THE COLLEGE AT BROCKPORT STATE UNIVERSITY OF NEW YORK

POLICY MANUAL FOR RESEARCH ACTIVITIES INVOLVING HUMAN PARTICIPANTS

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1. Statement of Principles

It is the policy of The College at Brockport State University of New York to ensure that the rights and welfare of human research participants are adequately protected in research activities conducted under its auspices.

In addition, federal and state laws and regulations require these protections. In order for the College to fulfill its responsibilities and to comply with the law and regulations, all human participants research conducted under College auspices (including class projects) must receive appropriate review and approval. In our Federal Assurance on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, 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 funding (if any).

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 (Belmont Report).

Since the conduct of research with human beings may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of research will be drawn between funded and non-funded research, or between research conducted by faculty, staff, students, other College personnel, or affiliated researchers.

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

2. Definitions

The College at Brockport SUNY has adopted the definitions included in the Federal regulations for the protection of human participants in research (45 CFR 46.102).

A. Department or Agency Head means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

B. Research means a systematic investigation (including research development, testing and evaluation) designed to contribute to general 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.

C. **Human participant** means a living individual about whom an investigator (whether faculty, staff or student) conducting research obtains:
   1) data through intervention or interaction with the individual, or
   2) 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 to obtain the information to constitute research involving human participants.

D. **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the participant’s participation in the procedure(s) involved in the research.

E. **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.

3. **Institutional Responsibilities**

A. **Scope of Responsibility**
   1. The College has established an Institutional Review Board (IRB) to review and approve human participants research. The IRB is limited in its composition to reviewing social and behavioral research.

   2. The College acknowledges that it bears 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.

   3. The College and the individual members of its faculty, staff, and student body acknowledge and accept their responsibilities for protecting the rights and welfare of human participants in 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 The College at Brockport State University at New York faculty, staff or students in connection with the fulfillment of institutional responsibilities or academic requirements or
is performed with or involves the use of College records, facilities, or equipment belonging to the College.

2. The College encourages and promotes constructive communication among research investigators, the IRB, and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants. The College assumes responsibility for communicating and explaining these policies to faculty, staff, students, and other personnel, and for providing procedural guidelines to effect their observance.

B. Performance Sites
The College is responsible for ensuring that no performance site engaged in the conduct of federally sponsored research to which the College Federal Assurance applies does so without Federal department or agency approval of an appropriate assurance and satisfaction of IRB certification requirements.

C. Protections for Vulnerable Populations
The College requires more stringent safeguards for certain research activities and for participants likely to be vulnerable to coercion or undue influence such as:
1. children
2. prisoners
3. pregnant women
4. physically or mentally disabled persons
5. economically or educationally disadvantaged persons
6. other potentially vulnerable groups.

D. Provision of Resources
The College will provide the IRB with resources, meeting space, professional staff, and support staff to carry out its responsibilities efficiently and effectively.

E. Education and Training
The College will ensure that the IRB Chair, the IRB members, IRB Administrator, IRB Coordinator, human participant investigators, and relevant administrative personnel complete appropriate initial and continuing education related to the protection of human participants before reviewing or conducting human participant’s research. Certification is renewable every three years.

F. Collaborating Institution
The College will ensure that all engaged institutions (including subcontractors and subgrantees) engaged in human participants research that is federally supported have appropriate approved assurances on file with OHRP prior to the initiation of research.
G. **Administrative Oversight**

The IRB Administrator and Coordinator will exercise appropriate administrative overview to ensure that the rights and procedures designed for the protection of the rights and welfare of human participants are effective and are in compliance with the requirements of 45 CFR 46.103 and this policy. A copy of this policy manual will be available at the IRB Administrator’s office, on the College website section on the IRB, and will be sent to all faculty, staff, or students requesting copies.

4. **Responsibilities of the Institutional Review Board Administrator**

A. The Research Foundation of SUNY and The College at Brockport State University of New York has assigned compliance with federal regulations and College policy regarding human participants research to the Institutional Review Board Administrator and Coordinator.

