Shepherd University
Institutional Review Board Policy Manual

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Introduction

Shepherd University expects a commitment not only to the pursuit of academic excellence, but honesty, truth, integrity, and the highest standards in all endeavors. In accordance with these expectations, the University requires that any associated activities are conducted with the highest ethical standards. This University policy on research involving human participants is designed to fully comply with the regulations of the Office for Human Research Protections (OHRP) and to implement the principles outlined in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. In addition, all federally funded research conducted at this institution that involves human participants will comply with the Code of Federal Regulations Title 45, Part 46 (hereafter 45 CFR 46). Shepherd University has adopted these regulations to cover all research activities involving human participants. Any revisions or updates to any federal documents used in this policy supersede this document. The University will update this document accordingly when it receives notification of those changes. All other revisions or updates to this document are subject to approval by the Shepherd University Administrative Council. Common definitions and explanations of terms relevant to ethical research and misconduct in research and research-related activities can be found in the appendices attached to this policy. Procedures for filing complaints and the disciplinary actions facing any individual or groups engaged in misconduct in research are provided elsewhere.

1.0 Statement of Principles

In its commitment to the pursuit of excellence in teaching, research, and public service, Shepherd University is intent on protecting the welfare of every person who may be involved in research and training projects. To uphold the highest standards of freedom of inquiry and communication, members of the University community accept the responsibility this freedom offers: for competence, for objectivity, for consideration of the best interests of the University and society, and for the welfare of every participant in a project. Shepherd University gives assurance that it will comply with all Department of Health and Human Services regulations for the protection of human research subjects, including requirements that provide additional protections for children involved in research.

The institution affirms the principles identified below. In addition, these principles should be interpreted in the broad context provided by the code of medical and general ethics promulgated by the World Medical Association as the Declaration of Helsinki and by the American Psychological Association's Ethical Principles of Psychologists and Code of Conduct.

1.1. Since the participation of humans in research and training projects may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, staff, or other University employees, regardless of the location of the research project.

1.2. All activities involving human participants must provide for the safety, health and welfare of every individual. Additionally, the rights of each individual, including the right of privacy, must not be infringed upon.

1.3. The benefits (direct or potential) to the participant, or the importance of the knowledge to be gained, must outweigh the inherent risks to the individual participating in the project.

1.4. Participation in any and all projects must be voluntary, and informed consent must be obtained from all participants, unless this requirement is specifically waived by the Institutional Review Board (IRB) as provided in 45 CFR 46. Research methods that are in accordance with the requirements set forth in 45 CFR 46 and that are adequate and appropriate to the risks of the specific project must be used to obtain informed consent from each participant.

1.5. Whenever possible, informed consent should be obtained directly from the participants themselves. If a participant is not legally or physically capable of giving informed consent, a legally authorized representative may do so. Careful consideration must be given to the legal representative's depth of interest and concern with the participant's rights and welfare. For example, parents cannot expose their child to risk except for that child's benefit.

1.6. An individual does not abdicate any rights by consenting to participate in a research project or study. Every participant has the right to withdraw from or refuse to participate in a research project at any time without the loss of benefits to which the participant would otherwise be entitled. Furthermore, a participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment during and/or after the research project.

1.7. Safeguarding information that has been obtained about all individuals during a research study is a primary obligation of the principal investigator. In those cases where the principal investigator is a student, the responsibility for the conduct of the research project and the supervision of human participants lies with the Faculty Sponsor. All members of the research team are required to ensure that information is not communicated to others unless the following conditions are met:

a. Explicit permission for the release of identifying data is given by the individual participant.

b. Information about individuals may only be discussed for professional purposes and only with persons clearly concerned with the project. Every effort must be made to avoid an invasion of privacy, and written and oral reports must present only data relevant to the purposes of the project.

Provisions must also be made to ensure confidentiality in the preservation and ultimate disposition of any data collected. It is the responsibility of the Principal Investigator to identify, describe, and carry out security measures that are acceptable to the IRB until the records are destroyed. Records containing personal information shall be destroyed as soon as possible in keeping with the long-range goals of the research project.

1.8. Research projects will be given initial and continuing review by the IRB as set forth in the **Review Procedures and Criteria for Approval** section. All members of the University community involved in research and training are responsible for continual monitoring to assure that their research is and remains compliant with these principles.

1.9. No individual involved in the conduct and/or supervision of a specific research project may participate in IRB review of that project. An exception may be granted when the IRB requests information from an individual involved in or supervising a research project.

