The University of Scranton

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

## Policies and Procedures

**Revised March 2023**

## Section 6: DEFINITIONS PERTAINING TO

the research could place the subject at criminal or civil liability or be damaging to the subject's reputation, employability, or financial standing. Such sensitive information could include the subject's drug or alcohol use, aspects of sexual behavior, or illegal conduct, **OR**

(b) it is anticipated that the data generated will be used for research, the results of which will be disseminated outside of the University community.

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If the answer to both questions is yes,

One of the primary differentiators between Exempt and Expedited research is that Expedited research is not anonymous. Only the IRB Administrator or the IRB Chairperson are authorized to determine whether research meets expedited status requirements, and the interpretation of related regulations exclusions.

Expedited review and approval of research proposals can be undertaken if:

- Risk to participants is minimized,
- Risk to participants is reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result,
- Selection of participants is equitable,
- Informed consent is sought from each prospective subject or their legally authorized representative,
- Informed consent is appropriately documented,
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, and
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, including any personally identifiable information.

## 5.05. Submission and Timeline [illegible]

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.

**5.07. Submission and Timeline for Review of Full Review Applications**

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responsible for consulting the Chairpersons of these committees to determine if IBC and/or IACUC review and approval is required.

information is collected. Researchers should be aware however, that collection of information regarding other unique individual characteristics (indirect identifiers) could make it possible to identify an individual from a pool of participants.

(c) **Confidential** indicates that the research team knows that any particular individual has participated in the research but is obligated not to disclose that information to others outside the team. When data are confidential, there continues to be a link between the data and the individual who provided it. The research team is obligated to protect the data from disclosure outside the research according to the terms of the research protocol and the informed consent document. Note that coded data are not anonymous.

(d) **De-identified** data are those data that have NO direct identifiers or codes linking it to an individual subject. For data to be deemed 'de-identified', all direct or indirect identifiers or codes linking the data to the individual subject's identity are destroyed.

### 6.04 Deception

Deception in human subjects research involves not informing the subject of all aspects of the study so that the subject is not able to give full informed under the Expedited Review procedure (Section 5.05) unless the proposed changes render the project ineligible for continued Expedited determination.

Such changes that may result in a change of project determination include (but are not limited to) submission for external funding, increase in the risk level, changing the manner of identification of the subjects, inclusion of vulnerable populations, therefore requiring submission for full IRB or DRB review.

### 7.02 Changes to a Full Review Application

**1. Minor (non-substantive) changes** to a protocol approved under **Full Review** may be submitted for review and approval by two members of the IRB or by the DRB. A change is considered to be minor (non-substantive) if it does not 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, OR
(d) Change in investigator contact information in the informed consent information and written consent document.

**2. Substantive changes** to an application that received Full Review must be submitted for full IRB or DRB review (unless it includes participants from a group defined as a vulnerable population). Substantive changes to Full Review protocols that include members of a vulnerable population require full IRB review. A change is considered to be substantive if:

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(a) Changes any information in the informed consent information and written consent document other than investigator contact.
(b) Is likely to reduce the validity of the study, e.g., decreases the number of subjects to a level

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

(a) **Projects originally approved as an Expedited Application** 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 **Expedited Review**, 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) **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 [45 CFR 46:111]

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 l 0 r be be

authorized representative.  (Section 7)
(d) Informed consent must be appropriately documented. (Section 9.01)
(e)  When appropriate,
   (1)   the research plan makes adequate provision

**9.01. Informed consent is central** 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 responsibilities whenever potential subjects have circumstances which might affect their ability to give informed and voluntary consent to participate in a research project, whether or not the subject patient's interests.

**9.02.04. Pregnant Women, Human Fetuses, and Neonates -** There are special provisions in place regarding risks and benefits and definitions particularly related to viability.

### 9.03. Project with Risk Beyond Everyday Life (More than Minimal Risk)

Risks must be enumerated to allow the patient to decide whether or not to participate. Also included should be any protections to lower the potential risk and an injury clause (see Elements of Informed Consent; Section 9.05).

### 9.04. Deception

Deception in human subjects' research involves not informing the subject of all aspects of the study so that the subject is not able to give full informed consent. As early as feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection,

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(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(c) Any additional costs to the subject that may result from participation in the research;
(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
(f) The approximate number of subjects involved in the study.

**9.05.01. Exceptions/Waivers -** The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or may waive the requirement to obtain informed consent provided the IRB documents its findings in accordance with 45 CFR 46:116 (ce).

**9.05.02. Exculpatory language** may not be included in any informed consent (oral or written). Subjects or their representatives cannot be made to waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

## 9.06. Documentation of Informed Consent

### 9.06.01. Informed in Writing

The subject or a legal representative signs a written consent document, which explains all of the elements of informed consent. Due to the individual nature of informed consent, the University IRB does not encourage the use of templates for written consent. However, samples of written consent documents are provided by the Office of Research and Sponsored Programs (ORSP) and are available on the ORSP Human Subjects Research website to serve as guides for investigators.

### 9.06.02. Informed Orally

The subject or a legal representative signs a document indicating the subject had all of the elements of informed consent explained orally and that s/he understands this description and s/he agrees to participate in the activity described. In addition, an auditor-witness to the oral presentation must be present and must sign the consent form as "witness." A **written script** of the oral presentation must be approved by the IRB and will be retained as a part of the IRB records.

### 9.06.03. Exceptions/Waivers

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(a) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, OR
(b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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.

### 10.01.01 Recruitment of Participants by External Researchers

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) ExternalResearcher- a person not employed by the University of Scranton or otherwise affiliated with the University.
(b) JurisdictionalIRB - the primary IRB that has approved the external protocol. This is usuall0 0 12 Td( )Tj0.2