Slippery Rock University

Institutional Review Board

Handbook for Investigators

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The format of this handbook is based on Wayne State University's Handbook for Investigators

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CHAPTER 1:

BACKGROUND ON THE IRB

This Handbook for Investigators is designed to provide direction and assistance to faculty, staff and students or other personnel who are conducting human participant research at Slippery Rock University (SRU). The content of the Handbook is based on policies and procedures of the SRU Institutional Review Board (IRB). It is essential that investigators and key personnel familiarize themselves with applicable policies, procedures and Federal regulations before submitting documents to the IRB and before beginning their proposed research. In addition to referring to this Handbook, investigators have access to educational and training resources through the IRB Office and website, as well as through on-line training modules from the Collaborative Institutional Training Initiative (CITI) at https://about.citiprogram.org/en/homepage/.

Most of the links referenced in this document are located on the IRB's website at http://www.sru.edu/offices/institutional-review-board where additional information is available. Contact the IRB Office for further assistance at 724-738-4846.

Location and Contact Information

The SRU IRB Office is located in room 008, Old Main. The address and contact information are as follows:

Address: Institutional Review Board
Slippery Rock University
104 Maltby, Suite 008
Slippery Rock, PA 16057
Phone: 724-738-4846
Web Address: http://www.sru.edu/offices/institutional-review-board

Introduction

The IRB is responsible for the protection of human participants in research conducted by faculty, staff and students at SRU. All members of the SRU community who engage in activities that are classified as research involving human participants must submit their research proposals to the IRB for review and approval prior to the beginning of the research. The IRB assures compliance with Federal and state regulations and SRU policies.

The primary goal of the IRB is the protection of human research participants. The Board does not endorse the quality of the research and approval does not absolve researchers from the responsibility to monitor and maintain the project within their professional guidelines. It is the function of this IRB to assess the balance of risks and benefits to human participants that may be expected from the proposed research. The ultimate responsibility for the ethical conduct of research remains with the researchers.

Authority

SRU's IRB must review and approve all research involving human participants before research commences.

SRU has established a **Federal Wide Assurance (FWA, 00006788)** through the Office for Human Research Protections (OHRP) to conduct human participant research. SRU's FWA covers all human participant research conducted at SRU. This FWA covers faculty, staff, students, trainees and anyone conducting such research under the auspices of SRU.

All research that meets the Federal definitions of human participant research is subject to the policies and procedures of the SRU IRB and review by the SRU IRB.

The IRB is a standing committee, constituted according to Federal regulations. The IRB is responsible for ensuring that the rights and welfare of human research participants are protected. The IRB has the authority to approve, require modifications or table human research activities at SRU; to suspend or terminate approval of research not being conducted in accordance with pertinent laws, IRB requirements or University policy; and, to observe, or have a third party observe, the consent process and other aspects of the conduct of the research.

The IRB has the authority to determine that a project submitted by an investigator does not meet the regulatory definition of human participant research.

The IRB has the authority to require Progress Reports from investigators and to conduct continuing reviews of approved human participant research studies at intervals appropriate to the degree of risk.

The IRB has the authority to approve, prospectively, all modifications to previously approved research protocols and/or informed consent documents; the only exception being a protocol deviation that may be necessary to eliminate an apparent immediate hazard to a given research participant.

The IRB has the authority to suspend or terminate the approval of human participant research activities that are not being conducted in accordance with the IRB's requirements or have been associated with unexpected serious harm to participants.

The IRB has the authority to place restrictions on human participant research activities.

The IRB has the authority to verify that ongoing research studies comply with regulations and may suspend or terminate approval for ongoing studies under its jurisdiction. Furthermore, the

IRB has the authority to determine whether or not any activity is covered by these policies and procedures and whether it requires review by the IRB.

The IRB has the authority to restrict research activity of individuals who have not been compliant with IRB regulations or Federal guidelines for conducting research.

