The University of Scranton

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

Policies and Procedures

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Section 1: POLICY STATEMENT

The University of Scranton (University) is committed to safeguarding the rights and welfare of human participants in all research under its sponsorship and to serving as their protector on behalf of the community of persons that comprise the University. This policy and all supporting procedures 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 January 22, 2018 and effective June 19, 2018]].* This is often referred to "The Common Rule"

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

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

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

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

Research procedures and design may affect the use and experience of human subjects in research activities. In this context, the IRB/DRB has the responsibility to require modification or change in the design of the research, to assure that the use of human subjects is valid and the risks to the subjects are minimized. However, it is not the intention of the IRB or DRB to provide full scientific review. 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.

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

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 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,
(2) ascertaining opinions, experiences or preferences of the University community,
(3) providing necessary information to characterize the University.

Institutional research is excluded from IRB regulations, and 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.

Members of the University using human subjects in institutional research are encouraged to contact the IRB if they have questions about whether or not their project falls within the institutional research category.

External Agency, Consortia or other Surveys
From time to time, University employees may seek to administer surveys or studies on behalf of agencies, consortia, or other groups with which the University is affiliated. Such activities may be considered institutional research (e.g., limited to program/service quality improvement) by the sponsoring entity, and may include an external IRB approval secured by that entity. However, prior to the administration of any survey or study on the University campus, the University employee sponsoring the activity is responsible for ascertaining if any University IRB review is required.

2.04 Other Excluded Research

The 2018 update to 45 CFR 46 (The Common Rule)**,** in defining research**,** states that the following activities are deemed not to be research that falls under the scope of IRB:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, t**hat focus directly on the specific individuals about whom the information is collected.**

However, if the journalistic activity moves beyond a focus on the specific individual(s), it may in fact fall under human subjects' research regulations and IRB oversight. Federal guidance states that, "if the activity involves collecting and using information about individuals for the purpose of drawing generalizations about such individuals or a population of which they are members, then the activity does not fit the parameters of this exception, and the activity may fall within the 2018 Requirements' definition of 'research'." Contact the IRB administrator for more information.

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

3.01. The University of Scranton's IRB consists of a staff IRB Administrator, and IRB Committee. The IRB chair and members of the IRB Committee are appointed by the Provost/Vice President of Academic Affairs to represent the interests of the University and the community, following the recommendation of the IRB Administrator and Associate Provost/Director of Research. The IRB Chairperson and committee 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 committee, 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. Faculty may be recommended or self-nominate for membership based on their interest, experience, and credentials relative to human subjects' research. The IRB Administrator serves as a voting member of the IRB Committee.

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 Committee Chairperson is appointed annually by the Provost from among the IRB members; responsibilities include:
(a) convening and conducting meetings,
(b) reviewing, approving, and 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

Appointed by the Provost, 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 records and documentation,
(e) reviewing, approving, and consulting as needed with the IRB Committee Chairperson on Exempt and Expedited applications (section 5)
(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, and
(i) coordinating IRB-related compliance activities

3.05. IRB Education Program

Completion of an IRB-approved education program is required of all individuals involved in Human Subjects Research and its review including IRB Chairperson and members, IRB

Administrator, DRB chairpersons and members, investigators, and research assistants and any other personnel who interact with subjects and/or have access to data which contains personal identifiers.

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

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. DRBs are approved to operate by the Associate Provost/Director of Research, in consultation with the IRB administrator. All approved DRBs must maintain documented procedures describing their activities in compliance with University policy (see Section 14).

The following departments have been approved to operate DRBs: Communication & Media; Counseling and Human Services; Education; Health Administration/Human Resources; Nursing; Physical Therapy/Occupational Therapy; Psychology; and Political Science/Sociology & Criminal Justice. Applications from all other departments require review by the IRB.

Applications for review by a DRB may be submitted only by the respective department's faculty, staff, and students. If a research project includes researchers from multiple departments, the protocol may be reviewed by the primary investigators' DRB unless that DRB recommends review by the IRB. All applications must be submitted via IRBNet, and will be routed as appropriate by the IRB Administrator based upon review type determinations.

The DRB may review research that falls under the classifications of (1) Expedited or (2) Full Committee Review, unless that research includes vulnerable participants, in accordance with its approved written guidelines (section 14).

DRBs may not review Exempt research applications. 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.
(c) Research that is to be submitted for extramural funding or support.

(d) Research requiring waivers of any part of informed consent, unless approval authorization is granted by the IRB for specific circumstances.
(e) To be conducted by an investigator from outside of, but involving, the University.

Section 4: INVESTIGATORS - DEFINITIONS AND RESPONSIBILITIES

4.01. Definitions – Primary Investigators and Co-Investigators

For IRB purposes:
(a) The Primary Investigator is the individual(s) principally responsible for the preparation, conduct, and administration of a human subjects research project.
(b) Co-Investigators are defined as all project personnel who contribute to the design and implementation of a study protocol, who interact with subjects, and/or have access to research data. This may include faculty, student researchers, research assistants, community partners, and other personnel taking part in the research project, including through collection and analysis of data.

