PROCEDURE TITLE:	RESEARCH INVOLVING HUMAN SUBJECTS
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1.0 PURPOSE

1.1 The purpose of these procedures is to support the implementation of SSU Policy 5.25 Rev. Research Involving Human Subjects and the conduct of the University's Institutional Review Board (IRB). These procedures comply with, reference, and incorporate federal law including Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects (45 CFR 46) and all its sub-parts and sections.

1.2 Shawnee State University may enter into an agreement with other institutions that do not have an IRB to review proposals for research involving human subjects. All applicable policies and procedures established by Shawnee State University will be followed by all investigators as a part of this agreement. See Section 9.5, External Principal Investigators, for more information.

1.3 Agreements will be reviewed by the IRB Chair and the Associate Provost or designee (referred as Associate Provost thereafter) prior to final approval signature of the Provost.

1.4 Academic units may develop their own procedures related to the development and submission of research proposals that would be in addition to the procedures herein. In situations where conflicts between unit level and university level procedures exist, university level procedures take precedence.

2.0 DEFINITIONS RELATED TO RESEARCH AND THE IRB PROCESS

The University recognizes and utilizes the definitions of federal regulations related to Human Subjects research, specifically 45 CFR 46 in all application and review processes.

3.0 APPOINTMENT AND TERMINATION OF IRB MEMBERS

3.1 Appointments

3.1.1 IRB appointments will be made by the Provost in consultation with the University Faculty Senate, the Associate Provost, and the Chair of the IRB. As necessary, the Provost will seek nominations for IRB membership. Self-nominations may be accepted. Federal requirements for membership will be used to determine eligibility for the Provost's appointment of any IRB member with respect to diversity of representation and science and non-science backgrounds of members.

3.1.2 The appointment of External IRB members will be made by the Provost in consultation with the IRB Chair and the Associate Provost.

3.1.3 Federal requirements for membership will be used to determine eligibility for UFS's recommendation and Provost's appointment of the external member.

3.1.4 When appointing an external IRB member, Ohio's Ethics Commission definition of "family" will be used and includes grandparents, parents, spouse, children (dependent or not), grandchildren, brothers and sisters, or any person related by blood or marriage and residing in the same household.

3.1.5 The term for each member will be three years and will commence at the beginning of a Fall Semester and end at the conclusion of the summer term of the final year of service. Appointments will be proportionately staggered. Members may serve more than one term.

3.2 Termination

The Provost may terminate the service of any IRB member when the member fails to meet the performance expectations as stated in sections 3.4 and 3.5 or other federal or University policy related to human subjects research.

3.3 IRB Chair and Chair-Elect

3.3.1 The IRB Chair is a faculty member of the IRB and appointed by the Provost in consultation with the Associate Provost. The IRB Chair will have at least one year of service on an IRB prior to being appointed to this position. This service may be at another institution's IRB. If no experienced faculty are willing to serve in the Chair position, or no faculty meet the qualifications for the position, the Provost may appoint a Chair from all willing members or interested, eligible, University personnel.

3.3.2 The Provost will provide the Chair of the IRB with sufficient time, support, and/or compensation to execute the duties of the position.

3.3.3 The IRB Chair will report directly to the Associate Provost in all matters related to the IRB. The Office of the Provost will provide administrative and technical support for the functions of the IRB Chair.

3.3.4 The IRB Chair will call meetings of the IRB, plan the agenda for the meetings, determine or approve the appropriate review status of each proposal submitted (exempt, expedited, or full), communicate to investigators the results of all reviews or requests for additional information, and request annual or project completion updates, and other duties as noted in these procedures or required by University policy.

3.3.5 The IRB Chair-elect is a faculty member of the IRB and appointed by the

Provost in consultation with the Associate Provost.

3.3.6 The IRB Chair-elect will assist the Chair in the execution of the duties of the IRB. The Chair-elect will serve as Chair in the absence of the Chair at regular meetings, in cases of conflict of interest research proposals, and any other situation as necessary. The Chair-elect will assume the position of IRB Chair when the Chair vacates the position and/or upon appointment as such by the Provost.

3.4 IRB University Members

3.4.1 All university employees holding full-service appointments are eligible to serve as IRB members provided they meet federal guidelines and university requirements for this service. Federal guidelines defining membership requirement are located in 45 CFR §46.107 IRB membership.

3.4.2 All university members must complete the human subjects research training as required for membership and other trainings offered by the University to ensure currency of information related to the responsibilities of IRB members. Each IRB member will submit a copy of the certificate of human subjects research training to the Associate Provost upon initial appointment to the IRB. Current human subjects research training or approved continuing education will be documented every three years or at the beginning of a new term of service, whichever is most recent. Approval of human subjects research training and/or continuing education will be the responsibility of the IRB Chair. Evidence of completion will be stored with IRB records.

