

State University of New York  
College at Cortland

Institutional Review Board



# Policies and Procedures Manual

  
Institutional Review Board

P.O. Box 2000

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*Acknowledgement:* The following procedures manual is written for SUNY Cortland human participant researchers and Institutional Review Board members in accordance with FWA Assurance Requirements under <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

## Introduction

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Consistent with the mission of our comprehensive college, SUNY Cortland supports and fosters research in order to advance scientific knowledge, promote scholarship, and serve the public interest. Active programs of scholarship strengthen the intellectual climate and further the understanding that we are all still learning. The results of research, scholarship, and intellectual activities conducted at SUNY Cortland are disseminated in a wide array of professional venues and in the classroom.

On those occasions when the scholarly work of faculty, staff, or students includes the study of humans or data collected from human subjects, the Institutional Review Board (IRB) reviews the research proposal prior to data collection. When reviewing research proposals, the institution is guided by the ethical principles expressed in [The Belmont Report](#), codified in the Department of Health and Human Services (HHS) Title 45, part 46 of the Code of Federal Regulations ([45 CFR 46](#)). Under the direction of HHS, the Office of Human Research Protections ([ORHP](#)) maintains regulatory oversight and guidance to individuals and institutions engaged in a human subjects research.

This manual outlines ORHP regulations as implemented at SUNY Cortland. The purpose of this manual is to provide the operational details of the SUNY Cortland IRB process and outline its major functions. Questions, concerns, and suggestions, as well as IRB applications and supporting materials, are to be directed to: Institutional Review Board, by email at [irb@cortland.edu](mailto:irb@cortland.edu).

The SUNY Cortland Institutional Official is Mark Prus, Ph.D., Provost and Vice President for Academic Affairs. Dr. Prus can be reached at Miller Building Room 4048A by telephone (607) 753-2207, or by email at [irb@cortland.edu](mailto:irb@cortland.edu) or [Mark.Prus@cortland.edu](mailto:Mark.Prus@cortland.edu). SUNY Cortland's Interim Director for Research and Sponsored Programs (RSPO) is Elizabeth Speziale. She may be reached by telephone (607) 753-2511, or by email at [irb@cortland.edu](mailto:irb@cortland.edu), or [Elizabeth.Speziale@cortland.edu](mailto:Elizabeth.Speziale@cortland.edu).

Mark J. Prus, Ph.D., Provost and Vice President for Academic Affairs, is the signing authority for SUNY Cortland (IORG0004382). The Provost provides institutional, facilities, and material support required to maintain the official federal wide assurance (State University of New York College at Cortland: FWA00009541) and the registration of the IRB (SUNY - Cortland IRB #: IRB00004790).



# Part I

Information for Investigators:

IRB Review and Research Conducted at  
SUNY Cortland

## IRB Procedural Overview

Individuals affiliated with SUNY Cortland (faculty, staff, or students) are conducting human subjects research when:

- they engage in an activity involving the gathering of information about a living person (or persons);
- they hope to learn something about that individual(s) which may apply to another individual(s) now or in the future; and,
- the intent of the information gathering (research) is to communicate the results to others off-campus or outside of the SUNY System so that others can benefit from the knowledge gained.

The definition of research, human subject, and generalizable knowledge as used in this manual include:

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge;

A Human Subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

Generalizable knowledge (contributing to) means that (1) conclusions are drawn from particular instances, and (2) the information from the investigation is to be disseminated beyond the SUNY Cortland campus.

Research activities conducted by faculty, staff, and students at SUNY Cortland, in the area of social and behavioral sciences, across all three schools (Arts and Sciences, Professional Studies, Education) fit the federal definition of human subjects research. In addition, teaching activities may meet this definition; for example, studies of teaching effectiveness to be published, communicated, or disseminated off-campus require IRB review.

The federal government established regulations (45 CFR 46) that govern the way research is conducted. The regulations are established and monitored by the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP) (see <http://www.hhs.gov/ohrp/>). SUNY Cortland possesses a federal wide assurance, an agreement with the federal government binding us all to comply with these regulations. OHRP publishes an IRB Handbook and periodically releases guidance documents that explain how the regulations are to be applied by Institutional Review Boards (IRB), a local committee that reviews and monitors research at colleges, universities, and other institutions. The basic process of requesting IRB review at SUNY Cortland appears in the table below.

