COLUMBUS STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Policies and Definitions

Columbus State University promotes and supports human research. Basic tenets of human research are voluntary participation and the ethical treatment of the subjects in the research process. The basic ethical principles are defined in the Belmont Report. The Code of Federal Regulations (CFR) defines the basic rules by which research should be evaluated (45 CFR 46). The purpose of the Institutional Review Board (IRB) is to ensure that the rights and welfare of all human subjects are protected.

Position Statements:

- All research involving human subjects will undergo preliminary evaluation by the University's Institutional Review Board.
- Neither the amount of funding nor source of the research funds will interfere with or influence the review process of human research subject protocols.
- All research will adhere to the Federal Codes, State laws, and University rules and regulations regarding the use of human participants in research. *(Note: This adherence includes FERPA and HIPAA regulations).*
- The full IRB will review applications that do not meet the Federal guidelines for "exempt" or "expedited" status. Exempt research qualifies for a streamlined review process; however, it still must be submitted to and approved by the IRB.
- All researchers using human subjects must follow current IRB procedures. Note: *Research that involves the use of animals as research subjects must get approval from the Institutional Animal Care and Use Committee (IACUC).*

122.1 Board

The IRB, or sub-committee thereof, shall serve as the reviewing and recommending body for all research proposals and projects which involve human subjects.

122.2 Policy

Safeguarding the personal integrity, rights and welfare of all human subjects involved in research undertakings at Columbus State University shall be of primary importance. In order to provide for this responsibility, it shall be the policy of Columbus State University that all research endeavors involving

human subjects shall be described in writing to the IRB, in advance of beginning such research. The IRB shall review the proposal and shall recommend approval, modification, or rejection of the project. The IRB shall be concerned only with ethical and legal issues surrounding the protection of human subjects, including, but not limited to issues of informed consent. The IRB is not responsible for judging the overall quality or scientific merit of the proposed research.

Cooperative Research - At the discretion of the IRB, the IRB may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort for a cooperative project under the criteria in 45 CFR 46.114.

122.3 Applicability

The policy applies to all research endeavors in which data or biospecimens are obtained, used, analyzed, or collected from human subjects with the intention of publishing and/or presenting the results in a public forum regardless of whether there is any perceived risk. Research, as defined in 45 CFR 46.102, means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The following activities do not require IRB approval:

(1) Class activities resulting in collection of data for class discussion or the teaching of research methods provided all the following conditions are met:
   (a) project involves no more than minimal risk to subjects;
   (b) results of the study are limited to the classroom will not be published or presented to a professional audience; and
   (c) subjects will not be videotaped or audiotaped during the study.

   Class activities that meet the above criteria can be approved by the instructor and/or department chair depending on departmental policies. However, all applicable precautions and protections should still be observed including the acquisition of informed consent. Class activities that do not meet the above requirements must be submitted to the IRB for approval.

(2) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (45 CFR 46.102(l)(1))

(3) Institutional or programmatic research intended for assessment, evaluation, or development

provided all the following conditions are met:

(a) project involves no more than minimal risk to subjects;

(b) results of the study are limited to institutional or programmatic use and will not be published or presented to a professional audience; and

(c) subjects will not be videotaped or audiotaped during the study.

The IRB will not review and approve applications for activities that do not require IRB approval, as defined above in 122.3(1)-(3), unless review or approval is required to meet the conditions set forth for a grant award or otherwise required under University policy or state/federal law.

122.4 Subject

This term describes any student, faculty, staff, employee, or volunteer who provides data or participates in any research of a psychological, biological, sociological, medical, or educational nature. This term applies equally to persons who have either unrestricted civil freedom or restricted civil freedom (e.g., prisoners or patients).

122.5 Minimal Risk (45 CFR 46.102)

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

122.6 Categories of Review

There are three categories of review. Which category an application belongs depends on the level of potential risk to subjects.

Full Board Review - For research with human subjects that is deemed to involve more than minimal risk or for which a wider range of expertise is required for review. In addition, full board review may be required for research activities involving vulnerable subject populations, including, but not limited to, pregnant women and fetuses, children, international research, prisoners, and cognitively impaired/psychiatric patients. The research proposal is presented and discussed at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those voting members present. (Note that, in effect, an abstention counts as a negative vote.)

