

**STATE UNIVERSITY OF NEW YORK
CANTON COLLEGE OF TECHNOLOGY
INSTITUTIONAL REVIEW BOARD FOR THE
PROTECTION OF HUMAN SUBJECTS**

**GUIDELINES AND PROCEDURES FOR
REVIEW**

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What Is the Institutional Review Board?

The State University of New York, Canton College of Technology Institutional Review Board (the Board) is an administrative body established to protect the rights and welfare of individuals recruited for participation in research conducted under the auspices of the university or its affiliates. Its mission is to advance an organizational culture and infrastructure that supports the highest ethical standards in the review and implementation of research with human participants. The State University of New York, Canton College of Technology gives the Board ultimate authority for approval of research with human participants.

To accomplish its mission, the Board:

- ensures adherence to the principles of ethical research promulgated in the *Belmont Report*
- implements the federal regulations found at §45CFR46
- monitors the behaviors of university investigators through its review of research utilizing human research participants

Does My Project Have to Be Reviewed?

Projects require review by the Board only when they involve research on human subjects as defined by the federal regulations for the protection of human subjects (45CFR46). A project may meet the definition of research, but not that of human subjects. A project may involve interaction/intervention with or collection of data about individuals, but does not involve research or human subjects as defined by the regulations.

Definitions in 45CFR46:

Research is defined as a systematic investigation designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge in a particular field of study. Generalizable knowledge is knowledge that has implications for a broader group of people or that will be used to influence policy or practice. It is usually described in a formal protocol utilizing scientific methods that sets forth an objective and a set of procedures to reach that objective.

Human Subject means a living individual about whom and investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) individually identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, drawing blood, dispensing drugs, administering other treatments) and manipulations of the subject or the subject's environment (controlling environmental light or sound, presenting sensory stimuli, making voice, digital or image recordings) that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject through surveys, interviews, focus group meetings, etc. (including mail and on-line surveys.)

Individually Identifiable data includes, but is not limited to, names, social security numbers, medical record numbers, addresses, phone and fax numbers, email addresses, account numbers, license or certificate numbers, vehicle identifiers, codes which the researcher could reasonably use to identify a living individual, or combinations of information from which a persons identity could easily be determined. Data could be from previously conducted surveys or interviews, from medical, educational or financial records, or from a publicly available database.

Private data includes biological specimens and information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information or specimens provided for specific purposes which the individual can reasonably expect will not be made public (e.g., a medical or student record). Private data must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information, either directly or through a coded link) in order for obtaining the data to constitute involvement of human subjects.

Projects meeting the definitions above must be submitted to the Board for review. If your project does not involve research on human subjects, as defined above, but does involve either interaction/intervention with or collection of data about individuals, please complete and submit an IRB Registration Form.

The responsibility for determining whether an activity constitutes human subjects research rests with the investigator. Since the University will hold them responsible if the determination is not correct, investigators are urged to submit the registration form to request confirmation from the Board that an activity does not constitute human subjects research.

Investigator Certification

To become certified to conduct research involving human subjects, Board applicants are required to read certain documents related to the protection of human subjects and to submit a signed Investigator Certification form. The form must be on file with the Board before any research involving human subjects will be approved. The form can be submitted with your IRB application. The required readings are:

1. The Belmont Report – the document that guided the development of Federal regulations covering human subjects protections.
2. Title 45 Code of Federal Regulations Part 46 – the Federal regulations under which the Board conducts its reviews.
3. The Required Elements of Informed Consent
4. These Guidelines

Applicants should complete the Investigator Certification form and send it to the Board with a copy of your curriculum vitae (students do not have to submit a curriculum vitae).

Review of Student Research

Student projects may be reviewed in one of two ways – 1. the Classroom Based Protocol Certification process; or 2. the regular IRB application. It is important to be aware that students are **not permitted** to be Primary Investigators, rather, their faculty mentor must serve as the PI for their project, and the student must be listed as a co-investigator. Faculty advisors/mentors should be aware that it is their duty to work with their student(s) throughout the IRB application process to ensure that all forms are prepared in a professional manner before the student submits the forms for IRB review. This will ultimately make the application process quicker for the student.

