

Dixie State University Policy

607 Institutional Review Board (IRB)



- I. Purpose
- II. Scope
- III. Definitions
- IV. Policy
- V. References
- VI. Procedures
- VII. Addenda

I. Purpose

- 1.1 Dixie State University (DSU) safeguards the rights and welfare of human subjects involved in all research projects conducted under institutional auspices. Research projects conducted under institutional auspices" means research conducted by any employee, student, or agent either in the course of his or her institutional responsibilities or when using the University name, symbols, property or services in connection with the research.
- 1.2 DSU assures the government and the public that it will comply with federal regulations for the protection of human research subjects. The function of the Dixie State University Institutional Review Board (IRB) is to ensure adherence to all federal, state, local, and institutional regulations concerning the protection of human subjects in research. The DSU IRB review is required for both funded and non-funded human subjects research.

II. Scope

- 2.1 This policy applies to all faculty, staff, and students whenever they are supervising or conducting research activity involving human subjects, regardless of whether the subjects are members of the University community. Non-University personnel may also come under the purview of this policy when their research or related activities utilize members of the University community. Both funded and non-funded research activities are covered by this policy. [45 CFR 46.103 (b)(1)]
- 2.2 Human subject is defined by the Code of Federal Regulations (CFR) as "a living individual about whom an investigator obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." Under Department of Health and Human Services (DHHS) regulations activities are

"research" when they are a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction included communication or interpersonal contact between investigator and subject.

- 2.3 No research involving human subjects may be conducted by University faculty, staff, or students, or by non-University personnel in instances where members of the University community are serving as the subjects, prior to approval being granted under the appropriate provisions of this policy. This restriction applies equally to all three categories of review: standard (full), expedited, and exempt. No contact of any kind may be made for purposes of research with actual or prospective subjects until after the appropriate application and informed-consent form has been reviewed and approved or a waiver of informed consent has been granted. [45 CFR 46.116]

- 2.4 Final responsibility for the protection of human subjects and adherence to ethical standards rests with the University in the case of all research projects conducted under University auspices; however, in particular the Principal Investigator, and in general the faculty, staff, and students conducting such research share the primary responsibility for assuring that their research is properly conducted. Consequently, the University requires that all persons at DSU involved in activities involving human subjects be familiar with, and at all times comply with, the provisions of this document.
 - 2.4.1 Tenured or tenure track DSU faculty, including emeriti, who are certified by Dixie State University as having received training in the conduct of research using human subjects are eligible to serve as Principal Investigators (PI) for DSU projects involving human research subjects. Other faculty and staff members who fall into one of the following categories may be eligible to serve as PI with approval from the Office of the Provost: 1. Non-tenure track faculty, and other senior academic staff whose appointments include responsibility for the direct, independent design and direction of research; 2. Clinical faculty; 3. Senior administrative staff with appointments as Director (or equivalent) and responsibility for the direct, independent design and management of projects; and, 4. Visiting faculty. PI status may be limited to a specific research protocol (project) or activities associated with a specific grant, or have other conditions or limitations associated with approval, as designated by the IRB.

Projects which ordinarily do not require IRB approval or oversight:

- 2.5 An example of an activity that is not research requiring approvals by the IRB would be any evaluation of an employee, course, program, or service in which such evaluation is not designed to lead to generalizable knowledge. If an activity does not involve research, it does not require approval or review by the IRB. If the investigator has any doubt as to whether an activity constitutes research, he or she should contact the Chair of the DSU Institutional Review Board or the member of the IRB from your academic unit.
- 2.6 The University encourages novel and innovative classroom activities in support of its teaching mission. Most class assignments do not require review by the IRB. Many student class assignments, such as those commonly used in research methods courses do not meet federal regulatory definition of research. Therefore, ordinarily class assignments do not fall under the jurisdiction of the IRB and do not require IRB approvals or oversight. A student class assignment not requiring IRB approval, in general, is:
- 2.6.1 An activity designed as part of a course requirement for purposes of learning research methods, such as the consent process or data collection;
- 2.6.2 An investigation that a student conducts as a class assignment designed to teach human subject research methodology; and
- 2.6.3 A project not intended to produce findings that will be applied more broadly to the population at large.
- 2.6.4 A project not intended to produce findings that will not be reported in anyway outside of the classroom (i.e., campus conference, academic conference, etc.).

