The University of Scranton

Institutional Review Board (IRB) for the Protection of Human Participants

Policies and Procedures

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The University of Scranton (University) is committed to safeguarding the rights and welfare of human participants in all research under its sponsorship and to serving as their protector on behalf of the community of persons that comprise the University. This policy and all supporting procedures and guidelines result from the desire of the University to define its responsibilities and to comply with all applicable federal, state, and local regulations.

Principal guides for the University's human subjects review system are:

- x [The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979].
- x [Code of Federal Regulations - 45 CFR 46, revised January 22, 2018 and effective June 19, 2018]. This is often referred to "The Common Rule"

All research involving human subjects, conducted at the University or under its sponsorship at another location, must be reviewed and approved by the Institutional Review Board for Protection of Human Subjects (IRB) or its designated reviewer(s) under the policies and procedures outlined in the following document. As defined within federal regulation 45 CFR 46,

- x Research: a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- x Human subject: a living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

When reviewing research proposals, the Institutional Review Board (IRB) or authorized Departmental Review Board (DRB) is primarily interested in safeguarding the rights and well- being of the human subject and in assessing the ethical implications of the proposed procedures. As set forth in the Belmont Report, the following ethical principles serve as the guide for the IRB/DRB's review of all research activities:

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Research procedures and design may affect the use and experience of human subjects in research activities. In this context, the IRB/DRB has the responsibility to require modification or change in the design of the research, to assure that the use of human subjects is valid and the risks to the subjects are minimized.

However, it is not the intention of the IRB or DRB to provide full scientific review. In analyzing the risk/benefit ratio of a research activity, both the stated goals and the scientific merit of the

research will be considered. Therefore, the research must be described to the IRB or DRB in a manner that allows adequate review of all these aspects of the research.

Activities within the scope of the Human Subjects review policy include research, development, and related activities which would normally be construed as biological, behavioral, or psychological investigations involving human[(2 (a)4 (nng humTw 28.55 0 Td( )TjEMC E5ij-3.9 (at)-6.1 (e r)

If the intent of such projects is to gather data or information that consider

The University of Scranton's IRB consists of a staff IRB Administrator, and IRB Committee. The IRB chair and members of the IRB Committee are appointed by the Provost/Vice President of Academic Affairs to represent the interests of the University and the community, following the recommendation of the IRB Administrator and Associate Provost/Director of Researchem3.9 (a[(em)d I)6e m

The IRB may, at its discretion, consult with or invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The IRB functions independently of, but in coordination with, other institutional regulatory and research committees. Approval by other institutional bodies cannot substitute for IRB approval.

- Approval by the IRB does not constitute approval by other committees or operational areas that may be required under other University policy and procedures.
- Research covered by this policy that has been approved by the IRB may be subject to further appropriate

(b) For which an investigator requests IRB review in addition to, or in substitution for, the departmental review process, even if this activity falls within the departmental guidelines. Under these conditions, the DRB chair will be advised of the IRB determination and will be provided with a copy of the protocol.
(c) Research that is to be submitted for extramural funding or support, including federal and other grants.
(d) Research requiring waivers of any part of informed consent, unless approval authorization is granted by the IRB for specific circumstances.
(e) To be conducted by an investigator from outside of, but involving, the University.

Completion of an IRB-approved education program is required of all individuals involved in Human Subjects Research and its review including IRB Chairperson and members, IRB Administrator, DRB chairpersons and members, investigators, and research assistants and any other personnel who interact with subjects and/or have access to data which contains personal identifiers.

All persons involved in the research protocol must complete an approved education program prior to approval of protocol activity. Protocols must include documentation of human subjects' research training for all investigators and project personnel. The education program must have been completed less than 3 years prior to submission of the application. Certification must be renewed on a regular basis as defined in the IRB education program. Information about current training requirements is available on the IRB web site. The IRB administrator is authorized to approve whether training completed by non-University personnel meets University requirements.