1. Classroom-Based Protocol Certification –

Please Note: This Certification is completed by the classroom instructor/faculty – NOT the student.

The Board recognizes that many student research projects conducted to fulfill course requirements involve human subjects. Such research occasionally entails certain risks to the subjects involved. As students vary in expertise regarding research procedures designed to protect the rights of human subjects, the Board has developed the following guidelines regarding classroom-based research projects. These guidelines are intended to provide clarification and simplify the process for obtaining Board approval for classroom-based research projects.

For classroom-based projects for which the subjects are **not**:

- identifiable by name or description (i.e. completely anonymous);
- drawn from vulnerable populations;

and the subject matter is not **sensitive** as noted below; instructors should submit the *Certification for Classroom-Based Protocols form* to the Board prior to the beginning of classes in order to obtain approval for classroom-based research protocols using human subjects. This certification is submitted on behalf of the entire class.

The Board will record the classroom-based certification in its records and the instructor may then permit students to proceed with their research without further review, assuming all projects meet the Classroom-Based Certification guidelines.

Please note that all human subjects must provide informed consent when participating in any protocol submitted under the Classroom-Based Certification. To protect subject anonymity, the Board recommends the use of passive informed consent procedures when developing protocols for use under this Guideline. Passive informed consent requires informing the prospective subject about the research to be performed, but waives the requirement to obtain a signed consent form from each participant.

Informed consent information can be provided to the subject verbally or in a descriptive information sheet. In addition, the prospective subject must be offered the opportunity to decline participation.

2. The Regular IRB Application

Even though a project is classroom-based, it requires a regular IRB application when the project has one or more of the following characteristics: 1. investigation of a sensitive topic; 2. human subjects are identifiable during or after the project; or 3. subjects are drawn from vulnerable groups.

Student researchers who want to investigate the opinions, behaviors, and/or experiences of human subjects in sensitive topic areas, even for a classroom-based project, must submit a regular IRB application. Sensitive topics include, but are not limited to:

- sexual orientation
- AIDS or HIV
- incest, rape or date rape, sexual molestation
- substance use and/or abuse
- eating disorders or behaviors
- contraception, pregnancy or abortion
- questions dealing with subjects' mental health
- religious orientation and /or views
- veteran or wartime experiences
- illegal activities

Student researchers must also file a regular IRB application for any protocol that systematically selects human subjects from potentially vulnerable or sensitive groups and asks questions regarding their opinion, behavior or experiences. Vulnerable or sensitive groups include:

- children
- persons who abuse illegal substances
- cognitively impaired persons
- prisoners/arrestees
- traumatized or comatose patients
- persons seeking emergency treatment
- institutionalized persons
- persons geographically located outside the U.S.
- terminally ill persons

Development of a Protocol and Application for Review

The university's IRB application requires the investigator to answer questions related to human subjects and to describe the intervention or other research techniques to be utilized in the protocol. The application requires the investigator to attach copies of surveys, interview questions, and all instrument to be used with the subjects. Copies of informed consent forms,

scripts to be read to subjects and any other pertinent information should also be attached. For research using secondary data, information on the original purpose for the data collection, the list of data elements, and evidence of permission to access the data, if not publicly available, are also required.

Please Note: All protocols developed in connection with a grant or contract must include a complete copy of the proposal.

Once the completed IRB application is submitted, a determination will be made about whether it is exempt from further review, receives expedited review, or requires full board review. These procedures are described in more detail later in these guidelines.

Research Design

The Board requires all applicants to state the research question, design, and methodology of their project in the IRB application. This includes a description of the purpose and significance of the research, a description of all procedures that will be used, the characteristics of the study population, and, where applicable, the measurement instruments.