4.02. Responsibilities of Primary Investigators

Primary Investigators 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 via IRBNet for each research project involving human subjects, including any and all additional documentation/forms necessary for the project.
(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 and
(f) assure that all personnel involved with a human subjects' research project have completed required training.

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

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 meets the federally defined categories for Exempt or Expedited research; and if any vulnerable populations are included.

It is the role of the IRB, not the researcher, to determine the level of risk and other determining elements, and the type of category of IRB review required. For questions about the appropriate category, please contact the IRB Administrator or IRB Committee Chairperson for assistance.

5.01. Exempt Status Determination Applications

For research to meet the regulatory criteria to be classified as 'exempt,' three criteria must be met:

(a) involves no more than minimal associated risk to the participants; *and*
(b) participation is anonymous, and information from participants is gathered and recorded in such a way that no participant can be identified either directly or through personal identifiers linked to the individual, regardless of whether that information is used or distributed as part of the project analysis or publication; *and*
(c) the research falls into one of the six federally defined categories listed in Appendix A.

An Exempt status classification DOES NOT mean that the research is exempt from IRB review and approval; rather, exempt status means that the research is exempt from certain elements of federal regulation. Exempt projects must still be submitted for IRB review and approval. Only the IRB Administrator and the IRB Chairperson are authorized to determine whether research meets exempt status requirements, and the interpretation of related regulations.

As defined within the federal regulation, to be anonymous, no personally identifying information may be collected from the individual, and no one, not even the researcher, will know who took part or can connect the data to the individual who provided it. **If any personally identifiable data is known, used during, or collected by the researcher, then the project is not anonymous and cannot be exempt.** See Section 6.02 for more information about anonymity and confidentiality.

For the purposes of this policy, personally identifiable information includes, but is not limited to, participant names, telephone numbers, physical/mailing addresses, email addresses, personal identifiers such as social security or student ID numbers; personal characteristics, or other information that could make them easily traceable.

Examples of exempt status research includes: use of existing data; anonymous surveys in which personally identifiable information (such as name or email address) is neither known or collected via the survey or other documentation (such as entering into an incentive drawing, or via informed consent), nor in any way connected to individual respondent data via a survey or other information gathering instrument; 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.

5.02 Submission and Timeline for Review of Exempt Applications

Exempt applications are submitted via IRBNet and reviewed upon submission by the IRB Administrator. Every effort is made to complete exempt reviews as soon as possible. However, the review time may vary depending on the completeness, quality and clarity of the application, and whether there are concerns, questions, or requests for modifications that will need to be addressed by the PI. This type of application does not need to wait for an IRB Committee meeting date for review, nor are exempt applications reviewed by DRBs.

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

- Abstract describing the background, nature, and objective(s) of the project, including its context in relation to existing research;
- Research methodology, including copies of any tools, such as surveys, to be used in the research;
- Description of the subject population and recruitment plans;
- Any communications that will be used during the recruitment and research processes;
- Consent documentation and other materials, if applicable;
- Actions to protect privacy and/or confidentiality of the participants;
- Documentation that training requirements have been met for all personnel engaged in the research project.

5.03 Changes to Approved Exempt Research

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 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 Expedited Applications

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.

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 for Review of Expedited Applications

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

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

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

5.06. Full Review Applications

A full committee review by the IRB is required if the research involves **more than minimal risk** to

human subjects **and** special precautions may need to be taken to protect the rights and welfare of the participants; full committee review is required if the **research involves one or more of the following populations**: minors under the age of 18; economically/educationally disadvantaged persons; fetus/fetal tissue; non-English speaking participants; pregnant women; prisoners; or cognitively impaired persons. In addition, full review may include protocols that have been referred to the committee by the IRB Administrator, Chair, an expedited reviewer, or a DRB. Researchers from departments with DRBs may also request that their project be reviewed by the IRB.

5.07. Submission and Timeline for Review of Full Review Applications

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

Procedures are designed so that all IRB members receive materials for project review at least one week prior to the meeting or such time as sufficient to allow for review of the materials before a convened IRB meeting. **Only protocols received by the due date listed on the IRB Committee meeting schedule will be reviewed at the next scheduled meeting**. Investigators will typically receive a letter approving the protocol or requesting modifications required for approval within one week of the meeting date. The total review time will vary depending on the quality and clarity of the application, and whether there are concerns, questions, or requests for modification that will need to be addressed by the PI.

Full Review Application Form Submissions

Investigators must submit an application for Full IRB Review via IRBnet. Investigators should provide enough information for the reviewers to understand the nature and goals for the project, such that they may make a determination. Investigators must include the following information in the form, in addition to any other relevant information and documentation:

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

5.08 Review by other Research Committees and University Personnel

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.