The Ethical Basis for Human Subjects Research

SRU is committed to ensuring that all human participant research in which it is engaged is conducted in accordance with the ethical principles stated in the Belmont Report. The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, provides the ethical foundation for the Federal regulations for the protection of human research participants. The Belmont Report provides three guiding ethical principles – respect for persons, beneficence and justice (https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html).

Respect for persons: Incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy (e.g. minors, prisoners) are entitled to protection. Application of this principle requires that human participants are enrolled into research studies only under the conditions of effective informed consent. This involves a process in which participation in the research is acknowledged by the research participant (or by a legally authorized representative) as a voluntary act free from coercion or undue influence from the investigator or members of the research team. Exceptions to this informed consent must be outlined in the Federal regulations and subsequently approved by the SRU IRB.

Beneficence: Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. The research study must be designed and implemented to maximize possible benefits and minimize possible harms. Application of this principle involves a risk/benefit analysis in which the risks to participants must be reasonable compared to the potential for benefit either to participants directly or to society. Risk evaluation must include the consideration of both the probability and magnitude of harm, including psychological, physical, legal, social and economic harm.

Justice: Requires fair procedures and outcomes in the selection of research subjects. The possibility for benefits and the potential burdens of the research should be equitably

distributed among the potential research participants. Application of this principle requires close scrutiny of the enrollment process to ensure that particular classes (welfare patients, racial and ethnic minorities, or persons confined to institutions) are not selected for their compromised position or convenience to the research investigator.

The IRB adheres to the following regulations and policies for human participant research activities that fall under its authority:

1. The Federal Policy regulations for the protection of human research participants (45 CFR 46; "Common Rule")
2. The provisions of the Federal Wide Assurance Agreements (FWA)
3. Policies and procedures established by the SRU IRB
4. Where applicable, other Federal, state and local regulations regarding research involving human participants
5. When making determinations concerning the rights and welfare of human participants in research studies, the IRB will also refer to current versions of the OHRP's *Protecting Human Research Subjects; Institutional Review Board Guidebook;* the *FDA's Information sheets for IRBs and Clinical Investigators*; and to other interpretative directives, information documents and guidance materials disseminated by OHRP, DHHS, the National Institutes of Health (NIH), the FDA and other Federal agencies (e.g., Office of Civil Rights).

Additional Readings

- The Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
- The Nuremberg Code: https://history.nih.gov/research/downloads/nuremberg.pdf
- Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- The Federal Policy and 45 CFR 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
- Common Rule: https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-resources/index.html

CHAPTER 2:

INFORMATION ABOUT SRU'S IRB

Composition of the IRB

SRU's IRB includes members as required by Federal regulations:

- At least five members (both men and women), with varying backgrounds, to promote complete and adequate review of research activities commonly conducted at SRU;
- At least one member whose primary concerns are in the scientific areas and at least one member whose primary concerns are in non-scientific areas;
- At least one member who is not otherwise affiliated with SRU and who is not part of the immediate family of a person who is affiliated with SRU;
- The IRB membership reflects "diversity of its members, including race, gender and cultural backgrounds and sensitivity to such issues as community attitudes," which is meant to accomplish the same thing;
- The IRB members are appointed by the Provost and Vice President for Academic and Student Affairs for a renewable term of one year. The IRB Chairperson provides recommendation to the Provost; and,
- The IRB Chairperson is a faculty member nominated by the Provost for a renewable term of one year.

Undue Influence

To prevent undue influence, the IRB acts independently of university officials or anyone who is not an official member of the IRB. No individual shall attempt to influence the IRB inappropriately on any matter before the IRB, or within the IRB's jurisdiction.

Meeting Schedules and Deadlines

Full Board protocols must be submitted to the IRB Office no later than one week prior to the meeting date. Meeting schedules and deadlines can be found at: http://www.sru.edu/offices/institutional-review-board/how-to-apply-to-the-irb.

CHAPTER 3:

WHAT IS HUMAN PARTICIPANTS RESEARCH?

All research involving human participants conducted by any faculty, staff or student at SRU must be submitted to the SRU IRB for review and approval prior to beginning any research activities. In order for you to determine if your work involves research, and more specifically, research involving human participants, please refer to the following step-by-step guide that is provide by the Office of Human Research Protections at the U.S. Department of Health and Human Services: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html.

