The College at Brockport State University of New York
Institutional Review Board Procedures

1. Statement of Principles

The following principles serve as the foundation for The College at Brockport State University of New York, Institutional Review Board procedures described in this document.

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 laws 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), 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 made between funded and unfunded research, or between research conducted by faculty, staff, students, other College personnel, or affiliated researchers.

2. Definitions

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

A. 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 these procedures, 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.

B. 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.

C. **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.

D. **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 Review Board**

   A. **Composition** – the College has established its IRB in accordance with the requirements of 45 CFR 46.107.
   1. The IRB shall consist of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the College.

   2. 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.

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

   4. 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.
5. 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.

6. 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.

B. IRB Appointment

1. The Provost or his/her designee (IRB Administrator) with input from the IRB Chair shall make appointments to the IRB for one year renewable terms that shall begin at the start of the College’s academic year.

2. The Provost or his/her designee (IRB Administrator) shall appoint the Chair of the IRB on an annual basis.

3. Board members may be removed at the discretion of the IRB administrator.

C. IRB Membership Lists and Qualifications

1. 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.

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

D. Training of IRB Members

The IRB Chair, the IRB members, IRB Administrator, IRB Coordinator and the official designated from the Federal Wide Assurance Form (FWA) (whom IRB reports to) will have successfully completed initial and continuing education related to the protection of human participants before reviewing human participant research protocols. Currently, training is provided through giving each of those named above a copy of the comprehensive IRB orientation written manual, and their completion of the CITI human research participant’s online training modules. Training is to be renewed every three years as mandated by federal regulations.

E. Conflicts of Interest

In accordance with HHS regulations 45 CFR 46.107(c) no member of the IRB involved in any way with a protocol being reviewed by the IRB will be present in the room during the discussion of the protocol except to answer relevant questions posed by IRB members. This will be so noted in IRB meeting minutes.
4. **IRB Operational Details**

In compliance with HHS regulations 45 CFR 46.103(b)(4) and (5), The College at Brockport State University of New York’s IRB has adopted the following procedures.

**A. IRB authority and responsibility**

The IRB will 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 IRB member or administrator involved in the conduct and/or supervision of a specific project shall participate in IRB review, except to provide information.

**B. Levels of review**

Research projects are reviewed at one of three levels depending upon the IRB’s interpretation of the project’s risk to 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 makes the initial determination regarding the appropriate category of review, the IRB Chair and IRB Coordinator will make the final level of determination. Any member of the IRB may request full review of any research submitted under expedited review.

**C. Elements of Informed Consent and Review of Protocols**

The review of human participants research is confined solely to procedures affecting the rights and welfare of human participants. No evaluation is made of the scientific merit of the project unless participants are found to be “at risk,” at which time the risk/benefit ratio of the project will be evaluated. Review of protocol focuses on issues of:

- **Risk/benefit ratio** – a) risks to participants are minimized by using procedures which are consistent with sound research design and 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. The IRB will examine study design or scientific merit only within the context of its risk/benefit analysis.

- **Equitable selection of participants and recruitment** - selection criteria should consider all populations that might potentially benefit from the research, not just those readily available. The IRB will take into account
the purposes of the research and setting in which the research will be conducted. The IRB ensures 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 45 CFR 46.116 and 46.117 (Code of Federal Regulations). The reviewers will look for the process used to obtain informed consent not just the informed consent document. Reviewers must be convinced that all information regarding the study that would be relevant to participants’ ability to make an informed decision to participate has been provided. A written signature is documentation of consent and is required for all Category 3 proposals. Proposals that fall into an exempt (Category 1) or expedited (Category 2) category do not require signed informed consent. A cover page including the following consent information must accompany the research protocol: a) identify the researcher and institutional affiliation, b) description of the project, c) what is expected of participants, d) length of time required for participation, e) location of study, f) state participation is “voluntary,” g) indicate “subject can withdraw at any time without penalty,” h) indicate “subject does not have to answer any question(s) they do not want to,” i) payment (if applicable and procedures for distributing payment), j) taping (if applicable) must include information about what will be done with the tapes for storage and disposal, j) include referrals (if applicable), k) include a risk/benefit statement – if there are no anticipated risks, so indicate, l) the study is confidential or anonymous and how the data will be disseminated, m) contact information for investigator and/or faculty advisor with phone number and email.

- **Privacy and confidentiality** – the IRB will determine that adequate provisions have been taken to protect the privacy of participants and for ensuring confidentiality of participants and 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 minors, prisoners, pregnant women, physically 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.

