POLICY STATEMENT

Subject: Policy for the Oversight of Research Involving Human Subjects

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Addition		Originating Office:	President's Approval
Deletion			
New Item	X	Research & Innovation (Formerly SGSR)	

PURPOSE: To establish a policy for the oversight of human subjects research conducted by IUP faculty, managers, administrators, staff, students, and other researchers formally affiliated with the university.

SCOPE: This policy shall apply to all current and former IUP faculty, managers, administrators, staff, students and formally affiliated researchers who engage, plan to engage, or engaged prior to their separation from IUP, in human subjects research. Because participation of humans in research raises fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or among projects carried out by students, faculty, managers, administrators, staff, and other formally affiliated researchers, on-campus or off-campus.

OBJECTIVE: This policy seeks to help ensure the protection of human research subjects and the integrity of research and scholarship at IUP. This policy defines human subjects research and describes the responsibilities of both the researcher(s) and the Institutional Review Board for the Protection of Human Subjects (IRB), which provides oversight for human subjects research in accordance with the Code of Federal Regulations (CFR) 45 CFR Part 46.

POLICY:

It is the policy of Indiana University of Pennsylvania to foster an academic environment that advances ethical conduct in all human subjects research. The IRB is the university group that provides oversight of all human subjects research conducted by IUP faculty, managers, administrators, staff, students, and other researchers formally affiliated with the university, regardless of whether or not the research is funded/sponsored. In compliance with 45 CFR Part 46, this oversight includes: (i) determinations of whether or not IRB review is required for a given research project; (ii) review of new human subjects research protocols, changes made to existing human subjects research protocols, and the continuing review of human subjects research protocols; (iii) monitoring of approved human subjects research protocols, including receipt of adverse event reporting; and (iv) reporting non-compliance with this policy to the university Research Integrity Officer for review, consistent with IUP's Policy for Responding to Allegations of Research Misconduct.

DEFINITIONS:

A "human subject" is a "living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." (45 CFR Part 46.102(e)(1)).

"Research" is a "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." (45 CFR Part 46.102(1)).

The "Institutional Review Board" (IRB) is a body established in accord with and for the purposes expressed in 45 CFR Part 46. IRB membership is prescribed in 45 CFR Part 46.107; functions and operations are prescribed in 45 CFR Part 46.108; review is prescribed in 45 CFR 46.109-114; record-keeping is prescribed in 45 CFR Part 46.115; and registration with the US Department of Health and Human Services is prescribed in 45 CFR Part 46.501-505. The purpose of the IRB is to protect participants in

research as well as to protect researchers and research integrity at IUP.

RESPONSIBILITIES: Research projects involving the use of human subjects must be reviewed by the IRB. If it is unclear whether the proposed research falls under the purview of the IRB, the researcher must seek assistance from the Director of Research Compliance or the IRB chair.

The IRB determines if oversight is required for proposed research and establishes procedures for the timely evaluation of human subjects research protocols for exempt, expedited, and full board reviews. The IRB reviews and monitors protocols following guidance from 45 CFR Part 46 for all funded and unfunded research. The IRB maintains documentation related to the review and monitoring of protocols and decisions made regarding protocols. All documents are maintained for the statutorily prescribed period (at least three years from the completion of the research; 45 CFR 46.115(b)). The IRB shall notify the University's Research Integrity Officer (RIO) of any failures to comply with this policy.

It is the responsibility of any researcher associated with IUP to protect the rights and welfare of their research participants. For projects over which the IRB has purview, researchers are required to submit a research protocol for review and this protocol must be submitted and approved prior to commencement of any recruitment of subjects or data collection. Researchers are also responsible for submitting any requests for changes to existing human subjects protocols and/or requests for continuing review of existing protocols and must receive approval from the IRB for these activities prior to their commencement. It is the responsibility of the researcher to complete their human subjects research in the exact manner as dictated in their IRS-approved research protocol and to retain all data and consent documents for at least three years beyond the completion of the research. It is also the responsibility of researchers to report issues and adverse events to the IRB within 48 hours. Student researchers are further required to comply with IUP's Policy for the Preparation and Training of Students Working with Human and/or Animal Subjects.

PROCEDURES Human subjects research protocols must be submitted to the IRB via the designated electronic platform well in advance of the proposed date for commencement of research activities. All protocols received are logged, routed for a determination of the

required level of review (exempt, expedited, or full board), and reviewed accordingly. All communication to researchers about their human subjects research protocols is sent electronically via IUP email. Human subjects research may not commence until IRB approval is granted.

Some departments have established a departmental review board (ORB) to review human subjects research protocols prior to their submission to the IRB. This review is in addition to, not in lieu of, review and approval by the IRB.

An expedited or exempt review procedure is possible for those human subjects research protocols that involve no more than minimal risk to subjects and also fall under one of the research categories eligible for expedited review or fall under the categories exempted from continuing review by federal regulations. Final determination as to whether a specific project is eligible for such review can only be made by the IRB.

If a researcher wishes to make any changes to an approved human subjects protocol, the researcher must submit a request for change via the IRB's electronic platform. The IRB will review the request and communicate a decision to the investigator. The researcher may not enact the change until approval is granted.

Approved research protocols may be selected for periodic post-approval monitoring to ensure researchers are following the exact procedures approved by the IRB.

The IRB will send researchers an annual electronic reminder about forthcoming protocol approval expiration dates (where applicable) and instructions for renewal or project close-out.

More detailed information for human subjects researchers, including model protocols, protocol submission tutorials, educational and training materials, IRB full board meeting dates, and committee membership, can be found on the university's IRB web site.

DISTRIBUTION All faculty and managers annually by Research and Innovation.