



Drexel Research Agent Eligibility and Responsibilities – Standard Operating Procedures

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1. Overview

Purpose

The purpose of these procedures is to define and outline the role of the Drexel Research Agent, acting on behalf of the Institution, and to outline the eligibility, responsibilities, and expectations for the Drexel Research Agent 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., Human Research Protection Program (HRPP)-Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Office of Sponsored Programs (OSP)). Federal and State laws and University policy require assurances that research conducted at and on behalf of the University is done with the highest regard for the rights and welfare of all research subjects and the University community. These procedures extend from the ORI Standard Operating Procedures (SOP), ORI-002, Principal Investigator Eligibility and Responsibilities, inclusive of Drexel Research Agents beyond the Principal Investigator (PI) role and including other study personnel. Please refer to [ORI-002, Principal Investigator Eligibility and Responsibilities](#) for the eligibility and responsibilities specific to the project PI.

Please note that if the 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 engagement of research activities (e.g., St 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.

Adjunct Faculty is an individual who has a faculty teaching appointment at Drexel on a course-by-course contractual basis who may have a full-time or primary employment elsewhere.*

Casual Employee/Faculty is an individual scheduled to work a maximum of 19 hours per week and is scheduled to work on a regular basis (as opposed to per diem schedule).*

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.



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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.

Faculty (Full-Time) is an individual, inclusive of tenured/tenure-track (TT) and non-tenured/non-tenure-track (NTT) faculty, providing full-time effort contributing significantly to the mission of the University, including Assistant Professor, Associate Professor, Professor, Teaching Faculty, Instructor, Clinical Faculty, Faculty of Practice, and Research Faculty.*

Faculty (Part-Time) is an individual, inclusive of non-tenured/non-tenure-track (NTT) faculty, providing 20-39 hours of effort contributing significantly to the mission of the University, including Teaching Faculty, Clinical Faculty, Faculty of Practice, and Research Faculty.*

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.

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 humane 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 Associate (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.

Per-Diem Employee is defined as an individual who is scheduled to work on an "as needed" basis.



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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.

Professional Staff (Full-Time) is an individual employed in any non-faculty category by Drexel University, including an individual who is deemed to be either exempt or non-exempt under the provisions of the Fair Labor Standards Act (FLSA) and/or applicable state law and who is regularly scheduled to work 40 hours per week.

Professional Staff (Part-Time) is an individual employed in any non-faculty category by Drexel University, including an individual who is deemed to be either exempt or non-exempt under the provisions of the Fair Labor Standards Act (FLSA) and/or applicable state law and who is regularly scheduled to work at least 20 hours but fewer than 40 hours per week.

Temporary Employee/Faculty is defined as an individual who is working either full-time or part-time less than 6 months in a rolling 12-month period.*

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

Volunteers provide services without the expectation of pay and are not considered university employees for any purpose. Volunteers do not displace professional staff, are not entitled to employment and can be terminated by either party at any time. Individuals who volunteer their services are not eligible for University benefits or Workers' Compensation and are expected to carry own personal medical insurance.

**These definitions are an interpretation of current practices at Drexel University and may be subject to change per Human Resources (HR) and Provost policies.*

3. Eligibility

3.1 Drexel Research Agent Eligibility Table

Drexel Employment/Faculty Status	Institutional Animal Care and Use Committee (IACUC)	Institutional Review Board (IRB)	Office of Sponsored Programs
<u>Faculty</u>			
Faculty (Full-Time)	Yes	Yes	Yes
Faculty (Part-Time)	Yes	Yes	Yes
Adjunct Faculty	No*	No*	No*
Affiliated Faculty	Yes	Yes	Yes
Volunteer Faculty	No*	No*	No*
Hospital/Clinical Faculty	Yes	Yes	Yes



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Emeritus Faculty	Yes ⁺	Yes ⁺	Yes ⁺
Temporary Faculty	No*	No*	No*
Visiting Faculty	No*	No*	No*
Casual Faculty	No*	No*	No*
Courtesy Faculty	No	No	No
<u>Staff/Others</u>			
Full-Time Professional Staff	Yes	Yes	Yes
Part-Time Professional Staff	Yes	Yes	Yes
Casual, Temporary, or Per-Diem Employee	Yes	Yes	Yes
Non-Employee Associate, Volunteer	No*	No*	No*
<u>Students</u>			
Post-Doctoral Fellows	Yes	Yes	Yes
Graduate Level Students and above	Yes	Yes	Yes
Undergraduate Students	Yes	Yes	Yes
⁺ Indicates the faculty is considered a Drexel Research Agent provided they do not have a primary appointment elsewhere [*] Indicates 3.4 Exception Form and Investigator Agreement requirement			

3.2 Drexel Research Agent

Individuals engaged in research activities on behalf of Drexel University, as outlined in Table 3.1, are considered Drexel Research Agents, require oversight by the ORI and are permitted to utilize Drexel resources. These individuals must fulfill the Drexel Research Agent responsibilities as outlined in 4.2. Individuals who do not meet the criteria of the Eligibility Table and individuals who are external to the Institution are not considered Drexel Research Agents unless approved by the appropriate ORI group through the exception process outlined in 3.4.