## D. Operational details by category of review

1. **Procedures for all protocols** - all protocols received in the IRB Office are assigned a number, logged into the IRB Log (by number, title, researcher(s) name and initial review category as indicated on the IRB cover page) by the IRB Coordinator and placed in a numbered folder with a standard form completed and
placed in the left hand side of the folder. The IRB Chair is contacted to review proposals as they are received. They are reviewed by the IRB Chair within 1-4 working days of receipt. If the IRB Chair will be out of town for longer than a week during the academic year an alternate IRB Chair will be designated from among the IRB members.

The IRB Coordinator pre-reviews the proposal for completeness and verifies the category of review based upon the IRB policy manual. The IRB Coordinator sends a Category 2 proposal to a second IRB reviewer, and a Category 3 proposal to the entire IRB board. Category 1 proposals are reviewed by the IRB Chair. The Chair makes hand written or electronic notes which are kept in each IRB folder as to his/her response. The notes are then given to the IRB Coordinator for appropriate follow-up depending on the Chair’s response. (See specifics under each of the three categories below).

2. Exempt review – (Category 1)
   A. To qualify for exempt review a research activity must present no possible risks to subjects 18 years of age and older and be one of the following activities:
      • anonymous, mailed survey on innocuous topics
      • anonymous, non-interactive, non-participating observation of public behavior
      • secondary analysis of existing data
   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.

   B. Operational detail – if after review of a protocol the IRB Chair determines that it meets one of the three activities listed above he/she will: a) approve the project as submitted, or b) conditionally approve the project pending revisions. The IRB Coordinator will contact the investigator by phone or email within 1-2 business days of receiving the file from the IRB Chair informing the investigator (and faculty supervisor if a student) of the Chair’s decision. If revisions are needed they are submitted to the IRB Coordinator in writing (hard copy or electronically). Once the required revisions have been made, the investigator (and faculty supervisor if a student) is told by the IRB Coordinator by phone or email that they can begin the project immediately. All contact with investigators and responses are recorded by the IRB Coordinator with the date in the project file.

   A written approval letter is sent to the investigator by the IRB Coordinator within 3 working days of the project’s approval. A copy is kept in the protocol file. If the project involves an anonymous mailed survey the informational letter attached to the survey that includes the required elements of informed consent is date stamped with the approval date and sent with the approval letter. The researcher is instructed to use this
version of the letter in their mailing. The approval letter also states that project approval will expire one year from the date of approval and that it is the responsibility of the researcher to notify the IRB Coordinator if the project will continue past that date, if any modifications are made to the protocol, or any adverse reactions occur as a result of the research project.

3. **Expedited Review** (Category 2)

   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 HHS regulations 45 CFR 46.100. Examples of research activities reviewed on an expedited basis include:

   - research on educational curricula or teaching methods involving normal educational practices
   - 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
   - continuations of approval for previously approved no-risk research with no more than minor changes in procedures.

   B. **Research activity involving 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 protocol and given to the reviewer(s) with other materials. If it is not provided when originally submitted, final approval will be delayed until it is submitted to the IRB Coordinator.

   C. **Operational detail** – if after review of a protocol the IRB Coordinator determines that it meets one of the activities listed above he/she will send the entire proposal\(^1\) to another IRB member for review, who will be asked to complete the review within seven business days. Approval is requested electronically, using the IRB review form. The IRB Chair and IRB member will independently review the proposal. If both approve the project as submitted, the P.I. is notified by email or phone by the IRB Coordinator within two business days that the project has been approved and the project

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\(^1\) Complete proposals include cover sheet signed by P.I., responses to all questions, informed consent form(s), surveys, interview questions, agency letters of permission, standardized tests, appendix materials, copy of certificate of completion of required training.
can begin immediately. Hard copy of approval letter will be sent within one week by IRB Coordinator. If either reviewer conditionally approves the proposal, the P.I. will be notified that revisions are required. The IRB Coordinator will contact the P.I. (and faculty supervisor, if applicable) of the changes necessary for approval of the protocol. Any changes required are communicated within 1-2 business days to the P.I. by email. When the IRB Coordinator receives complete and satisfactory revisions from the investigator (as determined by the IRB Coordinator) s/he will inform the P.I. the project can begin immediately. Reviewers are selected by the IRB Coordinator based upon their expertise and availability.

