Institutional Review Board
Sponsored Programs Office, Buckham Hall B-206
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Federalwide Assurance ID#: 00007126

POLICY MANUAL FOR RESEARCH ACTIVITIES INVOLVING HUMAN PARTICIPANTS

I. OVERVIEW

It is the policy of Buffalo State University 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 University to fulfill its responsibility and to comply with the law and regulations, all human participants research conducted under University auspices at any location must receive appropriate review and approval. The University 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 University 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 University personnel, or affiliated researchers.

The policies in this document apply equally to all research involving human participants conducted under the auspices of Buffalo State University, 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 University has adopted the definitions included in the Federal regulations on the protections of human participants in research (45 CFR 46.102).

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 investigator and participant. Private information includes communication 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. 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.

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.

III. INSTITUTIONAL RESPONSIBILITY AND REVIEW

Buffalo State University 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 Buffalo State University faculty, staff, or students in connection with the fulfillment of institutional responsibilities or academic requirements; or is performed with or involves the use of University records, facilities or equipment belonging to the University.

The University assumes responsibility for communicating and explaining these policies to faculty, students, and other personnel, and for providing procedural guidelines.

The University has established an Institutional Review Board (IRB) to review and approve human participants research. The University will ensure that the IRB Chairperson, the IRB members, Compliance Office staff, human participants investigators, and relevant administrative personnel complete appropriate initial and continuing education training related to the protection of human participants before reviewing or conducting human participants research.

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

The Sponsored Programs Office will:

- Receive from investigators all research protocols that involve human participants and keep investigators informed of review decisions.
- Accept, review, and approve Certificates of Exemption.
- Serve as staff liaison 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 and limited IRB review processes.
- 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 University has established its IRB in accordance with the compositional requirements of 45 CFR 46.

The IRB shall be comprised of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the University. Members will include faculty, administrators, and at least one community representative unaffiliated with the University.

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 Signatory Official or designee, with input from the Research Compliance Manager, will make appointments to the IRB.

The Signatory Official or designee, with input from the Research Compliance Manager, will also appoint the 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 Buffalo State University 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 or limited review procedure is applicable, the IRB reviews proposed research at convened meetings at which a majority of the members are present. 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 four levels, 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. Department Review (Level 1)

Certain student research projects do not have to be submitted for Institutional Review Board approval but should be reviewed at the department level. Projects that may be reviewed at the Department Level include laboratory projects, educational exercises and class projects, and action research within a classroom with performance or grades as the sole outcome measure. Each department is to designate one representative to the IRB to serve as the reviewer for Department Level protocols.

In order to qualify for Department Level Review, the research must be disseminated only within the BSC campus. For example, research presented at the Student Research and Creativity Celebration or theses bound and filed in the library may be reviewed departmentally, but any research that will be presented at regional or national conferences or published in journals should be reviewed at the Exempt, Expedited, or Full Board levels.

All faculty research, all research that may be risky or on a sensitive topic, or that includes children, except as noted for action research, must be reviewed at the Exempt, Expedited, or Full Board levels.

2. Exempt Review (Level 2)

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

(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. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes 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 the following criteria is met:

(i) 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;

(ii) 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

(iii) 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 subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)(i) 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 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 the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

When appropriate, the limited review procedure is carried out by the IRB chair or one or more experienced reviewers designated by the IRB.

3. 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, e.g., observation of regular classroom activity.
- Research on individual or group behavior of normal adults where there is no psychological intervention or deception, unless the research qualifies for an exemption.
- Interviews and interactive surveys of children on non-sensitive topics, unless the research qualifies for an exemption.

- Continuing review of research previously approved and no additional risks have been identified.

The expedited review procedure is carried out by the IRB Chair or one or more 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) believes that full committee review is warranted. A research activity may be disapproved only after review in accordance with Full Review procedures.

4. Full-Board 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.

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 University 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 University 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 Sponsored Programs Office which will inform other appropriate institutional officials, and Department or Agency head, as applicable.

G. Continuing Review

- The revised federal regulations no longer require continuing review for Exempt and some Expedited review studies. The revised federal regulations also no longer require continuing review for full-board studies for which data collection is complete and the only research activities are data analysis and write up. If this change applies to your study, there will simply be no ending date listed on your letter of approval. However, we would appreciate it if you would close your study in the online SUNY Pre-Award and Compliance System (SUNY PACS) IRB when it is completed so that we can know what research is ongoing on our campus.

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 in SUNY RF PACS with all supporting documents, e.g., questionnaires, recruitment flyers, consents, etc.

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.

J. IRB Policy of Research Conducted Without IRB Approval

- Research activities involving the use of human participants under the auspices of Buffalo State University 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 (e.g., 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 Research Compliance Manager 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 Research Compliance Manager. The investigator should be prepared to present reasons that he/she believes that the proposed research is in compliance with University 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.

V. RESPONSIBILITIES OF THE INVESTIGATOR

Research investigators who conduct human participants research under the auspices of the University (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 well being 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 Buffalo State University 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 a 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 required that investigators keep all records for a minimum of three (3) years following completion of the research activity. In the case of student research, the sponsoring faculty member must retain the consent forms.
- **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.