CANTON

STATE UNIVERSITY OF NEW YORK

POLICY MANUAL FOR RESEARCH ACTIVITIES INVOLVING HUMAN PARTICIPANTS

I. OVERVIEW

It is the policy of SUNY Canton to ensure that the rights and welfare of human research participants are adequately protected in research activities conducted under its auspices. Federal and State laws and regulations require these protections. In order for the College to fulfill its responsibility and to comply with the law and regulations, all human participants research conducted under College auspices at any location must receive appropriate review and approval. The College assures compliance with all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all federally-sponsored research and all other human participants research regardless of source of support. The website for Title 45, Part 46 can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.

The College is guided by the ethical principles set forth in the Report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research entitled, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report").

No distinctions in the monitoring of research will be drawn between funded and non-funded research or between research conducted by faculty, students, other College personnel, or affiliated researchers.

The policies in this document apply equally to all research involving human participants conducted under the auspices of SUNY Canton including collaborative projects. All faculty members, staff, students and affiliated researchers who conduct research projects (either on or off campus) involving human participants are responsible for familiarizing themselves and complying with these policies.

II. DEFINITIONS

The College has adopted the following definitions included in the Common Rule.

Research means a systematic investigation (including research development, testing and evaluation) designed to contribute to generalizable knowledge. Activities that meet this definition constitute "research" for purposes of this policy whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

Human participant means a **living** individual about whom an investigator (whether faculty or student) conducting research obtains data through **intervention or interaction** with the individual or identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between the investigator and the participant.

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.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (i.e., a medical record). . Private information must be individually identifiable (i.e., the identity of the participant 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 participants.

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

III. INSTITUTIONAL RESPONSIBILITY AND REVIEW

SUNY Canton acknowledges that it bears full responsibility for the performance of all research involving human participants conducted under its auspices including compliance with Federal, State, or local laws as they relate to such research. This policy applies to all research involving human participants and all activities which, even in part, involve such research regardless of sponsorship if the research is conducted by or under the direction of SUNY Canton faculty, staff, or students in connection with the fulfillment of institutional responsibilities or academic requirements; or it is performed with or involves the use of College records, facilities or equipment belonging to the College.

The College will require that all collaborating institutions (including subcontractors and subgrantees) engaged in human participants research have appropriate approved assurances prior to the initiation of research.

Administrative Oversight

The College has assigned the administration of human participants' policies and procedures to the Office of Research and Sponsored Programs (ORSP). A copy of this policy manual is available in the Office of Research and Sponsored Programs (ORSP) and on its website. The Provost is the Signatory Official with overall responsibility for committing the College to the ethical principles and Federal regulations related to human protections. The Provost oversees the work of the Coordinator, Office of Research and Sponsored Programs a ORSP employee. The Coordinator, ORSP, under the auspices of the Signatory Official, is responsible for ensuring compliance with the Federal regulations and the College policy regarding human subjects in research. The Coordinator, ORSP is responsible for administrative functions relating to human subjects including preparing reports, maintaining files, and disseminating information.

The Office of Research and Sponsored Programs will:

- Receive from investigators all research protocols that involve human participants and keep investigators informed of review decisions.
- Accept, review, and forward documents to the Chairperson and Vice Chairperson for Certification of Exemption.
- Serve as supervisory advisor to the IRB, scheduling and providing administrative support to meetings.
- Forward certification of IRB approval of proposed research to the appropriate Federal department or agency.
- Facilitate the expedited review process.
- Provide advice to investigators on the preparation of the protocol and other documents to facilitate the IRB review process.
- Maintain and arrange access for inspection of IRB records for a minimum of three years in accordance with 45 CFR 46.
- Ensure constructive communication among research administrators, department heads, research investigators, human participants, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants.
- Arrange for and document that each individual who conducts or reviews human participants has ready access to this policy, copies of 45 CFR 46, regulations of other Federal departments or agencies, and all other pertinent Federal policies and guidelines related to the involvement of human participants in research.
- Ensure (a) solicitation, receipt, and management of all assurances of compliance, and (b) certifications of IRB review (where appropriate) for all performance sites of this institution.

IV. THE INSTITUTIONAL REVIEW BOARD (IRB) REVIEW PROCESS

This College has established its IRB in accordance with the compositional requirements of 45 CFR 46.

The IRB shall be comprised of at least five members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the College. Members will include faculty, administrators, and at least one community representative unaffiliated with the College.

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The IRB may, at their discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

A. IRB appointment

The Provost, with input from the Coordinator of Research and Sponsored Programs, will make appointments to the IRB.

The Provost, with input from the Coordinator of Research and Sponsored Programs, will also appoint the chair and co-chair of the IRB.

The names, qualifications and affiliations of the members of the IRB will be on file with the U.S. Office for Human Research Protections and at the Human Protections Office.