Please Note: the Board requires that all student research projects be reviewed and approved by a faculty advisor (or faculty committee as appropriate) prior to submission of the project to the Board. Prior review by a faculty advisor ensures higher quality research design and greater protection for human subjects.

Risks and Benefits

Section 46.111 of 45CFR46 provides the applicant with guidance on risks and benefits. The regulations indicate that Boards must review applications to ensure that risks to subjects are minimized. According to §46.102 (i), 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.

The regulations also specify that protocol procedures must be consistent with sound research design that does not unnecessarily expose subjects to risk. In addition, the regulations require that risks be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In other words, studies posing higher risks to subjects should demonstrate unambiguous adherence to good research design principles, greater anticipated benefits to subjects, and the strong potential to gain important knowledge.

Informed Consent

Except in rare circumstances, informed consent forms must provide contact information for the researcher (phone number, email address) and contact information. The specific language to be used for Board contact information is:

The State University of New York, Canton College of Technology Institutional Review Board for the Protection of Human Subjects has approved this project. For questions about your rights as a research participant, please contact the IRB Chair, Sarah Todd, todds@canton.edu or Telephone: (315) 379-3975.

If the researcher intends to obtain written informed consent from subjects, an unsigned copy of the informed consent form should be provided to the subject so that he or she will retain information about the project and how to contact the researcher.

Please note that subjects under the age of 18, and subjects with legal guardians, cannot provide legally effective informed consent to participate in research. Researchers must obtain informed consent from the parents or legal guardian of these subjects. Nevertheless, in most cases, subjects between the ages of 7 and 18, as well as subjects with legal guardians, can provide **assent** to participate. Once written informed consent is obtained from parents or legal guardians, the researcher should also provide the minor subjects with an assent form that explains the research. The assent form should be written with the age, cognitive ability and educational level of the subject in mind. The goal is to ensure that subjects truly understand their role in the project.

Signed informed consent and assent forms must be retained by the researcher in a locked area and should only be viewed by the research team. The forms must be retained for at least three years after completion of the research. If the research is funded by an external agency, the required retention period may be longer. Please contact the Board if you have any questions about retention of informed consent and assent forms.

Waiver of Documentation of Consent

In studies where the subjects are anonymous, or when a signed consent form would be the only identifying information received, the Board may waive the requirement to collect a signed consent. This is particularly appropriate with mail and on-line surveys. In these cases, a statement that fully informs the subjects of the purpose and procedures is provided and the subject is told that their voluntary response will serve as their consent.

Waiver of Written Informed Consent

The Board may waive the requirement for all or some of the elements of informed consent under special circumstances. Per §46.116(d), the Board may waive written consent if the:

- research involves no more than minimal risk;
- waiver will not adversely affect the rights and welfare of the subjects;
- research could not be practicably carried out without the waiver; **and**
- subjects will be provided with pertinent information after participation.

The Board does not waive parental written informed consent for projects involving children, except as permitted at §46.408 and §46.409 of the CFR.

Privacy and Confidentiality

The Board requires researchers to maintain strict protection of subject privacy in the conduct of human subjects research. Whenever possible, the Board recommends that researchers obtain data from subjects anonymously.

For protocols that match subject data from multiple data sources or research sessions (such as a pre-/posttest research design), a match-list of subject identifiers (such as subject name and a code number) should be created, and kept separate from the research data. Utilization of this technique ensures subject confidentiality because only the code number will identify subject data. The match-list should be available only on a “need to know” basis (usually only the research team would have access to it); it must be maintained in a locked or secure area; and it should be destroyed at the end of the research project. Any deviations from these procedures (e.g. need to maintain the match list for a potential follow up study) should be outlined in the IRB application with a rationale for the deviation.

If the research protocol requires the audio-taping or video-taping of subjects, the tapes should be treated in the same way as a match-list. Tapes must be kept in a locked area; the tapes should be available only to the research team; and the tapes should be erased at the end of the research project. In addition, subjects should be informed about audio- and videotaping in the informed consent form for the project and specifically asked to approve their participation in a separate signature block or check box on the consent form. Any deviations from these procedures should be outlined in the IRB application with a rationale for the deviation.