Expedited Review - For certain kinds of research involving no more than minimal risk, and for minor changes or amendments to approved research. Two designated voting members review the proposed research rather than the entire IRB. It cannot be assumed that research poses minimal

risk because it involves only interview or survey data collection. Sensitive questions may lead to distress that exposes subjects to greater than minimal risk. Loss of confidentiality can cause harm to subjects, their relatives, and others. Expedited review categories are specified in the regulation that governs the Institutional Review Board (45 CFR 46.110).

Exempt Review - For specific kinds of low-risk research that have a specified exemption in 45 CFR 46.101. In order to qualify for exemption, a research project study must fall entirely within one or more of the eight categories for exemption, it cannot place subjects at greater than minimal risk and cannot use vulnerable subjects. Even if a researcher believes their project is classified as exempt, an application must still be submitted to the IRB for approval before any recruitment begins, any data are collected (unless the research meets the criteria in category #4 below), or any other research procedures begin. Exemption status does not excuse the researcher from meeting the ethical intent of the Belmont Report and Common Rule or from obtaining informed consent (if applicable) for research participation. The following are the exempt categories (#1 – 8) as listed in 45 CFR 46.104(d):

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

(2) Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of 3 criteria are met:

   (a) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

   (b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

   (c) the information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the

determination required by 45 CFR 46.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality).

(3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

   (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects;

   (b) Any disclosure of the subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

   (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

(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 conducted by or subject to the approval of Federal department or agency heads and designed to study, evaluate, or otherwise examine public health benefit of service programs (Not available to anyone but Federal government).

(6) Taste and food quality evaluation and consumer acceptance studies.

(7) Storing and maintaining identifiable private information/specimens for secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research use of identifiable private information/specimens for specific secondary research studies.

The exemptions (#1 – 8) do not apply to research involving prisoners, fetuses, or newborns.

Further, the exemption in category #2, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except in research involving observations of public behavior when the researcher(s) do not participate in the activities being observed.

122.7 Informed Consent

Informed consent assumes that the subject individual has been fully informed and indicates understanding of the nature of experimental techniques to be applied, studied, or manipulated. It additionally assumes that the subject is capable of understanding at the short- and long-range levels the normally expected risks and hazards (if any) and gives consent freely, especially where Columbus State University students are involved, without pressure of threat to academic grades. Informed Consent must adhere to the requirements set forth in 45 CFR §46.116 and documentation of Informed Consent must adhere to the requirements set forth in 45 CFR §46.117.

122.8 Stored and Retrieved Data

This policy requires that data and information about individuals obtained during scientific/scholarly research and experimentation will be protected against compromise and/or unauthorized visibility and that such data will be removed to the "objective" category at the earliest possible time--that is, the names and other identities of the human subjects will be removed from the data and destroyed, and all "keys" for such re-identification will be likewise rendered useless.

122.9 Publication of Research Findings

All authors and researchers will be obliged to adhere to the rules as outlined in this document of confidentiality, ethics, and consideration of the individual's personal welfare in any subsequent publication of research findings.

122.10 Interpretation

Questions and disputes arising from the implementation of this policy, which the IRB Board cannot resolve, shall be settled by the Executive Vice President of Academic Affairs or such other authority as the President of Columbus State University may designate.

122.11 Research Team Responsibilities

The Principal Investigator (PI) has the primary responsibility for protecting the rights and welfare of the participants involved in their research. The PI must provide members of the research team with sufficient oversight, training, and information to facilitate appropriate safety procedures and protocol adherence. Key personnel include any individual who has contact with potential participants and/or

participants (e.g., screening participants, collecting/recording data or implementing an intervention). Personnel who will not have access to participants or identifiable data do not need to be added to an application.

Changes to Original Protocol- Any change in personnel, participants, recruitment, or data collection must be submitted by the PI or Co-PI to the IRB for review prior to implementation using a modification form.