The University of Scranton

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

Policies and Procedures

Revised March 2023

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Section 1: POLICY STATEMENT

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:

- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

- Protection of Human Subjects] 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 regulations 45 CFR 46,

- Research a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- 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 the following ethical principles serve as the guide for the IRB/DRB's review of all research activities

Respect for Persons - Informed Consent,
Beneficence - Assessment of Risks and Benefits, and
Justice - Equitable Selection of Subjects;

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 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.

Section 2: SCOPE

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

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

Section 3: INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS (IRB)

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

3.04 Consultants

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.

3.05 Further Review of Research

(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.

subjects involved in their research in accordance with University policies, all applicable federal,

(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 9.01.01.

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 and can connect the data to the individual who provided it. [illegible]

- Abstract describing the background, nature, and objective(s) of the project, including its context in relation to existing research;
- Research methodology, including copies of any tools, such as surveys, to be used in the research;
- Description of the subject population and

confidentiality of data, including any personally identifiable information.

5.05 Submission and Timeline for Review of Expedited Applications
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 in 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

5.06 Full Review Applications
A full committee review by the IRB is required if the research involves more than minimal risk to human subjects and special precautions may need to be taken to protect the rights and welfare of the participants; full committee review is required if the research involves one or more of the following populations: 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 the committee by the IRB Administrator, Chair, an expedited reviewer, or a DRB. Researchers from departments with DRBs may also request that their project be reviewed by the IRB.

5.08 Submission and Timeline for Review of Full Review Applications
Since this type of application requires review by the fully convened IRB at a scheduled meeting, it is recommended that investigators refer to the IRB Meeting Schedule when planning a submission. Meetings are scheduled monthly throughout the academic year, and as needed during the summer months.

Procedures are designed so that all IRB members receive materials for project review at least one week prior to the meeting or such time as sufficient to allow for review of the materials before a

convened IRB meeting. Only protocols received by the due date listed on the IRB Committee meeting schedule will be reviewed at the next scheduled meeting. Investigators will typically receive a letter approving the protocol or requesting modifications required for approval within one week of the meeting date. The total review time will vary depending on the quality and clarity of the application, and whether there are concerns, questions, or requests for modification that will need to be addressed by the P

6.02. Risk Beyond Everyday Life (more than minimal risk) includes psychological and social as well as physical risk.

A project may entail more than minimal risk 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 project by either a DRB or [illegible]

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 at the conclusion of the data collection, the investigator will inform the subjects about the deception, and permit subjects to withdraw their data.

6.05 Vulnerable Populations

Vulnerable subjects, which may be at an increased risk and require additional protections, include the following groups:

- Pregnant women, human fetuses, fetal tissue, and neonates
- Children (minors under the age of 18)
- Prisoners
- Mentally disabled/Cognitively impaired persons
- Economically or educationally disadvantaged persons
- Non-English speaking persons

Research involving any of the above must be reviewed via Full IRB review, and may not be reviewed by DRBs. See additional details about vulnerable populations and informed consent.

Section 7: PROTOCOL REVISIONS

7.01 Changes to an Expedited Application may be submitted to the IRB Administrator or DRB under the Expedited Review procedure unless the proposed changes render the project ineligible for continued Expedited determination. 77( )Tj 0.00lci1ub2 (a)4 (F)6

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have the potential to alter the level of risk, and is an:
(a) Extension of the time of the study due to circumstances which kept the investigator from completing the project as approved,
(b) Increase or decrease in the number of subjects, within statistically valid limits,
(c) Extension of data analysis without involving more subjects,
(d) Change in investigator contact information in the informed consent information and written consent document, or
(e) Addition of additional researchers to the project.

2. Substantive changes to an application that received Full Review must be submitted for full IRB

inclusion of vulnerable populations, therefore requiring submission for Full IRB Review.
(b) Projects originally approved under Full Review (with or without the inclusion of vulnerable populations) proposing no substantive changes require review and approval by 2 members of the IRB.
(c) Projects originally approved by DRB proposing no substantive change will be reviewed by the DRB.
(d) Projects originally approved by DRB proposing substantive change should be submitted to the DRB. The DRB may send the protocol for full IRB review if warranted.
(e) Application for continuation of a project originally approved by the IRB which proposes substantive change requires submission for full IRB review.

Section 8: RESEARCH REVIEW

8.01. Review Criteria

In order to approve research covered by this policy the IRB (and DRB) must determine that all 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. (See Section 7)

(d) Informed consent must be appropriately documented. (See 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 maintain

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.

8.02 NIH-supported investigators 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 racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any subpopulation. If ethnic, racial, and gender estimates and continuing review numbers are not included in the background data for a protocol, the investigators must provide a clear rationale for exclusion of this information.