### IRB Procedures to be followed by all researchers at SUNY Cortland

<b>Training</b>	<ul style="list-style-type: none"> <li>• Complete the CITI Program modules (online human subjects ethics education), which include reading The Belmont Report and becoming familiar with the definitions used by OHRP and IRBs (CFR §46.102). Investigators are to complete the basic modules and optional modules that pertain to their area of research (research using the internet, international research, research involving children)</li> <li>• Read this Policies and Procedures Manual</li> </ul>
<b>Protocol Preparation</b>	<ul style="list-style-type: none"> <li>• Choose a level for review appropriate for the sample, procedures, and risk of the research activity (exempt, expedited, or full review); complete the application corresponding to the level of review and include Appendix A- Investigator Assurance (signature page). Applications/appendices, instructions, examples and help files for protocol preparation are available at <a href="http://www2.cortland.edu/offices/irb/index.dot">http://www2.cortland.edu/offices/irb/index.dot</a></li> </ul>

	<ul style="list-style-type: none"> <li>• Prepare a proposed legally effective informed consent written at a level that the research population can comprehend; include assent when children are participants; include recruitment materials, advertisements, and letters to potential participants as all of these are viewed as part of the consent process</li> <li>• Prepare copies of surveys and measures; include information about all tools, supplies, and equipment or apparatus used for the research activity</li> <li>• Obtain legally effective permission letters (and MOUs, when applicable) from the signing authority for all locations where recruitment, advertisement, or data collection is to occur</li> <li>• Contact the IRB if you have any questions or need assistance (email: <a href="mailto:irb@cortland.edu">irb@cortland.edu</a>)</li> </ul>
<b>Protocol Submission</b>	<ul style="list-style-type: none"> <li>• Submit the application and all supporting materials electronically as email attachments to <a href="mailto:irb@cortland.edu">irb@cortland.edu</a>; Appendix A (signature page), permission letters and MOUs can be sent by campus mail, fax, or email as a PDF file</li> </ul>
<b>IRB Review</b>	<ul style="list-style-type: none"> <li>• Protocols confirmed as exempt and expedited are normally reviewed by the IRB designated primary reviewer depending on School</li> <li>• Those confirmed in primary review as full review are submitted to the IRB Chair to be placed on the next available opening on the Full Board agenda; copies of all materials are made available to the Full Board members</li> <li>• The IRB Secretary notifies investigators of the date/time of their IRB review</li> <li>• At all levels of review, the IRB notifies investigators of the outcome of the review and provides details regarding any revisions or clarifications required</li> </ul>
<b>Investigator Responsibility</b>	<p>If the IRB approves an application and if the project is undertaken, all investigators agree:</p> <ul style="list-style-type: none"> <li>• The information provided in the application is accurate and complete;</li> <li>• All named individuals on the project have read and understand the procedures outlined in the protocol;</li> <li>• All named individuals on the project, paid assistants, and all graduate students working on the project have completed the CITI Course for the Protection of Human Subjects. All undergraduates working on the project have been made aware of the “common Rule” (45 CFR Part 46) and have read the Belmont Report. The lead investigator assures that all individuals working on the project understand the principles of the aforementioned documents as well as SUNY Cortland’s policies and procedures;</li> <li>• All recruitment, experiments, and procedures involving human subjects will be performed under the lead investigator’s supervision or that of another qualified professional listed on the protocol;</li> <li>• The lead research will submit to the IRB any and all modifications and/or changes to the project and will promptly provide the IRB any information requested. All research personnel agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following: <ul style="list-style-type: none"> <li>- Providing legally effective informed consent to all human subjects or their legally authorized representatives; assent will be provided to minors;</li> <li>- Documenting the legally effective informed consent/assent (unless documentation of consent is waived by the IRB.</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• Assuring the appropriate administration and/or documentation of federally mandated forms other than informed consent (e.g. HIPPA, MSDS);</li> <li>• Refraining from any advertisement, recruitment, or data collection until all requests for information or documents are satisfied and IRB approval has been obtained;</li> <li>• Promptly and completely complying with an IRB decision to suspend data collection or withdraw its approval for the project;</li> <li>• Obtaining continuing review prior to the date of protocol expiration except for exempt research which requires annual notification to the IRB to maintain an active protocol. Notify the IRB of any substantive changes to the documents or procedures before they are implemented (referred to as “modifications to existing research”).</li> </ul>
<b>Incident Reports</b>	Report to the IRB ( <a href="mailto:irb@cortland.edu">irb@cortland.edu</a> ), within three working days, a detailed description of any undesirable event or incident that may have negatively affected a participant or others, whether that event or incident is directly or indirectly related to participation in research. This could include any new information coming to light that changes the level of risk, any adverse event, unanticipated problems, or harm to participants (causing physical, psychological, economic, or social loss); this reporting should occur immediately upon discovery