B. The Institutional Review Board Coordinator shall receive from investigators all research protocols that involve human participants, and keep investigators informed of review decisions.

C. The Institutional Review Board Administrator shall forward certification of IRB approval of proposed research to the appropriate Federal department or agency only after all IRB required modifications have been incorporated to the satisfaction of the IRB.

D. The Institutional Review Board Coordinator will inform the IRB of all approved exempt and expedited reviews on a monthly basis.

E. The Institutional Review Board Coordinator shall provide advice on the preparation of the Institutional Review Board review form and other documents, and other advice that will facilitate the IRB review process.

F. The Institutional Review Board Administrator and Coordinator shall maintain and arrange access for inspection of IRB records, in accordance with 45 CFR 46, Section 115.

G. The Institutional Review Board Coordinator is responsible for ensuring 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.

H. The Institutional Review Board Coordinator shall arrange for and document in her/his records that each individual who conducts or reviews human participants research has ready access to this policy, copies of 45 CFR 46, regulations of other Federal departments or agencies as may apply, the *Belmont Report*, and all other pertinent Federal policies and guidelines related to the involvement of human participants in research. Documentation will consist of current CITI training certification.
5. The Institutional Review Board (IRB) Review Process

A. Membership of the IRB
   The College has established its IRB in accordance with the compositional requirements of 45 CFR 46, Section 107.

1. IRB membership requirements.
   a. The IRB will be comprised of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the College.

   b. The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes and issues related to vulnerable populations, to promote respect for its advice and counsel safeguarding the rights and welfare of human participants.

   c. The IRB will be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice and shall, therefore, include persons knowledgeable in these areas.

   d. The IRB will include qualified persons of both sexes so long as no selection is made on the basis of gender.

   e. The IRB will include at least one member whose primary concerns are in a non-scientific area and at least one member whose primary concerns are in a scientific area.

   f. The IRB will include at least one member who is not otherwise affiliated with the College and who is not part of the immediate family of a person who is affiliated with the College.

   g. 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.

   h. The IRB may, at its 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 to the IRB through meeting or written comments.

2. IRB Appointment
   a. The Provost or designee with input from the Institutional Review Board Administrator and IRB Chair shall make appointments to the IRB for one-year, renewable terms. The term begins at the start of the College’s
academic year each fall. Board members may be removed at the discretion of the IRB Administrator.

b. The Provost or designee with input from the Institutional Review Board Administrator shall appoint the Chair of the IRB on an annual basis.

3. **IRB Membership Lists and Qualifications**
   a. The names, qualifications, and affiliations of the members of the IRB shall be on file with the U.S. Office for Human Research Protections (OHRP), in accordance with the requirements of the Federal Assurance Form, and at the office of the IRB Administrator and Coordinator.

b. All board members must renew CITI training every three years as mandated by the federal guidelines.

c. All changes in IRB membership are reported to OHRP as appropriate.

**B. General Principles of IRB Review**

1. It is the policy of the College that its IRB review all research involving human participants. The IRB has the responsibility and authority to review, approve, disapprove, or require changes in and monitor research activities involving human participants. No individual involved in the conduct and/or supervision of a specific project shall participate in IRB review, except to provide information.

2. In accordance with the compositional requirements of 45 CFR 46, the College has established an IRB. A list of members is in the attached appendix.

3. 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, unless waived in accordance with federal regulations. It is the responsibility of any investigator to obtain approval from the IRB prior to the initiation of any research, including pilot or pre-test studies involving the use of human participants.

4. 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.

5. 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. Further, a participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.
6. 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.

7. 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.

8. Participation in projects must be voluntary. Informed consent must be obtained from all participants and must be documented (unless the requirements for documentation of consent is specifically waived by the IRB). Methods in accordance with the requirements of 45 CFR 45.116 and 45.117, appropriate to the risks of the research, must be used to obtain the participants’ informed consent.