If the research requires follow up with subjects at a later date, the informed consent form must mention this requirement and specifically request the subject’s permission to be contacted in the future for follow up purposes.

Debriefing

When an intervention or experiment involves deception the Board strongly recommends that researchers provide subjects with a debriefing sheet at the completion of a subject’s participation. Subjects should be informed about the true purpose of the research project. In addition, if the research touches on sensitive topics, subjects should be directed to counseling or other appropriate services available in the community that might be of assistance if there are further questions or adverse reactions. Phone numbers and addresses of these services should be provided to all participants.

Other Regulations Affecting Research with Human Subjects

HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 included provisions to protect the privacy of personally identifiable health information (PHI). To implement these protections, the U.S. Department of Health and Human Services issued a final Privacy Rule, which was to be implemented by April 14, 2003.

The Rule governs how health care providers use and disclose PHI on their patients, including use and disclosure for research purposes. Health plans, healthcare providers and healthcare clearinghouses are all “covered entities” under the Privacy Rule. Another category of “hybrid entities” includes organizations that are not covered as a whole but contain specific units that are covered. The University of Akron is a hybrid entity. At this time the only units within the university that fall under the Privacy Rule are the Audiology and Speech Center and the Benefits Administration Office.

Even researchers who don’t qualify as “covered entities” under the Rule may be affected if their research protocols require the use of PHI obtained from a health care provider who is covered. Researchers who are accessing, using, and/or disclosing PHI from a covered entity will need to address HIPAA in their IRB application.

Personally identifiable health information (PHI) is information, including demographic data, that relates to:

- the individual’s past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,

and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. PHI includes many common identifiers (e.g., name, address, birth date, social security number).

If a project falls under HIPAA, the researcher must do one of the following:

1. Include a HIPAA Authorization Form as part of the IRB application. This form is to be given to each subject for signature. The Authorization form may be provided by the covered entity or developed by the researcher. If developing your own form, follow the Authorization Guidelines to insure you have included all required elements.
2. Request a waiver of HIPAA Authorization. Certain criteria must be met to qualify for a waiver.
3. Propose the use of a limited data set. Specific identifiers must be removed to qualify as a limited data set. Use of a limited data set will require a signed data use agreement between the researcher and the covered entity. Please contact the Office of General Counsel for assistance in obtaining a signed data use agreement with an outside agency.

Conflict of Interest

Applicants are asked to indicate if they have any potential conflict of interest related to the conduct of the research to be reviewed by the Board. A potential conflict of interest may arise if you anticipate financial rewards such as additional employment/salary, gifts, consultant agreements, stock options, ownership or equity in a company, royalties, etc. to be offered, based on the research outlined in the application.

International Projects

If you intend to perform human subjects research internationally (outside the U.S.), special provisions apply to your project.

Per [guidance](#) from the Office of Human Research Protections (OHRP), the Board must obtain an understanding of the local context where the research will be performed. Therefore, an individual who is familiar with the local context (aside from the researcher) must review the research project. The researcher can provide reviewer names to the Board to facilitate this review. The local context review is in addition to the regular IRB review process outlined in the next section of this Manual.

The researcher must also tell the Board if the government of the international site requires special permits or licenses before the research may be performed. If permits, approvals or licenses are required, the researcher must provide the Board with a copy of them as part of the IRB application process.

If the researcher intends to work with an organization or agency at the international site, a research authorization letter from the agency should also be provided to the Board. The letter must be on agency letterhead.

Finally, the protections afforded to human research participants in the U.S apply to human research participants internationally. The same rules and guidance for research design, informed consent, risks and benefits, privacy, and conflict of interest should be utilized. Special consideration must be given to differences in culture and values. In addition, differences in educational attainment should be recognized in the creation of informed consent and informational documents. Subjects should be able to read about the project and consent to participate by viewing documents that are written in their language. If subjects cannot read, oral scripts should be created in the subject's language to ensure informed consent. See the [OHRP Guidance on International Research](#) for more information. The researcher should provide to the Board copies of all documents provided to the subjects, in both English and the subjects' language.