If an individual's Drexel employment or student status changes and they no longer meet eligibility as a Drexel Research Agent per the Eligibility Table (e.g., former employee or graduated student/alumni), they are not permitted to conduct research on behalf of Drexel University or under the oversight of the ORI.

Individuals listed on Institutional Biosafety Committee (IBC) applications should follow the Drexel Research Agent eligibility criterion of the related IACUC or IRB protocol, if applicable. Individuals listed on an IBC application who are not also included on a related IACUC or IRB protocol must reach out to the IBC coordinator for review and consideration of inclusion on the IBC protocol.

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Individuals who are community advisory board (CAB) members are not considered Drexel agents unless they otherwise meet the requirements in Section 3.1, Drexel Research Agent Eligibility Table, i.e., per diem employee.

3.3 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), if Drexel University is engaged and, per regulatory requirements, who is responsible for oversight, additional oversight requirements, and to engage with other entities, institutions, or companies appropriately.

As a reminder, all Drexel Research Agents are responsible for reporting any salary, pay, or any other incentive as outlined in the Institutional COI Policy and Research COI Policy, in accordance with these policies to ensure an appropriate management plan.

3.4 Exception and Investigator Agreement

In exceptional circumstances, adjunct faculty, volunteer faculty, and others, as indicated by the asterisks in the 3.1 Drexel Research Agent Eligibility Table, may serve as Drexel Research Agents with an Exception Form and Investigator Agreement on an individual project basis as completed and certified by the Project PI, and as evaluated and permitted by the Institutional Official or designee, 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 a Drexel Research Agent per the regulatory requirements to ensure appropriate oversight and responsibilities and may have additional submission requirements.

The Exception Form and Investigator Agreement should be prepared and attached to applicable submissions. The form includes written confirmation and assurances that the Individual understands and accepts the responsibilities of acting as a Drexel Research Agent.

4. Responsibilities

4.1 Office of 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 provide oversight by the Institutional Official and may be designated to others as permitted by the regulations and formally documented.



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The Office of Research & Innovation maintains these procedures, applicable tools, training, granting exceptions, and monitoring.

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 ORI.

4.2 Drexel Research Agent Responsibilities

Responsibilities for individuals who act on behalf of the institution as a Drexel Research Agent, exercise institutional authority or responsibility, or perform institutionally designated activities include the following:

- 1) Compliance with all University policies and procedures. This includes, but is not limited to, training requirements, intellectual property, international travel, records retention, IT policies, and privacy policies.
- 2) Compliance with all applicable federal, state, and agency regulations related to the research project.
- 3) Compliance with all project-specific guidelines and procedures (e.g., export control, COI, IACUC, IRB, OSP).
- 4) Maintaining professional licensure(s) and certifications applicable to the conduct of the research project. Changes in professional licensure(s), e.g., failure to renew a medical license or state board suspension of license, must be reported to the project PI as well as the applicable ORI groups, e.g., HRP-IRB, IACUC, OSP, if the conduct of the research project is affected by the change in professional licensure.

Failure to adhere to these responsibilities may impact your ability to conduct research activities.

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

4.3 Principal Investigator and Department 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. 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 regarding engaging individuals as Drexel Research Agents, oversight of the Drexel Research Agents, and submitting the applicable documentation and exceptions to the appropriate ORI groups.



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5. Resources

- ORI-002 Principal Investigator Eligibility and Responsibilities
- Drexel Research Agent Exception Form and Investigator Agreement

6. Revision and Workgroup Members

6.1 Revision

- Version 001/Effective Date 04/17/2024 - Original Document-Procedures and Guidance for Drexel University Research Community.
 - A minor revision was made on 04/26/2024 to update the examples requiring exception as described in Section 3.4, version number not changed.
- Version 002/Effective Date 02/11/2025 – Drexel Research Agent Eligibility and Responsibilities – Standard Operating Procedures
 - Minor revision to Section 3.4 to specify that exceptions are granted by the Institutional Official or designee.

6.2 Workgroup Member

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

Work Group Members	
Seena Ajit, PhD Professor, Pharmacology & Physiology College of Medicine	Janet Matthews, MSN, RN Senior Director, Research Program Development College of Medicine
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Tammy DellaFave Grants Manager School of Education	John Roberts, BA, CIP Executive Director of Human Research Protections Program Office of Research & Innovation



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