9. 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 participants, and the written consent of the participant (unless otherwise waived by the IRB), containing the substance of the explanation, shall be obtained and kept as a matter of record.

C. IRB Responsibilities

1. The IRB shall follow the written policies and procedures of the College for the protection of human participants in research. These policies and procedures are in compliance with Federal regulations and State law.

2. Except when an expedited review procedure is applicable, the IRB shall review proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it will receive the approval of a majority of those members present at the meeting.

3. The IRB will review and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities, including changes in previously approved human participants research.

4. The IRB will require that information given to participants as part of the informed consent process is in accordance with 45 CFR 46.116. The IRB may require that information, in addition to those required elements specified in 45 CFR 46.116(a), 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.

5. The IRB will require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.117.
6. The IRB, through the IRB Coordinator, shall notify 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 shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. If a proposal requires full review (Category 3) and meeting of the IRB Board the investigator(s) will be invited to be present at the meeting and will be informed of any needed revisions verbally and in the meeting minutes.

7. Certification of IRB review and approval for all Federally-sponsored research involving human participants will be submitted to the IRB Administrator for forwarding to the appropriate Federal department or agency. Compliance will occur within the time and manner prescribed for forwarding certifications or IRB review to DHHS or other Federal department(s) or agency.

8. The IRB Administrator will designate procedures for the retention of The College at Brockport State University of New York IRB records and documents for six years after completion of the research activity in compliance with New York State and Federal regulations.

9. The IRB will attempt to review all categories of proposals within 2-3 weeks of receiving a completed package (this may be longer during certain periods of the school year).

D. Scope of Review
IRB review and approval is required for any research involving human participants that is conducted by or under the direction of The College at Brockport State University of New York faculty, staff, or students in connection with the fulfillment of institutional responsibilities or academic requirements; or is performed with or involves the use of College records, facilities or equipment belonging to the College.

E. Levels of Review
Research projects are reviewed at one of three 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:

- Category 1 – exempt review
- Category 2 – expedited review
- Category 3 – full review.

While the investigator shall make the initial determination regarding the appropriate category of review, the IRB Coordinator and Chair shall make the final determination. The IRB may require full review of any research submitted or approved under expedited review.
1. Exempt review

a. To qualify for exempt review, a research activity must present no possible risk to subjects 18 years of age and older and be one of the following activities:
   • anonymous, mailed survey on innocuous (not sensitive) topics
   • anonymous, non-interactive, non-participating observation of public behavior
   • secondary analysis of existing data already approved by the IRB or in the public domain.

The research is exempt from the requirements of informed consent but the investigator is still responsible for protecting the rights, such as privacy and welfare of the subjects.

2. Expedited review

a. 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 46.100. Example of research activities reviewed on an expedited basis include:
   • educational research involving no interaction with students – e.g. regular classroom activity
   • research involving the use of educational records if information taken from these sources is provided to the researcher in such a manner that participants cannot be identified
   • research on individual or group behavior of normal adults (18 years of age or older) where there is no psychological intervention or deception
   • interviews and interactive surveys on non-sensitive topics.
   • minor changes in previously approved research
   • continuation of approval for previously approved no-risk research with no more than minor changes in procedures
   • research involving the Internet may be under category 2 in some circumstances. Refer to the IRB guidelines for specific situations.

b. The expedited review is carried out by the IRB Chair and one other voting member of the IRB designated by the IRB Coordinator. In reviewing the research, the reviewers may exercise all of the authority of the IRB. The reviewers may also refer the research protocol to the full committee whenever the reviewer feels that full committee review is warranted. A research activity may be
disapproved only after review in accordance with Full Review procedures. The IRB Coordinator receives the written comments of the Chair and one other IRB member and notifies investigator as to any changes that are needed prior to final approval (if needed). The investigator is notified immediately upon approval by phone or e-mail by the IRB Coordinator.