3.4.3 IRB members will attend every regular meeting as scheduled, unless excused; read all proposals as provided; solicit information; and offer regular, substantive, and appropriate comments for each proposal prior to the meeting at which the proposal will be reviewed. Each member will be expected to serve as an expedited review proposal reader at least once per year. Additional readings may be necessary depending on submission load.

3.5 IRB External Member

3.5.1 The IRB external member is a person not otherwise affiliated with Shawnee State University and not part of the immediate family of a person who is affiliated with the University. See Section 3.1.4 for the definition of "family."

3.5.2 All external members must complete the human subjects research training offered by the University and ensure currency of this training by submitting a certificate of training to the Associate Provost. Current human subjects research training or approved continuing education will be documented every three years or at the beginning of a new term of service, whichever is most recent. Approval of continuing education will be the responsibility of the IRB Chair.

3.5.3 External IRB members will attend every regular meeting as scheduled, unless excused; read all proposals as provided; solicit information; and provide regular, substantive, and appropriate comments for each proposal prior to the meeting at which the proposal will be reviewed. Each IRB member will be expected to serve as an expedited review proposal reader at least once per year. Additional readings may be necessary depending on submission load.

4.0 ADMINISTRATION OF THE INSTITUTIONAL REVIEW BOARD

4.1 The Associate Provost has administrative oversight of the IRB's operations and provides administrative and technical support to the IRB process at the University. The Associate Provost serves as the first administrative level of appeal.

4.2 The University General Counsel serves in an advisory capacity to the IRB.

4.3 The Provost serves in an advisory capacity to the IRB and as the final level of appeal for any decisions of the IRB.

4.4 The IRB will report, through the Chair, to the Associate Provost.

4.5 The Office of the Provost will provide administrative and technical support for the IRB, including providing for the on-going communication between and among the IRB Chair, the IRB members, Principal Investigators, and others; the regular and ongoing maintenance of the IRB website to ensure accuracy and availability of documents and other IRB resources and information; and the ongoing maintenance of IRB records.

4.6 The Office of the Provost will provide administrative support to the IRB meeting functions including, but not limited to the following:

4.6.1 Preparation and distribution of all materials for the consideration of proposals

4.6.2 Meeting minutes and records of IRB actions

4.6.3 Document storage

4.6.4 Update of all electronic notices on the IRB website

4.6.5 Preparation, distribution, and management of all communications of the IRB Chair and investigators with respect to IRB

4.6.6 Decisions pursuant to 45 CFR 46

4.6.7 Informed consent form storage

4.7 Informed consent forms will be maintained by the IRB, Office of the Provost in secure storage for a period of three years for all approved studies. After the three-year period, the forms will be destroyed unless otherwise directed by the Principal Investigator or necessitated by the nature of the study, or as required by law.

5.0 IRB MEETINGS

5.1 The IRB will hold regular monthly meetings during the academic year and at least one meeting during summer semester to consider all complete proposals submitted according to these procedures.

5.2 The IRB meetings will be scheduled by the IRB Chair. Each meeting will be posted on the IRB website. Each meeting will have an agenda that includes each proposal under consideration and any other business items that may be necessary for the operation of the IRB. IRB meetings may be cancelled due to a lack of business to be conducted.

5.3 Minutes of meetings will include proposal(s) reviewed, all votes taken, and if any proposal is rejected, the reason for rejection.

6.0 STANDARDS FOR IRB REVIEW AND APPROVAL OF PROPOSALS

6.1 The objective of IRB review is to determine whether the research is subject to Policy 5.25REV and these procedures, and, if so, to ensure that the rights and welfare of the subjects are adequately protected and that all activities involving human subjects are in compliance with University policies and federal regulations to assure that:

6.1.1 Selection of research subjects is equitable

6.1.2 Informed consent is obtained and documented where appropriate

6.1.3 Risks to subjects are minimized

6.1.4 Risks are reasonable in relation to anticipated benefits to subjects and others.

6.1.5 Privacy and confidentiality are protected

6.1.6 Data handling and safety monitoring provisions are adequate

6.1.7 Vulnerable subjects are provided special safeguards against undue influence or coercion to participate in the research.

6.2 Approval of research under these policies and procedures is for a one-year period, unless the IRB determines the risk is sufficiently high to require more frequent review.

6.3 An IRB Continuing Project Form must be submitted for review for any research project that lasts for more than one year (See Section 16.0).

