

**The University of Scranton**  
**Institutional Review Board (IRB) for the**  
**Protection of Human Participants**  
**Policies and Procedures**  
**Revised October 2018**

## TABLE OF CONTENTS

<b>Section 1: POLICY .....</b>	<b>1</b>
<b>Section 2: SCOPE .....</b>	<b>2</b>
<b>Section 3: INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS (IRB).....</b>	<b>3</b>
<b>Section 4: INVESTIGATORS - DEFINITIONS AND RESPONSIBILITIES.....</b>	<b>5</b>
<b>Section 5: CATEGORIES OF REVIEW, TIMELINES, AND SUBMISSION.....</b>	<b>5</b>
<b>Section 6: DEFINITIONS PERTAINING TO RISK.....</b>	<b>9</b>
<b>Section 7: PROTOCOL REVISIONS.....</b>	<b>10</b>
<b>Section 8: RESEARCH REVIEW.....</b>	<b>12</b>
<b>Section 9: INFORMED CONSENT.....</b>	<b>13</b>
<b>Section 10: GUIDE FOR SUBMISSION OF APPLICATIONS.....</b>	<b>17</b>
<b>Section 11: CONVENED MEETINGS AND REVIEW PROCEDURES .....</b>	<b>19</b>
<b>Section 12: SUSPENSION OR TERMINATION OF RESEARCH.....</b>	<b>21</b>
<b>Section 13: REPORTING UNANTICIPATED RISKS, MISCONDUCT AND NON-COMPLIANCE.....</b>	<b>21</b>
<b>Section 14: DEPARTMENTAL REVIEW BOARD (DRB) GUIDELINES.....</b>	<b>22</b>

## Section 1: POLICY

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.

These policies and procedures 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](#)** [*The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979*].

**[Protection of Human Subjects](#)** [*Code of Federal Regulations - 45 CFR 46, revised November 13, 2001, effective December 13, 2001*].

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.

When reviewing research proposals, the IRB or 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. The ethical principles and their translation into action:

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

set forth in the *Belmont Report* serve as the guide for the IRB/DRB's review of all research activities.

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.

## 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, 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.

**2.02. Human subjects research includes** 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.

**2.03. Institutional (internal) research** is the gathering of data from University employees, students or offices which will be used solely for internal program improvement, informational or required data-collection purposes, for example:

(a) Course evaluations

(b) Surveys or other data collection methods for:

(1) improving University services or procedures,

(2) ascertaining opinions, experiences or preferences of the University community,

(3) providing necessary information to characterize the University.

IRB review is not required for institutional research *except* when

- (a) the information deals with sensitive subject matter and disclosure of the responses outside of 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.

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

**3.01. Members** of the IRB are appointed by the Provost/Vice President of Academic Affairs of the University to represent the interests of the University and the community. IRB members are ordinarily appointed for a three-year term and may be reappointed when this initial term expires. There are at least seven members of the IRB, with various backgrounds and fields of expertise, including at least one faculty representative from the humanities, natural sciences, and one community member from outside of the University.

The IRB may, at its discretion, 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.

#### **3.02. Further Review**

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the University. However, those officials may not approve the research if it has not been approved by the IRB.

#### **3.03. IRB Chairperson**

The IRB Chairperson is appointed annually by the Provost from among the IRB members; responsibilities include

- (a) convening and conducting meetings,
- (b) consulting as needed with the IRB Administrator on Exempt and Expedited applications (section 5),
- (c) reviewing additional information submitted following IRB review as empowered by the board.

#### **3.04. IRB Administrator**

Responsibilities of the IRB Administrator include:

- (a) scheduling and sending notification of IRB meetings,
- (b) disseminating meeting materials and applications in timely manner for review prior to a convened meeting,
- (c) recording minutes of IRB meetings,
- (d) maintaining IRB files,
- (e) reviewing and approving Exempt and Expedited applications in consultation with the IRB

Chairperson if needed,

- (f) notifying investigators of IRB actions,
- (g) notifying IRB Chairperson and other University officials as appropriate of reported adverse events,
- (h) coordinating the IRB education program.