## Requirements for Program Evaluation

Program evaluation (or quality improvement activities as it is termed by OHRP), as a rule, does not constitute human subjects research and does not require IRB review (see <http://www.hhs.gov/ohrp/policy/faq/index.html>). However, in some cases IRB approval should be sought. The requirement for IRB review lies within intent. If the researcher’s intent is to gather assessment data to improve practice, the evaluation does not require IRB approval. However, if the researcher intends to gather assessment data to improve practice **and** contribute to *generalizable* knowledge through publication or presentation outside of SUNY Cortland, the evaluation falls within and under the jurisdiction of the IRB.

Another question you may consider in helping to determine IRB approval requirements for evaluations is to ask, ; “What person or group’s practices are intended to be informed/improved by this evaluation?”

If the answer is “SUNY,” “SUNY Cortland,” “curriculum or a program at SUNY Cortland only,” or “my teaching in my classroom” (for example), then the activity does not require IRB Approval. This is why Course Teacher Evaluations (semester-end CTEs) and the activities of the Office of Institutional Research do not require IRB review.

If the answer is, for example “educators across the SUNY system,” “NY State teachers,” “sociology professors,” and the researcher hopes to publish the results in a teaching journal, or you hope to present the results at a conference, then that research requires IRB review. It requires IRB review precisely because, in all of these cases, the intent is to produce *generalizable knowledge*.

### Routine Program Evaluation

Most simply defined, program evaluation is *research that is conducted in order to determine the effectiveness of a program*. **Program evaluation is for internal use only**. Collecting and reporting data required by SUNY or participation in federal assessment initiatives, as most activities conducted by the office of Institutional Research and Assessment do not require IRB review. The data is collected by SUNY, funded by SUNY, and is intended only

to inform SUNY and local administration, faculty, and staff who manage and deliver the programs. Nonetheless, by SUNY policy, when program evaluations do not require IRB review, procedures should conform to human subjects rules and regulations (federal, state, and local) in particular informed consent, voluntary participation, and right to withdraw with information maintained as confidential.

## Human Participant Training Requirements

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### Human Participant Program Ethics Training Requirements at SUNY Cortland

To satisfy multiagency training requirements, SUNY Cortland subscribes to the **CITI Program, Collaborative Institutional Training Initiative**, an accredited on-line tutorial program in research ethics. All individuals affiliated with the College (faculty, staff, students, administrators) who are involved with human participant research are to complete training appropriate to their role on the research project. The CITI Course includes basic modules and optional modules that pertain to areas of research for which special rules and regulations may be required (e.g. research using the internet, international research, research involving children, biomedical research).

### Investigators, co-investigators, undergraduate/graduate training requirements

Key personnel shall be defined as the primary personnel responsible for the research project and may include faculty, staff, students, or administrators. Anyone who is responsibly engaged in the research design, participant recruitment, or the analysis or management of confidential information obtained from participants is to be considered key personnel.

### Training Required for Administrators and IRB Members

IRB members are required to complete all CITI basic social and behavioral sciences modules. In addition, IRB members should complete all biomedical sciences and optional modules before reviewing protocols in those areas. The Institutional Signing Authority (Provost) is required by OHRP to complete Module 1 of the training program. The IRB Chair and primary reviewers must complete OHRP assurance training Modules 1 through 3.

## Preparation of IRB Protocols

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### Levels of IRB Review

Research projects are reviewed at one of three levels, depending upon the investigator(s) and IRB's understanding of the target population to be sampled, the risk to participants posed by the recruitment, procedures, data retention, and dissemination plans; and the federal guidelines that define the categories of IRB review.