6.4 If, after the initiation of research, it appears that an unapproved project should have had prior IRB review, the investigator(s) or anyone with information about the project should contact the IRB Chair to determine ways to maximize human subjects protection for any aspects of the study that are still in process and to maintain confidentiality of existing data. Refer to Policy 5.25REV, U.S. Department of Health and Human Services regulations for the Protection of Human Research Subjects, 45 CFR 46 and each section for definitions of research that requires IRB approval.

7.0 CRITERIA FOR IRB APPROVAL OF RESEARCH (45 CFR 46)

According to federal guidelines the IRB shall determine that all of the following requirements are satisfied:

7.1 Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

7.2 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 should consider 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 should 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.

7.3 Selection of subjects is equitable. In making this assessment the IRB should 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.

7.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR), in accordance with, and to the extent required by 45 CFR 46.116.

7.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

7.6 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7.7 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7.8 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.

8.0 TYPES OF RESEARCH REVIEW AND REVIEW PROCESSES

8.1 The type of review that a research project undergoes is determined by the level of risks to the participants and the types of participants involved in the research. There are three types of reviews for research: exempt, expedited, and full. The investigator must evaluate risk and type of participants to determine which type of review, and, therefore, which application may be appropriate for the project. The "What Type of IRB Review?" flowchart is helpful in determining the type of review required and can be located on IRB website.
https://www.shawnee.edu/sites/default/files/documents/type-of-review.pdf

8.2 Level of Risk

The IRB will evaluate the risk and determine if the risks are reasonable in relationship to the anticipated benefits of the research to the subjects, if any, or the knowledge that may reasonably be expected to result. There are, generally, three levels of risk associated with human subjects research. Brief descriptions of each are below. Investigators should make every effort to minimize the level of risk involved in the research design. Additional information may be found at the website for Policy 5.25, U.S. Department of Health and Human Services regulations for the Protection of Human Research Subjects, 45 CFR 46.

8.2.1 No more-than-Minimal-Risk

No more-than-Minimal-Risk is research in which there is no known physical, emotional, psychological, or economic risk. This research may qualify as exempt if it does not involve a vulnerable population and falls in an exempt category.

8.2.2 Minimal-Risk

Minimal-risk includes research that presents only the kind of risks encountered in daily life by most people (e.g., moderate exercise testing, minor stress from psychological tests, or surveys involving sensitive topics). This research may qualify as expedited if it does not involve a vulnerable population and falls in an expedited category.

8.2.3 Greater-than-Minimal-Risk

Greater-than-minimal-risk research procedures may include risk beyond that ordinarily encountered by subjects (e.g., maximal exercise testing, stressful psychological testing, questions about illegal activities). This type of research requires a full review.

8.3 Description of Participants

8.3.1 Principal Investigators are required to consider the population from which their study's subjects will be drawn. Protection of the subjects must be commensurate with the vulnerability of the population. Vulnerable populations require a higher level of protection, thus a higher level of scrutiny for the research procedures. Research considered to be no more-than- minimal-risk for non-vulnerable adults is considered as minimal-risk for vulnerable populations.

8.3.2 Prisoners, mentally disabled persons, and children are considered vulnerable because their ability to give truly voluntary and informed consent may be limited.

8.3.3 Pregnant women are considered vulnerable in the case of research procedures that pose any hazard to the fetus.

9.0 PRINCIPAL INVESTIGATORS SUBJECT TO IRB REVIEW PROCESS

9.1 Principal Investigators are those individuals engaged in a formal research study. Investigators may include any full or part-time employee or student of the University as well as individuals from outside the University who wish to conduct a research study utilizing University personnel, students, or facilities.

9.2 Principal Investigators shall obtain approval for proposed human subjects research prior to recruiting subjects or collecting data from subjects. This applies to preliminary and pilot studies which are developing or testing instruments and procedures, as well as the full study.

9.3 University Personnel as Principal Investigators

University personnel conducting a research study will follow all federal and University policies and procedures which are appropriate to the nature of the study.

9.4 IRB Chair Serving as Principal Investigator

If the IRB Chair is the Principal Investigator of a study submitted for any review, they will not be involved in the direct review. The Chair-elect will assume the duties of the Chair for that proposal only.

9.5 External Principal Investigators

9.5.1 Individuals from other institutions who wish to conduct research using Shawnee State University students or personnel as subjects must provide proof of IRB approval from their home institution to the IRB Chair. If the IRB Chair is satisfied with the proposal materials and the home institution's IRB approval, they may grant permission for the research to begin. The IRB

Chair may request additional information or require the use of Shawnee State University's IRB procedures.