Principal investigators are responsible for assuring that all research personnel have completed required IRB training, and that documentation has been submitted to and approved by the IRB, before they begin engagement with the project.

subjects involved in their research in accordance with University policies, all applicable federal, state, and local regulations, and the code of ethics of their professions. Specific responsibilities of investigators are to:

(c) the research falls into one of the six federally defined categories listed in Appendix A.

An Exempt status classification DOES NOT mean that the research is exempt from IRB review and approval; rather, Exempt status means that the research is exempt from certain elements of federal regulation. Only the IRB Administrator and the IRB Chairperson are authorized to determine whether research meets Exempt status requirements, and the interpretation of related policy, guidelines, and regulations. Exempt research must still be voluntary and should address core elements of informed consent as described in section

For a study to be anonymous, no personally identifying information may be collected from the individual, and no one, not even the researcher, will know who took part or can connect the data to the individual who provided it. Information about participants may be collected

confidentiality of data, including any personally identifiable information.

Expedited applications must be submitted via IRBNet. Investigators should typically expect an initial review period of approximately 7-10 business days. The review time may vary depending on the quality and clarity of the application, and whether there are concerns that will need to be addressed by the PI. This type of application does not need to wait for a meeting date for review.

Investigators should provide sufficient information and detail for the reviewers to understand the nature, goals, and recruitment and participation of human subjects for the project, such that reviewers have sufficient detail to make a determination. Investigators must include the following information in the form, in addition to any other relevant information and documentation:

- Abstract describing the background, nature, and objective(s) of the project, including, if not novel research, its context in relation to existing research;
- Research methodology, including copies of any tools, such as surveys, to be used in the research;
- Any communications that will be used during the recruitment and research processes;
- Consent documentation and other materials, if applicable;
- Description of the subject population and recruitment plans;
- Actions to protect privacy and/or confidentiality of the participants;
- Documentation that training requirements have been met for all personnel engaged in the research project

A full committee review by the IRB is required if the research involves to human subjects special precautions may need to be taken to protect the rights and welfare of the participants; full committee review is required if the : minors under the age of 18; economically/educationally disadvantaged persons; fetus/fetal tissue; non-English speaking participants; pregnant women; prisoners; or cognitively impaired persons.

In addition, full review may include protocols that have been referred to 2 (aue)-6.004 Tc 0.004 Tw 0.28 0 Td[(s)-

includes psychological and social as well as physical risk.

A project may entail if

(a) sensitive questions (such as sexual preferences or behavior, criminal behavior, abuse situations) are included in questionnaires or interviews,
(b) fully informed consent cannot be obtained because the procedure includes deception,
(c) fully informed consent cannot be obtained due to age or mental condition, OR
(d) there is an increased potential for coercion (for example, institutionalized persons).

Any project involving more than minimal risk will be reviewed as a Full Review protocol by either

be approved by the IRB unless the investigator has demonstrated to the IRB that:

(a) The use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective non-deceptive alternative procedures are not feasible;
(b) Procedures in the study cannot be reasonably expected to cause physical pain or severe emotional distress; AND
(c) As early as feasible, preferably at the conclusion of their participation, but no later than

inclusion of vulnerable populations, therefore requiring submission for Full IRB Review.
(b)
require review and approval by 2 members of the IRB.
(c) will be reviewed by the DRB.
(d) should be submitted to the DRB. The DRB may send the protocol for full IRB review if warranted.
(e)
requires submission for full IRB review.

[45 CFR 46:111]

In order to approve research covered by this policy the IRB (and DRB) must determine that of the following requirements are satisfied:

(a) Risks to subjects are minimized:

(1) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, AND
(2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
(3) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(b)Selection of subjects is equitable. In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
(c) Informed consent must be sought from each prospective subject or the subject's legally authorized representative. (Section 7)
(d)Informed consent must be appropriately documented. (Section 9.01)
(e) When appropriate,

(1) the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
(2) there are adequate provisions to protect the privacy of subjects and to

such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

are required to provide details of the proposed involvement of humans in the research, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and

sufficient opportunity to consider and make an independent choice whether or not to participate. The information that is given to the subject or representative must be in language understandable at the individual's level of comprehension.

