI as stated above, CVs, resumes, or other "documentation" may be requested as part of the review (e.g., IRB, IACUC, OSP) or monitoring process (e.g., FDA, USDA, Internal and External Monitors).

### **4.3 PI Responsibilities**

The Principal Investigator is ultimately responsible for the conduct and oversight of the study, technical goals of the research project, and fiscal management regardless of involvement by students, study team members, and collaborators. The PI is responsible for several critical areas as documented by the approval routing process as certified by the PI, submitted to the Department and ORI, including the following:

1. Compliance with all applicable University policies and procedures related to the specific research project. This includes, but is not limited to, intellectual property, international travel, records retention, IT policies, and privacy policies.
2. Compliance with all applicable federal, state, and agency regulations related to the project.



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3. Compliance with all project-specific guidelines and procedures (e.g., export control, COI, IACUC, IRB, OSP).
4. Ensure all submissions, proposals, reports, journals, publications, or any other required forms, documents, or requests for information have been reviewed by the PI and completed in a true and accurate manner.
5. Ensure all study personnel have appropriate Drexel University status, expertise, experience, and credentials to conduct research activities under the PI’s oversight.
  - a. If students, staff, or co-investigators leave the institution or their status changes (e.g., student to non-paid associate), the PI must inform the applicable ORI offices, execute necessary agreements, or remove them from personnel lists.
6. Ensure continuous oversight, regardless of sabbaticals, leave, transfers, or retirement, by collaborating with the PI’s Department and applicable ORI offices of the affected projects to manage plans and relevant timelines.

Please note as different institutions have different requirements, rules, and expectations, please ensure Drexel University’s policies, procedures, and guidelines prior to conducting research, projects or programs have been reviewed.

## 5 Resources

- PI/Faculty Mentor Exception Form
- ORI-003 Departing Faculty Guideline and Checklist

## 6 Revision and Workgroup Members

### 6.1 Revision

Version/Effective Date 11/01/2023- Original Document-Procedures and Guidance for Drexel University Research Community.

### 6.2 Workgroup Member

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

<b>Work Group Members</b>	
<b>Rose Ann DiMaria-Ghalili, PhD, RN, FASPEN, FAAN, FGSA</b> Senior Associate Dean for Research Professor College of Nursing and Health Professions	<b>Janet Matthews, MSN RN</b> Senior Director, Research Program Development College of Medicine





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<p><b>Lacee Harris, PhD</b> Executive Director, Research Compliance Office of Research and Innovation</p>	<p><b>Cassandra Myers, BS</b> Associate Vice Provost Research Compliance and Regulatory Affairs Office of Research and Innovation</p>
<p><b>Elizabeth Hann, BS</b> Director of Animal Welfare, Radiation Safety, and IBC Office of Research and Innovation</p>	<p><b>Flavia Padovani, Ph.D.</b> Associate Professor Department of English and Philosophy College of Arts and Sciences</p>
<p><b>Gwynne Grasberger, M.S.</b> Associate Vice Provost Research Development Office of Research and Innovation</p>	<p><b>Ramesh Raghupathi, Ph.D.</b> Professor Department of Neurobiology &amp; Anatomy College of Medicine</p>
<p><b>Shintaro Kaido, MBA</b> Vice Provost for Innovation and Executive Director of Drexel Applied Innovation Office of Research and Innovation</p>	<p><b>John Roberts, BA, CIP</b> Executive Director of Human Research Protections Program Office of Research and Innovation</p>
<p><b>Jennifer Katz-Buonincontro, Ph.D.</b> Professor School of Education</p>	<p><b>Sarah Saxton, MA, MEd</b> Executive Director of Sponsored Programs Office of Research and Innovation</p>