If a response is not received within 7 business days then the IRB Coordinator will send a reminder notice by email or voice mail requesting the reviewer’s response. The response date of the reviewer(s) is recorded on the form in the protocol folder. All reviewer forms are kept in the protocol folder. The IRB Coordinator sends the investigator a standard approval letter with a date stamped copy of the final approved consent form within 3 business days. The date stamped is the day that the approved revisions have been received by the IRB Coordinator. The protocol is approved for one year from that date. Additionally, the memo notes that the investigator must immediately contact the IRB Coordinator if: a) there are any modifications needed; b) a subject is injured; c) level of risk increases for participants.

If the IRB Coordinator, in consultation with the IRB Chair, concludes that this is a Category 3 protocol and requires full IRB review the investigator (and faculty supervisor, if applicable) is contacted by phone or email by the IRB Coordinator within 1-2 business days of the IRB Chair’s review and asked to submit the paperwork for a full review and the steps under a full review are then followed.

4. Full review (Category 3)

A. All proposed research deemed by the IRB to present more than minimal risk to human participants is subject to full review by the IRB.

B. Examples of research activities that must be reviewed by the full IRB include:

- research which might put subjects at risk
- 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, prisoners, mentally incompetent persons or minors that do not meet the criteria for an exempt or expedited review
- research which for IRB review requires the expert opinion of an
occasional consultant

- international research, including class projects conducted in another country. International research may require additional approval from an IRB (or similar body) in that country and a copy of the translation of the informed consent document and any survey or interview questions.

C. Operational details – IRB Board meetings are scheduled at the beginning of every semester and follow a bi-weekly time frame. After review of a Category 3 protocol submission (or determination by the IRB Chair, IRB Coordinator or member of the IRB Board that a proposal should have full review) the investigator (and faculty advisor if applicable) is asked by the IRB Coordinator to attend the next scheduled IRB Board meeting. The IRB Coordinator will mail to all IRB Board members (those who can attend and those who cannot) a copy of the entire protocol. Materials will be mailed or hand delivered to IRB members a minimum of 1 week prior to the IRB meeting.

D. IRB meeting – The standard review form will be completed by all IRB members and electronically submitted to the IRB Coordinator preferably no less than 2 days prior to the scheduled meeting. IRB member comments on the IRB form are the basis for the discussion of the proposal at the meeting. The IRB meets in executive session to discuss the proposal, then invites the investigator to join the meeting to discuss the proposal with the Board. Executive session should typically last no more than 15 minutes.

E. IRB minutes - the IRB Coordinator (or designee) takes minutes at the IRB meetings as stipulated by OHRP regulations at 45 CFR 46.115(a)(2). The minutes document: a) separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB; b) the vote on all IRB actions including the number of members voting for, against, and abstaining. If a member is unable to attend the meeting but shares comments in advance with the IRB Chair or IRB Coordinator these are shared with the IRB by the IRB Chair and noted in the minutes. In accordance with HHS regulations at 45 CFR 46.108(b) initial and continuing reviews of research are conducted by the IRB at meetings at which a majority of members are present, including at least one member whose primary concerns are in nonscientific areas for Category 3 reviews. Approval of the research is by a majority vote of the quorum. Should the quorum be reduced during a meeting (e.g., loss of quorum due to departure of a member) the IRB will not take any further actions or votes unless the quorum can be restored. Minutes are distributed as per the process in these procedures detailed under the section of Notification to IRB Members.

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2 Cover page signed by P.I., responses to questions in IRB guidelines pertaining to a Category 3 review, survey instruments, interview questions, test forms, publicity, consent document(s), permission letters, copy of certificate of completion of required training in human subjects protection, copy of grant proposal (if externally funded research), appendix material, etc.
F. **IRB action** – With a formal vote, one of three determinations is made by the IRB at a meeting:

- **Approval without questions, concerns or requests for modifications.**
- **Approved pending modifications.** The IRB will list the modifications necessary prior to the protocol being approved. These will be noted in the meeting minutes and communicated in writing to the P.I., who will submit necessary changes to the IRB Coordinator for approval. The research activity may not be undertaken until each of the IRB’s concerns are addressed and submitted to the IRB Coordinator for review and approval by the IRB Chair. The IRB members have the option to determine at the meeting if the modifications are serious enough to warrant their review in addition to the IRB Chair’s prior to final approval. The decision is recorded in the meeting minutes.

- **Disapproved.** While this action is very rarely taken, the IRB may disapprove a proposed activity with serious and substantive problems and/or that fails to meet College, Federal or State guidelines for the protection of human participants.

