FREQUENTLY ASKED QUESTIONS: ORI-002 PROCEDURES FOR PRINCIPAL INVESTIGATOR ELIGIBILITY AND RESPONSIBILITIES

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

A1. Drexel University's ORI has received requests from multiple departments and researchers seeking guidance for PI responsibilities, who can serve as PI, as well as departmental oversight and responsibilities during project review/sign-off. 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 PI eligibility and oversight responsibilities for PIs and departments.

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 PI responsibility, appropriate expertise, experience, and oversight.

Q2. Can the project continue if a current PI on an ongoing project does not meet the PI eligibility requirements?

A2. Yes, for the safety and welfare of potential animal or human subjects, and provided you already have approval for the project, it may continue as approved. As we proceed through the implementation window, HRPP-IRB, IACUC, or OSP may request a PI exception form or require additional changes based on the study status, remaining activities, and overall risk level of the research. These changes will be communicated directly with individuals, allowing for adequate revision time.

Q3. What if a PI's employment status changes throughout the study lifecycle?

A3. 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. Please see section 4 of the procedures for additional information.

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

A4. The procedures under ORI-002 do not limit schools, departments, or others from establishing additional guidance and requirements for PI eligibility and responsibilities. ORI-002'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 PI through the PI exception process?

A5. The PI exception process requires multi-step approval, including certification from the dean, director, or department head that the PI applicant has the appropriate expertise to function in the PI role. The applicable ORI group(s), e.g., OSP, IRB, and IACUC, will review the PI exception request form and retain the final authority to approve the PI exception request.

Q6. What are the responsibilities of the Faculty Mentor when the Faculty Mentor is not listed as the PI of the study?

A6. Although a student may be designated as the PI of a project, the Faculty Mentor assumes the same responsibilities as the PI, as outlined in ORI-002 3.7 and 4.3. Faculty Mentors must also meet the PI eligibility requirements and ensure adequate oversight over the project in collaboration with the student PI.

Q7. How do I document a student PI and Faculty Mentor in a COEUS submission prior to the new system rollout?

A7. For IRB and OSP submissions where the student meets the PI eligibility table and has been permitted at the discretion of the Faculty Mentor and department, please list the student in the Principal Investigator role. The Faculty Mentor should be listed as a Co-Investigator and noted in the submission notes that the PI is a student and proceeded by the Faculty Mentor, e.g., This is a student project, and [INSERT STUDENTS NAME] will be overseen by [INSERT FACULTY MEMBERS NAME] as Faculty Mentor. As applicable, OSP, IRB, and others may request additional documentation from the Faculty Mentor during this transition.

Q8. How do I document a student PI and Faculty Mentor in an InfoEd submission prior to the new system rollout?

A8. For IACUC submissions where the student meets the PI eligibility table and has been permitted at the discretion of the Faculty Mentor and department, please list the student in the Principal Investigator role. The Faculty Mentor should be listed as a Co-Investigator and noted in the "Responsibilities" section that the individual is acting as the Faculty Mentor for the student PI. Please also include a note in the "Goals" section of the submission that the PI is a student and proceeded by the Faculty Mentor, e.g., This is a student project, and [INSERT STUDENTS NAME] will be overseen by [INSERT FACULTY MEMBERS NAME] as Faculty Mentor. As applicable, the IACUC, and others may request additional documentation from the Faculty Mentor during this transition.

Q9. How will these procedures change in the new electronic management system (COEUS/InfoEd replacement system)?

A9. 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 12–18-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, designation of PI and faculty mentor roles, 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.

Q10. What if I have questions about the SOP or who can serve as a PI?

A10. If you have questions about ORI-002: Procedures for Principal Investigator Eligibility and Responsibilities, the PI exception process, or other items, please contact Marisa Corbett at mjc535@drexel.edu or Cassandra Myers at cjm523@drexel.edu.