9.5.2 If the external investigator's institution does not have an IRB, the investigator must submit to the Shawnee State University IRB according to the procedures herein. The decision of the Shawnee State University IRB is final.

9.5.3 Standard appeal procedures are available to external Principal Investigators. Unless a formal agreement between the University and another institution exists, a memorandum of understanding (MOU) will be developed and signed by the institution's chief research officer or Provost/Vice-President for Academic Affairs, as appropriate for that institution.

9.5.4 University personnel may, at their discretion, participate in research studies as representatives of their professional fields or members of their profession when their affiliation with Shawnee State University is not the primary condition of their selection as a study participant. When University affiliation is a condition for selection to be a subject in a study, the IRB Chair should be consulted for a determination as to whether IRB review is necessary.

9.6 Student Investigators

9.6.1 Student research projects designed to add to generalizable knowledge through dissemination of results in publications or presentations beyond the classroom are covered by the policy and procedures on human subjects research. All student research meeting this definition must be supervised by a University faculty member who assumes responsibility for the conduct of the research.

9.6.2 Faculty members who assign or supervise research conducted by students are responsible for ensuring that the proposed research is reviewed and conducted in accordance with University policy and the student is qualified to adequately safeguard the well-being of the subjects.

9.6.3 Class projects designed to provide hands-on experience or research training to students are not treated as research projects in accordance with this policy and do not require formal IRB review. Projects in this category are expected to be confined to the specific class and end at the termination of that class.

9.6.4 If it is anticipated that the research project will be used in other classes, published, or presented beyond the classroom, the project should be submitted to the IRB for review.

9.6.5 Faculty members who assign research learning experiences are responsible for assuring that people used in such projects are treated ethically.

9.6.6 Faculty members must provide information to students on University policies and guidelines on human subjects research and develop class procedures in a manner that protects the privacy, dignity, and welfare of participants. Questions should be referred to the IRB Chair.

10.0 APPLICATION SUBMISSION INFORMATION

10.1 Applications

10.1.1 Principal Investigators who propose to conduct research involving human subjects shall prepare and submit either an Exempt Review Application, Expedited Application, or Full Review Application, as appropriate, to the IRB. Applications must be approved prior to any subject recruitment or contact with subjects. The "What Type of Review?" flowchart is available to help determine the most appropriate application form for the research study as listed on IRB website.
See https://www.shawnee.edu/sites/default/files/documents/type-of-review.pdf. Also, see Section 11.0, Proposal Types, for more information.

10.1.2 Student investigators must have a faculty supervisor who is familiar with the study and the area of investigation. The faculty supervisor must review the research proposal and application materials and sign all applications submitted to the IRB by their supervisee. The supervisor assumes responsibility for the conduct of the research by their supervisee.

10.1.3 Any departmental policies or procedures associated with the development and/or submission of research proposals are outside the purview of these procedures. Once a proposal bears the signature of the faculty supervisor and is submitted to the IRB, departmental support for the project is assumed.

10.1.4 Principal Investigators must complete the required education program on research ethics for human subjects prior to approval of an application. Options for current training are listed on the IRB website. Other options for certification can be considered by IRB Committee. Once the training has been successfully completed, the certificate will be submitted with the application packet. Only applications which include the certificate of training will be considered by the IRB. If a current certificate is on file, investigators will indicate this on the application form as directed and will not need to re-submit the certificate.

10.1.5 The application form and instructions for completing the application may be obtained from the IRB website (Only complete application packets will be accepted. All application packets must be submitted electronically. If the Principal Investigator is unable to submit any portion of the application packet electronically, they will notify the Associate Provost or IRB Chair as soon as possible to determine an appropriate alternative submission process.

10.2 Initial Proposals

10.2.1 All new research projects involving human subjects shall be submitted to the IRB, Office of the Provost, and will be reviewed and approved by the IRB prior to beginning the proposed project. Each submission will use either the Exempt Review Application, the Expedited Application, or the Full Review Application form. See Section 12.0, Review Process for Proposal Types, for additional information related to application submissions.

10.2.2 The Principal Investigator and faculty supervisor, if applicable, will be contacted to submit any requested changes or additional documentation as required by the IRB for a thorough review.

10.2.3 The IRB Chair will communicate approval status and an assigned IRB Research Proposal Number via email once review is completed. Any forms requiring an IRB Research Approval Number (i.e., consent, assent, recruitment materials) will be returned to the Principal Investigator with approval notification. Documentation of approval date, along with all communication during the approval process will be included with IRB record retention.

10.3 Revisions of Approved Proposals

10.3.1 Any changes in an approved proposal, including subject population, study location, procedures, or project personnel must be submitted to and reviewed and approved by the IRB Chair prior to initiating the changes. Investigators shall submit, electronically, a description of the proposed changes, and the revised documentation that incorporates the proposed changes.

