POLICY STATEMENT

Subject: Policy for the Preparation and Training of Students Working with Human and/or Animal Subjects

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Addition _____ Deletion _____ New Item __X___	Originating Office: Research & Innovation (formerly SGSR)	President's Approval

1. PURPOSE: To establish a policy requiring all IUP students engaged in human and/or animal subject studies to successfully complete training on the ethical treatment of human and/or animal subjects, as appropriate for their field of endeavor, prior to initiating their activities.

2. SCOPE: This policy shall apply to all IUP students who engage, or plan to engage, in systematic interaction with human and/or animal subjects that requires approval by the Institutional Review Board for the Protection of Human Subjects (IRB) or by the Institutional Animal Care and Use Committee (IACUC). This policy shall also apply to IUP students pursuing for-credit independent study, externships, internships, and clinical experiences as well as non-IUP students who wish to use IUP as a study site for projects for which IRB or IACUC-approval is required.

3. OBJECTIVE: This policy seeks to help ensure that students understand their obligations to protect their human and/or animal subjects and to protect the integrity of research and scholarship at IUP. To that end, this policy sets forth the requirement that all IUP students engaged in studies requiring IRB and/or IACUC approval must first successfully complete prescribed training on the ethical treatment of human and/or animal subjects, as appropriate for their endeavors, prior to initiating their activities.

4. POLICY: It is the policy of IUP to foster an academic environment that encourages ethical conduct in all

research and scholarship. To this end, IUP shall require that all students who engage, or plan to engage, in systematic interaction with human and/or animal subjects that requires approval by the IRB and/or the IACUC first complete ethical training prior to the initiation of their activities. It is further the policy of IUP that non-IUP students who wish to use IUP as a study site for their IRB or IACUC-approved projects must also complete IUP's prescribed ethical training prior to the initiation of their activities at IUP.

5. DEFINITIONS:

Institutional Review Board for the Protection of Human Subjects (IRB): the regulatory body of IUP that is responsible for the review of research that involves human participants.

Institutional Animal Care and Use Committee (IACUC): the regulatory body of IUP charged with ensuring compliance with federal regulations concerning the use and welfare of animals in teaching and research.

6. RESPONSIBILITIES:

It is the responsibility of students to inquire with their supervisors, the IRB chair, and/or the IACUC chair to determine if IRB and/or IACUC approval is needed for the planned activities. If such approval is needed, it is the responsibility of the student to complete the prescribed ethics training prior to submission of their research protocol to the IRB/IACUC.

It is the responsibility of Research and Innovation to make prescribed ethics training available to students. Such training will be available in an on-line format, unless the student is conducting externally-sponsored research for which the external (non-IUP) sponsor requires face-to-face training. If face-to-face training is required by the external research sponsor, it will be the responsibility of Research and Innovation to provide such training.

It is the responsibility of the IRB and the IACUC to confirm that student-submitted protocols and faculty/staff-submitted protocols in which students will participate include copies of official on-line ethics training completion certificates for each student named on the protocol. If student participants on faculty/staff protocols have not been identified at the time of submission, it is the responsibility of the IRB

and/or IACUC to require in their protocol approval letters that names and completion certificates be forwarded as soon as student participants are identified and before the student participants begin work on the faculty/staff project.

It is the responsibility of the research supervisor to alert the IRB/IACUC chair if students not initially named on the IRB/IACUC approved protocol will be conducting research under the approved protocol and to provide copies of official on-line ethics training completion certificates for each of these added students. For supervisors overseeing classroom research meeting the IRB definition of such and/or outreach activities that have been deemed by the IRB/IACUC chairs to meet the standards for classroom research and/or outreach, the supervisor must complete prescribed ethics training. Completion of ethics training for students participating in classroom research and/or outreach activities is recommended but not required unless otherwise stated in writing by the IRB/IACUC chairs.

7. PROCEDURES:

Students shall consult with their supervisor, the IRB chair, and/or the IACUC chair, to determine if the planned studies require IRB and/or IACUC approval prior to initiating their activities.

If IRB and/or IACUC approval is required, students must complete a prescribed on-line ethics training program. Directions for accessing this training can be found on the IRB/IACUC protocol forms.

With respect to human subject studies training: Students conducting social, behavioral, and educational human subjects research must complete the on-line training for “Social, Behavioral, and Educational Research Investigators;” students conducting biomedical human subjects research must complete the on-line training for “Biomedical Research Investigators;” students conducting human subjects research for which there will be no direct contact with human subjects, for example archival, data, or laboratory specimen research, must complete the on-line training for “Research with Data or Laboratory Specimens Only;”

With respect to animal subject studies training: Students conducting animal subjects laboratory research must complete the on-line training for “Students Working with Animals;” and students

conducting animal field research must complete the on-line training for “Field Researchers.” Upon successful completion of their training, students will receive an official completion certificate. This certificate must be attached to any IRB and/or IACUC protocol submitted for review on which the student is a named participant. If students not initially named on the IRB/IACUC approved protocol will be conducting activities under the approved protocol, an official completion certificate must be submitted via email to the IRB/IACUC chair, with the approved protocol log number, for each of these added students.

Failure to comply with the requirements of this policy may result in termination of study activities, inability to utilize collected data, and/or disciplinary hearings in accordance with the Undergraduate or Graduate Academic Integrity Policy and Procedures.

Additional recommended on-line training programs may be available, including responsible conduct of research, conflict of interest, biosafety/biosecurity, and export control, but are not required for students under this policy unless the student is conducting externally-sponsored studies for which the external (non-IUP) sponsor requires completion of such training programs.

8. RECISION: Not applicable

9. PUBLICATIONS STATEMENT: Not Applicable

10. DISTRIBUTION: All faculty and managers annually by Research and Innovation.