

INSTITUTIONAL REVIEW BOARD

POLICY STATEMENT

Delta State University maintains a federally certified Institutional Review Board which has been established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University and other affiliated entities in the region. DSU IRB policies are extensions of the [Belmont Report](#) (1979) and the [Code of Federal Regulations, Title 45, Part 46](#), also known as 45CFR46. Both of these documents can be found and downloaded from the Health and Human Services (HHS) [Office of Human Research Protections \(OHRP\)](#). The federal regulations apply to “all research involving humans subjects conducted, supported, or otherwise subject to regulation by any federal department or agency.” However, DSU has adopted the federal regulations as its institutional policy and all human subject research, regardless of funding support, is subject to these regulations. ***IRB clearance must be obtained prior to the beginning of any research involving human subjects.***

DEFINITIONS

DSU has adopted definitions of “research” and “human subjects” in accordance with the Code of Federal Regulations, Title 45, Part 46 (45CFR46): Protection of Human Subjects. These definitions are as followed:

Research – a systemic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

Human Subjects – living individual(s) 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.

PROCEDURES AND RESPONSIBILITIES

Jurisdiction and Authority. The Institutional Review Board has the authority to approve, require modifications, or disapprove any research activities conducted under the auspices of Delta State University that fall within its jurisdiction. Research that has been approved by the IRB may be subject to review and disapproval by University officials. However, University officials may not approve research if it has been disapproved by the IRB.

It is the responsibility of the IRB to determine whether it has jurisdiction, not individual researchers, principal investigators, or University officials. All research protocols involving human subjects must be submitted to the IRB for review. The IRB determines if the research activity is exempt from review or is subject to an expedited or full IRB review. Researchers are responsible for complying with all IRB decisions, conditions, and requirements and reporting the progress of the research at least annually to the IRB. This IRB exists for the purpose of the

protection of human subjects and has no jurisdiction or authority to review research involving animals.

The IRB has the 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. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and will be reported immediately to the investigator, department chair, and dean.

Functions. It is the responsibility of the IRB to:

- 1) review and approve, require modifications, or disapprove any research activities involving human subjects.
- 2) require that information given to subjects as part of informed consent meets the general requirements of informed consent as outlined in §46.116.
- 3) require documentation of informed consent or waive documentation in accordance with federal regulations.
- 4) notify investigators and the appropriate Chair and Dean or Administrator in writing of its decision to approve, require modifications or disapprove the proposed research activity, providing a written statement for disapprovals.
- 5) conduct continuing review of research at least once per year, at intervals appropriate to the degree of risk.
- 6) maintain adequate documentation of IRB activities, including copies of all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, and copies of correspondence between the IRB and investigators.
- 7) report to university officials and the OHRP any unanticipated problems involving risk to subjects of others, any serious and continuing noncompliance with 45 CFR Part 46, and any suspension or termination of IRB approval of research.

IRB membership. The Chair of IRB is the Dean of Graduate Studies and Continuing Education or as appointed by the Provost/VPAA. The IRB will consist of at least six members representing both scientific and non scientific disciplinary backgrounds, and will be diverse with respect to gender, race, academic discipline, and cultural background. The IRB members will be appointed by the IRB Chair in consultation with the Academic Deans. The IRB will include at least one individual who is not affiliated with DSU, nor is an immediate family member of someone who is affiliated. Each member must complete the online tutorial "[Protecting Human Research Participants](#)" through the National Institutes of Health Office of Extramural Research or equivalent course and submit certification of completion to the IRB Chair as a condition for membership.

Individuals with competence in specific areas may be invited to assist in a review in the event that there are issues which require expertise beyond that available on the current IRB, however, these individuals may not vote. In the event that an IRB member has a conflicting interest with a project to be reviewed, it is his/her responsibility to disclose such conflict and recuse him/herself from the review.

Procedures:

- 1) **Tutorial.** The principal investigator/researcher and any co-investigators must complete the online tutorial [“Protecting Human Research Participants”](#) through the National Institutes of Health Office of Extramural Research *or equivalent course* and submit certification documenting completion to the IRB Chair. Students conducting research are also required to complete the training. Required training must be completed prior to application submission and there must be a current certification on file in the IRB office.

- 2) The principal investigator/researcher submits the Request for IRB Clearance form with original signatures to the IRB Chair. In addition to the Request for IRB Clearance form, the researcher must submit a typed narrative that includes the following:
 1. Brief statement of project goals
 2. Research Protocol including:
 - Research procedures
 - Description of the subject population
 - Criteria for selection
 - Recruitment procedures
 - Number and age of subjects
 - Length of research procedure and time commitment required of subjects
 - Location of the study
 - Methodology (attach a copy of the data collection tool)
 - Description of who will gather the data and how will they be trained
 - Special situations
 3. Benefits to the subject or to others
 4. Risks – Describe the possible risks, discomforts, and inconvenience to the subjects and the precautions that will be taken to minimize them (include physical, psychological and social risks). Describe appropriate controls, screenings methods, follow-up procedures. Describe what constitutes termination from the study before its completion. Describe how confidentiality will be maintained including confidentiality of data collection and who will have access to the data.
 5. Informed Consent. Describe the procedures that will be used in obtaining informed consent, keeping in mind that informed consent is a process, not just a form. Submit informed consent documents/forms. Ensure that informed consent addresses at the minimum the following:
 - a. Purpose and description of the research
 - b. Amount of time required of the subject
 - c. Voluntary participation