Procedure for Review of a New IRB Application

The initial review of an IRB application is conducted to ensure that the application is complete, signatures have been obtained and attachments provided as necessary. The Investigator Certification form must also be on file, or included with the application. The Board next reviews the protocol and identifies any issues related to the risks and benefits; subject selection information; informed consent; privacy/confidentiality; and vulnerability of subjects. The applications, and any comments, are sent to the IRB as well as the principal investigator noted on the application.

EXEMPT & EXPEDITED REVIEW

All reviews are conducted pursuant to the regulations outlined in §46.111 as noted below:

1. In order to approve any research the Board shall determine that all of the following requirements are satisfied:
 - (a) Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - (b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the reviewer should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies or interventions subjects would receive even if not participating in the research). The reviewer should not consider possible 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 the Board's responsibility.
 - (c) Selection of subjects is equitable. In making this assessment the reviewer should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.
 - (d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116; or criteria is met for approval of waiver or alteration of informed consent, as permitted under §46.116(d).
 - (e) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117; or criteria is met for waiver of documentation, as permitted under §46.117(c).
 - (f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - (g) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
2. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Exemption

A protocol may be exempt from Board review if the research poses minimal risk to a subject and matches one of the following federal exemption categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **(This exemption cannot be used with surveys or interviews of minors, or observation unless no interaction with subjects occurs.)**
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects conducted by or subject to the approval of Department or Agency heads, and designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
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.

Although the investigator is asked to suggest which category their project is reviewed under, only the Board can determine if a protocol is exempt. Investigators not permitted by federal regulation to make this determination.

Expedited Review

If the protocol is not exempt from Board review, the Chair and Board next determines if the protocol is eligible for expedited review. The federal government has provided guidance with regard to what types of research are eligible for expedited review. The categories for expedited approval include:

1. clinical studies of drugs and medical devices for which either an investigational new drug application is not required; or for which (i) an investigational device exemption application is not required or (ii) the medical device is cleared/approved for marketing and the device is being used in accordance with its cleared/approved labeling
2. collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as permitted per expedited review procedures
3. prospective collection of biological specimens for research purposes by noninvasive means
4. collection of data through noninvasive procedures routinely employed in clinical practice
5. research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
6. collection of data from voice, video, digital, or image recordings made for research purposes
7. research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
8. continuing review of research previously approved by the convened Board as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis
9. continuing review of research, not conducted under an investigational drug application or investigational device exemption where categories (2) through (8) do not apply but the Board has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

In addition, the Board may use the expedited review procedure to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized (§ 46.110(b)(2))

Although the investigator is asked to suggest which category their project is reviewed under, only the Board can determine if a protocol is expedited. Investigators not permitted by federal regulation to make this determination.

Full Board Review

If the protocol is neither exempt nor eligible for expedited review, the protocol must be reviewed by the full Board at a convened meeting. SUNY Canton's Board currently meets on a monthly basis to review all protocols submitted during the previous month.

Section 46.111 provides guidance on the parameters of discussion that should be undertaken by the Board when it reviews a protocol. Particular care is taken to discuss the level of risk to subjects; research design; risks and benefits; equitable selection of subjects; informed consent and documentation thereof; and additional safeguards for vulnerable populations such as children, prisoners, cognitively disabled individuals, or economically disadvantaged persons.

Applicants are invited to attend the Board meeting. They are asked to provide a short, verbal description of the protocol as well as clarify any items necessary for the board to complete its review. Attendance is strongly recommended as any unresolved issues may defer approval until the next convened meeting.

Upon review of a protocol at a convened meeting, the Board votes to disapprove, approve, or defer approval of the protocol. If a protocol is approved, the applicant will receive notification soon after the meeting. If approval of a protocol is deferred, the applicant will be asked to resubmit materials to the Board for review at the next convened meeting.