Parameters for class assignments not requiring IRB approvals and oversight.

- 2.7 **NO VULNERABLE POPULATIONS:** The project cannot include minors or any other vulnerable populations such as pregnant women, prisoners, those who lack the capacity to consent, non-English speaking individuals, etc. **Exception:** Projects conducted in established or commonly accepted educational settings, involving normal educational practices, such as: work on regular and special education instructional strategies, or work on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.

- 2.8 **NO MORE THAN MINIMAL RISK:** "Minimal risk" means 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. This also precludes the study of any illegal activities, vulnerable populations as outlined in 45 CFR 46.111 (a)(3) or the collection of private information that could put the participants at risk through a breach of confidentiality.

III. Definitions

- 3.1 **Adverse Event:** Any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research, or had an unfavorable impact on the risk/benefit ratio; Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.
- 3.2 **Assent:** An agreement by an individual not competent to give legally-valid informed consent (e.g., a child aged 7+ or cognitively-impaired person) to participate in research
- 3.3 **Assent of a Child:** Assent means a child's affirmative agreement (verbal or written) to participate in a clinical investigation. Mere failure to object may not, absent affirmative agreement, be construed as assent.
- 3.4 **Belmont Report:** A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978. The principles are Justice, Beneficence and Respect for Persons. <http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
- 3.5 **Certificate of Confidentiality:** A document that provides additional protection of data from legal subpoena. The Certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. <http://grants.nih.gov/grants/policy/coc/index.htm>
- 3.6 **Class Assignment:** A student class assignment, in general, is:

- 3.3.1 An activity designed as part of a course requirement for purposes of learning research methods, such as the consent process or data collection;
 - 3.3.2 An investigation that a student conducts as a class assignment designed to teach human subject research methodology; and
 - 3.3.3 A project not intended to produce findings that will be applied more broadly to the population at large.
- 3.7 **Common Rule:** The Common Rule, which governs research with human subjects conducted or supported by 15 federal departments and agencies including EPA, establishes a comprehensive framework for the review and conduct of proposed human research to ensure that it will be performed ethically. The central requirements of the Common Rule are:
- 3.8 That people who participate as subjects in covered research are selected equitably and give their fully informed, fully voluntary written consent; and
 - 3.9 That proposed research be reviewed by an independent oversight group referred to as an Institutional Review Board (IRB), and approved only if risks to subjects have been minimized and are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.
- 3.10 **Consent:** These are the documents presented to a subject or parent guardian prior to beginning a study. Most studies will have this document submitted with the proposal, unless requesting a Waiver (see below). The IRB has provided a template on the web site for investigators to prepare their documents.
- 3.10.1 ***Adult Informed Consent:*** This is required when subjects are 18 years and older. This should be written to the subject using appropriate language ("you").
 - 3.10.2 ***Parental Permission Document:*** This is required when subjects are 17 years and younger. This should be written to the parent/guardian using appropriate language ("your child").
 - 3.10.3 ***Assent Document:*** Assent is an agreement by an individual not competent to give legally valid informed consent (e.g., a child aged 7+ or cognitively-impaired person) to participate in research. This is required for children enrolled in studies that are 7-17 years of age. If the board deems appropriate, this can be requested for younger children.

- 3.11 **Federal Wide Assurance:** A standing agreement that Dixie State University has on file with the Office for Human Research Protections that describes in detail the procedures it will use to protect the rights and welfare of the human subjects. An institution must have an FWA in order to receive HHS support for research involving human subjects. Each FWA must designate at least one IRB registered with OHRP. Before obtaining an FWA, an institution must either register its own IRB (an "internal" IRB) or designate
- 3.12 **Helsinki Declaration:** A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It has been revised several times, most recently in 2013 <http://www.wma.net/en/30publications/10policies/b3/index.html>
- 3.13 **Human Subjects Research:** According to IRB policy, research involving human subjects (participants) is defined as any one of the following:
- 3.14 ***Human subjects research subject to DHHS regulation:*** Activities are human subject research subject to DHHS regulations when they meet the DHHS definition of "research and involve a "subject" as defined in DHHS regulations.
- 3.14.1 Under DHHS regulations activities are "research" when they are a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 3.14.2 Under DHHS regulations "subjects" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
- 3.14.3 Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- 3.14.4 Interaction included communication or interpersonal contact between Investigator and subject.
- 3.14.5 Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of