10.3.2 The IRB Research Proposal Number must be included in all documentation and communications submitted regarding an approved proposal.

11.0 PROPOSAL TYPES

11.1 Exempt, Expedited, and Full Review Eligibility

Based on the level of risk and type of population included, studies will be eligible for one of three different types of review. Each research proposal will be considered for Exempt, Expedited, or Full Review. See Section 12.0 for more information.

11.2 Exempt Review

Exempt Review is used for studies which meet the exemption categories of 45 CFR 46.104. An exempt application must still be submitted to receive this determination.

11.2.1 All human subjects research, even research believed to be exempt by the Principal Investigator, must be reviewed under the exempt process to assure that it is exempt from further review.

11.2.2 Research activities in which the only involvement of human subjects is in one or more of the categories listed in 45 CFR 46.104(d) may qualify for review under the exempt category.

11.2.3 Research that falls into one of the general categories that is normally exempt may not be exempt if it involves sensitive topics (e.g. recreational drug use, sexual practices, use of alcohol by minors, criminal behavior, etc.) or vulnerable participants (e.g., some groups of children, victims, persons with decreased decision-making capacity).

11.2.4 Exempt applications are reviewed by the IRB Chair or a committee member designated by the Chair. The investigator must not begin contacting research participants or collecting data until written approval is received from the IRB. This usually requires at least five working days for processing after exempt proposals are submitted.

11.2.5 More information on the process for Exempt Review is below (Section 12.1).

11.3 Expedited Review

Expedited Review is used for research presenting minimal risk to non-vulnerable participants or no more-than-minimal risk to vulnerable participants.

11.3.1 Expedited Review does not require a convened meeting of the IRB. Two reviewers, the IRB Chair and one IRB member selected by the Chair, will review the proposal. The IRB Chair will notify the Principal Investigator and faculty supervisor, as applicable, of the results of the review. This may require up to two weeks for review after it is received by the IRB.

11.3.2 Research involving no more-than-minimal risk and in which the involvement of non-vulnerable participants is in one or more of the categories as listed in the Federal Register may be reviewed using the Expedited Review procedures. See 45 CFR § 46.110, Expedited review procedures for certain kinds of research involving no more-than-minimal risk and for minor changes in approved research.

11.3.3 Information on the review process for Expedited proposals is below (Section 12.2).

11.4 Full Review

Any research that does not meet the qualifications listed under exempt or expedited review will be reviewed by the IRB at a regular meeting using the Full Review

process. Information on the review process for proposals requiring a Full Review is below (Section 12.3).

12.0 REVIEW PROCESS FOR PROPOSAL TYPES

12.1 Exempt Review Process

Research projects that the Principal Investigator and faculty supervisor, as applicable, believe are eligible for exempt status must be reviewed by the IRB Chair or their designee and officially granted such status before the Principal Investigator begins contacting participants or collecting data. The Principal Investigator will submit the Exempt Review Application form and required materials to the IRB, Office of the Provost.

12.1.1 Upon receipt by the IRB, Office of the Provost, each proposal will be assigned an IRB Proposal Number according to the numbering scheme established by the IRB. This number should appear on all subsequent communications about the proposal to or from the IRB.

12.1.2 Once the IRB Chair has reviewed the application packet and determined that exempt review status is appropriate, the IRB Chair will notify the Principal Investigator that they may begin the project. The Chair will notify the IRB of this action. At least one week will be allowed for this process.

12.1.3 If the IRB Chair determines that the study does not qualify for exempt review status, they will seek further information from the Principal Investigator as necessary or direct the Principal Investigator to re-submit the application materials to the IRB using the Expedited or the Full Review Application.

12.2 Expedited Review Process

Applications for Expedited Review will be submitted using the approved Expedited Application Form. Upon receipt by the IRB, Office of the Provost, each proposal will be assigned an IRB Proposal Number according to the numbering scheme established by the IRB. This number should appear on all subsequent communications about the proposal to or from the IRB.

12.2.1 If, after an initial review by the IRB Chair, the Chair determines that expedited review is appropriate, the Chair will select one IRB member to review the proposal. The Chair of the IRB and the other member will provide an expedited review of research activities that pose minimal risks to the human subjects and are included on the list of activities subject to the expedited procedures in 45 CFR § 46.110 and the Federal Register.

12.2.2 Any research activities afforded an expedited review will be reported to the full IRB by the IRB Chair. The IRB may require a review of the research activities.