3. Full Committee Review

a. All proposed research deemed by the IRB to present more than minimal risk to human participants must be reviewed by the IRB.

b. 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 that do not meet the criteria for an exempt or expedited review
   - research conducted outside the United States regardless of the procedures involved
   - research conducted on the Internet if it does not fall under expedited review. (refer to IRB guidelines)
   - research which might put participants at-risk.

c. Attendance of the investigator (and their faculty supervisor if appropriate) at the IRB review meeting at which their research activity is discussed is strongly encouraged.

d. The IRB will come to one of three determinations regarding an application:
   - approval without questions, concerns or requests for modification
   - approved pending clarification and/or modifications. This indicates 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’s Chair for review and approval
• disapproved – while this action is rarely taken, 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.

e. All IRB Category 3 initial review and continuing review protocols shall be distributed to all members of the IRB prior to the meeting.

f. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol will also be distributed to the consultants or experts prior to the meeting.

g. A majority of the membership of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols.

h. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the IRB can conduct its review of research.

i. For a research protocol to be approved, it must receive the approval of the majority of those voting members present at the convened meeting.

j. 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 require project continuation review and approval by the IRB.

k. Investigators will be notified in writing of the IRB’s decisions through the IRB Coordinator, in accordance with 45 CFR 46.109(d).

l. When the research activity involves an outside agency (e.g. hospital, public school, etc.), the investigator must secure written approval on agency letterhead from an appropriate official within the agency prior to conducting the research. This should be submitted with the IRB proposal. If it is not, final approval will be delayed until it is submitted to the IRB Coordinator.
m. The IRB may not have a member participating 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.

F. Criteria for IRB Approval of Research

1. Risk/Benefit – in order to approve research covered by this policy, the IRB shall determine that the following requirements are satisfied:
   a. Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
   b. 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.
   c. In evaluating risks and benefits the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits that may result from therapies participants would receive even if not participating in the research). The IRB will not consider long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. The IRB will examine study design or scientific merit of a proposed study within the context of its risk/benefit analysis.

2. 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.

3. 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 46.116 and 46.117.
4. **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.

5. **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, physically or mentally disabled persons, or educationally or economically disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these participants.

6. **Review by College** – Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the College. However, College officials may not approve the research if it has not been approved by the IRB (CRF 46.112).

7. **Monitoring of data** - When appropriate, the research plan shall include adequate provision for monitoring the data collected to ensure the safety of participants.

**G. Suspension or Termination of IRB Approval of Research**

1. 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 hardship to participants (45CFR 46.113).

2. 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 Provost. The Provost and the IRB Administrator shall inform other appropriate institutional officials, and Department or Agency Heads, as applicable.

**H. Continuing Review**

1. 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 and the date for submitting a request for continuation.

1. For research with a one-year approval period, investigators
must request a continuation for the approval yearly if the activity lasts more than one year. Only two continuations will be granted for a given project. After three years, the project must be resubmitted, as a new protocol to the IRB for review and approval.

I. **Modifications**

All modifications to currently approved research are required to have IRB review and approval prior to implementation. Minor changes that do not increase the risk to research participants may receive an expedited review. Modifications to approved research projects that may affect the risk to participants are forwarded to the IRB for full review.

J. **Reviewing Reports of Adverse Events**

1. 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.

2. 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.

3. Site visits for specific projects must be made by the IRB Chair, Coordinator, Administrator and possibly IRB Board members only “for cause.” Cause is defined as reporting of an adverse event. Additional oversight of projects may be required on a case-by-case basis.

K. **IRB Policy Regarding Research Conducted Without IRB Approval**

1. Research activities involving the use of human participants under the auspices of The College at Brockport SUNY 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.

2. Any research activity initiated or completed will be reviewed by the IRB on a case-by-case basis. The IRB will review the project at an IRB meeting, 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 obtain 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.