1.10. A second review may be required if (a) a long interval (greater than one year) has elapsed between IRB review and project initiation; (b) if the proposed effort is in a rapidly changing scientific area; or (c) if the Principal Investigator wishes to change procedures after the proposed project has been reviewed by the IRB. In no case will work take place on any research project that has not been subject to at least an initial review.

1.11. In all cases, an Investigator should show practical regard for the Shepherd

University community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles (i.e. those concerning confidentiality, informed consent, debriefing, and regard for the health, safety, and welfare of all human participants) could impugn not just the Investigator's own name but also the reputation of the University. An Investigator does not abdicate ethical and legal responsibility merely by complying with this protocol. It is always the responsibility of the Principal Investigator to obtain clearance from the IRB before beginning any research project involving human participants. Failure to obtain IRB clearance may endanger federal funding to the University and may result in restrictions on an individual's research activities.

2.0 IRB Membership

The structure of the IRB must be in compliance with federal regulations as described in 45 CFR 46. In accordance with these regulations the IRB will have no fewer than five members with varying backgrounds so that a complete and adequate review of commonly conducted research activities can be completed. All IRB members are expected to bring their expertise, interest and representation to the board, but are not required to advocate for their constituency. At no time shall one member fill more that one of the roles on the committee. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects (45 CFR 46). The membership of the IRB must include the following:

- A person whose primary concerns are in scientific areas.
- A person whose primary concerns are in nonscientific areas.
- A person who has no affiliation with Shepherd University and who is not part of the immediate family of anyone employed by the University.
- An individual with expertise in psychology or counseling.

2.1. If a member of the IRB has an interest in a proposal/project for review, that member shall not participate in the review process, except to provide information as requested by the IRB.

2.2. To ensure a full review, the IRB may invite individuals with expertise in special areas to assist in reviews of complex issues that exceed the qualifications of the members. In these

cases, those invited to provide expertise will not have voting rights or privileges.

2.3. The Shepherd University IRB shall include no fewer than seven voting members. Three of the voting members will be appointed by the President, and the remaining members will be elected from existing Schools. The elections and appointments of the voting members will be done as follows:

2.3.1. One member will be elected from each existing School by a vote of all full-time tenured or tenure track faculty in the corresponding School. This person can be a tenured or tenure track faculty member.

2.3.2. One member without affiliation to Shepherd University will be appointed by the President.

2.3.3. Two at-large members from the Shepherd University faculty will be appointed by the President. These faculty members can be emeritus, tenured, or tenure track faculty members of any of the Schools.

2.4. This process recognizes that the faculty in each School are best suited to identify those faculty members who can best represent the School and University in ensuring that all research involving human participants is conducted with the highest moral and ethical standards and in keeping with accepted practices in the disciplines within each School. The process also recognizes the importance of the President in oversight of all research at Shepherd University.

2.5. The members of the IRB will elect one of the members as Chair, subject to approval by the University President. The Chair will serve for a term of three years. If the Chair resigns, the voting members will elect a new Chair from among the remaining voting members of the IRB, subject to approval by the President. That Chair will serve out the remainder of the term. The voting members of the IRB may also elect from among the voting members a Secretary. Duties of the IRB Secretary shall include taking minutes of all meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution. In addition, the IRB Secretary will work with the IRB Chair to maintain documentation as required by the federal regulations governing IRB activities.

2.6. Terms for voting members will be for three years, and voting members can be re-elected/reappointed for an unlimited number of terms. Membership should be staggered so that at no time will all terms end in the same academic year. This process will allow for some continuity of membership so that at no time will the entire membership of the IRB be new members.

2.7. If an elected voting member resigns from the IRB, an election will be held to select a faculty member from that School to complete the term.

2.8. If an appointed voting member resigns from the IRB, the President will appoint a replacement member to fulfill the remainder of the term.

2.9. All members of the IRB are required to complete an IRB-approved training course. The current list of approved courses is available on the IRB website. After completing the training course, the member must download the certificate of completion and submit a copy to the IRB Chair. Certification will be valid for three years.

3.0 Institutional Responsibilities

The IRB shall have administrative authority concerning protecting human participants in research at Shepherd University. The IRB will ensure that research, funded or non-funded, is both ethically compliant and compliant with the letter and spirit of those federal regulations governing research studies involving human participants. Ultimately, the IRB is responsible for determining the level of risk to a human participant involved in a research project, as well as determining if the level of risk is within acceptable federal requirements.

3.1. All student or faculty Investigators working with human participants must complete an approved training course. A list of currently approved options may be found on the IRB website. After completing the training course, the member must submit appropriate documentation to the IRB Chair. Certification is valid for three years.