G. **Approval period** – the IRB has the option (although rarely if ever used) of approving a project for less than one year and requiring the investigator to provide required status report within a specified period of time. This would be so noted in the IRB meeting minutes and in the approval letter sent to the investigator. When the IRB Coordinator receives complete and satisfactory revisions from the investigator she/he will inform the investigator (and faculty supervisor if applicable) by phone or email within 2 business days that the project has been approved and research can begin immediately using the approved consent form, surveys, and interview questions. The IRB Coordinator will send a formal approval letter and date-stamped copy of the final approved consent form and survey and/or interview questions (if appropriate) to the investigator (and their faculty supervisor if a student) within 3 business days. The date stamped is the day that the IRB met to review the protocol. The protocol is approved for one year from the date of the IRB meeting unless the IRB has mandated a shorter period of time at their meeting. Additionally, the approval letter states that the investigator must contact the IRB Administrator (or IRB Coordinator) immediately if: a) there are any modifications needed to the project; b) a subject is injured or complaints are made; c) the level of risk increases for participants.

H. **IRB Consultants** – if it is determined that consultants or experts will be required to advise the IRB in the review of a protocol (e.g., international research) the research protocol will also be
distributed to the consultant or expert prior to the meeting of the IRB. The IRB Chair or Administrator will decide if this is necessary before the meeting. If IRB member(s) desire additional expertise as part of their review then a consultant may be contacted after the initial meeting and the consultant’s response will be provided to the full IRB by email or written mail after the meeting. At the meeting the IRB will decide if they need to meet again to consider this information or if this can be addressed by mail.

I. Research activity involving 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 protocol and given to the reviewer(s) with other materials. If it is not provided when originally submitted, final approval will be delayed until it is submitted to the IRB Coordinator.

5. Continuing Review

A. Operational details – at the beginning of each month the IRB Secretary refers to the IRB log and sends out a standardized memo to all investigators who had their projects approved 11 months ago. The memo (see appendix) reminds the investigator that their project was approved for 12 months and that if they wish to continue they must seek approval for an additional 12 months by submitting the information detailed in the memo to the IRB Coordinator immediately.

B. Continuing review process – the information to be submitted to the IRB Coordinator by an investigator seeking continuation of any protocol includes: a) number of subjects involved in the previous year; b) a description if applicable of any adverse events or unanticipated problems involving risks to subjects or others; withdrawal of subjects from the research, or complaints about the research during the previous year; c) a summary of any recent literature, findings or new information about any risks associated with the research; d) a copy of the current informed consent document; e) a general summary of research findings from the previous year; f) detailed explanation of any changes requested for the next year in procedures, recruitment, number and type of participants, etc.

The IRB Coordinator puts the information for a continuing review into the original folder for this investigator and contacts the IRB Chair to review the information. This will be done within 4 business days of receiving the information (during the academic year). The IRB Chair then determines if the project category has changed since it was previously approved. (Projects can only have two continuing reviews – after the third year it must go through the entire IRB approval process).
a) If it fits the activities for an expedited proposal and no substantial changes or problems have occurred then the Chair either approves the request or requests revisions.
b) If the protocol originally required a full Category 3 review then the same process will be followed as listed for a Category 3 review in the previous section. If there are only minor or no changes to the project the IRB Chair may elect to have the review conducted by mail without a formal meeting. In this case the proposal is mailed to every member of the IRB Board within 2 days of the Chair's decision, by the IRB Coordinator. Unanimous approval must be received in writing from each Board member for it to be approved. Responses are requested in one week. If unanimous approval is not received from each member of the IRB then a full Board meeting is scheduled by the IRB Coordinator within 10 business days of receiving the continuing review request.

C. IRB meeting minutes – will document as separate deliberations all actions and votes regarding continuing reviews that require full review.

D. Protocol approval - When the IRB Coordinator receives complete and satisfactory revisions from the investigator or the IRB immediately approves the continuing review she/he will inform the investigator (and faculty supervisor, if applicable) by phone or email within 2 business days that the project has been approved and research can begin immediately using the approved consent form. The IRB Coordinator sends a date stamped copy of the final approved consent form, survey and/or interview questions (if appropriate) and standard approval letter with the date-stamped copies to the investigator (and the faculty supervisor if applicable) within 3 business days. The protocol is approved for one year unless the IRB mandates a shorter period of time. The approval date is the date that all revisions were received and approved if an expedited (Category 2) review, and the date of the IRB meeting if a full (Category 3) review. Additionally, the approval letter states that the investigator must immediately contact the IRB Coordinator if: a) there are any modifications needed; b) a subject is injured or a complaint made; c) the level of risk increases for participants.