2. A letter from the IRB Coordinator 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 investigator is a student.

L. **Research Lacking Definite Plans for the Involvement of Human Participants**

As provided for under 45 CFR 46.118, applications and proposals lacking definite plans for involvement of human participants will not require IRB review and approval prior to external funding. However, except for research exempt or waived under 45 CFR 46.110(b), human participants may not be involved in any project supported by such awards until IRB review and approval has been certified to the appropriate Federal or State department or agency.

M. **Research Undertaken Without the Intention of Involving Human Participants**

As required under 45 CFR 46.119, the IRB will review proposed involvement of human participants in Federal research activities undertaken without prior intent for such involvement, but will not permit human participants involvement until certification of the IRB’s review and approval is received by the appropriate Federal department or agency.

N. **IRB Records**

1. The IRB Coordinator with secretarial assistance shall prepare and maintain adequate documentation of IRB activities, in accordance with 45 CFR 46.115, including the following:

   a. Copies of all research proposals reviewed, approved
consent forms, progress reports submitted by investigators, and reports of injuries or harms to participants.

b. Minutes of IRB meetings which shall be of sufficient 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 controversial issues and their resolution.

c. Records of continuing review activities.

d. Copies of all correspondence between the IRB and investigators.

e. A list of IRB members in the same detail as described in 45 CFR 46.103(b).

f. Written procedures for the IRB in the same details as described in 45 CFR 46.103(b)(4) and (5).

g. Statement of significant new findings provided to participants as required by 45 CFR 46.116(b)(5).

2. The records required by this policy shall be retained for at least six years, and the records related to research that was conducted shall be retained for at least six 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.

O. Appealing an IRB Decision

1. 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 IRB Administrator. 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.

2. If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision, in writing, to the IRB.
3. In developing their 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.

4. The investigator must appear before the IRB to present their 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.

6. Responsibilities of the Investigator

In accordance with the provisions of the College’s Federal Assurance Filing 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 and the following:

A. 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 students and the faculty sponsor. All student research must have a faculty sponsor.

B. Preparation of Human Participants Review Form

1. Researcher investigators shall prepare the IRB Application that includes a complete description of the research protocol. In the form, investigators shall make provision for the adequate protection of the rights and welfare of prospective research participants and ensure that pertinent law and regulations are observed. The IRB Application is available from the IRB Coordinator (6th Floor, Allen Administrative Building in Academic Affairs) or can be accessed on the College’s IRB web site (www.brockport.edu/irb/)

2. Research investigators shall include the proposed informed consent form(s) and copies of all relevant information and documentation (surveys, test instruments, recruitment tools, scripts, debriefing statements, contact letters, consent forms, approval letters from institutions where research will be conducted, etc.) to their IRB Application.

C. Submission of the Human Participants Review Form

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 College for review and approval.

It may not be readily clear if a proposed research project involves human participants. The investigator is strongly encouraged to consult the IRB Coordinator on the question. Final authority for making the determination on whether the research is human participant research rests with the IRB.

D. Reporting Modifications in the Research

1. Research investigators are responsible for promptly reporting any changes in the research protocol to the IRB.

2. 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).

3. In most cases, requests for minor modifications will be reviewed on an expedited basis in accordance with established IRB procedures. A request for a major modification will be considered at an IRB meeting.

4. An application for modification includes the submission of all proposed changes with a rationale for each proposed change.

E. Submission of Requests to Continue Research

Approval of a human participants protocol is not for more than one year, although the IRB may grant an approval for less than one year – depending upon the nature of the research. One month before the expiration of the approval, the IRB Secretary will send the investigator a courtesy reminder that approval for the protocol will soon expire. A “continuation” form will be sent to the investigator for studies that continue beyond one year.

F. 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 their willingness to continue participation.

G. Complying With IRB Decisions

Research investigators shall be responsible for complying with all IRB decisions, conditions, and requirements.

H. Providing Consent Forms to All Participants
Research investigators are responsible for providing a copy of the IRB-approved and signed (if applicable) consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement.