The federal definition of *minimal risk* provides the benchmark for considering the degree of risk a protocol poses. *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 IRB must also be assured that, when participants could be vulnerable to coercion or undue influence (e.g., college students in a classroom setting), additional safeguards be in place to protect the rights and welfare of these participants. While the investigator indicates the initial determination regarding the appropriate category of review, the IRB will make the final determination. The categories for review are summarized below:

### Category I – Exempt Review

The IRB has adopted the HHS procedure for identifying exemptions as cited in [45 CFR §46.101\(b\)](#). According to the regulations, exempt review involves research presenting less than minimal risk to human participants and includes one of the activities cited in the federal regulations ( [45 CFR §46.101\(b\)](#) or <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or 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 information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and 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.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.
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 which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or 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.

### Category II – Expedited Review

To qualify for expedited review, the research must present *no more than minimal risk* to participants and correspond to a category appropriate for expedited review or represent a minor change in previously Full Board approved research that involves no additional risks to research participants, in accordance with HHS regulations [45 CFR §46.110](#). Research categories for expedited review can be accessed in the [Federal Register](#) or at <http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/ucm119074.htm>: or <http://www2.cortland.edu/offices/irb/application-portal.dot> (as extracted from and including):

1. Clinical studies of drugs and medical devices;
2. Collection of blood samples by finger stick, heel stick, ear stick, or **vein puncture**;
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice (e.g. moderate exercise by healthy volunteers; and/or moderate exercise with

minor stimulants such as caffeine; muscular strength training, body composition assessment, measurements of weight and height of healthy volunteers)

5. Collection of data from voice, video, digital, or image recordings made for research;
6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies; (**NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subject (45 CFR 46.101(b)(2) and (b)(3)). The above listing refers only to research that is not exempt.)
7. Continuing review of research previously approved by the convened IRB 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.

**Note:** Under the above expedited review procedures, the review may be carried out by the IRB chairperson or by a primary reviewer depending on School. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. Disapproved research may only occur at convened meetings of the IRB with a majority present, including at least one member whose primary concerns are in nonscientific areas. Investigators are notified in writing and provided an opportunity to meet with the IRB in person or respond in writing (46.109 (d)) should their protocol be disapproved.

### Category III – Full Review

Any research that does not fit Category I or Category II is to be submitted for full review. Any feature of a research project could prompt a full review; these include recruitment, sampling, participant characteristics, method/procedure, measures, storage plan, or dissemination. Examples of full review research includes:

1. Research which may put research participants at risk *greater than minimal risk*;
2. Research involving psychological or physiological intervention or non-curricular, interactive research;
3. Research involving deception;
4. Interviews or surveys relating to topics the Cortland community would define as being particularly sensitive when researching sexual activity, alcohol or drug use, or illegal behavior, and when identifiers are used or confidentiality could be compromised in investigating sensitive topics;
5. Research targeting special populations (e.g., minors, prisoners, pregnant women, persons with diminished capacity or other vulnerable populations) if the research is conducted outside of a normally supervised classroom/school project not affiliated with course objectives or field practicum or student teaching;
6. Any other category specifically added to this list by HHS and published in the Federal Register.

### IRB Applications, Appendices, and Other Required Documents

IRB Applications and instructions are available online at <http://www.cortland.edu/irb/app.html>. HHS regulations (CFR §46.111) set forth the criteria for the IRB to approve research. Investigators are to complete the application appropriate for the level of review, as each application has been designed to elicit the information required to classify and review the research.

The investigator is responsible for providing to the IRB documents, materials, and information about the research in sufficient detail to make the determinations required under HHS regulations at [CFR §46.111](#). These criteria include:

1. Risks to subjects are minimized (e.g., procedures are consistent with sound research design, and do not unnecessarily expose subjects to risk, and proper safeguards are used);
2. Risks to subjects are reasonable in relation to anticipated benefits;
3. Selection of subjects is equitable;
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative (to the extent required by [CFR §46.116](#)) – see next section for critical details;
5. Informed consent will be appropriately documented (to the extent required by [CFR §46.117](#));
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects; and,
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Materials submitted for review, at minimum, include a protocol (application form; exempt, expedited, or full review), legally effective informed consent (assent), and Appendix A (signature page). Other materials may be required, when applicable to the research. For example, research falling under the National Institutes of Health (NIH) requires investigators to submit a complete copy of their grant proposal in addition to IRB protocol forms for the institution so that IRB members can cross reference research procedures outlined in the NIH proposal with SUNY Cortland's IRB forms.