B. General Principles of IRB Review

- The IRB has the responsibility and authority to review, approve, disapprove, or require changes in and monitor all research activities involving human participants.
- No involvement of human participants in research, including recruitment, is permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained.
- All activities involving humans as research participants must provide for the safety, health, and welfare of every individual. Rights, including the right to privacy, must not be infringed. No participant in a research activity shall be exposed to unreasonable risk to health or well-being.
- An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. A

participant has the right to privacy and confidentiality in the use of personal information and to be free from undue embarrassment, discomfort, anxiety, and harassment.

- The direct or potential benefits to the participant, or the importance of the knowledge to be gained, must not preclude consideration of the inherent risks to the individual.
- The confidentiality of information received from participants in experiments or respondents to questionnaires or surveys shall be fully protected both during and after the conduct of a research activity within the limits of the law.
- Participation in projects must be voluntary. Informed consent must be obtained from all participants and be documented (unless the requirement for documentation of consent is waived by the IRB).
- In research involving more than minimal risk or substantial stress or discomfort, such risk, stress, or discomfort shall be carefully explained to the participant before his or her participation and justified by the expected benefits of the research. The investigator shall be satisfied that the explanation has been understood by the participant; and the written consent of the participant, containing the substance of the explanation, shall be obtained and kept as a matter of record.

C. IRB Procedures and Responsibilities

- The IRB follows the written policies and procedures of SUNY Canton for the protection of human participants in research. These policies and procedures are in compliance with Federal regulations and State law.
- Except when an expedited review procedure is applicable, the IRB reviews proposed research at convened meetings at which a majority of the members are present and/or online utilizing Blackboard. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
- The IRB reviews and has the authority to approve, require modifications in, or disapprove all research activities, including changes in previously approved human participants research.
- The IRB requires that information given to participants as part of the informed consent process is in accordance with 45 CFR 46. The IRB may require that additional information be given to participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of the participants.
- The IRB shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.
- The IRB notifies investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of research activity. If the IRB disapproves or requests modifications to the research activity, it includes in its written notification a statement of the reasons for its decision and gives the investigator an opportunity to respond in person or in writing.
- Certification of IRB review and approval for all Federally-sponsored research involving human participants will be submitted for forwarding to the appropriate Federal department or agency.

D. Levels of Review

Research projects are reviewed at one of three levels at SUNY Canton, depending on the IRB's interpretation of the project's risk to the human participants and on the Federal guidelines that define the categories of review.

The IRB or its designee will determine the appropriate category of review.

1. Exempt Review

Certain types of research may be exempt from IRB review. Examples include:

- Research conducted in established or commonly accepted educational settings such as on regular and special education instructional strategies or research on the effectiveness of or the comparison of instructional techniques.
- Research involving the use of educational tests, survey procedures, or interview procedures **UNLESS** the information is recorded in such a manner that human subjects can be identified and disclosure could reasonably place the subject at risk because the information gathered concerns sensitive aspects of the subjects' behavior, or children are being interviewed or surveyed.
- Observation of public behavior where identifiers are not recorded by the investigator and there is neither a risk of harm to the subject and the observation does not include sensitive aspects of the subjects' behavior **UNLESS** children are used in the study.
- Research involving the use of educational tests (cognitive, aptitude, achievement) with procedures that guarantee confidentiality during and after the research **UNLESS** the human subjects are elected or appointed officials or candidates for public office.
- Research involving the collection or study of existing data, documents or records, or pathological or diagnostic specimens, where publicly available, or the information is private but identifiers are not recorded by the investigator.
- Research and demonstration projects designed to study, evaluate, or examine public benefit or service programs and procedures for obtaining benefits under these programs and/or possible changes or alternatives to these programs.
- Taste and food quality and evaluation and consumer acceptance studies if wholesome foods without additives are consumed, or if the food consumed contains a food ingredient at or below the level found to be safe, an agricultural, chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the FDA or the Food Safety Inspection Service.

2. Expedited Review

To qualify for expedited review, a research activity must incur no more than minimal risk for participants or represent a minor change in previously approved research that involves no additional risks to research participants, in accordance with 45 CFR 46.

Examples of research activities reviewed on an expedited basis include:

- Educational research involving no interaction with students, i.e., observation of regular classroom activity.
- Research on individual or group behavior of normal adults where there is no psychological intervention or deception.
- Interviews and interactive surveys of children on non-sensitive topics.
- Continuing review of research previously approved and no additional risks have been identified.

The expedited review procedure is carried out by a minimum of two people comprised of the IRB Chair, Co-chair and/or experienced reviewers designated by the IRB. In reviewing the research, the reviewer(s) may exercise all of the authority of the IRB except the reviewer(s) may not disapprove the research. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believe(s) that full committee review is warranted. A research activity may be disapproved only after review in accordance with Full Review procedures.