Is this Quality Improvement or Research?

Investigators often plan to conduct quality improvement or process improvement projects in their institutions. Because there are questions that usually arise about whether or not these projects fit the definition of human participants research, it is strongly suggested that you contact the IRB Office prior to beginning any project involving a quality improvement or process improvement study for additional guidance on whether or not the study should be submitted for IRB review.

CHAPTER 4:

INVESTIGATORS QUALIFICATIONS AND RESPONSIBILITIES

The Principal Investigator (PI) who accepts responsibility for conducting research with human participants must have the experience, expertise, professional qualifications and the research facilities and resources necessary to ensure that the rights and welfare of the human participants are protected. PI's must consider the design of the research project as it pertains to minimizing risks to participants. SRU's IRB recognizes **only *one* individual** as the PI on any given protocol. All other investigators on the protocol are considered "co-investigators" or "research assistants." All communication from the IRB Office will be with the project's PI. All forms must be signed by the PI. Students are not permitted to be the PI's, but are required to have a SRU faculty or staff member supervise the research. Student researchers should be listed as co-investigators or research assistants.

It is the responsibility of the PI to complete and submit the application materials to the IRB Office in order to maintain the project's timeline. PI's are required to inform the IRB Office of any changes to approved research and any adverse events or unanticipated problems.

It is the responsibility of the PI to ensure that the design and conduct of research involving human participants complies with institutional policies, state laws and Federal regulations.

The Role of the Principal Investigator

The PI must be a member of the university faculty, administration or staff. A student may not be the PI.

It is the responsibility of the PI to:

1. Develop a research plan that is:
    a. Scientifically valid;
    b. Consistent with sound research design; and
    c. Minimizes risk to human participants.
2. Obtain IRB approval prior to initiation of any research involving human participants prior to conducting any investigation.
3. Ensure that all facilities and resources necessary to protect participants are present before conducting the research study.
4. Maintain oversight of the research protocols and research staff. The PI's signature on forms submitted to the IRB certifies that they have reviewed all of the submitted information and affirms that it is accurate to the best of their knowledge.
5. Adhere to any educational requirements set forth by the IRB. All investigators must complete the CITI online training course specific to SRU prior to conducting research at SRU.
6. Manage the development of the project in accordance with accepted scientific standards.
7. Ensure the integrity and safeguarding of all collected data.

8. Ensure project review of all human participant research by the university IRB, prior to the initiation of the study.
9. Ensure that participants in research be apprised of all risks and benefits so that their consent to participate is based on pertinent information.
10. Assure project adherence to approved research protocols and policies.
11. Notify the IRB of any changes made to the protocol and or participant consent process/document.
12. Report any potential changes in the risk/benefit ratio that are manifested/discovered during the research process.
13. Meet the continuing review requirements established by the IRB.
14. Report all serious and adverse events encountered during the investigation to the IRB.
15. Immediately notify the IRB if a protocol is completed or withdrawn.
16. Provide a complete final report when the study is concluded.
17. Remain aware of, and comply with, the policies of the IRB at SRU.

IRB policies are subject to change. It is the responsibility of all researchers to be familiar with the current IRB policies.

Laws, Regulations, Ethical Standards and Internal Policies

1. Conduct the study in accordance with: (a) The protocols as approved by the SRU IRB, (b) Ethical standards (e.g., the Belmont Report, the Declaration of Helsinki), (c) Applicable Federal regulations (45 CFR 46), (d) Applicable state and local laws, (e) All SRU internal IRB policies, standard operating procedures and any conditions of approval imposed by the IRB.

Conduct of the Study

1. Conduct the study according to the signed protocol, the investigational plan and all pertinent regulations.
2. Obtain legally effective informed consent from participants or their legally authorized representative.
3. Ensure that the currently approved version of the consent form is being used for all participants, and that it is appropriately documented.
4. Recruit participants in a fair and equitable manner, weighing the potential risks and vulnerability of the participants with the potential benefits of the research.
5. Monitor the safety and well-being of all research participants and remain current on literature related to the research study.
6. Submit a Final Report Form at completion of the study (http://www.sru.edu/offices/institutional-review-board/how-to-apply-to-the-irb).