- d. Confidentiality of data
- e. Contact information of the researcher
- f. Information concerning the IRB

Where necessary other documents that must be submitted are:

- Survey/research instruments
- Copy of Consent and Assent forms
- Communication that will be provided to parents and/or external organizations such as schools, clinics, etc
- List of external organizations that will be contacted

- 3) Once the IRB Chair or his/her designee determines that an activity meets the requirements of definitions of research and human subjects, it is then determined if the research is exempt from the regulations requiring IRB review. The PI can request exemption, indicating the exemption category 1-6 below, on the Request for IRB Clearance form. However, the determination that a research activity is exempt rests with the IRB. Exemption can be granted by the IRB Chair or one or more experienced reviewers that he/she designates.
- 4) **Exemptions.** Research activities in which the only involvement of human subjects fall in one or more of the following categories may be exempt from further IRB review:
- 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identified linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - 3) Research involving the use of educational tests (cognitive diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under exemption #2, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 - 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - 5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate,

or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternative to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- 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 FDA or approved by the EPA or the Food Safety and Inspection Services of the USDA.

If the research meets one of the above criteria for exemption, the researcher is notified by the IRB and may begin his/her research.

5) Expedited Review. The PI can request Expedited Review on the Request for IRB Clearance Form. The IRB may use expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in previously-approved research. The research categories that are eligible for expedited review are:

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

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases 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 (21 CFR Part 812) 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.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant 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 children², 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring 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) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase 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 subgingival 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.

(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.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

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

(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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)

(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.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (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.

Under the Expedited Review procedure, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. Only the Full Review Board can disapprove an application. If approved through Expedited Review, the researcher will be notified and can begin their research.

- 6) Full Review.** If the application is neither exempt nor eligible for Expedited Review, it will be scheduled for review by the full IRB. Allow up to 3 months for full review. **No research on human subjects may begin until cleared by the IRB.** Following the full review, the IRB will issue one of the following determinations: Approved, Modifications Required, or Disapproved.

If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person and/or in writing. An appeal of a disapproved research project must be reviewed at a full board meeting. In the case of a decision by the IRB to disapprove, suspend, or terminate a project, the decision may not be reversed by any other officer or agency of the University, state government or federal government.

The IRB retains the final authority for approval of proposed research with human subjects.

- 7) Criteria for approval.** The IRB reviews research based on the basic ethical principles as set forth in the [Belmont Report](#): the principles of respect of persons, beneficence, and justice. In

order to approve research, the IRB must determine all of the following requirements are satisfied:

- 1) Risks to subjects are minimized.
 - 2) Risks to subjects are reasonable in relation to anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result.
 - 3) Selection of subjects is equitable.
 - 4) Informed consent will be sought and received from each prospective subject or their legally authorized representative.
 - 5) Informed consent will be appropriately documented.
 - 6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - 7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - 8) Research is in compliance with local, state, and HIPAA regulations.
- 8)** Investigators/researchers, including co-investigators/researchers, are to immediately report any incident or event that jeopardizes human subjects, and any major irregularities or changes in the research design or protocol, to the IRB Chair within 24 hours of the incident/event. After assessing the risks and/or the severity of noncompliance, the DSU IRB will report to the Provost/Vice President for Academic Affairs, to the funding source, and to OHRP.
- 9)** Projects that are longer than 12 months must have a Continuing Review from the IRB each year. Continuing Review can be requested by the IRB through the use of [Form B](#). The IRB may request more frequent reviews of the research if deemed necessary by the IRB.
- 10)** While the majority of DSU's research activities will be covered under 45 CFR 46 subpart A, in the event that human subjects represent a special class that are particularly vulnerable, the appropriate regulations relating to the Subpart that addresses the vulnerable population must be adhered to. In particular, these vulnerable populations consist of fetuses, pregnant women, children and minors, cognitively impaired persons, and prisoners.
- 11)** In complex and highly technical medical research, the DSU IRB may have to refer research proposals to larger IRB's with more staff and resources. Judgments of resource limitations will be made jointly by the IRB Chair, the IRB, and the Provost/Vice President for Academic Affairs.

IT IS ESSENTIAL THAT YOU PROVIDE ADEQUATE TIME FOR YOUR PROPOSAL TO BE REVIEWED. IN ORDER TO ASSURE ADEQUATE TIME FOR POTENTIAL REVISIONS, RESEARCHERS ARE ENCOURAGED TO SUBMIT THEIR PROPOSALS THREE (3) WEEKS PRIOR TO THEIR ANTICIPATED DATE FOR RESEARCH TO BEGIN. THE ACTUAL TIMELINE MAY VARY DEPENDING ON THE IRB MEETING SCHEDULE, AND MAY TAKE UP TO 3 MONTHS FOR A FULL REVIEW. CALL THE IRB OFFICE IF YOU HAVE ANY QUESTIONS (662-846-4700).

Responsible Office and/or the **Policy Owner:** Academic Affairs

RELATED DOCUMENTS

- Academic Council minutes, 12-13-11
- [Belmont Report](#) (1979)
- [Code of Federal Regulations, Title 45, Part 46](#)
- [Office of Human Research Protections \(OHRP\)](#)

STATUS

Active

DATE(S)

Policy Effective Date: 12-13-11