Other examples of materials required by the IRB include copies of recruitment announcements such as research brochure,(s) flyers, newspaper advertisements, press releases, emails, or news-related stories about the study that contain contact information for the researcher. Public relations stories, press releases, and other forms of news/journalism about research are subject to IRB review also when the public may respond to the story by contacting the researcher to volunteer for the study. These communications must be pre-approved by the IRB in the same form the participants will see, hear, or read them. All communications about a study must contain language that is permissible for informed consent documents.

### **Legally effective informed consent is required**

IRB review requires that IRB members focus on the research, from the perspective of the participant. The primary reviewer begins the protocol review by reading recruitment materials and the consent form. Then the primary reviewer proceeds to read the materials and protocol (IRB application). Legally effective informed consent is one of the central protections provided to human research participants under the HHS regulations at [45 CFR part 46 \(CFR §46.116 and CFR §46.117\)](#). This requirement is founded on the principle of respect for persons, one of the three ethical principles governing human subjects research described in [The Belmont Report](#). The principle of respect for persons requires that every individual be treated as an autonomous agent, “an individual capable of deliberation about personal goals and of acting under the direction of such deliberation” (The Belmont Report). Respect for persons requires that prospective research subjects “be given the opportunity to choose what shall or shall not happen to them” and thus necessitates adequate standards for voluntary informed consent and adequate provisions for the protection of those with diminished autonomy.

**Legally effective informed consent contains a minimum of eight elements that will be provided to each subject (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>):**

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**The consent form may be either of the following:**

1. A written consent document that embodies the elements of informed consent required as above in §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
2. A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

**The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:**

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Requests for a waiver of informed consent should be adequately justified in the IRB application, in accordance with the requirements of CFR §46.116 or CFR §46.117. For assistance requesting a waiver, contact the IRB. In cases in

which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**The consent form and any other information that is given to the subject or the representative shall be in language understandable to the subject or the representative.**

1. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
2. The approval date for each document and the expiration date for the research protocol are to appear on recruitment materials and consent documents, unless this requirement is waived by the IRB.

The researcher is required to store the signed consent form, except when a waiver has been approved by the IRB. [Food and Drug Administration (FDA) regulations at 21 CFR Part 50 may also apply if the research involves a clinical investigation regulated by FDA.]

Informed consent is not a single document that researchers ask participants to sign. Informed consent is best described as an active, ongoing process of sharing information between the investigator and the prospective subject. The exchange of information between the investigator and prospective subject(s) can occur via any type of communication medium. The informed consent process should ensure that all critical information about a study is completely disclosed, and that prospective subjects or their legally authorized representatives adequately understand the provisions of consent and the research procedures so that they can make informed choices.

The consent procedures and forms should be revised when deficiencies in its accuracy or completeness are noted, when new information about risks/benefits becomes available, or when other additional information becomes known that will improve the consent process. Such revisions must be reviewed and approved by an IRB prior to the revised consent being utilized except when necessary to eliminate apparent immediate hazards to subjects (CFR §46.103(b)(4)).

### **Research Involving Children: Parental Consent and Child Assent**

Adequate provisions must be made for soliciting the assent of children, *after* securing the consent of the parents/guardians (CFR §46.408, CFR §46.402(c)). Assent refers to a child's affirmative agreement to participate in research. Effective child assent documents contain the elements of legally effective informed consent, written at the level the child can understand [CFR §46.116 (a through f)]. Assent is to be sought from any child who is able to give assent in some way (by signature, verbal agreement, or by behavioral cues of voluntary participation). Mere failure to object should not, absent affirmative agreement, be construed as assent (CFR §46.402(b)). Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under *certain circumstances* in accordance with CFR §46.116 and CFR §46.408(a).

**NOTE:** In some cases where research is conducted in school settings as part of the normal educational activities, district policy precludes investigators from obtaining parental consent for individual studies due to the fact that parental consent given at the beginning of the school year. When investigators are confronted with this situation for exempt or expedited protocols, the IRB requires that the investigator request an IRB waiver of consent and provide the IRB with a written statement by the district's authorizing official that parental consent has been obtained for the school year and under what circumstances research may be conducted within the classroom. In all related circumstances, the investigator will provide a parental notification letter that describes the research and contact information for questions.