I. Retention of Signed Informed Consent Documents

Research investigators are responsible for retaining the informed consent documents signed by research participants in a manner approved by the IRB.

J. Submission of Adverse Events Reports and Reports of Unanticipated Problems Involving Risk

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.

K. Attending IRB Meetings

Research investigators are strongly encouraged to attend IRB meetings in which their IRB Category 3 (full review) applications are being considered.

L. Education and Training

Prior to the submission of an IRB application for IRB review, the investigator and all key personnel listed on the protocol (including faculty advisors) must successfully complete the required CITI human participants training program modules required by the College. The IRB will not give approval to IRB applications until the investigator and key personnel have successfully completed this requirement.

M. Cooperative 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.

7. Cooperative Research

A. The College at Brockport State University of New York will ensure that any of its collaborating entities (i.e., those engaged in human participant research by virtue of subject accrual, transfer of identifiable information, and/or in exchange for something of value, such as material support, co-authorship, intellectual property, or credits) materially engaged in the conduct of non-federally sponsored research involving human subjects will possess mechanisms to protect
human subjects that are at least equivalent to those procedures provided for in the ethical principles to which the College is committed.

B. The College will comply with the requirements set forth in 45 CFR 46.114 regarding cooperative research projects.

C. The College may enter into a joint review arrangement, rely upon the review of another qualified IRB that adheres to similar standards of human participant protection, or make similar arrangements for the purpose of meeting the IRB review requirements and obviating duplication of effort. Such arrangements must be: a) in writing, b) approved and signed by the IRB Administrator, c) signed by the correlative officials of each of the cooperating institutions. These arrangements may be entered into on a case-by-case basis if arrangement is needed for the review of a single research project. Or, for ongoing cooperative research, a more formal arrangement may be entered into – e.g., a memorandum of understanding detailing the joint review mechanism(s).

D. The College at Brockport State University of New York research studies involving a collaborating institution must include a statement in the consent form indicating the existence of the collaborative relationship. Use of a single, consolidated informed consent form for such studies is strongly encouraged. Additionally, copies of all correlative protocols and consent documents required at collaborating institutions must be kept on file at The College at Brockport SUNY.

E. Researchers wishing to conduct research at The College at Brockport SUNY, who have already obtained written approval from their institution’s IRB, do not have to apply to the Brockport’s IRB for approval. However, they must provide the IRB Coordinator with a copy of their complete application to their IRB and a copy of the approval letter from their IRB prior to beginning research.

8. Education and Training

In accordance with Federal regulations, the College will ensure that the IRB Chair, the IRB members, IRB Administrator and Coordinator, human participant investigators, and relevant institutional personnel complete appropriate education related to the protection of human participants before reviewing or conducting human participants research.

A. The Signing Official for the College on the FWA, the IRB Chair, the IRB Administrator, IRB Coordinator and IRB members must successfully complete the required CITI training program. Additionally, IRB members will be required to participate in ongoing educational and training programs as identified. New IRB members must complete an orientation program to the IRB process offered by the IRB Administrator.
B. Prior to the submission of human participants review forms for IRB review, the investigator and all key personnel listed on the application must successfully complete the College required CITI training program. If the investigator is a student, their faculty advisor must also complete the CITI training program.

9. Appendices  
A. Roster of IRB Members  
B. IRB Guidelines

These policies were unanimously approved by the IRB on February 26, 2010. Revised June 13, 2013
IRB Members, 2014

Betsy Balzano, IRB Chair—Education and Human Development

Christopher Williams, IRB Vice Chair—Kinesiology, Sport Studies & Physical Education

Jennifer Boyle—Health Science (Fall 2013)

Diana Flow—Community Representative

Lori Ann Forzano—Psychology (Fall 2013)

Swaminathan Madhu—Community Representative

Craig Mattern—Kinesiology, Sport Studies & Physical Education

Barbara Thompson—CSTEP/McNair Program

Pamela Viggiani—Great Rochester Collaborative, MSW Program