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. To qualify as either exempt or expedited, research must be no more than minimal risk.

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

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

Any project involving more than minimal risk will be reviewed as a Full Review protocol by either a DRB or the IRB, unless the project is otherwise ineligible for DRB review.

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 research and the way that their data are collected and maintained for analysis.

(a) Anonymity addresses both *subject participation* (knowing any individual was involved in the research project) and *data* (whether data gathered through the project can be connected in any way to an individual participant).
(b) **Anonymous** indicates it is impossible to determine whether any individual participated 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, either as part of the study methodology or documentation such as informed consent forms or other releases. A study should not collect identifying information of research participants unless it is essential to the study protocol. Anonymity cannot be guaranteed if any personally identifiable (PII)

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 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.

6.05 Vulnerable Populations

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

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

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

Section 7: PROTOCOL REVISIONS

7.01 Changes to an Expedited Application may be submitted to the IRB Administrator or DRB

under the Expedited Review procedure (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:
(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.

7.04 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.

7.05 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.

7.06 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.
(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.

8.02 NIH-supported investigators are required to provide details of the proposed involvement of humans in the research, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any subpopulation. If ethnic, racial, and gender estimates and continuing review numbers are not included in the background data for a protocol, the investigators must provide a clear rationale for exclusion of this information.

8.03 The University of Scranton IRB as IRB of Record
In the instance where a University of Scranton faculty, staff, or student is primary investigator on a research project conducted conjointly with another institution, or where a co-investigator is from another institution with an approved IRB, the applicant may apply for the University to serve as the approving IRB/IRB of record (single IRB). This is the case for either Expedited or Full review applications. A signed copy of this agreement must be included with the IRB protocol in IRBNet. Researchers conducting research under the auspices of certain federal grants may be required to determine and utilize an institution of record for IRB purposes.

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

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

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

Section 9: INFORMED CONSENT

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 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. The IRB may identify instances when other additional protections may be warranted as a condition of IRB approval.

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/Cognitively Impaired - 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 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, and at an appropriate reading level, 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: 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 to the IRB by members of 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.

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) *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.

Application Review:

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

The University of Scranton IRB reserves the right to grant or deny permission to external investigators to recruit subjects on campus. The decision of the IRB to deny permission for participant recruitment by an external investigator may not be reversed by any other University of Scranton authority. IRB approval for the research activity does not constitute approval to utilize University programs, facilities, or services/practices for research purposes. Researchers should consult with relevant University administrators to secure any other approvals or permissions required.

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.

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

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

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

10.03 Submission to the DRB

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

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

10.05 Prior Research

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

Section 11. CONVENED MEETINGS AND REVIEW PROCEDURES

11.01. Convened Meeting

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

11.02. Minutes

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

11.03 Quorum

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

11.04. Review Procedures

Applications requiring Full Review will be considered at a convened meeting of the IRB. Only applications received by the due date listed on the IRB web site will be included in the subsequent IRB meeting for review. Applications will be distributed by the IRB Administrator to all IRB members before the meeting date to permit adequate time for review and consideration.

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

explanation of risks and protection for human subjects.

The IRB will decide by a majority of the members present (Section 11.03):
(a) to approve the proposal,
(b) to approve the proposal with restrictions or conditions,
(c) to 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. Records are retained for at least three years after completion of the research, and in accordance with 45 CFR 46:115 (a - b).

These records contain the research proposal reviewed, scientific evaluations, approved sample consent documents, progress reports, 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 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 Research, and other University personnel, including 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 the Associate Provost/Director of Research.

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 under Expedited and Full Review Protocols, if there is no inclusion of vulnerable populations. Exempt research is reviewed only by the IRB.
(b) **Ethical Standards:** A statement of the ethical standards with which such activities must comply.
(c) **Membership:** A DRB should consist of a minimum of 4 members. A member of the DRB who is the investigator or faculty mentor or sponsor on a project under review cannot be present at the deliberations, counted in the quorum, or vote. Members must meet and maintain current University IRB education requirements.
(d) **Quorum:** Attendance by a majority, but not less than 3, members eligible to vote constitutes a quorum.
(e) **Meetings:** Review of Full Review applications must take place in a convened meeting of the

DRB with a quorum present. It is recommended that the DRB meet as needed, at least within 1 week of receipt of an application for review.
The DRB may designate one or two individual reviewers for Expedited protocols. A designated reviewer may not review his/her own protocol.
(f) **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.
(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 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. The IRB administrator will record the DRB action within IRBNet. However, letters of approval will be issued by the DRB Committee Chair.

For more information about IRB regulations, activities, and this Policy, contact the IRB Administrator.

Appendix A: Exempt Research Categories

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.

Appendix B: Expedited Research Categories

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 increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
    Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
    Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic

resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3).

End.