



Principal Investigator and Faculty Mentor Exception Form

In exceptional circumstances, individuals who do not meet the eligibility requirements outlined in “ORI 002-Procedures for Principal Investigator Eligibility and Responsibilities Procedures” may serve as PI or Faculty Mentors by requesting a PI Exception. This form must be completed on an individual project basis and certified by the proposed PI’s dean/director and departmental head, 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, these 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.

Please note when assessing whether a PI or Faculty Mentor exception is granted, the IO, HRPP-IRB, IACUC, or other ORI offices, as applicable, will consider the specifics of the study, including the funder, level of expertise, and experience of the individual, the institutional resources required to conduct the project, as well as the risk level of the research, project or program to subjects, the institution, and the research community.

The proposed PI or Faculty Mentor requesting the exception should prepare, obtain signatures from the dean/director and department head, and attach a signed copy of this form to the applicable submission. Please note that an approved exception for one project does not guarantee approval of future exceptions and may vary for the same project (e.g., an exception granted for the PI of the proposal with OSP but not the PI of the protocol with the IRB).

General Information

Name of Proposed Principal Investigator/Faculty Mentor:

Current Appointment/Status (e.g., Part-Time Faculty):

Department/School/Institute Name:

Study Title:

Is this project sponsored?

If Yes,

Who is the sponsor?

What is the start date of the award?

What is the end date of the award?

IACUC#:

IRB#:

Proposal#:

Brief Description of the Work:

Study Specific Justification Reasoning

1. Please explain/justification/reason why this PI exception is needed:
2. Please provide how your research experience, expertise, and training lends itself to the proposed project to ensure appropriate oversight:
3. Please explain where this project will physically be conducted and what access to both Drexel and non-Drexel equipment, facilities, and systems, if any, will be needed:
4. If you are faculty, staff, agent, or otherwise employed by another entity, institution, or organization, please provide the details of this engagement, why you are requesting to conduct this work at Drexel, and if this other entity, institution, or organization has provided permission to proceed:
5. Have you ever received a 483 (FDA), been sanctioned or debarred by an institution, regulatory agency, or funder, or had your PI or research personnel privileges suspended or terminated? If no, please state NA, otherwise please provide additional information (e.g., timeline, resolution, institution):
6. Have you received a Serious or Continuing Noncompliance determination in the last three years? If no, please state NA, otherwise please provide additional information (e.g., timeline, resolution, institution):

Proposed Principal Investigator/Faculty Mentor:

My signature below indicates the following:

1. The information above is true and accurate to the best of my ability. Failure to provide true and accurate information can lead to immediate suspension of PI privileges, impact my employment with Drexel University, and reported as required to regulatory agencies.
2. I understand that I am ultimately responsible for the conduct of this research.
3. I have reviewed all documents associated with my project/proposal and understand that if permitted to proceed as a PI, I am acting as an Agent of Drexel University under the purview of Drexel University's Institutional Official.
4. I understand it is my responsibility to be aware of and abide by all applicable regulations and requirements governing my specific project/proposal.
5. I understand it is my responsibility to be aware of and abide by Drexel University's policies, procedures, and guidelines, as well as institutional and research requirements, which may include additional PI requirements.
6. I understand that any data or materials associated with this project are considered Drexel University property and cannot leave the institution unless permitted by an appropriately executed MTA or DUA.
7. I will complete and maintain all Drexel University required training for the duration of this project.
8. If my information above changes (e.g., licensure expiration, suspension of PI privileges), I will notify Drexel University's Office of Research and Innovation immediately, no later than five calendar days.

Proposed Principal Investigator/Faculty Mentor Signature

Date

Dean/Director and Department Head:

My signature below indicates the following:

1. The individual has the necessary experience, expertise, licensures, and credentials to independently conduct this proposal/project and to provide oversight to students and staff as necessary.
2. The department, school, or institute is committed to supporting the proposed PI by providing appropriate space, resources, and administrative oversight if the exception is granted.
3. The department, school, or institute will ensure that the proposed PI has completed all institutional requirements to conduct the proposed research prior to the initiation of activities.
4. Should the proposed PI leave Drexel University or they are no longer permitted to be the PI, the department, school, or institute agrees to assume responsibility for the project/proposal, including research record retention.
5. If we are made aware of any of the proposed PI's information changing (e.g., licensure expiration, suspension of PI privileges), we will notify Drexel University's Office of Research and Innovation immediately, no later than five calendar days.

Dean/Director Signature

Date