### **3.05. IRB Education Program**

Completion of an IRB approved education program will be required of all individuals involved in Human Subjects Research and its review including IRB members, IRB Administrator, DRB members, investigators, and research assistants (section 4) 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. 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.

### **3.06. Departmental Review Board (DRB)**

The IRB delegates review and approval of certain research activities to Departmental Review Boards (DRBs) in those departments which routinely conduct human subject research.

The following departments have been approved to operate DRBs: Communication, Counseling; Education, Health Administration/Human Resources, Nursing, Physical Therapy/Occupational Therapy; Psychology, and Political Science/Sociology & Criminal Justice. **Applications from all other departments require review at a fully convened meeting of the IRB.**

Applications for review by a DRB may be submitted only by the respective department's faculty, staff, and students.

The DRB may review research that falls under the classifications of Expedited or Full Committee Review in accordance with its approved written guidelines (section 14). DRBs may not review research protocols classified as Full Committee Review, but involving:

- (a) Risk beyond everyday life, and/or
- (b) Deception, and/or

(c) Vulnerable participants

In addition, the DRB may not review research

- (a) For which the IRB provides notice to the investigator or department that the IRB is exercising its oversight responsibility and requires IRB review and approval, or
- (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.

## **Section 4: INVESTIGATORS - DEFINITIONS AND RESPONSIBILITIES**

### **4.01. Definitions - Investigators and Research Assistants**

For IRB purposes:

- (a) **Investigators** are defined as all persons who contribute significantly to the design and implementation of a study protocol.
- (b) **Research Assistants** are all persons who contribute to the implementation of the study, including interaction with subjects and/or access to data, but do not participate in the design and development of the study protocol.

### **4.02. Responsibilities of Investigators**

Investigators at the University are entrusted with the primary responsibility for protecting the human 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:

- (a) Submit an adequately prepared form (section 5) via IRBnet for each research project involving human subjects.
- (b) Request a continuing review if the research extends beyond the initial review period.
- (c) Notify the IRB and the departmental chairperson of any injury - physical, psychological, or social - suffered by a subject because of his or her participation in a research activity.
- (d) Retain adequate records, documents, and informed consent forms for at least three (3) years following the completion of the approved project or activity, or for a longer period as judged necessary.
- (e) Maintain current certification in Human Subjects Education.
- (f) Assure that all research assistants participating in the protocol receive complete training, and

that an "IRB/DRB Research Assistant Training Certification" form is filed with the IRB Administrator or appropriate DRB Chairperson for each research assistant.

## **Section 5: CATEGORIES OF REVIEW, TIMELINES, AND SUBMISSION**

**Three categories of IRB applications are accepted for review by the IRB:**

- (a) Exempt Review
- (b) Expedited Review
- (c) Full Review

For questions about the appropriate category, please contact the IRB Administrator for assistance. Researchers who clearly explain all procedures in the protocol applications will increase the likelihood of quicker approval. In many cases, applications are submitted that are vague in key areas that reviewers need to evaluate in order to ascertain any risk to the participants.

### **5.01. Exempt Status Determination Applications**

Research that meets the regulatory criteria to be classified as 'exempt' indicates that there is no more than minimal associated risk to the participants and no identifiers are collected. **Note: This classification DOES NOT mean that the research is exempt from IRB review and approval!** The IRB Administrator or the IRB Chair are authorized to determine research that meets exempt status requirements and the interpretation of the regulations and exemptions. Examples of exempt status research includes use of existing data, evaluation of de-identified medical records, and research on de-identified pathologic specimens as this type of research usually has little, if any, associated risk, particularly if there are no subject identifiers attached to the information. Below are the specific regulatory categories for exempt determination.