If a protocol is disapproved, the applicant will be notified promptly in writing and will be provided the opportunity to respond within seven days of notification of the disapproval. If the applicant is not satisfied with the Board's decision after appeal, he or she may appeal to the Vice President for Research.

Contingent Approval

Protocols may be approved occasionally on a contingent basis. Such contingent approval may occur only if the required revisions are not substantive and require only simple concurrence by the investigator. Upon submission of the non-substantive contingency revisions by the applicant, the Chair may approve the changes to the protocol via the expedited review procedure. Nevertheless, when the Board requests substantive clarifications, protocol modifications, or informed consent document revisions to a protocol, Board approval of the proposed research will be deferred, pending subsequent review by the full Board of responsive material.

Institutional Disapproval

On rare occasions, the Board may decide that a protocol does not conform to university policies. Accordingly, the Board is authorized to disapprove the protocol.

Continuing Review

Federal regulations require Boards to perform continuing review of research not less often than annually. SUNY Canton's Board reviews continuing applications as required by federal regulation and its Federal-Wide Assurance. The initial approval letter identifies the expiration date for the approval (usually one year from the approval date). It is the responsibility of the researcher to submit for continuation before the approval expires. Any protocol not submitting an application for continuation prior to expiration will be considered closed. A letter is sent notifying the researcher that the project is closed and requesting a final report.

The procedure for submission and review of a continuing review application is similar to that for a new application. The Chair generally undertakes the initial review of the continuing application. If a continuing protocol is approved by the full Board, the Chair will provide the applicant with an approval letter. If the protocol is disapproved, the Chair will notify the applicant. The applicant will have seven days upon receipt of notification to respond in writing or in person in order to appeal the disapproval.

Adverse Consequences

As part of the continuing review process, the researcher should report to the Board all adverse consequences that may be related to the research project ***as they occur***. If the protocol is funded by a sponsor, adverse findings will be reported immediately to the agency funding the research (as applicable in accordance with university policies) and, at a minimum, the following will be reported: injuries or any other unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with the regulations or requirements of the Board; and any suspension or termination of Board approval. The research may be terminated by the Board if such action is necessary.

Protocols Requiring Review More Often than Annually

On occasion, the Board will require a protocol to be reviewed more often than annually. In general, the criteria that the Board follows to make such a determination include the level of risk to subjects, the possible consequences of a breach of confidentiality, the type of intervention or action performed by a subject, and other areas of concern that may be particular to a protocol. If the Board determines that a protocol requires review more often than annually, the schedule of review will be provided to the researcher as part of the approval letter.

Protocol Violations

A protocol violation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the Board and the actual activities performed by the research team. Protocol violations may be minor or major.

Minor protocol violations would include violations that:

- have no substantive effect on the risks to subjects

- have no substantive effect on the value of the data collected (scientific analysis of the results is not confounded)
- did not result from willful or knowing misconduct on the part of the researcher(s)

Major protocol violations would include:

- violations that have harmed or posed a significant risk of harm to subjects
- violations that have damaged the scientific integrity of the data collected for the study
- willful or knowing misconduct on the part of the researcher(s)
- serious or continuing noncompliance with federal, state or local research regulations

Initial Review by Chair

The Board Chair will assess all information related to the potential violation, contrast the violation with the approved protocol, and make a conclusion regarding the seriousness of the violation. Consultation with experts in the particular area of research may be obtained as needed. The initial review of a potential protocol violation will be completed within two weeks.

Minor Protocol Violation Procedure

If the findings of the Chair's initial review reveal that a minor protocol violation occurred, the Chair will issue a memo to the researcher(s) stating what must be done to bring the protocol into compliance. The Chair will provide the memo within two weeks of the completion of the initial review. Upon receipt of the principal investigator's response and completion of any requirements to bring the protocol into compliance, the Chair will notify the principal investigator that the protocol is in compliance. If a response from the principal investigator is non-compliant, the Board Administrator will inform the PI to provide a compliant response by a deadline. If nothing is received by the deadline, or if the response is non-compliant, the Board Chair will suspend the protocol until the PI provides the necessary revisions or information.