3. Full Committee Review

All proposed research deemed by the IRB to present more than minimal risk to human participants must be reviewed by the full IRB. Examples of research activities that must be reviewed by the full IRB committee include:

- Research involving deception.
- Research involving psychological or physiological intervention.
- Non-curricular, interactive research in schools.
- Interviews or surveys on sensitive topics.
- Research involving the use of "vulnerable populations," including pregnant women, children, prisoners, or mentally incompetent persons.
- Research conducted outside the United States, regardless of the procedures involved.

Attendance of the investigator at the IRB review meeting in which his or her research activity is scheduled for discussion is encouraged.

The IRB will come to one of four determinations regarding an application:

- **Approval without questions**, concerns or requests for modifications;
- **Approved pending clarification and/or modifications**. Approval of the IRB has been withheld pending clarification and/or modification of specific points or components of the protocol. The research activity may not be undertaken until the IRB's concerns are addressed and submitted to the IRB or designated member(s) for review and approval.

- **Deferred (tabled).** This indicates approval by the Board has been withheld as substantive concerns or significant requests for clarification have been raised and/or the proposed research does not meet College or Federal guidelines for the protection of human participants. The research activity may not be undertaken until the IRB's concerns are addressed and submitted to the full IRB for review and approval.
- **Disapproved.** The IRB may disapprove a proposed activity with serious and substantive problems and/or that fails to meet College or Federal guidelines for the protection of human participants.

Approval of the proposed research is usually granted for a period of 12 months commencing on the date the approval is granted by the IRB. Based upon the degree of risk to human participants, the IRB may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. Continuation of projects past the approval period requires project continuation review and approval by the IRB.

Investigators will be notified in writing of the IRB's decisions. When the research activity involves an outside agency, the investigator must secure written approval from an appropriate agency official prior to conducting the research.

E. Criteria for IRB Approval of Research

- **Risk/Benefit:** In order to approve research covered by this policy, the IRB shall determine that the following requirements are satisfied:
    - Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
    - Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result from the research.
- **Equitability of Participant Selection and Recruitment:** Selection criteria should consider all populations that might potentially benefit from the research. Utilization of populations based solely upon ready availability should be avoided. The IRB will take into account the purposes of the research and the setting in which the research will be conducted. The IRB shall ensure that the recruitment of participants is equitable and free of coercion.
- **Informed Consent Process:** Informed consent will be sought from each prospective participant or the participant's legally authorized representative and will be appropriately documented, in accordance with and to the extent required by 45 CFR 46.
- **Privacy and Confidentiality:** The IRB shall determine that adequate provision has been taken to protect the privacy of participants and for ensuring the confidentiality of an individual's participation and confidentiality of study data, as appropriate.
- **Special Populations:** When some or all of the participants are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these participants.

F. Suspension or Termination of IRB Approval of Research

- 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 harm to participants (45 CFR 46).
- Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and to the Office of Research and Sponsored Programs which will inform other appropriate institutional officials and department or sponsored agency head(s) as applicable.

G. Continuing Review

- The IRB is required to reevaluate research projects at intervals appropriate to the degree of risk but not less than once a year. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. The approval letter from the IRB will indicate the approval period. Ninety, sixty and thirty days before the protocol expiration date, the investigator will receive a courtesy reminder that the protocol will soon expire.
- Investigators must request a continuation for the approval if the activity lasts beyond the approval period.

H. Modifications

No changes to an approved protocol can be implemented until the changes have been approved. This includes subject recruitment methods, consent form changes, survey changes, etc. Submit a modification with all supporting documents, i.e., questionnaires, recruitment flyers, consents, etc. to irb@canton.edu

I. Reviewing Reports of Adverse Events

- The IRB is responsible for reviewing reports of any adverse events to research participants or any unanticipated problems that involve risk to human participants in the course of approved research.
- Upon the receipt of an adverse event, the IRB will determine whether the study should be modified to reduce the level of risk to participants or whether the consent form should be modified to include a description of activities or procedures that could result in adverse effects.

IL IRB Policy of Research Conducted Without IRB Approval

- Research activities involving the use of human participants under the auspices of SUNY Canton may not be conducted without prior review and approval by the IRB. The IRB cannot give its approval or disapproval of research that has already been conducted.
- Any research activity initiated or completed will be reviewed by the IRB on a case-by-case basis. The IRB will review the project, consider how the project was conducted (i.e.,

if the investigator has initiated or conducted the research without approval or was unaware of the requirement) and if the procedures used in the research violated any of the College's standards of ethical conduct in research. In these cases, the IRB will decide if the investigator:

- ❖ can use the data already collected;
- ❖ must provide proof of consent, re-consent participants, or retroactively consent;
- ❖ can continue the research (if not already completed) or what, if any, modifications need to be made;
- ❖ must destroy all data collected to date.