3.2. Research projects involving the use of human participants must be submitted to the IRB for approval. Student projects will follow the Student Research Policy. If it is unclear whether the proposed research involves human participants, the Investigator should seek assistance from the School IRB representative and/or IRB Chair. IRB applications that support proposals for external funding must be submitted well in advance of the agency deadline, as many agencies require documentation of IRB approval as part of the funding application. **Please be aware that IRB approval cannot be retroactive.** If the possibility exists that either the instructor or the student would consider disseminating the data as generalizable knowledge, the research must be submitted for IRB review prior to the commencement of research.

3.3. The IRB schedules meetings with due regard for an efficient but thorough assessment of applications. Therefore, to ensure consideration of an application by the IRB, the Principal Investigator must submit a completed application electronically to the IRB chair. The IRB chair will then disseminate the application to other committee members for review and comment. An annual list of IRB deadlines is provided on the IRB website.

3.4. For applications involving research that poses no more than minimal risk to participants, an expedited review may be possible. For an expedited review to be allowed, the research must also either fall under one of the research categories eligible for expedited

review, or fall under the categories exempted by federal regulations. (See **Expedited Review** and **Exemption from Annual Review** sections for a complete list of categories.) The IRB Chair will determine if the application is eligible for an expedited review.

3.5. The IRB will consider the following primary factors when reviewing a proposal:

3.5.1. The research proposal adequately protects the rights and welfare of the participants. The IRB will ***not*** approve a procedure that contains unacceptable or unnecessary risks to participants. The study must provide adequate safeguards and emergency measures. Researchers must keep proper records and protect the anonymity and/or confidentiality of collected data. Finally, researchers must attempt to minimize participants' potential personal embarrassment, mental anguish, or questions of conscience. In short, the proposed research must make every effort to adequately protect both the mental and physical well-being of all participants.

3.5.2. The risks to the participants are reasonable given the anticipated benefits of the proposed study. The IRB will evaluate each proposal and determine if the risks to participants and the researchers are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be gained based on the expected outcomes of the proposed study. The IRB expects that human participants will not be utilized in poorly designed projects. However, the responsibility for monitoring research design quality lies primarily with the Principal Investigator or Faculty Sponsor.

3.5.3. Informed consent of participants will be obtained by adequate and appropriate methods as described in the **Informed Consent** section of this policy. The Investigator will fully inform all participants of the procedures to be followed, including discomforts, risks, and possible benefits, if any. When describing possible risks, terms that are understandable by the participants must be used. Unless specifically waived by the IRB in accordance with 45 CFR 46, informed consent of all participants must be obtained.

3.6. Final approval by the IRB shall require that a majority of all members present agree that the proposed research protects human participants in accordance with established standards. A majority vote of the IRB members establishing quorum shall constitute certification of approval. The IRB Chair will then send a letter of approval to the Principal Investigator or Faculty Sponsor and other institutional officials as appropriate.

3.7. In the case of a proposal being submitted to an external funding agency, certification of approval of the protocol, if required, will be made at the time the proposal is submitted in the form required by the agency.

3.8. For any research being conducted in a public or private school, Shepherd University requires approval from the school district. This approval must come from the superintendent or a properly appointed designee. Approval from a classroom teacher or a principal (unless the district has given authority to the principal) is not acceptable for the purposes of this policy.

3.9. When research is conducted in cooperation with another institution, approval from that cooperating institution's IRB is required. If the cooperating institution does not have an IRB, then an approved representative from the cooperating institution must commit to adherence to the Shepherd University Human Participants policy.

4.0 Review Procedures and Criteria for Approval

4.1. The Principal Investigator or Faculty Sponsor may be asked to meet with the IRB if clarification of statements in the application or modification of the methodology is required. IRB members who are involved in the conduct and/or supervision of the research project will recuse themselves and not participate in the review, except to provide information at the request of other IRB members. The IRB may elect to impose additional restrictions or recommendations under which the project shall be conducted, regardless of the outcome of the vote.

4.2. The IRB Chair will provide reasons for a negative decision to the Principal Investigator or Faculty Sponsor in a timely manner. A researcher may choose to modify the proposed project to meet the objections of the IRB and resubmit the application for further consideration. The researcher may request a personal hearing before the IRB to discuss the reasons for the negative decision and necessary changes to the proposal prior to resubmission.

4.3. If in the course of the research, the protocol changes substantially, problems emerge, or hazardous conditions for the participant develop, the Principal Investigator or Faculty Sponsor must report this immediately to the IRB. In addition, the research must immediately be suspended, and an amended protocol must be submitted to and approved by the IRB before the research is resumed. (See **Managing Critical Events** section.)

4.4. Following initial approval, the IRB provides the Principal Investigator or Faculty Sponsor with the minimum time that can elapse before re-evaluation of a continuing project is required. Routine projects may be reviewed annually, while more complex and potentially dangerous projects may be reviewed more frequently. Exempt projects (as defined in **Exemption from Annual Review** section) require a review every five years. When applying for renewal review, the Principal Investigator or Faculty Sponsor must include both a progress report and a description of anticipated design changes, if any. If participants involved in the research lodge a complaint with the IRB, or if the Principal

Investigator or the Faculty Sponsor reports problems with the research, an IRB review must occur. In the case of problems with the research, the IRB will review the data collected to that point, and will interview both the project personnel and persons under risk.

4.5. Ongoing projects that are modified to include human participants are to be suspended until proposals are submitted to the IRB for review and until written IRB approval has been received. When this involves an externally funded project, the granting agency shall be notified of the IRB action prior to the appropriation cycle for a budget period during which the inclusion of human participants is to begin.

5.0 Informed Consent

Informed consent is a process essential to the ethical conduct of research involving human participants. Legally effective informed consent of the participant or the participant's legally authorized representative is required before anyone can participate in a research project. It is crucial that this consent be requested under circumstances providing sufficient opportunities for the participant to freely consider whether to participate. The possibility of coercion or undue influence must be minimized when human participants are asked to provide consent. It is unacceptable to seek negative consent, or require a participant to decline to participate.

5.1. The participant or the participant's legally authorized representative must be given information that is in simple, easily understood language. If all or part of the participant population is not English speaking, the informed consent must be presented in the appropriate language(s). If it is not possible to prepare the information in the appropriate language(s), it is acceptable to have a translator present to read and translate the documents, as well as to translate questions and answers.

5.2. Unless specifically waived by the IRB, written documentation of the consent process (i.e. a cover letter or cover sheet) is required. All required elements must be included in the informed consent document regardless of whether a cover letter is included or not. The consent document shall be signed by the participant or the participant's legally authorized representative unless this requirement is waived by the IRB. Consent forms should generally be limited to one page, whether letter or legal size. If a consent form must be longer than one page, add an initial and date line to the bottom of each page (other than the page with the full signature line), and number the pages, e.g., “1 of 2,” “2 of 2.” A copy of the consent document is to be given to the participant and a second copy is to be kept by the researcher. The IRB will only grant a waiver of the requirement of written informed consent in accordance with 45 CFR 46 if the Investigator can provide adequate justification for the request.

5.3. For participants who are minors (under 18 years of age), unless waived by the IRB, written parental consent is required. Investigators must also obtain the child's assent in addition to obtaining parental consent unless the child is too young or incapable of

giving assent and the IRB has waived the requirement. Child assent and parental consent must be obtained through separate processes to minimize undue influence by the parent(s).

5.4. If the written, signed informed consent form is the only record linking the participant to the research or data, its use may be waived by the IRB. If this is the case, a written description of the procedures and research objectives must be supplied to the participants using language that is easily understandable by the lay public. For example, if the research involves the analysis of a questionnaire that is distributed and returned anonymously through the mail, a cover letter sent with the questionnaire should include all the elements of informed consent. On the other hand, if informed consent is to be obtained orally (i.e. prior to a telephone interview), a written copy of what will be told to the participant must be provided to the IRB for review and approval.

5.5. No informed consent, whether oral or written, may waive or limit, in appearance or in fact, the participant's legal rights, including any release of the institution or its agents from liability for negligence.

5.6. The federal government and/or Shepherd University requires that the following information be included in all consent material in a language that is understandable and appropriate to the participant or participant's representative:

5.6.1. A concise and focused presentation of the key information that is most likely to assist a prospective subject 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.

5.6.2. A statement that the project is research, accompanied by an explanation of the scope, aims, and purposes of the research, as well as a description of the experimental procedures to be followed, including the expected duration of the participant's involvement.

5.6.3. A description of reasonably foreseeable risks or discomforts to the participant through participation in the research project.

5.6.4. A description of any potential benefits to the participant or to others that may reasonably result from the research project.

5.6.5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

5.6.6. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.

5.6.7. For any research project involving more than minimal risk, a statement regarding the availability of compensation and/or medical treatment if injury

occurs must be included. If compensation or medical treatment will be provided, provide details regarding how it may be obtained or where further information may be secured.

5.6.8. An explanation of the appropriate person 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. The following statement must be included in ***ALL*** written informed consents, including cover letters. This statement should be inserted at the bottom margin of the form, letter, or portion of the form that is to be retained by the participant (The IRB Chair's name and phone number can be found on the University IRB website):

ANY QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH PARTICIPANT MAY BE ADDRESSED TO THE SHEPHERD UNIVERSITY INSTITUTIONAL REVIEW BOARD (*CHAIR'S NAME*, IRB CHAIR, 304.876.*XXXX*). ALL RESEARCH PROJECTS THAT ARE CARRIED OUT BY INVESTIGATORS AT SHEPHERD UNIVERSITY ARE GOVERNED BY THE REQUIREMENTS OF THE UNIVERSITY AND THE FEDERAL GOVERNMENT. IN CASE OF A RESEARCH-RELATED INJURY, CONTACT THE ABOVE PERSON AS SOON AS YOU ARE MEDICALLY ABLE.

5.6.9. Statements detailing that 1) participation is voluntary, 2) refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and 3) the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

5.6.10. A statement detailing the approximate number of participants involved in the study.

5.6.11. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

5.7. The participant or the participant's legally authorized representative shall receive a copy of the consent form.

5.8. While federal law requires that copies of all informed consents be retained for a minimum

of three years after the completion of the research, for audit purposes, Shepherd University requires that all copies of consents must be kept for no fewer than five years after the completion of the project or acceptance of the final report. The Principal Investigator or Faculty Sponsor is responsible for maintaining and retaining the records. If the Principal Investigator or Faculty Sponsor leaves the University, these documents shall be delivered in a sealed container to the IRB Chair for maintenance and storage.

5.9. *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens*. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements above. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

5.9.1. A concise and focused presentation of the key information that is most likely to assist a prospective subject 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.

5.9.2. A description of any reasonably foreseeable risks or discomforts to the subject.

5.9.3. A description of any benefits to the subject or to others that may reasonably be expected from the research.

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

5.9.5. 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.

5.9.6. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.

5.9.7. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens

5.9.8. A description of the period of time that the identifiable private information or

identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).

5.9.9. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.

5.9.10. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject;

5.9.11. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

6.0 Exemptions from Annual Review

Based on current federal regulations, Shepherd University has designated certain research categories as exempt from annual IRB review. Exemption must be reviewed and approved by the IRB. To establish an individual research project as exempt from annual review, an Investigator must complete and submit an IRB application for review and approval and indicate that they are requesting an exemption. It is the prerogative and responsibility of the IRB to determine if the research project falls into an exempt category.

Once the IRB certifies that a specific research project is exempt from annual review, the Investigator does not need to submit the project for annual IRB review, as long as there are no modifications in the exempted procedures. To retain exempt status, the Investigator must submit a renewal application every five years. This renewal process allows the IRB to assess the project protocols considering any developments that may have occurred during the previous five years. **Investigators should note that the use of the term "exempt" refers to the requirement for annual IRB review, NOT the general requirements for informed consent and protection of participants.** Thus, even if a project is determined to be exempt from annual review, Investigators still must inform potential participants of the proposed procedures and their rights as participants.

Shepherd University, using 45 CFR 46, has adopted the following categories of exemption from IRB review:

6.1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

6.2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by Federal regulations.

6.3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by Federal regulations. (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

6.4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

6.5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

6.6. Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6.7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by Federal regulations.

6.8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use,

if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with Federal regulations; (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Federal regulations; (iii) An IRB conducts a limited IRB review and makes the determination required by Federal regulations and makes the determination that the research to be conducted is within the scope of the broad consent; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

7.0 Expedited Review

Certain categories of research are recognized by federal regulations to involve procedures for which clear standards can be set and that pose no more than minimal risks to participants. As a result, research proposals that fall under one of the categories listed below can be reviewed by the IRB Chair or designee in an expedited manner. When the IRB Chair receives a proposal for expedited review, the Chair will assess and, if in agreement, expedite the review. If the Chair does not agree that the proposal is eligible for an expedited review, the Chair will refer the proposal to the IRB for a complete review.

The IRB Chair provides a report to all IRB members that a proposal has received an expedited review. Members then have the option of requesting more information, requiring modification of the protocol, or disapproving the project.

Expedited reviews are considered for initial and continuing research protocols listed in one of the following categories as described in 45 CFR 46.

7.1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

7.2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period, and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the

lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.

7.3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
(c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

7.4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

7.5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

7.6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7.7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

7.8. Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

7.9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 7.2 through 7.8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

8.0 Managing Critical Incidents

While an Investigator makes every attempt to ensure that research projects are completed without incident, in some cases it is impossible to prevent incidents from occurring. During a research study, unanticipated problems can occur even when procedures are followed properly. It is also possible that in some cases, non-compliance with 45 CFR 46 or University policies may result, and it may be necessary to suspend or terminate IRB approval.

8.1. Unanticipated Problems/Adverse Events:

It is essential to have procedures in place to manage unanticipated or serious problems when human participants are involved in research projects. The Office of Human Research Protections (OHRP) provides guidance differentiating between unanticipated problems and adverse effect. In general, OHRP considers unanticipated problems to include any incident, experience, or outcome that meets *all* the following criteria:

- unexpected (in terms of nature, severity, or frequency) given 1) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and 2) the characteristics of the participant population being studied;
- related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse events, modified from the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice, are defined as any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding, extreme anxiety), symptom, or disease, temporally associated with the participant's participation in the research, whether or not considered related to the participant's participation in the research.

Shepherd University researchers engaged in any research involving human participants must

follow the procedures outlined below in response to an unanticipated problem or adverse event.

a. Emergency (life threatening)
    i. Call 911 for emergency response. 911 dispatches University Police for campus emergencies.
    ii. When reasonable to do so in the midst of an emergency, communicate the medical emergency to the appropriate office (for students the Vice President of Student Affairs, for faculty the Provost, and for staff the University Human Resources Office), and the IRB chair.
    iii. Complete the University Accident/Incident Form.

b. Non-emergency (not life threatening)
    i. Communicate any adverse condition as to buildings or grounds to Facilities. Communicate the nature of the problem to the IRB chair as soon as the event or problem is identified but no later than 72 hours after knowledge of the problem.
    ii. If applicable, complete the University Accident/Incident Form.

In non-emergency incidents, the IRB chair works with the Investigator to identify the appropriate steps to address the problem in the best interests of the participant(s) in accord with 45 CFR 46 and using the guidance documents provided by OHRP. After due consultation with the Investigator and University officials, the IRB Chair determines whether the IRB must convene to review the research protocol in light of the incident.

Depending on severity, such events may warrant consideration of changes to the research protocol, the informed consent process/document, or other corrective actions to protect human participants. For example, a single event may warrant more frequent and/or detailed reports by the Investigator. In any event, the following steps must be taken.

8.2. Steps for Resolving Critical Incidents that are Unanticipated Problems/Adverse Events

i) The IRB reviews critical incidents unless they are determined to be anticipated problems, are non-emergency, and are managed within the research protocols approved by the IRB.

ii) The Principal Investigator or Faculty Sponsor promptly completes an IRB Incident Report Form, found on the IRB website, and forwards the form with all explanatory documentation to the IRB Chair. The IRB Chair will report to necessary entities.

iii) The IRB Chair convenes a special IRB meeting related to the incident.

iv) The Principal Investigator or Faculty Sponsor meets with the IRB to discuss the critical incident and to determine, based on the nature of the critical incident, whether changes

to the research protocol are warranted, whether an outside expert should be consulted, or whether other steps should be taken.

v) A decision by the IRB to require protocol changes based on information provided by the Investigator is final, and must be implemented prior to continuation of the project.

vi) The Principal Investigator or Faculty Sponsor submits a revised proposal to the IRB that includes the new protocols prior to proceeding or in the timeframe and conditions deemed appropriate by the IRB.

vii) The research may continue once the IRB reviews and approves the revised protocol(s).

8.3. Steps for Resolving Critical Incidents Due to Non-Compliance

Individuals or groups conducting research involving human participants must abide by all IRB policies and procedures to protect humans participating in research. Complainants are protected from retaliation by University policies generally and by the Research Integrity Policies specifically. Reports may be made directly to the President, Provost, the IRB Chair, or any member of the IRB. In cases of serious or continuing non-compliance, the IRB Chair must report the findings of the IRB to the President and other parties as appropriate for action.

8.4. Steps for Resolving Critical Incidents Due to Suspension or Termination of IRB approval

In some cases, the problems or adverse events may be serious enough to warrant termination of approval of the research by the IRB. The failure of investigators to follow approved research protocols will also be grounds for the termination or suspension of the research and IRB approval. All suspension or termination decisions by the IRB are final. Research must stop and may not be resumed. Researchers have the option to revise their research and submit new research proposals for IRB approval if human participants are part of the revised research plan.

8.5. Reporting Responsibilities

In all cases of problems/adverse events, non-compliance, or termination of IRB approval of research, the IRB Chair must file a timely report with the President and others as directed by the President. As required, the appropriate reports are filed with the Office of Human Subjects Protection and the federal agency providing funding, where relevant, per the conditions of award and federal regulation.