12.2.3 If the IRB Chair and second reader both approve the proposal, then the proposal is granted approval and the IRB Chair communicates the decision to the Principal Investigator and the full IRB membership. At least two weeks will be allowed for this process.

12.2.4 If the second reader does not agree with the expedited review decision, the proposal is sent to the IRB for a full review and vote at the next regular meeting. The IRB Chair will notify the Principal Investigator of this decision. The procedures for the full IRB review will be followed.

12.3 Full Review Process

Proposals to the IRB will be made at least one week prior to the next scheduled IRB meeting date. The Full Review Application form will be used for this proposal.

12.3.1 Upon receipt by the IRB, Office of the Provost, each proposal will be assigned an IRB Proposal Number according to the numbering scheme established by the IRB. This number should appear on all subsequent communications about the proposal to or from the IRB.

12.3.2 The IRB Chair will provide a copy of the full application packet to each IRB member. A copy of each proposal will be kept on file electronically with the IRB, Office of the Provost.

12.3.3 Following an initial review by IRB members, comments, questions, or requests for additional information will be provided to the IRB Chair, who will compile them and provide them to the Principal Investigator and faculty supervisor, if applicable, for response. When additional information is requested, the application packet will be considered complete only when all the information has been provided.

12.3.4 Each complete proposal submitted by the deadline will be reviewed at the regular monthly meeting of the IRB. Proposals that are re-submitted as directed by the IRB Chair will also be reviewed at the next regular monthly meeting of the IRB. The IRB is not responsible for reviewing any proposal materials received after the stated deadline.

12.3.5 The IRB may approve, deny, or request additional information for any proposal on the agenda. The IRB Chair will notify the Principal Investigator of the decision of the IRB. Any request for supporting information related to the decision will be provided in writing. If the review cycle for an approved proposal differs from the typical twelve-month review cycle, this will be noted and the required review cycle will be identified in the supporting documentation.

12.3.6 Principal Investigators have the right to ask questions, seek clarification, present information to the IRB in person (see Section 13.0 Presentations to the IRB), or appeal an IRB decision (See Section 15.0, Appeals).

13.0 PRESENTATIONS TO THE IRB

13.1 Any proposal that is submitted for Full Review will be considered by the full IRB. The Principal Investigator for any proposal being considered may request to make a presentation to the IRB when such a presentation is thought to provide clarity to the project that cannot be communicated as efficiently in writing.

13.2 The IRB may also request a presentation by the Principal Investigator of a study. If the IRB requests a presentation by the Principal Investigator, the proposal will not be approved until the presentation has been made and the IRB has fully considered the proposal with the additional input of the presentation. If the study includes a research team, the Principal Investigator may select those who will present to the IRB.

13.3 The IRB may request additional written documentation to reflect the information received during the presentation (see Section 14.3).

14.0 IRB VOTING

14.1 In accordance with 45 CFR 46, a majority of voting members must be present to hold a vote on any proposal submitted for full review of the IRB. Of these voting members, at least one must be designated as a non-scientific field representative to the IRB and at least one must be designated as a scientific field representative to the IRB. A roster of IRB Members will indicate the scientific/non-scientific designation of the members.

14.2 When a quorum is present, a majority vote of members who are present at a meeting will determine the decision of the IRB.

14.3 If the vote results in a tie, the proposal will not be approved. Those members in opposition to the proposal must provide the Chair with specific issues of concern and the Chair will communicate those to the Principal Investigator with a request for additional information and/or an invitation for the investigator(s) to appear before the IRB in an attempt to more fully explain the proposal and to address any concerns. The IRB will re-consider the proposal at or before the next regularly scheduled IRB meeting, at which point a final decision will be rendered.

15.0 APPEALS

15.1 Concerns about the decisions of the IRB may be basis for an appeal. The Principal Investigator should first direct appeals, in writing (communication provided via official University email is considered to be written communication), to the IRB Chair. The IRB Chair will respond, in writing, to the Principal Investigator within ten (10) working days after receiving the written appeal. If the applicant is dissatisfied with the decision of the IRB Chair, they may provide their appeal in writing to the Associate Provost.

15.2 Upon receipt of the appeal, the Associate Provost will review records of IRB meetings and may schedule interviews with the applicant and the IRB Chair and/or IRB members, as necessary, to formulate a response to the appeal. The Associate Provost will respond, in writing, to the Principal Investigator within ten (10) working days after receiving the written appeal. If the applicant is dissatisfied with the decision of the Associate Provost, they may appeal to the Provost.

15.3 Upon receiving the appeal, the Provost may review all records pertaining to the case and schedule interviews and/or request additional information as necessary to make a determination. The Provost will respond, in writing, to the Principal Investigator within ten (10) working days after receiving the appeal. The decision of the Provost is final.

