



FREQUENTLY ASKED QUESTIONS: ORI-004 PROCEDURES FOR DREXEL RESEARCH AGENT ELIGIBILITY AND RESPONSIBILITIES

Q1. Why did Drexel University's Office of Research & Innovation (ORI) conduct workgroup meetings and establish procedures for Research Agent eligibility and responsibilities?

A1. Drexel University's ORI frequently receives questions about engagement of research personnel under various affiliations with Drexel University. In response, ORI developed a workgroup comprised of Researchers, Departmental Leadership, and ORI Compliance Offices to develop these procedures and establish a process for evaluating Research Agent eligibility and responsibilities. This SOP follows the release of ORI-002, Procedures for Principal Investigator (PI) Eligibility and Responsibilities and is inclusive of other study personnel beyond the PI role.

In addition to requests from departments and researchers, Drexel University holds multiple assurances (e.g., Federalwide Assurance, Animal Welfare Assurance) with DHHS and PHS to receive federal funds. These assurances require Drexel University to ensure adequate policies, procedures, and guidance, specifically around who qualifies as a Research Agent under these assurances, and the responsibilities of the Institution and its Research Agents.

Q2. Can work on a project continue if a current individual on an ongoing project does not meet the Research Agent eligibility requirements?

A2. Yes, for the safety and welfare of potential animal or human subjects, and provided you already have approval for the project and the individual as project personnel, it may continue as approved. As we proceed through the implementation window, HRPP-IRB, IACUC, or OSP may request a Research Agent exception form and investigator agreement, other documents such as CV/resume, or require additional changes based on the study status, remaining activities, and role of the Research Agent to the project. These changes will be communicated directly with individuals, allowing for adequate revision time.

Q3. What if a Research Agent's status changes throughout the study lifecycle?

A3. 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 unless approved through the exception process described in Section 3.4 of the procedures. The project PI should notify the applicable ORI offices of the change in personnel status and support any required follow-up or management.

Q4. My school or department has its own requirements, procedures, or guidance for who can be a Research Agent on a project. Am I required to follow these requirements as well?

A4. The procedures under ORI-004 do not limit schools, departments, or others from establishing additional guidance and requirements for Research Agent eligibility and responsibilities. ORI-004's procedures should be viewed as a baseline for which others may establish additional requirements based on a school or department's expertise and research portfolio.

Q5. Who has the overall responsibility for approving a Research Agent through the Research Agent exception process?

A5. The Research Agent exception process requires multi-step approval, including signing of an investigator agreement from the proposed Research Agent, and certification from the PI that the Research Agent has the appropriate experience and credentials to complete their role on the project. The applicable ORI group(s), e.g., OSP, IRB, and IACUC, will review the Research Agent exception request form and investigator agreement and retain the final authority to approve the Research Agent exception request.

Q6. How will these procedures change in the new electronic management system (COEUS/InfoEd replacement system)?

A6. Due to the forthcoming COEUS replacement system and rollout of the new electronic management system, this SOP has been given a 1-year revision cycle with a 12-month implementation. The SOP and submission procedures will be updated to reflect the capabilities of the new system, e.g., multi-department collaboration and sign-off, etc. During this transition, we ask Drexel University's research community for a good-faith effort to follow these procedures to help with future system implementation and compliance.

Q7. What if I have questions about the SOP or who qualifies as a Research Agent?

A7. If you have questions about ORI-004: Procedures for Research Agent Eligibility and Responsibilities, the exception process, or other items, please contact Marisa Corbett at mjc535@drexel.edu or Cassandra Myers at cjm523@drexel.edu.