the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- 3.14.6 Research that does not meet the definition of research involving human subjects must be determined by the IRB staff, not an individual investigator. Investigators must complete and submit an IRB new study application with any applicable documents.
- 3.15 **Informed Consent:** A process by which a participant or legal guardian voluntarily confirms his or her willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form approved by an IRB, unless such documentation is waived by the IRB (45 CFR 46).
- 3.15.1 A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25] (OHRP).
- 3.16 **Informed Consent Form:** A document that describes the rights of a study participant and provides details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document.
- Office of Human Research Protections (OHRP):** A federal government agency within the
- 3.17 Department of Health and Human Services (DHHS) charged with the protection of human subjects participating in government funded research. It issues assurances and oversees compliance of regulatory guidelines by research institutions. <http://www.hhs.gov/ohrp/about-ohrp/index.html>
- 3.18 **Protected Populations:** (see also Vulnerable Populations below)
- 3.18.1 Prisoners, an individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in

other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such s prosecution or incarceration in a penal institution. The definition of "minimal risk" for research involving prisoners differs somewhat from that given for non-institutionalized adults. <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartc>

3.18.2 (2) Pregnant women, human fetuses, neonates and fetuses

<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb>

3.18.3 (3) Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Code of Federal Regulations allows the IRB to approve research as described in sections §46.404. §46.405. §46.406 and §46.407.

<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd>

3.19 **Review Types: Exempt Review:** Research may be exempt from review when human participants conform to one of the categories from section 46.101(b) of 45 CFR 46. These studies are not usually reviewed by board members, but are reviewed by the chairman. These have been determined to fit certain federal regulations as exempt from IRB review.

3.20 **Expedited Review** of proposed research by the IRB Chairperson or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

3.21 **Full Review:** Any proposed research not qualifying for Exempt status or Expedited review requires a Full Review, in which a majority of IRB members review and vote on the proposal. These typically involve projects that place human subjects at more than minimal risk, or that involve sensitive topics or vulnerable populations such as prisoners, terminally ill patients, children, veterans, or cognitively impaired persons.

3.22 **Risk Determinations:** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (See also: Minimal Risk.) These can include:

- 3.22.1 **Moderate Risk:** The subject will undergo procedures that will increase their risks above those normally encountered in daily life. Equivalent term is "more than minimal risk." These can include, but are not limited to: clinical drug trials, device trials, genetic studies, and risks that include insurability and employability.
- 3.22.2 **Minimal Risk:** The subject will undergo procedures that do not appear to increase the risks above those normally encountered in daily life. These can include but are not limited to studies that involve survey, questionnaire, interview, medical records review, observation of behaviors, drawing a small amount of blood from a healthy individual, etc.
- 3.23 **Vulnerable Populations:** Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
- 3.24 **Waiver of Informed Consent:** Occasionally there are reasons to waive written consent or to alter the requirements of consent. Only the IRB can make the determination to waive some (written) or all (written and verbal) consent requirements. In order to qualify for a Waiver of Consent, the following conditions should be met: 1) that the research pose no more than minimal risk to subjects; 2) no adverse effects as a result of the waiver or alteration; 3) without the waiver or alteration the research in question could not be carried out; and 4) information will be provided after participation is completed, if appropriate.

IV. Policy

- 4.1 Human Subjects Researchers – University employees, students, and agents who are or who are expecting to be engaged in such research – must be familiar with this policy. The responsibility of Human Subjects Researchers will be guided by generally accepted ethical principles for human subjects research. The University adopts the report of the national Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled Ethical Principles and

Guidelines for the Protection of Human Subjects of Research, commonly known as *The Belmont Report*, (www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm), as its statement of these generally accepted ethical principles. Although the primary focus of *The Belmont Report* is on biomedical and behavioral research, its discussion of Basic Ethical Principles and Applications is easily adapted to most other types of research involving human subjects.