Reporting Responsibilities

1. Submit all protocol modifications or changes to the protocol to the IRB. No changes can be initiated prior to obtaining IRB approval **unless** immediate changes are required in order to prevent harm to the participants or others.

2. Submit a Change to Protocol form to the IRB approval prior to implementing any changes to the protocol.
3. Promptly report to the IRB any unanticipated events or adverse reactions involving risks to participants or others in accordance with IRB policies and procedures.
4. Report progress of the research at intervals as determined by the IRB.

Role of Co-Investigators

Co-Investigators are key personnel who have responsibilities similar to that of a PI on research projects. While the PI has ultimate responsibility for the conduct of a research project, the co-investigator(s) is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of research.

Co-investigators are expected to report to the PI any deviation from the approved protocol, increased participant risk or serious or adverse effects to research participants. Students and individuals not affiliated with the university may be co-investigators.

- All co-investigators are required to be listed on the IRB Application Form and also to sign the form as the co-investigator(s).
- Co-Investigators are required to complete the CITI Online Training Program.

Role of Research Assistants

Research assistants are individuals who are involved on the project, but are not crucial to conducting the research. For example, they can assist in collection and input of data into a database or serve as an aide to investigators.

- Research Assistants cannot consent or enroll participants in research projects that are more than minimal risk.
- Research Assistants are required to be listed on the IRB Application Form and also to sign the form as the research assistant(s).
- Research Assistants are required to complete the CITI Online Training Program.

Mandatory On-Line Training for Investigators and Research Staff

Federal regulations require that all investigators, including co-investigators and research assistants, must take the required on-line training in human research protections prior to being approved to begin any research activities. This training can be accessed at https://about.citiprogram.org/en/homepage/.

Instructions on Choosing a Course:

- **Social & Behavioral Research Course –** the majority of research at SRU falls under this module. The Social and Behavioral Modules is for research such as surveys, observation of human behavior, etc. At the end of the required modules, you must complete three out of eight elective modules.

- **Human Subjects Biomedical Course –** for researchers doing more invasive research such as those in the Exercise and Rehabilitative Sciences Department and the School of Physical Therapy, the Biomedical Course may be more appropriate. At the end of the required modules, you must complete three out of the six elective modules.
- **Students Conducting No More than Minimal Risk Research –** students conducting Action Research projects should complete this course. At the end of the required modules, you must complete three out of the six elective modules.
- **Responsible Conduct of Research (RCR) Course –** for researchers with NIH or NSF funding, it is mandatory that you complete the RCR Course.
- **Conflict of Interest (COI) Course –** for researchers with NIH funding, it is mandatory that you complete the COI Course.

CHAPTER 5:

IRB SUBMISSION & APPROVAL PROCESS

A new protocol must be submitted to the IRB Office. Depending on the level of risk to the participants and other considerations provided in the Federal regulations, initial protocol submissions will require one of the following types of reviews: **Full Board, Expedited, Limited Review or Exempt**.

Forms to Use for Initial Submission

All levels of review are submitted on the same application form, which can be found on the IRB's website under forms (http://www.sru.edu/offices/institutional-review-board/how-to-apply-to-the-irb).

Follow these steps to apply to the IRB:

1. Determine if the project meets the definition of human subject research.
2. Read through the Responsibilities of the PI.
3. Complete the required training course on the protection of human participants in research. The IRB subscribes to the CITI Online Training Program to comply with this regulation.
4. Determine the level of review (the IRB has the authority to review the protocol at the level they deem appropriate).
5. Complete the IRB Application Form found on the IRB website. Incomplete applications will be sent back to the PI without review.
6. Complete any necessary consent forms and/or appendices to your application.
7. Submit your IRB Application Form and any other necessary appendices and documentation of CITI training to the IRB Office, 008 Old Main.
8. Once a complete application is received, a protocol-specific number will be assigned by the IRB Office.
9. All communications to or from the IRB Office regarding the specific protocol must include the assigned protocol number.