E. Verification from other sources that no material changes have occurred – if the IRB has received complaints from participants in research projects or the investigator reports any adverse events the IRB will seek external verification of the actual process being followed by the investigator in conducting the research. The IRB Chair and/or IRB Administrator or Coordinator will themselves with at least one other IRB Member discuss the project's procedures with the investigator, a select group of participants, and other relevant people. This will be accomplished within 15 business days upon receiving the request for the continuation of the protocol. The IRB Administrator will provide the report to the IRB Board at least 48 hours prior to the IRB meeting to discuss the issue. The IRB will use this information in deliberations regarding approval of the
application and impose any modifications or changes they deem appropriate depending upon the case.

6. Expedited Review of Minor Changes

If modifications to a project fit the category of an expedited review (Category 2) described previously then the same actions taken for a review of an expedited process will be utilized. However, if the changes are substantial and the proposal was originally reviewed as a full (Category 3) review then the same process for a Category 3 review will be utilized.

7. IRB Review of Projects More Than Annually

Approvals of protocols are generally for one year. In rare circumstances, at an IRB meeting the Board may mandate a shorter approval period is warranted if they feel that the level of risk to participants warrants a shorter approval period. The specific dates of reporting to the IRB will be decided on a case-by-case basis and will be so noted in the minutes of the IRB meeting and the approval letter sent to investigators.

8. IRB Review in Emergency Situations

No biomedical research is conducted at our institution. However, if a participant in a research study should experience injury or self-harm during a research project approved by the IRB the IRB Administrator and Chair will call an emergency meeting of the IRB with the project investigator to address actions to be taken in accordance with the procedures listed in #9.

9. Reporting to the IRB and Other Agencies

A. The IRB approval letter (and continuing review reminder) sent to investigators clearly states that any changes in the procedures, consent forms, survey/interview questions, publicity, etc. or any adverse events must be reported immediately to the IRB Administrator or Coordinator. Once the IRB Coordinator receives this information she/he will contact the IRB Chair and Administrator and depending upon the changes or situation and the initial level of review an appropriate course of action will be taken following all of the procedures for the appropriate level of review.

B. Reporting to external agencies including OHRP or any external funding source of: a) any unanticipated problems involving risks to subjects or others; b) any serious or continuing noncompliance with 45 CFR Part 46; c) or any suspension or termination of IRB approval will be made by the IRB Administrator to the IRB Chair, IRB members, and Provost at The College at Brockport State University of New York, investigator (and
faculty supervisor if applicable), Department Chair and School Dean. If
the project does have external funding in addition to those individuals
previously cited the Research Foundation Operations Manager at
Brockport, the appropriate contact person at OHRP, and the funding
agency will also be informed in writing within 2 business days of the
reporting of the incident. Appropriate action/investigation will be carried
out immediately by the IRB Administrator and IRB Chair to determine the
next course of action. All research on this project will cease immediately
until resolution of the issue has occurred. The full IRB Board will be
provided with all relevant documentation and meet at an emergency
meeting with the investigator and any other relevant persons to determine
the most appropriate course of action. Their response will be shared in
writing with all of the individuals noted above.

10. Retention of IRB Records

The IRB Coordinator maintains IRB files in the Office of
Academic Affairs by year and numbered sequentially of all protocols
received. Specific information with the number, title, investigator’s
name, level of review, and approval date is kept in separate IRB logs
(notebooks) by year.

HHS regulations at 45 CFR 46.115(b) require that IRB records be
retained for at least 3 years after completion of the research. State law
requires they be retained for 6 years – this is our practice. Information
more than 4 years old is boxed, labeled and sent to the College’s library
for storage. All records are easily accessible for inspection and copying
by authorized representatives of OHRP and other relevant agencies.

11. Notification to IRB Members

A. IRB minutes – within 3 business days of an IRB meeting the minutes are
prepared by the IRB Coordinator (or designee) and emailed to members on
campus (hard copy mailed to community IRB members) and emailed to the
investigator (and their faculty advisor if applicable). Any changes to the
minutes are made immediately upon being brought to the attention of the
IRB Coordinator and revisions disseminated.

B. Notice to IRB of exempt and expedited actions – at the beginning of
each month during the academic year (September – May) a report is
prepared by the IRB Coordinator (based upon the IRB log) listing with
number, title, and investigator (and faculty advisor if applicable) a list of
all exempt and expedited proposals approved in the previous month(s).

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