Major Protocol Violation Procedure

If the initial review by the Chair produces findings that indicate a potential major protocol violation, the Chair will convene an ad hoc committee to review the facts of the matter. The committee will convene within three weeks of the completion of the initial review by the Chair.

The committee shall consist of the Board Chair, the Board, representatives from the researcher's department or discipline, and others as necessary or required.

If the committee determines that a major protocol violation has occurred, the Board Chair shall immediately suspend the research protocol. The Chair will provide a summary of the committee's findings to the principal investigator within two weeks of the committee's last meeting.

If suspension of the protocol would result in harm to subjects, the Chair will ask the researcher's supervisor to assign principal investigator duties to another qualified person. The newly

assigned principal investigator will submit a Continuing Application outlining the change in researcher and any changes in the protocol (including suspension if required by the Board Chair).

Any suspension of funded protocols will be reported to sponsors as required.

If the findings of the committee indicate that academic misconduct may have occurred, the matter will be remanded to the Vice President for Research for disposition per university policies, along with any pertinent information.

Appeals

The principal investigator may appeal the findings of the review by the Board Chair for minor protocol violations or the review of the committee for major protocol violations. The appeal must be forwarded to the Board Chair within seven (7) days of receipt of the Chair's or committee's findings. The Chair or the committee will re-review the evidence and provide a summary report to the principal investigator within two weeks of the appeal review.

The principal investigator may appeal to the Vice President for Research (VPR) if the second review by either the Board Chair or the committee has been completed and the results unfavorable to the PI. The researcher will have seven (7) days to prepare the appeal to the VPR after receipt of the results of the Board Chair's appeal procedure.

The VPR will review material provided by the Board Chair or committee as well as any information provided by the researcher. Per §46.112, Review by Institution, the VPR may not approve human subjects research that the Board has not approved. Nevertheless, the VPR may convene a meeting with the full Board to re-review the protocol if the researcher provides additional information or revisions that were not provided as part of the original review or the appeal to the Board Chair or committee. The decision of this convened meeting will be final.

The Board Chair will present a summary of any protocol violations at the next scheduled meeting of the full Board.

Additional Considerations

Research Conducted by University Researchers Off Campus

University researchers are expected to conduct human subjects research in an ethical and appropriate manner both on and off campus. Researchers who perform studies off campus must submit their protocols to the Board as well as to the Board of the institution or agency where research is to be conducted, if applicable. Research may not begin in advance of Board approval. If another Board has reviewed the protocol, a copy of the approval must be forwarded to the Board. If the off-campus site does not have an Board, the site must provide a letter of authorization for the conduct of the research project to the researcher. The letter must be on agency letterhead. A copy of this letter must be provided to the SUNY Canton Board.

Research Sponsored by Another Institution and Performed on SUNY Canton Campus

On occasion, researchers from other institutions may request permission to conduct human subjects research on SUNY Canton campus. If the outside researcher simply wants to advertise a study, with no involvement of SUNY Canton faculty or students other than as potential subjects, then SUNY Canton Board review is not required. However, the research must be approved by the investigator's home Board and a copy of the approval letter must be provided to the Board, along with a copy of any advertisements or recruitment materials.

Close Out of Protocols

When a protocol has been completed, the investigator must submit a final report to the Board. The final report should include a summary of the research findings, any adverse events or injuries to subjects, and any additional information that might be useful to the Board's understanding of the research. If the project was externally funded, the researcher may submit the abstract from the final report to the funding agency in place of the summary. The Final report form is available on the IRB website.

Submit applications to: SUNY Canton – Institutional Review Board

Attention: Sarah Todd
FOB 204
34 Cornell Dr.
Canton, NY 13617
(315) 379-3975