You must receive approval from the IRB before conducting your research. **DO NOT** begin your study until approval has been obtained. Doing so is a violation of Federal regulations.

A. Exemption, Limited Review, Expedited and Full Board Categories

Exemption

Categories of human participants research that meet the regulatory criteria for exemption from IRB review can be found at http://www.sru.edu/offices/institutional-review-board/how-to-apply-to-the-irb under the levels of review tab. The investigator cannot decide whether a protocol is exempt from IRB review: the IRB Chairperson or designee makes the determination of exemption based on regulatory and institutional criteria. The proposed study cannot be initiated

until the investigator receives formal concurrence from the IRB. It should be noted that the IRB may determine that the project needs to be reviewed as either an expedited or full board submission.

Limited Review

The new "limited IRB review" is intended to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens. Limited IRB review involves making and documenting the determination that adequate provisions are in place for protecting privacy and maintaining confidentiality.

IRB considerations for privacy and confidentiality safeguards:

- Extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- Use of the information;
- Extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- Likely retention period or life of the information;
- Security controls that are in place to protect confidentiality and integrity of the information; and,
- Potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

Expedited Review

The categories of research that may be reviewed through an expedited review procedure include:

1. Research activities that present no more than minimal risks to human participants, **and**
2. Research activities that involve only procedures listed in one or more of the specific categories listed in the regulations.

The list of expedited categories is found at http://www.sru.edu/offices/institutional-review-board/how-to-apply-to-the-irb under the levels of review tab. It should be noted that the IRB may determine that the protocol should receive a limited IRB review or a full board review.

Full Board Review

Review of a research protocol by a convened meeting of an IRB is required when a study is more than minimal risk to the participants, involves the enrollment of vulnerable subjects requiring special protections, or for a variety of other reasons.

B. Risk Assessment

Prior to submission of any protocol for IRB review, the PI needs to assess the actual and potential risks to participants in the research. To assist in this, the following are definitions and descriptors of minimal risk and risks that should be considered in a research study.

- **Minimal Risk** – defined in 45 CFR 46.102(i) is 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.

- **Risk –** the probability of harm, injury or loss (e.g. physical, psychological, social or economic) occuring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks can be classified in one of the following categories.

    - **Physical –** risks that may arise from the use of test agents such as chemicals or therapeutic drugs, devices, physical agents (including radiation) and clinical procedures.
    - **Psychological –** risks that may arise from the utilization of behavioral questionnaires or surveys, interview interactions, the collections of sensitive data or the emotional stress of study participation.
    - **Social –** risks that may lead to legal action against the participant such as investigation or arrest.
    - **Economic –** risks that may affect an individual's financial status, employment status or employability or insurability.

C. Informed Consent

Informed consent is one of the primary ethical requirements when conducting research with human participants; it reflects the basic principle of respect for persons. Informed consent seeks to ensure that prospective participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The elements of informed consent are mandated in 45 CFR 46.116 and must include the following:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the participant;
3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any medical treatments or compensation are available if injury occurs and, if so, what they consist of or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and

8. A statement that participation is voluntary and refusal to participate will not involve a penalty or loss of benefits to which the participant is otherwise entitled, that the participant may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled and that the participant will receive a copy of the signed informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each participant:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if they participant is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the individual's participation may be terminated by the investigator without regard to the participant's consent;
3. Any additional costs to the individual that may result from participation in the research;
4. The consequences of a participant's decision to withdraw from the research and procedures for early and orderly termination of the participant's participation;
5. A statement that significant new findings developed during the course of the research which may be related to the participant's willingness to continue participation will be provided to the participant; and
6. The approximate number of participants involved in the study.