### **5.03. Regulatory Categories for Exempt Determinations 45 CFR 46.101(b)**

For research activities to be approved under exempt status, risk must be minimal or less, information must be recorded in such a way that no participant can be identified either directly or through identifiers linked to the individual, and the only involvement of human participants must be in one of the following categories:

- (a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless:** Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil

liability or be damaging to the participants' financial standing, employability, or reputation.

(c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the previous statement, if: the human participants are elected or appointed public officials, or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(d) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

(e) Research and demonstration projects conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

(f) Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental 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.

Projects reviewed and approved under exempt status do not require subsequent submission of other forms for IRB review *unless* a change to the research results in a change to the Exempt Status Determination. Any exempt status project will be closed out one year from the approval date by the IRB Administrator.

For changes to research approved under Exempt Status, PIs are held responsible to consult with the IRB Administrator if the change may result in a change to the Exempt Status Determination. If changes to an approved exempt project will not result in a change in the review determination, additional forms do not need to be filed with the IRB.

#### **5.04 Submission and Timeline for Review of Exempt Applications**

Exempt applications are reviewed upon submission via IRBnet. Every effort is made to complete exempt reviews as soon as possible. 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 submit an Application for Exempt Status Approval via IRBnet (see <http://www.scranton.edu/academics/provost/research/sub%20pages/IRB.shtml> for more information). Investigators should provide enough information to allow the reviewer to make a determination and include the following information in the form:

- Abstract describing the objective(s) of the project

- Methods used for the research
- Description of the subject population and recruitment plans
- Actions to protect privacy and/or confidentiality of the participants
- Certificate of completion to document that the training requirements have been met
- IRBnet packages must be signed by the Investigator and all Co-investigators.

### **5.05. Expedited Applications**

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, in accordance with, and to the extent required by Sec. 46.116,
- Informed consent is appropriately documented,
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, and
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Research that meets the requirements for expedited review must involve no more than minimal risk to participants and the only involvement of human participants will be in one or more of the categories listed below. Research protocols that qualify for expedited review are determined for eligibility by the appointed reviewers, and in consultation with the IRB Chair as necessary.

### **5.06. Submission and Timeline for Review of Expedited Applications**

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 submit an application for Expedited IRB Review via IRBnet (see <http://www.scranton.edu/academics/provost/research/sub%20pages/IRB.shtml> for more information). Investigators should provide enough information to allow the reviewer to make a determination and include the following information in the form:

- Abstract describing the objective(s) of the project
- Methods used for the research
- Description of the subject population and recruitment plans
- Actions to protect privacy and/or confidentiality of the participants
- Certificate of completion to document that the training requirements have been

- met
- IRBnet packages must be signed by the Investigator and all Co-investigators.

### **5.07. Full Review Applications**

A full committee review by the IRB is required if the research involves more than minimal risk and special precautions may need to be taken to protect the rights and welfare of the participants.

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. Meetings are scheduled monthly throughout the academic year, and typically once during the summer months.

### **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 (see <http://www.scranton.edu/academics/provost/research/sub%20pages/IRB.shtml>). 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 that will need to be addressed by the PI.

#### ***Full Review Application Form Submissions***

Investigators should submit an application for Full IRB Review via IRBnet (see <http://www.scranton.edu/academics/provost/research/sub%20pages/IRB.shtml> for more information). Investigators should provide enough information to allow the reviewer to make a determination and include the following information in the form:

- Abstract describing the objective(s) of the project
- Methods used for the research
- Description of the subject population and recruitment plans
- Actions to protect privacy and/or confidentiality of the participants
- Certificate of completion to document that the training requirements have been met
- IRBnet packages must be signed by the Investigator and all Co-investigators.

## **Section 6: DEFINITIONS PERTAINING TO RISK**

**6.01. No Risk Beyond Everyday Life** is defined in the federal regulations as minimal risk.

It means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**6.02. Risk Beyond Everyday Life** 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).