A letter from the Chair of the IRB will be sent to the investigator indicating the reasons for the IRB's decision, what actions the IRB is requiring, and an opportunity to respond to the Board. A copy of the letter will be sent to the faculty advisor if the researcher is a student.

K. IRB Records

The Office of Research and Sponsored Programs or, when appropriate, the IRB shall prepare and maintain adequate documentation of IRB activities in accordance with 45 CFR 46 including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposed research, approved sample consent documents, progress reports submitted by investigators, and reports of injuries or harm to participants.
- Minutes of IRB meetings which shall be of sufficient enough detail to show attendance at the meetings; actions taken by the IRB; the votes on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators. A list of IRB members and their credentials.
- Written procedures for the IRB.

The records required by this policy shall be retained for at least three years, and the records related to research that was conducted shall be retained for at least three years after the completion of the research. These records must be appropriately secured. All records shall be accessible for inspection and copying by authorized representatives of supporting departments or agencies at reasonable times and in a reasonable manner.

L. Appealing an IRB Decision

If the IRB makes a decision that an investigator believes to be unfair, unsubstantiated, or unduly restrictive on his/her proposed research, the investigator should:

- First discuss the matter with the Chair of the IRB and the Coordinator, ORSP . The investigator should be prepared to present reasons that he/she believes that the proposed research is in compliance with College policy and Federal regulations for the protection

of human participants.

- If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision, in writing, to the IRB.
- In developing his/her appeal, the investigator is encouraged to seek the advice or opinion of an objective, qualified consultant (or consultants) to support the claim that the proposed research is in compliance with human participants policy and regulations.
- The investigator must appear before the IRB to present his/her appeal and any supportive material or documentation obtained through consultation. Based upon this appeal, the IRB will issue a final recommendation on the proposed research.

M. RESPONSIBILITIES OF THE INVESTIGATOR

Research investigators who conduct human participants research under the auspices of the College (faculty, staff, students, and affiliated researchers), acknowledge and accept their responsibility for protecting the rights and welfare of human research participants by:

- **Safeguarding Human Participants**. Safeguarding the wellbeing of and information about an individual is a primary responsibility of the investigator. When the investigator is a student, responsibility for the conduct of the research and for the welfare and supervision of human participants lies with both the student and the faculty sponsor. All student research must have a faculty advisor.
- **Submission of the IRB Protocol**. It is the responsibility of each investigator to bring all proposed research activity involving the use of human participants or activity involving data collection from or about human participants to the attention of the SUNY Canton IRB for review and approval. A complete research protocol must be submitted, including provisions for the adequate protection of the rights and welfare of prospective research participants and ensuring that pertinent laws and regulations are observed.
- **Reporting Modifications in the Research**. Research investigators are responsible for promptly reporting any changes in the research protocol to the IRB. Changes in research during the period for which IRB approval has already been given shall not be initiated by research investigators without IRB review and approval except where necessary to eliminate immediate hazards to the subject(s). An application for modification includes the submission of all proposed changes with a rationale for each proposed change.
- **Submission of Requests to Continue Research**. Approval of human participants protocol is for no more than one year though the IRB may grant an approval for less than one year depending upon the nature of the research. Ninety, sixty and thirty days before the protocol expiration date, the investigator will receive a courtesy reminder that the protocol will soon expire. Investigators must request a Continuing Review for studies that will continue beyond the original approval period.
- **Apprising Research Participants of Findings that May Affect Participation**. Research investigators are responsible for reporting to both participants and to the IRB significant findings developed in the course of the research that may relate to the willingness to continue participation.
- **Complying with IRB Decisions**. Research investigators shall be responsible for complying with all IRB decisions, conditions and requirements.
- **Providing Consent Forms to all Participants**. Research investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent unless the IRB has specifically waived this

requirement.

- **Retention of Signed Informed Consent Documents**. Research investigators are responsible for retaining the informed consent documents signed by human research participants in a manner approved by the IRB. It is suggested that investigators keep all records for a minimum of three (3) years following completion of the research activity.
- **Submission of Adverse Event Reports and Reports of Unanticipated Problems Involving Risk**. Research investigators are responsible for immediately reporting to the IRB any adverse events to research participants or any unanticipated problems that involve risk to human research participants in the course of their participation in approved research.
- **Attending IRB Meetings**. Research investigators are encouraged to attend IRB meetings in which their human participants protocol or research activities are under review.
- **Education and Training**. Prior to submitting the protocol for IRB review, the research investigator and all key personnel listed on the protocol must complete the CITI human participants training program (https://www.citiprogram.org).
- **Cooperative Research**. Research investigators must fully apprise the IRB of research activities at any collaborating site(s). Any change in a previously approved protocol regarding these activities must be submitted and approved by the IRB as a modification before being implemented.