Potential research participants must be provided with the information that a "reasonable person" would want to have. The responsibility remains for the investigator to provide more information when requested by participants, allow sufficient time and opportunity to discuss the research, and answer questions to improve a participant's understanding.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

It is **required** that all consent forms be developed using the SRU's IRB informed consent/assent/information and parent/guardian templates and printed on SRU department letterhead.

Once the informed consent/assent and parent/guardian documents have been approved by the IRB, all forms must have the IRB stamp of approval to be considered a valid informed consent documents. An IRB approved informed consent/assent/ and/or parent/guardian document will contain the approval and expiration dates established by the IRB. The informed consent documents expire when the protocol approval period expires.

Informed Consent Templates and All Forms:
http://www.sru.edu/offices/institutional-review-board/how-to-apply-to-the-irb

Informed Consent Options

Informed consent or waiver of informed consent must be obtained for every participant in a research study before that participant begins any aspect of participation in the research. Informed consent does not stop at the simple signing of a document, but continues throughout the study.

The documents for use in the informed consent process may include one or more of the following:

1. Written Informed Consent
2. Parental/Guardian Informed Consent
3. Assent Form
4. Informational Letter
5. Photo/Video/Audio Release Form
6. Informed Consent Checklist

Written Informed Consent

Generally, the IRB requires informed consent to be documented by a written consent form approved by the IRB. The written consent form should be written at a 6^{th} – 8^{th} grade reading level in a language that is understandable by the research participant and must be reviewed with the research participant (or the research participant's representatives) as part of the consent process.

Parental/Guardian Informed Consent

This consent is required to provide the parents/guardians of potential subjects the information necessary for them to make a decision about their child participating in research. Information in the parent/guardian consent document must be organized to facilitate comprehension and should be written in plain language, generally at the 8^{th} grade reading level. This consent must be reviewed with the parent/guardian as part of the consent process.

Assent Form

Permission from parents is obtained prior to approaching a child participant. In most cases, once parental permission has been obtained, the assent of the child participant is required. However, if the parent(s) gives permission for the child to be in the study and the child doesn't assent, the child cannot be enrolled in the study.

Informational Letter

An informational letter is to provide potential research participants or their legally authorized representatives with the information necessary for them to make a decision about participating in research. Information in this document must be organized to facilitate comprehension and written in plain language, generally at the 8^{th} grade reading level.

The informational letter is generally used in online surveys/questionnaires or anonymous surveys/questionnaires, since a signature from the research participant is not required.

Photo/Video/Audio Release Form

You may also need to obtain consent for specific activities when those activities are optional. Whether an activity is required or optional must be clearly described in the main body of the consent form. Some common optional research activities are photographs/audiotaping/videotaping. When using these methods, the release form must be attached at the end of the consent form for to gain permission from the research participants (see example of the consent with the release form on the IRB website).

Informed Consent Checklist

When using any of the above-mentioned consent forms, an informed consent checklist must be completed and submitted with your protocol application.

All appendices must be submitted with the initial application form. (i.e., consent forms, recruitment scripts and flyers, surveys, etc.). If the appropriate appendices are not included with the submission, the protocol will be sent back to the PI without review.

D. Continuing Review

Revisions to the Common Rule effective January 21, 2019 eliminates the requirement for continuing review of certain protocols based on several criteria. All protocols reviewed and approved prior to the implementation date remain under the pre-2018 regulations. These protocols retain their existing level of review and are subject to all other IRB requirements, including continuing review, but will be transitioned under the new Common Rule at the time of continuing review.

- **Full Board** –Progress Report forms will be required from the PI for annual review until the protocol is no longer enrolling research participants. The IRB will determine the need for continuing review at the time of the next scheduled continuing review submission.
- **Expedited** –Progress Report forms will be required from the PI for annual review until the protocol is no longer enrolling research participants. The IRB will determine the need for continuing review at the time of the next scheduled continuing review submission.
- **Exempt** – continuing review no longer required. The IRB Office will automatically close the protocol one year from the approval date unless the PI requests, in writing, a longer time period.