- The Researcher will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative.
- Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.
- Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence.

(c) should be obtained in a form which the child can understand. A signed assent form must be obtained from children old enough to render a signature.
(d) - explanations should match the level of understanding.

Particular attention to the issue of potential coercion is necessary.

A patient advocate is necessary to guard the patient's interests.

There are special provisions in place regarding risks and benefits and definitions particularly related to viability.

subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

(a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo

- University of Scranton students may submit applications with supervision of a mentor from the faculty, staff,

(a) Applications not approved by a Jurisdictional IRB will not be reviewed by the University of Scranton IRB.
(b) Applications will be reviewed either administratively for Exempt submissions, or via the processes defined in this policy for Expedited or Full IRB review, as appropriate.
(c) Recruitment may be approved for a period up to the expiration date of the Jurisdictional IRB approval.

The University of Scranton IRB reserves the right to grant or deny permission to external investigators to recruit subjects on campus. The decision of the IRB to deny permission for participant recruitment by an external investigator may not be reversed by any other University of Scranton authority.

IRB approval for the research activity does not constitute approval to utilize University programs, facilities, or services/practices, including obtaining contact information for or communication with members of the University community. Researchers must consult with relevant University administrators to secure any other approvals or permissions required before proceeding with their project.

Student research and training activities involving human subjects may range from assignments taking place within the classroom to independent research projects. The instructor or advisor is ultimately responsible for training and supervising the student, assuring that student projects have been prepared in accordance with requirements and reviewed by the appropriate review board (DRB or IRB) and meet any departmental or other approval requirements.

Course-related and Student Research Activities IRB or DRB review and approval include:

(a) Student-generated research projects, including independent study, honors papers, theses, dissertations, or other individual or small group projects. Application for IRB/DRB approval is submitted by the student(s) as the principal investigator(s) under the supervision of the mentor.
(b) Instructor-led class projects designed to teach research procedures and design - including projects where the instructor provides the protocol or where the class designs and generates the project. Application for IRB/DRB approval is submitted by the instructor.
(c) Classroom exercises conducted only with students in the class which involve the generating of sensitive information or entail more than minimal risk. Application for IRB/DRB approval is submitted by the instructor.

Activities requiring IRB or DRB review and approval:
(a) Classroom exercises conducted only with members of the class, involving no more than minimal risk, and including no sensitive material.
(b) Journalism, oral history, biography, and other scholarly activities that meet federal IRB exception guidelines (45 CFR 46.102) and are limited to recounting or documenting information about specific individuals themselves and is not for generalizing to other individuals, groups, or situations. See Section 2.04 (Excluded Research).

Protocols requiring Expedited or Full Review (sections 5.06, 5.07), and , may be submitted to the DRB by investigators whose departments have approved DRBs. Applications must be submitted via IRBNet. The investigator should indicate which DRB they are requesting review from. Exempt protocols and full review applications that include vulnerable populations may not be reviewed by a DRB.

Following submission, the IRB Administrator will confirm if an application is eligible to be reviewed by a DRB. Applications submitted via IRBNet will then be forwarded to the appropriate DRB chairperson. The DRB chairperson is responsible for assuring the application meets the standards of University policy. The DRB chairperson will communicate the decision of the DRB to the researcher, and to the University IRB Administrator. Information on dates of DRB meetings and deadlines for submission, as well as DRB procedures, are available from the appropriate DRB Chairperson.

The IRB does not review research that has already been conducted, or is in the process of being conducted, that would normally require IRB review.