- 4.2 All research that involves the use of humans (e.g., survey, experimental, evaluation, biomedical research) must be approved by the Institutional Review Board (IRB), according to the University's Federal Wide Assurance (FWA) with the Department of Health and Human Services. The Institutional Review Board is charged with the responsibility of maintaining institutional compliance with the U.S. Office of Human Research Protections (OHRP) regulations regarding the use of human subjects in research.
- 4.3 Research is defined in the Code of Federal Regulations (CFR) as "a systematic investigation designed to develop and contribute to generalizable knowledge."
- 4.4 Examples of activities that constitute research include:
 - 4.4.1 any study intended to result in publication or public presentation;
 - 4.4.2 any activity resulting in publication or public presentation, even though it involves only review of existing data that was collected with no intent to publish; or
 - 4.4.3 any use of an investigational drug or device.
- 4.5 Thus, research with human subjects includes survey and interview research, as well as evaluation studies.
- 4.6 Each Human Subjects Researcher must provide evidence to the University's Institutional Review Board (IRB), prior to engaging in research covered by this policy, that he or she has satisfactorily completed the required training course designated by the IRB.
- 4.7 If a student class assignment or an independent research project is collected in a systematic manner and is intended to be applied more broadly to the population at large, this is Human Research and an IRB application must be submitted for review and approval **prior** to conducting the study. For student class assignments that constitute Human Research, the instructor must be listed as the PI, and the student(s) may be listed as Co-PI. For independent research projects

that constitute Human Research, the student's advisor/mentor must be affiliated with DSU.

Training Requirements:

4.8 All persons acting as a Principal Investigator must complete the appropriate training course if they will be conducting a project during the course of a class.

4.8.1 Instructors assigning class projects are required to complete the required human subjects training program.

4.8.2 It is recommended that instructors require students to complete the IRB training tutorial as part of the learning experience, even in cases when student projects do not require IRB approval.

Independent Research Projects

4.9 Independent research projects, such as scholarly projects, internships, and honors projects, may fall under the jurisdiction of the IRB if the information is collected in a systematic manner and there is intent by the student researcher to apply the research findings and conclusions from the study to the population at large.

4.10 In the case of the scholarly project, internship, or practicum, the student may complete a project on behalf of an organization that would involve interaction with human subjects. The student's primary goal, however, is educational, whereas the organization for which the student is volunteering may use the information collected for quality improvement or publication. For the purpose of the DSU IRB, these projects do not constitute research. Activities conducted at another site in connection with the internship or scholarly project are subject to the review and approval of the other site.

Responsibilities of Researchers, advisors:

4.11 It is the researcher's responsibility to comply with all relevant laws and regulations affecting research involving human subjects. The researcher must submit to the IRB a research proposal following the guidelines provided by the IRB which is to accompany all research proposals. At the end of the study, the researcher must submit Summary/Continuation Form to the IRB. Approvals of federally sponsored human subjects research are only valid for 12 months and a continuation review is required.

- 4.12 If during the research an adverse event occurs, the researcher must stop the research and immediately report the event to the IRB.
- 4.13 Student projects must have a faculty advisor/sponsor. Under no circumstances can a student act as the Principal Investigator. Instructors conducting classroom projects and faculty advisors of student projects are responsible for insuring that student research conducted under their direction must conform to the requirements of federal law and regulations on research regarding human subjects.

Criteria for Approval of Research

- 4.14 In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:
- 4.15 Risks to subjects are minimized, either by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, or by using procedures which are already being performed on the subjects for diagnostic or treatment purposes.
- 4.16 Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and in relation to the importance of the knowledge that may reasonably be expected to result.
- 4.17 The selection of subjects is equitable. The IRB must be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- 4.18 Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be appropriately documented.
- 4.19 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 4.20 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- 4.21 When some or all of the subjects are likely to be vulnerable to coercion or other undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. [45 CFR 46.111]

- 4.22 The IRB shall consider only the risks and benefits of the research being reviewed relative to the possible harm of the human subjects involved. Research merit and social sensitivity or other considerations shall not enter into judgments concerning a protocol. Issues and concerns about research which arise during the IRB's deliberations, but which go beyond or are unrelated to the protection of human subjects, may be referred to back to the researcher.
- 4.23 The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. It shall have the authority to observe, or have a third party observe, both the consent process and the research itself. [45 CFR 46.103 (b) (4) (ii)]

Appeal of an IRB Decision

- 4.24 If a protocol is disapproved by the IRB, the reason(s) for disapproval shall be provided in writing to the investigator. The investigator may appeal a decision on procedural grounds only to the Office of the Provost within twenty (20) instructional days following written notification of the IRB decision. The Office of the Provost will review the appeal and may elect to confer with the IRB. Federal regulations, however, provide that a negative decision of the IRB may not be overturned by any other University official or body. [45 CFR 46.109 (d) and 46.112]

Suspension or termination of IRB approval of research.