The IRB has the authority to request continuing review on any protocol for reasons such as, but not limited to, the following:

- The study involves additional regulatory oversight.
- The research will be conducted internationally or at non-SRU sites.
- A change to the protocol or an incident report reveals new findings that require additional oversight.

- The investigator(s) has had a previous serious non-compliance or a pattern of non-serious non-compliance.
- The study is regulated by a sponsor that requires continuing review.

E. Change to an Approved Protocol

Any changes to a previously approved research protocol such as changes to the inclusion/exclusion criteria, study population, study procedures, consent process, change of investigators, etc., must be submitted to the IRB Office using the Change to Protocol Form found on the IRB's website (http://www.sru.edu/offices/institutional-review-board/how-to-apply-to-the-irb). Changes cannot be implemented until the IRB reviews and approves the change(s).

F. Closing a Protocol

To close an IRB Protocol, you must submit a Final Report, prior to the expiration date, to the IRB Office for review and approval from the IRB Chair. Once a protocol is closed, no participants may be enrolled and no data may be collected or analyzed. If the Progress or Final report is not received prior to the expiration date, the protocol will be closed administratively. This may result in suspension of your research privileges. You are still required to complete and submit the Final Report within sixty (60) days of the expiration date. If the PI desires to continue the research once the protocol has been closed, a new protocol must be submitted to the IRB Office for review and approval.

Questions

If you have any questions, please contact the IRB Office by phone at (724)738-4846 or via email at irb@sru.edu.

CHAPTER 6

DEFINITIONS AND TERMS

Anonymity
Refers to the best practices of data collection implemented by the researcher in order to secure the privacy of the research participant, by eliminating the "link" between the research participant's study data and personal identifiable information. Using these practices will not allow the researcher or any other individual to identify participants by the data collected. This approach is common in research involving one-time data collection, such as that which occurs when using survey methods, taking only one set of physical or psychological measurements, or having participant's complete questionnaires without asking for their names.

Assent
A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (*Protection of Human Subjects, 45 CFR Part 46:* § 46.402(b), 2009). This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. Children are persons who have not attained the legal age of consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted.

Child
A person who has not attained the legal age of consent to treatments or procedures involved in the research, under the applicable law of this jurisdiction in which the research will be conducted (*Protection of Human Subjects, 45 CFR Part 46; §46.402(a), 2009*).

Benign Behavioral Intervention
Behavioral (not biomedical) interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met. Only for research activities that pose little risk to subjects. Described as brief in duration, painless, harmless, not physically invasive, not likely to have a significant adverse lasting affect on the subjects and the investigator has no reason to think the subjects will find the intervention offensive or embarrassing.

Coercion
To compel or force someone to participate in or perform an action that would not ordinarily be done of the individual's own free choice.

Deception
Authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he/she will be unaware of or misled regarding the nature or purposes of the research.

Generalizable Knowledge

Results are intended/expected to be applied to a larger population beyond the site of data collection or the population studied.

Human Subject/Participant
A living individual about whom an investigator (whether professional or student) conducting research:

a. Obtains information or biospecimens through intervention or interaction with the individual and uses or analyzes the information or biospecimens; or
b. Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

Intervention included both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject(s) environment that are performed for research purposes.

Interaction including communication or interpersonal contact between investigator and subject.

Identifiable private information is private information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Intervention
Includes physical procedures and manipulations of the participant(s) environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and participant.

IRB Approval
The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institution and federal requirements.

Legally Authorized Representative
An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing the issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Limited IRB Review
A condition for exemption of the research activities under:

a. Identifiable and sensitive educational tests, survey procedures, interview procedures, or observation of public behavior (46.104 [d][2][iii]);
b. Identifiable and sensitive benign behavioral interventions (46.104 [d][3][i][c]); and
c. Secondary research use (46.104 [d][8]).

Minimal Risk

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 test.

Private Information
Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual, which the individual can reasonably expect will not be made public (for example, a medical record or academic record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research
A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs my include research activities. For purposes of this part, the following activities are deemed not to be research:

a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Writing or In Writing
Refers to writing on a tangible medium (e.g., paper) or in an electronic format