The IRB Committee meets once a month in formal session during the academic year. As needed, the IRB may convene during intersession or summer sessions. The schedule of regular IRB meetings is posted on the IRB web site at the beginning of the academic year. Investigators may also contact the IRB Administrator or Chairperson for the dates of the monthly meetings. A convened meeting is a meeting of the IRB consisting of a quorum.

Minutes will be taken at all IRB meetings. Records will be retained by the IRB for at least three years.

A quorum is defined for IRB purposes as a majority of the members eligible to vote. An IRB member who is an investigator on a protocol for review at a convened meeting must recuse him/herself from the meeting and may not be counted in the quorum for voting purposes. No IRB member may participate in the board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Applications requiring Full Review will be considered at a convened meeting of the IRB. Only

applications received by the due date listed on the IRB web site will be included in the subsequent IRB meeting for review. Applications will be distributed by the IRB Administrator to all IRB members before the meeting date to permit adequate time for review and consideration.

Upon request of the IRB, an investigator may be asked to provide additional information or to appear in person before the committee to describe the proposed research and present a full explanation of risks and protection for human subjects.

The IRB will decide by a majority of the members present (Section 11.03):

(a) to approve the proposal,
(b) to approve the proposal with restrictions or conditions,
(c) to provisionally approve the proposal pending final review/approval by the IRB chair or administrator;
(d) to table the proposal, pending substantial changes in the application or receipt of additional information from the investigator or consultants to the IRB, OR
(e) to disapprove the proposal.

In addition to these formal voting actions, the IRB may also

(a) Request additional information and/or require modifications to an application in order to secure approval. This action collates the summary of IRB member discussion, questions, and unresolved issues and does not require a formal vote. The investigator's response will be resubmitted to the IRB.
(b) Defer the proposal to the next convened IRB meeting. This action is generally reserved in instances when review is postponed due to lack of quorum, lack of time on agenda, or other administrative issues.

The IRB Administrator will inform the principal investigator in writing of the decision of the Board including any clarifications or changes which are required and/or recommended.

Applications requiring substantive clarification and/or change s the

IRB. The DRB must submit written guidelines for approval by the IRB and may not review applications until the guidelines are approved.

The IRB has set the following standards for the functioning of DRBs and the preparation of written DRB Guidelines:

(a) A description of the types of research involving human subjects which would normally be undertaken in the department, and which the department has sufficient experience to be able to review under Expedited and Full Review Protocols, if there is no inclusion of vulnerable populations. Exempt research is reviewed only by the IRB.

(b) A statement of the ethical standards with which such activities must comply.

(c) A DRB should consist of a minimum of 4 members. A member of the DRB who is the investigator or faculty mentor or sponsor on a project under review cannot be present at the deliberations, counted in the quorum, or vote. Members must meet and maintain current University IRB education requirements.

(d) Attendance by a majority, but not less than 3, members eligible to vote constitutes a quorum.

(e) Review of Full Review applications must take place in a convened meeting of the DRB with a quorum present. It is recommended that the DRB meet as needed, at least within 1 week of receipt of an application for review.

The DRB may designate one or two individual reviewers for Expedited protocols. A designated reviewer may not review his/her own protocol.

(f) Documentation of DRB actions must include

(1) Names of principal investigators and mentors, if applicable,
(2) Title of protocol,
(3) Type of application - faculty research, faculty led course assignment, student conducted course assignment, student independent research,
(4) Course number, if applicable,
(5) Category – Expedited or Full Review,
(6) Results of review, and
(7) Evidence that all investigators (faculty, students, and research assistants) have completed an approved human subjec0.23 0 Td[(Td[(a)4um)-2 -2 (e)2 (or)3 (s)td g4 (d)stm (nde)4 (pe)4 (s)-1c0.23 0 T

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

1. (i) The information obtained is recorded by the investigator in such a manner that the identity of th cshc 10.9 (e)-1c

agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable

accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography,