

Shepherd University Human Participants (Human Subjects) Policy

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. The University policy on activities 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 which involves human participants will be in compliance with the [Code of Federal Regulations \(CFR\) Title 45, Part 46](#). These regulations have been adopted by Shepherd University to cover all research activities involving human participants.

This policy contains the common definitions relevant to ethical research and also misconduct in research and research-related activities. Procedures for filing complaints and the disciplinary actions facing any individual or groups engaged in misconduct in research are provided. For purposes of this policy the term “researcher” is defined as any Shepherd University faculty, staff or student conducting research as an affiliate of the university, whether using Shepherd University facilities or not, and any other researcher conducting research on Shepherd University’s campus or with Shepherd employees or students. A number of other relevant terms are defined in Appendix A while Appendix B presents the relevant Student Research Policy. Finally, two reporting documents – an incident report form and a final closure form are found as attachments following Appendix B.

1.0 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” and as a result 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 are 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 for these recommendations and guidelines as similar recommendations were made by the World Medical Association in its Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, first adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and subsequently revised by the 29th World Medical Assembly, Tokyo, Japan, 1975, and by the 41st World Medical Assembly,

Hong Kong, 1989. The Declaration of Helsinki also provides more detailed descriptions of therapeutic and nontherapeutic 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 1966. 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, the 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 recommended that DHEW take administrative action requiring that these guidelines apply to research conducted or supported by DHEW. This report is known as The Belmont Report.

In 1981 both the Department of Health and Human Services (DHHS, formerly DHEW) and the FDA promulgated significant revisions of their human participant regulations in response to the Belmont Report and other recommendations by the Commission. The DHHS 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 involved the adoption of 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 the charge, this 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 participants research, while the second was to determine how well those rules were being implemented or enforced.

2.0 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. In order 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 the DHHS regulations for the Protection of Human Research Subjects (45 CFR 46, as amended). Additionally, the University will comply with the requirements providing additional protections for children involved in research as set forth in 45 CFR 46 Subpart D. 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 Ethical Principles in the Conduct of Research with Human Participants of the American Psychological Association.

- 2.1. 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.
- 2.2. 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.

- 2.3. 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.
- 2.4. 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 IRB as provided in 45 CFR 46.116(c). Research methods that are in accordance with the requirements set forth in 45 CFR 46.116 and 45 CFR 46.117 and that are adequate and appropriate to the risks of the specific project must be used to obtain informed consent from each participant.
- 2.5. 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.
- 2.6. An individual does not abdicate any rights by consenting to participate in a research project or study. Each and every participant has the right to withdraw from or to 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.
- 2.7. Safeguarding information that has been obtained about any and all individuals in the course of 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.
 - c. 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 to identify, describe, and carry out security measures that are acceptable to the IRB until the records are destroyed. Records which contain personal information shall be destroyed as soon as possible in keeping with the long range goals of the research project.

- 2.8. Research projects will be given initial and continuing review by the IRB as set forth in Section 5.0 (Review Procedures and Criteria for Approval) 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.
- 2.9. No individual involved in the conduct and/or supervision of a specific research project shall participate in IRB review of that project. The only exception will be when the IRB requests information from an individual involved in or supervising a research project.
- 2.10. 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 annual review.
- 2.11. 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 prior beginning any research project involving human participants. Failure to obtain IRB clearance may endanger federal funding to the University and result in restrictions on an individual's research activities.

3.0 IRB Membership

The structure of the IRB must be in compliance with federal regulations as described in 45 CFR Subpart A 46.107. In accordance with these regulations the IRB will have no less than five members with varying backgrounds so that a complete and adequate review of commonly conducted research activities can be completed. Each member of the IRB is expected to bring his or her expertise, interest and representation to the board but is not required to advocate for their constituency. At no time shall one member fill more that one of the roles on the committee. The membership shall be sufficiently diverse and have qualifications through experience and expertise to promote respect for those it advises and counsels when rendering decisions regarding the rights and welfare of human participants. Members shall not be entirely from one profession or gender. The membership of the IRB must include the following:

- 3.0.1. A scientist.
- 3.0.2. A lay person.
- 3.0.3. A person with no affiliation to Shepherd University.
- 3.0.4 An individual with expertise in the area of interest most often reviewed by the IRB.

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

3.2. In order to ensure a full review at its discretion 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.

3.3. The Shepherd University IRB shall be made up of seven (7) voting members and one (1) non-voting member. Four (4) of the voting members will be elected while three (3) of the voting members will be appointed by the President. The one (1) non-voting member will be appointed by the Faculty Senate and will report back to the Faculty Senate. The elections and appointments of the voting members will be done as follows:

3.3.1. One member will be elected from the School of Arts and Humanities by a vote of all full time tenure track faculty in this school. This member can be a tenured or tenure track faculty member of the School of Arts and Humanities.

3.3.2. One member will be elected from the School of Business and Social Sciences by a vote of all full time tenure track faculty in this school. This member can be a tenured or tenure track faculty member of the School of Business and Social Sciences.

3.3.3. One member will be elected from the School of Education and Professional Studies by a vote of all full time tenure track faculty in this school. This member can be a tenured or tenure track faculty member of the School of Education and Professional Studies.

3.3.4. One member will be elected from the School of Natural Sciences and Mathematics by a vote of all full time tenure track faculty in this school. This member can be a tenured or tenure track faculty member of the School of Natural Sciences.

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

3.3.6. 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 four academic schools.

This process recognizes the roles of the faculty in each School being 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.

3.4. The members of the IRB Committee will elect one of the voting members as Chair. While the Chair is elected by the committee members the President must approve the Chair. The Chair will serve for a term of three (3) years. If the Chair resigns, the remaining members will elect a

new Chair from the remaining voting members who, following approval by the President, will serve out the remainder of the term.

3.5. Following adoption of this policy four (4) of the three voting members will be elected or appointed for a two year term and the remaining three (3) voting members will be elected or appointed for a three (3) year term. After the initial elections/appointments, terms will be for three (3) years and voting members can be re-elected/reappointed for an unlimited number of terms. This process will allow for some continuity of membership so that at no time will the entire membership of the IRB Committee be new members.

3.6. If an elected voting member resigns from the IRB Committee prior to the expiration of his/her term an election will be held to select a faculty member from that School to complete the term.

3.7. If an appointed voting member resigns from the IRB Committee prior to the expiration of his/her term the President will appoint a replacement member to fulfill the remainder of the term.

3.8. *All* members (internal and external) of the IRB are required to complete the [NIH Office of Extramural Research](#) training course. After completing the training course the member must download the certificate of completion and submit a copy of the certificate to the President, the IRB Chair and the Shepherd University Research Corporation office. Certification will be valid for three (3) years.

4.0 Institutional Responsibilities

The Institutional Review Board shall have administrative authority concerning the protection of human participants in research at Shepherd University. The IRB will both ensure ethical compliance and that research, funded or non-funded, is fully 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 and if the level of risk is within acceptable federal requirements.

4.1. *All* investigators (students or faculty) working with human participants are required to complete the [NIH Office of Extramural Research](#) training course. After completing the training course the member must download the certificate of completion and submit a copy of the certificate to the President, the IRB Chair and the Shepherd University Research Corporation office. Certification will be valid for three (3) years.

4.2. Research projects involving the use of human participants must be submitted to the IRB for approval unless these are student projects. Student projects will follow the Student Research Policy (Appendix B). If it is unclear whether the proposed research involves human participants, the investigator should seek assistance from the following: Department Chair, IRB Chair, or a SURC Co-Director. Institutional review board applications that support proposals for external funding shall be submitted well in advance of the agency deadline as many agencies require documentation of IRB approval as part of the funding application.

4.3. The IRB will meet as needed with due regard for a thorough but speedy assessment of applications received for review. Therefore, to assure consideration of an application by the IRB in any given month, 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.

4.4. In those applications that the research involves no more than minimal risk to participants an expedited review may be possible. In order for an expedited review to be allowed the research must also fall under one of the research categories eligible for expedited review (refer to Section VII for a complete list of these categories) or fall under the categories exempted by federal regulations. (Refer to Section 7.0 for a complete list of exempt research categories.) The IRB Chair will make the determination if the application is eligible for an expedited review.

4.5. The IRB will proceed to weigh the following primary factors when reviewing a proposal that:

4.5.1. 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 IRB will ensure that adequate safeguards and emergency measures are provided. The IRB will ensure that the researcher will keep proper records and protect the anonymity and/or confidentiality of collected data. Finally, the IRB will ensure that researchers attempt to minimize personal embarrassment, mental anguish, and questions of conscience that could result by participants in the proposed study. In short, the IRB will make every effort to adequately protect both the mental and physical well being of all participants.

4.5.2. 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 PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR OR FACULTY SPONSOR.**

4.5.3. Informed consent of participants will be obtained by adequate and appropriate methods as described in Section 6.0. 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 will be used. Unless specifically waived by the IRB in accordance with 45 CFR 46.117 (c) (1) or (2) informed consent of all participants must be obtained.

4.6. Final approval by the IRB shall require that a majority of all members agree that the proposed research protects human participants in accordance with established standards. A majority vote of the IRB members shall constitute certification of approval. The IRB Chair will

then send a letter of approval to the Principal Investigator/Program Director or Faculty Sponsor, the SURC Co-Director, and other institutional officials as appropriate (See Section 5.0).

4.7. 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.

4.8 For any research being conducted in a school (public or private) 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.

4.9. When research is being conducting in cooperation with another institution approval from the cooperating university, institution, organization, or company IRB is required. If the cooperating institution does not have an IRB then an approved representative must commit to adherence to the Shepherd University Human Participants policy.

5.0 Review Procedures and Criteria for Approval

5.1. The Principal Investigator/Program Director or Faculty Sponsor may be asked to meet with the IRB if clarification of statements in the application or if modification of the methodology are required. A member of the IRB who is involved in the conduct and/or supervision of the research project will recuse himself/herself 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.

5.2. Reasons for a negative decision will be provided in writing to the Principal Investigator/Program Director or Faculty Advisor in a timely manner by the IRB Chair. A researcher may chose to modify the proposed project to meet the objections of the IRB and resubmit the application for further consideration. If the researcher so desires, he/she may request a personal hearing before the IRB Committee to discuss the reasons for the negative decision and necessary changes to the proposal prior to resubmission.

5.3. If any substantial changes in the protocol, emergence of problems or development of hazardous conditions for the participant occur during the research these must be reported immediately to the IRB by the Principal Investigator/Program Director or Faculty Advisor. 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 Section 9.0 Procedures for Managing Critical Events)

5.4. Following initial approval, the IRB will provide the Principal Investigator/Program Director or Faculty Advisor with the minimum time that will be allowed to elapse before re-evaluation of a continuing project is required. Routine projects may reviewed annually while more complex and potentially dangerous projects may be reviewed more frequently. Exempt projects will not require yearly review and will require a review every five (5) years. When submitting an

application for renewal review the Principal Investigator/Program Director or Faculty Advisor should 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 the Principal Investigator/Program Director or the Faculty Advisor reports problems with the research an IRB review must occur. In the case of problems with the research, the IRB will review the data that have been collected to that point and interview both the project personnel and persons under risk.

5.5. Ongoing projects that are modified to include human participants are to be suspended until proposals are submitted to the IRB for review and written approval has been received. When this involves an externally funded project, the granting agency will 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.

6.0 Informed Consent

Informed consent is a process, not just a piece of paper to be filled out by participants. This process is 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 shall be requested under circumstances providing sufficient opportunities for the participant to freely consider whether or not 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.

6.1. 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.

6.2. 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 should be signed by the participant or the participant's legally authorized representative unless this requirement is waived by the IRB. A copy of the consent document is to be given to the participant and a second copy is to be kept by the researcher.

6.3. For participants who are minors (under 18 years of age), unless waived by the IRB, written parental consent is required. The IRB will only grant a waiver of the requirement of written informed consent in accordance with 45 CFR 46.116(c) if the investigator can provide adequate justification for the request. 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).

6.4. 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 summary of what will be told to the participant must be provided to the IRB for review and approval.

6.5. 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.

6.6. The Federal government requires that the following information is to be included in ***ALL*** consent material in a language that is understandable and appropriate to the participant or participant's representative

6.6.1. A statement that the project is research accompanied by an explanation of the scope, aims and purposes of the research, There must also be a description of the experimental procedures to be followed that includes the expected duration of the participant's participation.

6.6.2. The following statement will be included in ***ALL*** written informed consents (including cover letters). It is suggested that this statement be inserted at the bottom margin of the form, letter or portion of the form that is to be retained by the participant.

ANY QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH PARTICIPANT MAY BE ADDRESSED TO THE SHEPHERD UNIVERSITY INSTITUTIONAL REVIEW BOARD (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.

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

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

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

6.6.6. 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, information about how it may be obtained or where further information may be secured is required.

6.6.7. 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.

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

6.6.9. 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.

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

In addition to the information required by Federal law the investigator should remember the following items relevant to the consent documents:

A copy of the informed consent shall be supplied to the participant or the participant's legally authorized representative.

While Federal law requires that copies of all informed consents be retained for a minimum of three (3) years after the completion of the research, for audit purposes, Shepherd University requires that all copies of consents must be kept for no less than five (5) years after the completion of the project or acceptance of the final report. The responsibility with maintaining and retaining the records lies with the Principal Investigator/Program Director or Faculty Advisor. If Principal Investigator/Program Director or Faculty Advisor leaves the University these documents are to be delivered in a sealed container to the IRB Chair for maintenance and storage.

7.0 Exemptions from Annual Review

Based on DHHS regulations published in the Federal Register on January 26, 1981 and March 4, 1983 Shepherd University has designated certain research categories as exempt from IRB review. While exempt categories exist, this exemption must be validated by the IRB. In order to establish an individual research project as exempt from annual review, an investigator must complete and submit an IRB application for review and approval indicating the request for exempt status. It is the prerogative and responsibility of the IRB to make a determination as to whether the research project falls into an exempt category.

Once a specific research project is certified as exempt from annual review by the IRB, the investigator is not required to submit the project for annual IRB review assuming there are no modifications in the exempted procedures. In order to retain exempt status a renewal application must be submitted by the investigator every five (5) years. This renewal process will allow the IRB to assess the project protocols in light of 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.

7.1. Shepherd University has adopted the following categories of exemption from IRB review:

7.1. Research that involves normal educational practices and conducted in established or commonly accepted educational settings. Examples would include, but not be limited to,

- a) research on regular and special education instructional strategies, and
- b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

7.2. Research using educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

- a) the information obtained is recorded in a manner that human participants can be identified, directly or through identifiers linked to the participants; and
- b) any disclosure of the human participants' responses outside the research could be damaging to the participants' financial standing, employability, or reputation and/or reasonably place the participants at risk of criminal or civil liability or;
- c) the research involves children as participants (legal age of consent in the State of West Virginia is 18 years old).

7.3. Research using educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under section 7.2, if:

- a) the human participants are public officials (elected or appointed) or candidates for public office; or
- b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

7.4. Research and demonstration projects conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or otherwise examine:

- a) public benefit or service programs;
- b) procedures for obtaining benefits or services under said programs;
- c) potential changes in or alternatives to those programs or procedures; or
- d) potential changes in methods or levels of payment for benefits or services under those programs.

7.5. Taste and food quality evaluation and consumer acceptance studies,

- a) if wholesome foods without additives are consumed or
- b) 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.

8.0 Expedited Review

Certain categories of research are recognized by DHHS 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 in an expedited manner. When the IRB Chair receives a proposal for expedited review he/she will review the proposal and, if in agreement, will expedite the review. If the Chair does not agree that the proposal is eligible for an expedited review the proposal will be referred to the IRB committee for a complete review.

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

Expedited review will be given only for research protocols that fall under one of the categories listed below.

8.1. Minor modifications or additions to existing approved studies;

8.2. Research on the behavior (individual or group) or characteristics of individuals. This would include but not be limited to studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants' behavior and the research will not involve stress to participants;

8.3. The study of existing data, documents, records, pathological specimens or diagnostic specimens;

8.4. Voice recordings made for research purposes;

8.5. Moderate physical or mental exercise by healthy volunteers;

8.6. Using venipuncture to collect blood samples in amounts that do not exceed a total of 450 milliliters in an eight week period and are taken no more frequently than twice per week, from participants 18 years of age or older who are in good health and not pregnant;

8.7. Collecting hair, nail clippings and deciduous teeth in a non-disfiguring manner; and permanent teeth if patient care indicates a need for extraction;