16.0 CONTINUING PROJECT REVIEW

16.1 All research involving human subjects must be re-reviewed at least every twelve months or more frequently if specified in the original approval notification. This applies to studies for which data are continuing to be collected or for which research data are being maintained with personal identifiers that can be linked to individual subject responses.

16.2 For review of continuing projects, investigators shall submit an electronic copy of a signed Continuing Project Form to the IRB Chair. The Continuing Project Form must be approved prior to expiration of the original approval end date.

16.3 A research project, not eligible for continuing review because the project's approval has expired, may be submitted as a new application. New proposals submitted according to this procedure must indicate such by listing the expired IRB Research Proposal Number on the application form and indicating the former status when submitted.

17.0 FINAL PROJECT REPORT

Upon completion of the research project, the Principal Investigator will submit a Final Project Report and the signed consent forms to the IRB. The Final Project Report will be signed by all investigators involved in the research as initially approved or approved revisions. Supervising faculty must sign the Final Project Report of student investigators.

18.0 RESPONSIBILITY OF INVESTIGATORS FOR THE CONDUCT OF RESEARCH

18.1 General Responsibilities

Investigators shall explain to subjects, prior to their decision about whether or not to participate, the objectives of the research, the procedures to be followed and the potential risks and benefits.

18.1.1 Investigators shall not use individuals as subjects unless satisfied that they, and/or others legally responsible for their well-being, fully understand the consequences of participation and freely consent to participate in the research. The IRB may waive certain aspects of these requirements only when persuaded that the research cannot otherwise be done, that its potential value outweighs any harm to the subject, and that the subject is not exposed to unnecessary risk or harm by participating.

18.1.2 Investigators shall seek informed consent from subjects to participate only under circumstances that provide the prospective subject sufficient opportunity to consider and decide freely whether or not to participate. Subjects shall be offered a copy of the informed consent materials to keep. Assent forms will be received from any subject not legally able to offer consent.

18.1.3 Investigators shall make clear to subjects that participation is voluntary and they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and without penalty or loss of benefits to which the subject is otherwise entitled. Any payment to subjects must be reasonable and prorated with partial payment in the event subjects discontinue participation during the course of the study.

18.1.4 Investigators, assistants, support staff, and anyone else involved in the project shall respect the privacy of subjects. They shall protect confidential information given to them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.

18.1.5 Investigators shall obtain approval from the IRB prior to making any changes in the research procedures.

18.1.6 Signed consent forms will be securely stored in the IRB, Office of the Provost for a period of three years unless guidelines related to the study require records retention for a period beyond three years.

18.2 Adverse Effects and Incident Reporting

Investigators have a responsibility to report to the IRB any adverse effects of the research to the participants or any complaints from participants regarding the research.

18.2.1 Principal Investigators must report any adverse effects or incidents to the IRB Chair within 24 hours of the determination of the effect or the occurrence of the incident. An Adverse Event Report Form or Incident Report will be submitted to the IRB, Office of the Provost within 72 hours of the determination of the effect or the occurrence of the incident. All adverse effects or incidents occurring during the implementation of a

research project will be noted in the project's Final Project Report (Section 17.0).

19.0 INFORMED CONSENT

19.1 Informed Consent Minimum Requirements

Informed Consent is a process in which the investigator provides adequate information about the risks and benefits of the research to give the prospective subject sufficient opportunity to consider whether or not to participate. It also minimizes the possibility of coercion or undue influence. Additional information and sample forms are located on the IRB website. Informed consent includes at least the following required elements:

19.1.1 A statement that the study involves research;

19.1.2 An explanation of the purposes of the research;

19.1.3 The expected duration of the subject's participation;

19.1.4 A description of the procedures to be followed;

19.1.5 Identification of any procedures which are experimental;

19.1.6 A description of any reasonably foreseeable risks or discomforts to the subject;

19.1.7 A description of any benefits to the subject or to others which may reasonably be expected from the research;

19.1.8 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

19.1.9 For research involving more than minimal risk, an explanation as to whether the subjects will receive any compensation, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

19.1.10 An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research–related injury to the subject;

19.1.11 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.

19.2 The approved consent form will bear an IRB approval stamp. Only copies of the approved forms with this stamp may be distributed to subjects/participants. A copy of the form must be offered to the participants. Informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative (LAR). A written copy shall be given to the person signing the informed consent form.

19.3 Waiver of Informed Consent

19.3.1 The process of informed consent may be waived or altered if the research meets all of the following conditions:

19.3.1.1 The research involves no greater than minimal risk.

19.3.1.2 It is not practicable to conduct the research without the waiver or alteration.

19.3.1.3 Waiving or altering the informed consent will not adversely affect the subjects' rights and welfare.

19.3.1.4 Pertinent information will be provided to the subjects later, if appropriate. This category of waiver includes cases in which the investigator needs to withhold some information about the research, which if known by the participant would bias the result of the study. Ordinarily, the investigator will plan a debriefing session after completion of the individual's participation to provide the missing information.

19.3.2 The Consent Form (Signed documentation of informed consent) may be waived if a) the research presents no more-than-minimal risk and involves no procedures for which written consent is normally required outside of the research context or b) the Consent Form would be the only record linking the subject and the research and the principal risk would come from a breach of confidentiality.

19.3.3 In the event that the Consent Form is waived, the Principal Investigator must provide the subject with the elements of consent so an informed decision is assured.

20.0 DEBRIEFING

20.1 When the informed consent procedures withhold information from the participants of the research or the research design involves deception, investigators will provide the participants additional information and correct any misperceptions that have been created through debriefing.

20.2 This information should be provided as early as possible, preferably at the end of the

participation, but at least by the conclusion of the research. When appropriate, the investigator should provide the participants with the opportunity to learn about the nature of the results and the conclusion of the research.

21.0 RESEARCH WITH CHILDREN (PERSONS UNDER 18 YEARS OF AGE)

21.1 Consent from parent(s) or legal guardian(s) is required for children under age 18. The investigator will make every reasonable attempt to identify the legal guardian.

21.2 For individuals with diminished decision-making capacity, consent must be obtained from a legally authorized representative (LAR). Definition of who can be a LAR is located here: Informed Consent FAQs | HHS.gov (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html).

21.3 For children and participants with diminished decision-making capacity, the parent/guardian/LAR provides consent, and an Assent form must be provided for participants.

21.4 Research involving children must be undertaken with care and meet strict ethical standards. Research with children is rarely considered exempt from IRB review, even if the same research procedures would be exempt with adult participants.

21.5 It is anticipated that most research conducted with children will present minimal or no more-than-minimal risk. Research involving more than minimal risk to children should be conducted only if sufficient potential benefits are anticipated.

21.6 If research involving more than minimal risks with children is proposed, it must meet the special considerations specified in 45 CFR 46.405 or 46.406 to be approved by the IRB. For the purpose of these rules a “child” is a person under the age of 18 who is not legally emancipated. See the additional information from the federal guidelines regarding research involving children: 45 CFR 46 Subpart D, 46.401 through 46.409 for additional information on the federal guidelines regarding research involving children.

21.7 In addition to parental or guardian consent, children should also be asked for their assent to participate in the research project in language appropriate to the subject’s age and maturity. Assent may be provided using written form or verbally, depending on the development abilities of the child.

21.8 College students who are under age 18 and who are not legally emancipated are considered children and are subject to the considerations established for children. If used as research subjects, minor college students must have parental or guardian consent and provide assent to participate.

21.9 Surveys, interview procedures, or participant observations are not eligible for exempt status when persons under age 18 are involved as subjects.

21.10 When engaging in research with children, the investigator may need to seek permission of the school district and parents or guardians as well as assent of the child. Permission of the school/district administration is required for any research that takes place in a school setting or involves school records.

21.11 Parental permission and child assent may be waived, if the research does not involve direct intervention with children or include personally identifiable information. Examples of such research include observations of public or classroom behavior and analysis of educational tests or existing data recorded without personal identifiers. Projects that involve direct intervention with children require permission from the parent or guardian and assent from the child.

22.0 CONSENT FOR PERSONS WITH IMPAIRED DECISION MAKING

22.1 As a general matter, if an adult lacks capacity to consent, for example, as a result of trauma, intellectual disability, some forms of mental illness, or dementia – whether temporary, progressive, or permanent – only a legally authorized representative (LAR) for that adult can give consent for participation in the research, unless the requirement to obtain informed consent is waived by the IRB in accordance with the requirements.

22.2 Legally authorized representative (LAR) means 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 (45 CFR 46.102 (i)). The issue as to who can be an LAR is determined by the laws of the jurisdiction in which the research is conducted (e.g., local or state law). Some states have statutes, regulations, or common law that specifically address consent by someone other than the subject for participation in research. Most states have no law specifically addressing the issue of consent in the research context. In these states, law that addresses who is authorized to give consent on behalf of another person to specific medical procedures or generally to medical treatment may be relevant if the research involves those medical procedures or medical treatment.

22.3 An assent form using a recommended format should be developed and used when appropriate. Verbal assent may be used in the event signing paper assent is not possible.

History
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