### **6.03 Anonymous, Confidential, or De-identified?**

The IRB often finds that the terms *anonymous*, *confidential*, and *de-identified* are not used correctly. These terms are described below as they relate to an individual's participation in the research and the way that their data are collected and maintained for analysis.

- (a) **Anonymous** indicates it is impossible to determine whether any individual was involved in the research project. Data are *anonymous* if no one, **not even the researcher**, can connect the data to the individual who provided it. No identifying information is collected from the individual. For example, participation in an online survey that cannot be linked in any way to the individual would be considered *anonymous*. 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.
- (b) **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*.
- (c) **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 consent. A study involving deception will not 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.

## **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 (Section 5.05) unless the proposed changes render the project ineligible for exemption.

Such changes 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.

**7.01 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.

**7.02 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 it

(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 which affects the statistical validity of the research,

(c) Changes the level of risk from a lower to a higher category,

(d) Alters the way in which subjects are placed at risk that is beyond everyday life.

### 7.03. Continuing Review

Continuing review includes review of protocols on an interim basis as determined by the IRB or DRB during initial review or for renewal of approval for an additional period of time.

### 7.04. Interim Review

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.

### 7.05. Renewal

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.

(b) 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.

(c) 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.

(d) Informed consent must be sought from each prospective subject or the subject's legally authorized representative. (Section 7)

(e) Informed consent must be appropriately documented. (Section 9.01)

(f) 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.

(g) 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.

**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. Quality Assurance**

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. 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.

## **Section 9: INFORMED CONSENT**

**9.01. Informed consent is central** to protection of human subjects in research.

It 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.

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 categories are included in the vulnerable populations defined in the federal regulations.

Investigators and the IRB must comply with the special requirements as set forth in the federal regulations [*45 CFR 46 Subparts B, C, and D*] for defined vulnerable populations.

### **9.02. Vulnerable Subjects**

Although only certain categories of subjects are mentioned specifically in the regulations, the researcher has special responsibilities whenever the potential subjects have circumstances which might affect their ability to give informed and voluntary consent to participate in a research project. Researchers must use extreme care to respect the rights of subjects when they develop consent procedures. When written consent or assent cannot be obtained, a verbal script must be submitted with the protocol.

#### **9.02.01. Children**

Permission to conduct research with children requires special attention to the child's age, ability to understand what is asked, and relationship to parents or guardians.

(a) **Parental/Guardian Consent** is required in writing for all minors (under the age of 18). A waiver of parental consent may be granted by the IRB if it deems that the request for waiver meets the spirit of the principles of the Belmont Report and is in accordance with the provisions of the regulations as set forth in *45 CFR 46:117* or *408(c)*.

(b) **Adolescent (junior/senior high) Assent** must be obtained in writing; the investigator should use supplementary verbal explanations when needed.

(c) **Child (elementary) Assent** 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) **Very Young Child** - explanations should match the level of understanding.

**9.02.02. Prisoners** - Particular attention to the issue of potential coercion is necessary.

**9.02.03. Mentally Disabled** - A patient advocate is necessary to guard the 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 (section 5.05) 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, the investigator must inform the subjects about the deception, and permit subjects to withdraw their data.

### **9.05. Elements of Informed Consent [[45 CFR 46:116](#)]**

In clear and non-technical language which is appropriate to the subject, subjects must be informed of:

- (a) The fact that the study is research.
- (b) The purposes of the research.
- (c) The expected duration of the subject's participation.
- (d) The procedures to be followed.
- (e) Any reasonably foreseeable risks or discomforts.
- (f) Any benefits to the subject or to others which may reasonably be expected from the research.
- (g) Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.

- (h) The extent, if any, to which confidentiality of data and privacy of subjects will be maintained.
- (i) For research involving more than minimal risk, whether any compensation and whether any medical treatments are available if injury occurs.
- (j) Whom to contact for answers to pertinent questions about the research, subjects' rights, and research-related injury to the subject.
- (k) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the 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 or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (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 \(c-e\)](#).