9.0 Appropriateness of Research Topics

The IRB is charged with evaluating the risks and benefits to human participants in proposed research. In keeping with this mission, the IRB seeks to ensure that research proposed and eventually approved will utilize methods that provide adequate safeguards to all participants. The IRB does not determine the appropriateness of the proposed research in terms of the mission of the University. Any questions about the appropriateness of proposed research topics should be referred to the Provost for resolution.

10.0 Student Research Policy

Shepherd University students – both undergraduate and graduate – engage in a wide range of research activities. Such activities may include class-related research projects, independent research, Honors or capstone projects, or graduate theses. The IRB requires that all student research activities be supervised by a faculty member. The IRB also recognizes that some student research projects may not require IRB review above and beyond faculty supervision.

10.1. General Policy

10.1.1. Independent student research projects always require review by the IRB.

10.1.2. Curriculum projects in which students conduct research involving human participants need not be reviewed by the IRB if the following conditions are satisfied:

- The project involves minimal risk to subjects.
- The project does not involve sensitive topics.
- The project does not involve persons from vulnerable populations as participants.
- The project must involve the voluntary participation of individuals without any coercion or pressure being placed upon them by the researcher. Though not required, it is recommended that instructors consider having their students provide a consent document to participants and fully informing them of the research they will be taking part in.
- The results of the project are not intended for dissemination and will never be distributed outside the classroom and/or institutional setting or used for publication, although the results may be presented to instructors or peers for educational purposes or as part of a class assignment.

10.2. Responsibility for Oversight of Student Research

The IRB requires that all student research involving human participants be supervised by a Faculty Sponsor who has completed one of the IRB-designated training courses.

All student researchers must also complete the NIH Office of Extramural Research training course before conducting research involving human participants. The Faculty Sponsor assumes the responsibility for 1) determining whether the projects meet the criteria for exclusion from IRB review, 2) ensuring that students are aware of and comply with appropriate ethical principles for the treatment of human participants, 3) notifying the IRB chair that the projects are occurring, 4) overseeing the conduct of the projects, and 5) all reporting required by the Human Participants Policy.

10.3. Definitions Unique to Student Research

10.3.1. Appendix B provides definitions of terms common to all research projects where human participants are used. In addition to these terms, it is important to identify/specify how student research and student researchers are defined/described.

10.3.2. “Independent student research projects” are those that employ systematic data collection with the intent of contributing to generalizable knowledge. Theses, dissertations, and capstone and Honors research projects involving human participants are considered research as defined by 45 CFR 46 (i.e., “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”). Investigations designed to develop or contribute to generalizable knowledge are those that seek to draw general conclusions, inform policy, or generalize findings beyond a single individual or internal program. While such research is often disseminated through scholarly publication or presentation of the data, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to “generalizable (scholarly) knowledge” makes an experiment or data collection research, regardless of publication.

10.3.3. “Student research” means any observation or intervention, including administration of survey or interview questions, by a student as part of a course that is designed to develop or contribute to student learning or class discussion, but that will not lead to generalizable knowledge or publication/dissemination of findings outside of the classroom. Research projects for which the overriding and primary purpose is a learning experience in the methods and procedures of research does not meet the federal definition of research.

10.3.4. "Student researcher” means any student enrolled in a course at Shepherd University who conducts research on human participants as an assignment or project within a course, excluding capstone projects or graduate thesis research, which must be reviewed under Shepherd IRB procedures.

Appendix A: HISTORY OF PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH

The development of the standards for judging and evaluating human experimentation can be traced to the Nuremberg Code, developed for the Nuremberg Military Tribunal as standards for evaluating human experimentation conducted by Nazi scientists. The Code articulates many of what are now considered to be underlying principles governing the ethical conduct of research involving human participants. The Code's first provision states that "the voluntary consent of the human subject is absolutely essential." Thus the cornerstone of ethical research on human participants is freely given consent. Additional details in the Code identify what is implied by the requirement for informed, freely given consent. These include the capacity to consent, freedom from coercion, and comprehension of the risks and benefits involved. The Code identifies other provisions to protect human participants that require the minimization of risk and harm, a favorable risk/benefit ratio, qualified investigators using appropriate research designs, and freedom for the participant to withdraw at any time. The Nuremberg Code is not unique in setting forth these recommendations and guidelines. The World Medical Association made similar recommendations in its Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, first adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and subsequently revised in 1975 and 1989. The Declaration of Helsinki also provides more detailed descriptions of therapeutic and non-therapeutic research to enable discrimination between these two types of research.

Regulations protecting human participants in the United States first became effective on May 30, 1974. After these regulations were passed, the Department of Health, Education and Welfare (DHEW) disseminated those regulations, which were raised to regulatory status in the National Institutes of Health's Policies for the Protection of Human Subjects in 1976. These regulations established the Institutional Review Board (IRB) as one mechanism through which human participants would be protected.