- 4.25 The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. **§46.113**

Violations of Human Subject Policies and Procedures.

- 4.26 The IRB will investigate alleged violations of these policies and procedures, and report its findings to government agencies as required by law to the Office of the Provost, and to the DSU President. **§46.113**

Administrative Review.

- 4.27 The IRB chair will prepare an annual report (submitted July 1) that includes a listing of all proposals submitted to the IRB and an indication of the action taken. The Office of the Provost will keep a record of all actions taken. This report and a copy of each proposal and documentation will be kept in the Office of the Provost's Office. A copy of the report will also be forwarded to the President.

Composition of IRB

- 4.28 The IRB membership includes at least one faculty member from each of the DSU college/divisions/schools (presently: Humanities, Education, Science and Technology, Business and Communication, Visual and Performing Arts), and at least one person not affiliated with DSU. The members of the IRB must have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. 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. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. At the discretion of the IRB Chair, an Ex Officio member be appointed to assist with the evaluation of compliance matters. See: **§46.107 IRB membership.**
- 4.29 **Appointment and Terms.** Members of the IRB will be appointed by the Office of the Provost or designee. Members serve three-year terms, except the representative from the community who serve one-year terms (renewable upon need and satisfactory completion). The chairperson of the IRB (“IRB chair”) will always be a member of the full-time faculty appointed by the Office of the Provost.
- 4.30 **Responsibilities and Duties.** The IRB will implement this policy in accordance with all relevant laws and regulations. To do so, the IRB will create procedures, forms and other instruments, as it deems necessary. If anything in this policy or in IRB procedures, forms, or other instruments (collectively “policy”) can be construed to conflict with governing law, then the IRB will bring such possible conflicts promptly to the attention of the University Senate and University counsel and, pending amendment of the policy, will implement the policy in a manner that conforms with the IRB’s understanding of the law.
- 4.31 The IRB shall have the authority to require modifications of a research protocol and of the project itself and to give ultimate approval or denial to the project. When the IRB approves or disapproves a protocol, it shall furnish a written

statement to the investigator. The decision to approve a protocol requires a majority of the quorum at the time of the vote (see Section III.E on Membership). The IRB may take any of the following actions:

- 4.31.1 Classify the protocol as exempt;
- 4.31.2 Approve the protocol as submitted;
- 4.31.3 Approve the protocol contingent upon the incorporation by the research of specified minor revisions;
- 4.31.4 Request outside review of the protocol prior to reconsideration;
- 4.31.5 Require significant modification of the protocol prior to resubmission;
- 4.31.6 Request the investigator to discuss identified problems with the IRB;
- 4.31.7 Reject the protocol. [45 CFR 46.109]

V. References

Code of Federal Regulations TITLE 45 HHS Part 46
PROTECTION OF HUMAN SUBJECTS

<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

[U.S. Office of Human Research Protections \(OHRP\)](#)

<http://www.hhs.gov/ohrp/about-ohrp/index.html>

VI. Procedures

- 6.1 For all research activity, the investigator- whether an administrator, faculty member, staff member, or student- must file a protocol, or description of the procedure(s) to be used to gather information from subjects, with the IRB. The IRB must then approve the protocol prior to the collection of any data or research information from the research participants (full details are available at the following URL: dixie.edu/IRB).
- 6.2 The guidelines have provisions for exemption of some studies that involve no risk to subjects and for expedited review for some types of studies involving no more than minimal risk to subjects. The determination of the type of review required must (by federal mandate) be made by the Institutional Review Board.

VII. Addenda

N/A

Policy Owner: Office of the Provost
Policy Steward: Chair, Institutional Review Board

History:
Approved 9/23/16