**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.

In cases in which the documentation requirement is waived, the IRB may require that the investigator provide subjects with a written statement regarding the research. A copy of this statement must be included with the materials in the IRB application, and the investigator must certify that the subjects have been informed.

### **9.07 . HIPAA and Informed Consent**

Informed consent shall comply with all requirements of the [Health Insurance Portability and Accountability Act \(HIPAA\), PL104-191](#), and the [Standards for Privacy of Individually Identifiable Health Information \(Privacy Rule\) 45 CFR 160 and 164](#).

The University is classified under HIPAA as hybrid entity, meaning that it has divisions which fall under HIPAA regulations and those which do not. Human subjects research is not considered health care and is therefore not a covered entity.

When using research subjects at a covered entity (e.g., hospital, clinic, doctor's office, or other health care facility), the investigator must abide by that institution's regulations, and the University's IRB will require an authorization to use protected health information (PHI) as an addendum to the consent form. Specific conditions are outlined in the regulations concerning use and disclosure of PHI in research. A researcher may enter into a "data use agreement (defined in the regulations)" with a covered entity allowing access to a limited data set which excludes specified direct identifiers, or the entity may allow use of PHI with individual authorization by the research subjects.

## **Section 10: GUIDE FOR SUBMISSION OF APPLICATIONS**

Any individual intending to conduct research involving human subjects, whether or not the research is supported by a grant, contract, or fellowship from any public or private agency, has the responsibility to file the approved IRB form following the procedures outlined in this handbook and in the application instructions.

### **10.01. Who May Submit a Proposal for Review**

Applications for review of human subjects research may be submitted by members of the faculty, staff, or administration of the University.

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 require supervision and sponsorship by an appropriate University faculty, staff, or administration member who has demonstrated expertise in the area of proposed research.

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 two years prior to submission of the application.

#### **10.01.01 Recruitment of Participants by External Researchers**

*External Researchers are required to submit their application in University of Scranton format (Exempt or Expedited and Full Review Applications) and include a copy of their Jurisdictional IRB approved protocol to the IRB Administrator, IMBM 201, University of Scranton, Scranton, PA 18510.*

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 the external researcher's home institution.
- (c) *Faculty/Staff Sponsor* - University of Scranton faculty, staff, or administrator who agrees to serve as the University contact person for the research.

Application Review:

- (a) Applications not approved by a Jurisdictional IRB will not be reviewed by the University of Scranton IRB.
- (b) Applications submitted by an External Researcher must have a University of Scranton Faculty/Staff Sponsor.
- (c) Applications will be reviewed either administratively for Expedited or Full IRB review as appropriate.
- (d) 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.

### **10.02. Procedure for Submitting Course-Related and Student-Conducted Research**

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.

Activities requiring IRB or DRB review:

- (a) Student-generated research projects, including independent study, honors papers, theses, 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 not requiring IRB or DRB approval:

- (a) Classroom exercises conducted only with members of the class, involving no more than minimal risk, and including no sensitive material.
- (b) Journalism activities.

### **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. Investigators in departments with DRBs may also submit Expedited or Full Review applications directly to the IRB via IRBnet.

Full Review applications that include the use of vulnerable populations may only be reviewed by the IRB.

Information on dates of DRB meetings and deadlines for submission are available from the appropriate DRB Chairperson. DRB applications can be found in IRBnet.

#### **10.04 Submission to the IRB**

Any Expedited or Full Review Application (sections 5.05, 5.07) may be submitted via IRBnet for review by the IRB.

**Exempt Applications** may only be submitted to the IRB via IRBnet.

Information on dates of IRB meetings, deadlines for submission, and applications is available from the IRB Administrator and on the website of the Office of Research and Sponsored Programs.