The National Research Act, passed in July 1974, established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission met from 1974 to 1978 and, in keeping with its charge, issued recommendations and reports that identified the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human participants. The Commission also established guidelines designed to ensure that research is conducted in accordance with those principles, and issued the "Belmont Report," which recommended that the DHEW take administrative action requiring that these guidelines apply to research conducted or supported by the DHEW.

In 1981, both the Department of Health and Human Services (DHHS) and the FDA made significant revisions to their human participant regulations in response to the Belmont Report and other recommendations by the Commission. These regulations are codified at CFR Title 45 Part 46. These "basic" regulations became final on January 16, 1981, and were revised on March 4, 1983 and June 18, 1991. The June 18, 1991 revision adopted the Federal Policy for the Protection of Human Subjects. The Federal Policy, or "Common Rule" as it is sometimes called, was promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate

human participant research; the FDA also adopted certain of its provisions. The intent of the Federal Policy is to codify a uniform human participant protection system for use by all relevant federal agencies and departments.

Additional protections for various vulnerable populations have been adopted by DHHS, as follows:

Subpart B, "Additional Protections Pertaining to Research, Development and Related Activities Involving Fetuses, Pregnant Women and Human in Vitro Fertilization," became final on August 8, 1975, and was revised effective January 11, 1978, and November 3, 1978.

Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects," became final on November 16, 1978.

Subpart D, "Additional Protections for Children Involved as Subjects in Research," became final on March 8, 1983, and was revised for a technical amendment on June 18, 1991.

The Revitalization Act of 1993 requires applicants to the National Institutes of Health to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study population, a specific justification for this exclusion must be provided.

Regulations specific to the Food and Drug Administration central to the protection of human participants are codified at CFR Title 21 Parts 50 and 56. Part 50, which sets forth the requirements for informed consent, became final on May 30, 1980, and was revised effective

January 27, 1981, March 3, 1989, and June 18, 1991. Subpart C, which provides special protections for prisoners, was adopted on July 7, 1981; the effective date of Subpart C has been stayed until further notice. Part 56, which sets forth the provisions for institutional review boards, was adopted on January 27, 1981, with revisions to some sections effective February 27, 1981, March 3, 1989, and June 18, 1991.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research met from 1980 to 1983 and published reports on a variety of aspects of medical ethics and biomedical and behavioral research. As part of its charge, the commission was given two mandates with respect to research involving human participants. The first mandate was to review the federal rules and policies governing human participant research, while the second was to determine how well those rules were being implemented or enforced.

Appendix B: DEFINITIONS

Broad consent refers to a new type of informed consent that may be obtained in lieu of the standard informed consent only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Department or agency head means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

Federal department or agency refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.,* the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record). *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Institution means any public or private entity, or department or agency (including federal, state, and other agencies).

IRB means an institutional review board established in accord with and for the purposes expressed in Federal policy.

IRB approval means 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 institutional and federal requirements.

Legally authorized representative 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. If there is no applicable law addressing this 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 refers to a a specific required review process by Federal regulations for proposals claiming exemption under Exemption Categories 2, 3, 7, and 8.

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

Public health authority means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: (1) Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) 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. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) 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. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Secondary research means re-using identifiable information and identifiable biospecimens that are collected for some other ‘‘primary’’ or ‘‘initial’’ activity.

Written, or *in writing,* for purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.

Appendix C: DOCUMENT HISTORY

02/15/2011 – Original policy document adopted.

02/01/2013 – Language added to Informed Consent section to require initials on pages of a multipage consent form that do not include the signature.

04/05/2013 - The Informed Consent form language required in the Informed Consent section was modified to include the IRB chair's name and position inside the parentheses to avoid confusion should research participants call the Chair's office and hear a voice mail message that does not mention the IRB.

03/27/2017 – Policy document was reviewed and updated. IRB approved (03/03/17) that the document should be thoroughly reviewed every three years.

04/12/2017 – Shepherd University Administrative Council approves March 2017 IRB policy updates, subject to successful amendment of the University Constitution section regarding IRB by the Shepherd University Assembly.

05/06/2017 – Shepherd University Assembly votes to amend the University Constitution section regarding IRB in order to fully enact March 2017 modifications.

01/21/2018 – Policy Manual revised in order to in order to comply revisions to Federal code ("the Common Rule") which were enacted on January 21, 2019.

*Note: Language used in description of categories in Exemption and Expedited Review sections and the Definitions appendix were copied directly from language used in 45 CFR 46.