8.03 The University of Scranton IRB as IRB of Record (Single IRB Review)
In an instance where (1) a University of Scranton faculty, staff, or student is primary investigator on a research project conducted conjointly with another institution, and the institution/researchers from that institution are considered engaged in research, or (2) where a co-investigator engaged in research activity is from another institution with an approved IRB, the applicant may apply for the University to serve as the reviewing IRB, or IRB of record. Research projects that fall into either Expedited or Full review may be eligible for single IRB review. It is the decision of the IRB, not the researcher(s), to enter into a reliance agreement. A signed copy of this agreement must be included with the IRB protocol in IRBNet.

Researchers conducting research under the auspices of certain federal grants may be required to determine and utilize a single IRB/institution of record.

In the case when an investigator is from an institution or organization without its own IRB, the investigator may need to submit an Individual Investigator Agreement form.

8.04 Quality Assurance of IRB Activities
Ongoing review of research activities may require random selection and review by the IRB of approved projects for assessment of the IRB/DRB activities and compliance. This may include sharing information about research projects under review, or approved, with external entities if required. IRB policies and procedures (including DRBs) should be reviewed annually. Review may be accomplished by two or three members of the IRB and/or the IRB Administrator.

In addition, the IRB Administrator and/or the Chief Research Officer may conduct, or request, other periodic audits of IRB policies and procedures in order to identify opportunities to improve IRB operations and compliance.

Section 9: INFORMES0 Tw 3.1.96 173.64 Tm [(S)-862 (dm)sISONT(an)-4 (ce)-10 (.)]TJ 0 T(de)4 (nt)-2

except in special circumstances described below, informed consent must be verified by a signed written consent form. The prospective subject or representative must be given sufficient opportunity to consider and make an independent choice whether to participate. The information that is given to the subject or representative must be in language understandable at the individual's level of comprehension.

9.06.03. Exceptions/Waivers

The IRB may waive the requirement for the investigator to obtain a signed consent form for

Applications for review of human subjects' research may be submitted to the IRB by members of the

Definitions:
(a) - a person not employed by the University of Scranton or otherwise affiliated with the University.
(b) - the primary IRB that has approved the external protocol. This is usually the external researcher's home institution.

Application Review:

(a) Applications not approved by a Jurisdictional IRB will not be reviewed by the University of Scranton IRB.
(b) Applications requiring University of Scranton IRB review will be reviewed either administratively for exempt

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Activities not 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.

10.03 Submission to the DRB

Protocols requiring Expedited or Full Review (sections 5.06, 5.07), and do not include participants from any vulnerable population, 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 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.

10.05 Prior Research

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.

Section 11. CONVENED MEETINGS AND REVIEW PROCEDURES

11.01. Convened Meeting

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.

11.02. Minutes

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

11.03 Quorum

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.

11.04. Review Procedures

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

Adverse decisions may be appealed by re-review of the proposal. Appeals will be heard only when the proposal has been revised and/or provides additional information.

In the event of severe time constraints, the IRB may conduct business by mail or e-mail if the research to be reviewed is no risk beyond everyday life. A project may be approved by a majority of members eligible to vote. However, if any IRB member requests Full IRB Review in a convened meeting, the application may not be approved until the IRB meets.

No application may be disapproved by any other procedure than vote at a convened meeting.

11.05. IRB Records

Records of the IRB are maintained by the IRB Administrator. Records are retained for at least three years after completion of the research, and in accordance with 45 CFR 46:115 (a - b)

These records contain the research proposal reviewed, scientific evaluations, approved sample consent documents, progress reports]TJ -0.004 Tc 0.004 Tw [illegible]

unauthorized use of privileged information, violation of federal regulations, and retaliation against a person who has in good faith reported suspected or alleged misconduct) involving risk to human subjects or other people are listed in the University of Scranton Misconduct in Research Policy. Copies are available from the Office of the Associate Provost/Director of Research.

Section 14: DEPARTMENTAL REVIEW BOARD (DRB) GUIDELINES

15.01 The IRB delegates review of certain categories of research to the DRB. Before the DRB functions in compliance with all the regulations and institutional policies applicable to the IRB. The DRB must submit written guidelines for approval by the IRB and may not review applications until the guidelines are approved.

14.02 Standards and Procedures

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

(a) Introduction: 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) Ethical Standards: A statement of the ethical standards with which such activities must comply.
(c) Membership: 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) Quorum: Attendance by a majority, but not less than 3, members eligible to vote constitutes

(g) Procedure for Submission of Applications: Investigators must submit protocols intended for DRB

Appendix A: Exempt Research Categories

(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 i5T1-1. <</MCI b-1

conducts a limited IRB review to make the determination required by

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(6) Taste and food quality evaluation and consumer acceptance studies:

1. (i) If wholesome foods without additives are consumed, or
2.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by apply

End.