### **Section 11. CONVENED MEETINGS AND REVIEW PROCEDURES**

#### **11.01. Convened Meeting**

The IRB 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 Human Subjects webpage of the Office of Research and Sponsored Programs (ORSP) 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 (Section 9.01) of the IRB.

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 the 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 defer the proposal, pending changes in the application or receipt of additional information from the investigator or consultants to the IRB, OR
- (d) to disapprove the proposal.

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 must be resubmitted to the IRB for further full board review.

The IRB may designate the IRB Chairperson, IRB Administrator, or a board member to review and either approve of the investigator's requested changes or require resubmission for review by the full board.

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 in the Office of Research and Sponsored Programs. Records are retained for at least three years and in accordance with [45 CFR 46:115 \(a - b\)](#).

Records of research protocols must be maintained for at least three years after completion of the research. These records contain the research proposal reviewed, scientific evaluations, approved sample consent documents, progress reports, reports of injuries to subjects, records of continuing review 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.

## **Section 12: SUSPENSION OR TERMINATION OF RESEARCH**

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.

## **Section 13: REPORTING UNANTICIPATED RISKS, MISCONDUCT AND NON-COMPLIANCE**

The Investigator is responsible for reporting unanticipated problems or adverse events to the IRB Chairperson and the appropriate department chair.

Any instance of serious or continuing non-compliance with the IRB policies and procedures or the requirements or determinations of the IRB will be reported in the same manner.

Procedures for reporting scientific misconduct (including fabrication, falsification, plagiarism, 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 Research and Sponsored Programs and on the ORSP website.

## **Section 14: DEPARTMENTAL REVIEW BOARD (DRB) GUIDELINES**

**14.01. The IRB delegates review** of certain categories of research to the DRB. Therefore 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 as no risk beyond everyday life, e.g., research covered under Expedited and Full Review Protocols, if there is no inclusion of vulnerable populations

(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.

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

(e) **Meetings:** Review of 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) **Records:** 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 subjects education program in accordance with the IRB guidelines.

(g) **Procedure for Submission of Applications:** Investigators must submit protocols intended for DRB review to the IRB Administrator through IRBnet. New users should register at [IRBnet.org](http://IRBnet.org) (see <http://www.scranton.edu/academics/provost/research/sub%20pages/IRB.shtml> for detailed instructions).

(h) **Procedure for Review of Applications:** Unanimous agreement of the DRB members eligible to vote at a meeting is required for approval of an application requiring Full Review. Expedited applications may be submitted for review by the DRB following the same submission and review processes (Section 14.02 (g)).

(i) **Actions:** Following review, the DRB may:

- (1) approve the application,
- (2) request specific changes and resubmission by the investigator for further DRB review,
- (3) notify the investigator of the concerns of the DRB and request that the investigator resubmit the application to the IRB, OR
- (4) notify the investigator that the application does not meet criteria for DRB review and must be submitted to the IRB for full review at a convened meeting.

#### **14.03. Procedures for Reporting DRB Actions to the IRB**

Report of DRB actions should be sent to the IRB Administrator within one week of the DRB meeting, following the outline for DRB documentation above.

#### **14.04. Activities Excluded from Departmental Review**

Applications must be submitted directly to the IRB for research:

- (a) Involving risk beyond everyday life (section 6.02) to human subjects,
- (b) To be submitted for extramural funding or support,
- (c) Involving any vulnerable subjects (section 9.02), except for the use of pre-existing data with no identifiers,
- (d) Involving deception (section 6.04),
- (e) Requiring waivers of any part of informed consent (section 9.05.01), unless approval authorization is granted by the IRB for specific circumstances,
- (f) To be conducted by an investigator from outside of, but involving, the University,
- (g) Which does not fall within a DRB's guidelines,
- (h) For which the IRB provides notice to the investigator or department that the IRB is exercising its oversight responsibility and requires IRB review and approval, or
- (i) 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.