8.8. Collection and analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;

8.9. Data recordings from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors applied to the surface of the body or at a distance and does not involve input of matter or significant amounts of energy into the participant or an invasion of the participant's privacy. (These procedures would

include weighing, testing sensory acuity, electrocardiogram, electroencephalogram, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography but not exposure to electromagnetic radiation outside the visible range, i.e., x rays, microwaves.);

8.10. Collection of both supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; and

8.11. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

9.0 Managing Critical Incidents

While an investigator will make every attempt to ensure that research projects are completed without incident in some cases it is impossible to prevent incidents from occurring. In the course of 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.

9.1. 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 effects. Key terms are discussed at <http://www.hhs.gov/ohrp/policy/AdvEvtGuid.htm> and this web page also cites the regulatory background underpinning 45 CFR 46.103(b)(5). The definitions provided here do not appear in 45 CFR 46, but in general OHRP considers unanticipated problems to include any incident, experience, or outcome that meets *all* of the following criteria:

- a) 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;
- b) related or possibly related to participation in the research (in this guidance document, 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
- c) 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 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 (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

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.

9.1.1. Emergency (life threatening)

1. If on campus, manage the emergency according to University procedures. If off-campus, call 911.
2. Communicate the medical emergency to the appropriate office (for students the Vice President of Student Affairs, for faculty the Vice President for Academic Affairs, and for Staff the University Counsel), the IRB chair or SURC Co-Director immediately.

9.1.2. Non-emergency (not life threatening)

1. 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.

In non-emergency incidents, the IRB chair will work 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 part 46 and using the guidance documents provided by OHRP. After due consultation with the investigator and university officials (President or designee, SURC Co-Director, others as appropriate), the IRB chair will determine whether the IRB Committee will be convened to review the research protocol in light of the incident.

Depending on severity, such events warrant consideration of changes to the research protocol, the informed consent process/document or other corrective actions in order 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.

9.2. Steps For Resolving Critical Incidents That Are Unanticipated Problems/Adverse Events

9.2.1. Critical incidents will be reviewed by the IRB unless they are determined to be anticipated problems, are non-emergency, and are managed within the research protocols approved by the IRB.

9.2.2. The Principal Investigator/Program Director or Faculty Advisor will complete an Incident Report Form (HS 7) promptly and forward the form with all explanatory documentation to the President, IRB Chair or SURC Co-Director. A copy of this form can be found following the appendices.

9.2.3. The IRB Chair will convene a special IRB meeting related to the incident.

9.2.4. The Principal Investigator/Program Director or Faculty Advisor will meet with the IRB to discuss the critical incident and 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.

9.2.5. 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.

9.2.6. The Principal Investigator/Program Director or Faculty Advisor shall submit a proposal to the IRB that includes the new protocols prior to proceeding or in the timeframe and conditions deemed appropriate by the IRB.

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

9.3. Steps For Resolving Critical Incidents Due to Non-Compliance

All Shepherd University employees and students have a moral and ethical obligation to report non-compliance with university policies and procedures. Individuals or groups conducting research involving human participants must abide by the policies and procedures in order 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, VPAA, the IRB chair, any member of the IRB committee, or either of the SURC Co-Directors. In cases of serious or continuing non-compliance, the IRB Chair must report the findings of the IRB to the President, the SURC Co-Director, and other parties as appropriate for action. Human Subjects Policy provides guidance for disciplinary actions that may be required in Section 2.11. Misconduct in Scholarly Research policy may also be applicable.

9.4. Steps For Resolving Critical Incident Due to Suspension or Termination of IRB approval

In some cases the problems or adverse events may be serious enough to 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 re-vision their research and submit new research proposals for IRB approval if human participants are part of the re-visioned research plan.

9.5. Reporting Responsibilities

In all cases of problems/adverse events, non-compliance, or termination of IRB approval of research, the IRB Chair shall file a timely report with the VPAA, the HPA, and others as directed by the VPAA. As appropriate, the Human Protections Administrator shall file the appropriate required reports with the Office of Human Subjects Protection and the federal agency providing funding, where relevant, according to the conditions of award and federal regulation.

10.0 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 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 Vice President for Academic Affairs for resolution.