The University of Scranton

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

Policies and Procedures

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 result from the desire of the University to define its responsibilities

research.

include research, development, and related activities which would normally be construed as biological, behavioral, or psychological investigations involving human subjects. The IRB is responsible for the review of all research activity that involves human subjects that is conducted:

(a) at the University and its sites

(b) by any University employee or student either at University sites or elsewhere who represents him or herself to the subjects as affiliated with the University with the following exceptions:

(1) Newly employed full and part-time faculty members' ongoing research projects, including but not limited to dissertation research, must provide evidence of initial and continuing IRB approval from the initiating institution.

(2) Part-time faculty members with research not initiated as a University project and not representing the University in any way must provide evidence of IRB approval from the employing or sponsoring institution.

(3) Any faculty member to whom (1) and (2) above do not apply, and who is conducting dissertation research at another institution, must submit an abstract of the dissertation project and a copy of the IRB approval letter from the doctorate-granting institution.

Information about the recruitment of research participants on the University of Scranton campus by external researchers is available in section 10.01.01.

not only studies involving adults and children, but also:

(a) use of graphic, written, or recorded information about individuals even when this information has been collected by other institutions or investigators.

(b) investigations of prenatal life.

(c) studies or procedures utilizing organs, tissues, or bodily fluids of a human.

(d) investigations of organizations.

is the gathering of data from University employees, students or offices which will be used solely for internal quality assurance or program improvement, informational or required data-collection purposes, including but not limited to:

(a) Course evaluations

(b) Surveys or other data collection methods for:

(1) improving University services or procedures,

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 yearr, DRberslerni must have erstier1i,

In reviewing submissions and determining their review category, IRB will consider first if the proposal (1) meets the definition of research, and (2) that the research involves human subjects.

If the answer to both questions is yes, to determine the category of review required, the IRB will consider the level of risk; whether the research is anonymous, or confidential/deidentified; if it

Research that meets the requirements for Expedited review must meet these criteria:

(a) no more than minimal risk to participants, and

(b) the only involvement of human participants will be in one or more of the federally defined categories listed in Appendix B.

- x Consent documentation and other materials, if applicable;
- x Description of the subject population and recruitment plans;
- x Actions to protect privacy and/or confidentiality of the participants;
- x 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

- x Consent documentation and other materials, if applicable;
- x Description of the subject population and recruitment plans;
- x Actions to protect privacy and/or confidentiality of the participants;
- x Documentation that training requirements have been met for all personnel engaged in the research project

In addition to IRB review, review by other research committees may be necessary depending upon the type of research to be undertaken. These committees include the Institutional Biosafety Committee (IBC), and Institutional Animal Care and Use Committee (IACUC). Researchers are responsible for consulting the Chairpersons of these committees to determine if IBC and/or IACUC review and approval is required. IRB approval for the research activity does not constitute approval to utilize University programs, facilities, or services/practices for research purposes. Researchers should consult with relevant University administrators to secure any other approval or permission required. IRB approval is separate from approvals or requests to use University data, such as student or employee email addresses, for research purposes. IRB approval does not constitute approval for these activities or access to such data.

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is defined in the federal regulations as .

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- x Mentally disabled/Cognitively impaired persons
- x Economically or educationally disadvantaged persons
- x Non-English speaking persons

Research involving any of the above must be reviewed via Full IRB review, and may not be reviewed by DRBs.

DRB during initial review or for renewal of approval for an additional period of time.

Based on initial review, the IRB may require review at intervals less than the normal approval period of one year. Reasons may include risk level or previous IRB violations by the investigator. Review may be conducted by 2 members of the IRB or the full IRB, as determined in initial review or based on findings.

All research protocols are approved for a maximum one-year period after which renewal may be requested for one additional year.

(a) may be submitted for continuation beyond the initial approval period by submitting a request for renewal from the IRB Administrator or DRB, unless the proposed changes render the project ineligible for , including (but not limited to) submission for external funding, increase in the risk level, 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 maintain the confidentiality of data.

(f) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, 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 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.

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.

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to protection of human subjects in research.

Informed consent is a process, not just a document. Informed consent must be obtained from every potential subject or the subject's legal representative. Fully informed consent must be documented by the investigator. Except in special circumstances described below, informed consent must be verified by a signed written consent form. In general, if the researcher is obtaining informed consent, the research project will not qualify as Exempt research.

The prospective subject or representative must be given sufficient opportunity to consider 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. Investigators have special

of the regulations as set forth in 45 CFR 46:117 or 408(c)

(b) must be obtained in writing; the investigator should use supplementary verbal explanations when needed.

(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. (d61 Tw 0.2P(sse)r2 (h)- (l)-62 (

research-

the faculty, staff, or administration of the University. All applications must be submitted via IRBNet.

- University of Scranton students may submit applications with supervision of a mentor from the faculty, staff, or administration as provided in the section below on course-related and student-conducted research.

- Individuals who are not students or employees of the University wishing to conduct research on the University campus must have IRB approval. Research activities may require supervision and sponsorship by an appropriate University faculty, staff, or administration member who has demonstrated expertise in the area of proposed research (see Section 10.01.01 below).

All persons submitting applications for review by the IRB or DRB must provide evidence of completion of a human subjects' education program approved by the IRB. Initial certification should be completed prior to submitting an application for review. Approval will not be granted unless a human subjects education program has been completed less than three years prior to submission of the application.

External Researchers are persons unaffiliated with the University of Scranton who wish to conduct research on the University of Scranton campus. External researchers must consult with the University's IRB administrator to determine what documentation and approvals are required to pursue their research project. External researchers must have jurisdictional IRB approval and provide that documentation to the IRB administrator.

Projects that have been approved as Exempt by the jurisdictional IRB and meet the University's Exempt classification may be eligible for Exempt IRB review. Researchers whose projects meet the requirements for either Expedited or Full review must submit an application in University of Scranton format (Expedited and Full Review Applications) and include a copy of their Jurisdictional IRB approved protocol to the IRB Administrator.

Depending upon the nature and scope of the research project, the IRB may require that the researcher have a University of Scranton faculty, staff, or administrator serve as a faculty/staff sponsor for the project. A faculty/staff sponsor is always required for a Full review project; this supervision and sponsorship must be undertaken by an appropriate University faculty, staff, or administration member who has demonstrated expertise in the area of proposed research. This individual would agree to serve as the University contact person for the research.

Definitions:
(a) External Researcher - a person not employed by the University of Scranton or otherwise affiliated with the University.
(b) Jurisdictional IRB - the primary IRB that has approved the external protocol. This is usually

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, a

and copies of correspondence between the IRB and investigators.

Minutes of the IRB meetings contain the attendance at the meetings, actions taken, the vote on the actions, the basis for requiring changes in or disapproving research, full documentation of any waivers granted, and a written summary of the discussion of issues and their resolution.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects. A list of the reasons for any suspension or termination will be provided to the investigator, all appropriate department heads and the Director of Research.

The primary investigator is responsible for reporting unanticipated problems or adverse events to the IRB Administrator. The IRB Administrator will consult with the IRB Chairperson, Director 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.

contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly

End.