By regulatory definition, children are “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted” (CFR §46.402(a)). In the United States, the legal age of adulthood is a matter of state and local law; in a large majority of states, as in New York, 18 years of age is the legal age of adulthood, but this is not true in every state, locality, or territory. Multisite research and international research must respect the laws applicable to the site where the data is collected. State law also may address specific circumstances in which a person younger than the age of adulthood is legally authorized to consent to medical procedures: for example, some states allow children younger than the legal age of adulthood to consent to the provision of contraceptive services. Certain states provide a mechanism for the emancipation of minors through which a child younger than the legal age of adulthood may gain certain civil rights, which might include the legal ability to consent to research participation.

**NOTE:** The risk posed to child participants is considered differently from risks presented to adults, and the provisions for consent/assent respect these differences. Under CFR §46.408(b) the IRB may find that the permission of one parent is sufficient for research to be conducted under CFR §46.404 or CFR §46.405. Where research is conducted under CFR §46.406 or CFR §46.407, permission must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

### Institutional Permissions

IRB approval should not be confused with other institutional approvals required for the use of college facilities or resources. Investigators seeking the use of campus facilities or resources (e.g. access to institutional lists serves for recruitment, datasets, or the administration of institutional surveys), requires the prior approval of the authorizing official responsible for the activity. Questions about who should be contacted for prior approvals can be submitted to the IRB Chair for investigator assistance. Research conducted at a site other than SUNY Cortland, also requires prior approval from the authorizing official of that site(s) to assure adequate protections and communications about the research.

## Miscellaneous Issues to Consider Before Submission

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This Policies and Procedures Manual focuses on researchers obligations under the **Common Rule**. The Common Rule (Federal Policy for the Protection of Human Subjects) is codified at many different federal agencies’ CFRs (fourteen at last count), some of which are not often associated with human subjects research. It is important for investigators to be familiar with these agencies so that their particular set of CFRs can be considered when planning research. Investigators who collect or use health-related information for research purposes should be aware of requirements for HIPAA compliance, which regulate the use and handling of personal identifiable health information (PIHI) (see **HHS, Office for Civil Rights-HIPPA**).

## Protocol Submission

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A protocol is ready for submission when:

1. training has been completed by the investigator and others associated with the research (e.g., co-investigators, faculty sponsor, students);
2. the principle investigator and all co-investigators, and the department chair or immediate supervisor, have signed Appendix A – Investigator Assurance (signature page); and,

3. the IRB has information about the research in sufficient detail to make the determination required under HHS regulations at [CFR §46.111](#) (all applicable documents, letters, and materials as described in the previous section).

All applications, documents, and correspondence at all levels of review are to be addressed to : [irb@cortland.edu](mailto:irb@cortland.edu). Appendix A, original permission letters, and other signed documents are to be sent as a PDF file to the IRB or can be sent through intercampus mail and forwarded to 402 Miller, Research and Sponsored Programs Office, SUNY Cortland, P.O. Box 2000, Cortland, NY 13045

## Summary of IRB Review Process

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SUNY Cortland uses a primary reviewer system. Each of SUNY Cortland's Schools (Arts and Sciences, Professional Studies and Education) has a designated reviewer as first contact who is responsible for reviewing protocols (from their School) on behalf of the IRB and communicating the IRB decisions for their School. After protocols are submitted to [irb@cortland.edu](mailto:irb@cortland.edu), the primary reviewer conducts an in-depth examination of all information and documents. Specifically, the primary reviewer confirms the classification of the research (exempt, expedited, full review) and ensures that the IRB has enough information in sufficient detail to meet HHS regulations at [CFR §46.111](#). Next, the primary reviewer also examines the proposed consent/assent document(s), and is available (upon request) to assist the researcher in making changes until each form (consent or assent) is legally effective. Should the primary reviewer find that revisions are required or further documentation is needed, he/she will contact the lead investigator with details concerning the request. All additional documents or information is to be sent to [irb@cortland.edu](mailto:irb@cortland.edu). IRB review is suspended until the requests have been satisfied by the investigator.

Once a protocol file is complete, the action the primary reviewer takes depends upon the level of review. Exempt and expedited protocols are reviewed by the primary reviewer and a summary of expedited protocols (only) is reviewed by the Full Board at its next schedule meeting to allow the IRB time for questioning or clarifications about the protocol. Full review applications are forwarded to the IRB Chair and are placed on the agenda for the next available Full Board Meeting. The IRB Secretary notifies the investigator of the location, date, and time of the protocol review. After the protocol review, the IRB Chair will notify the investigator of the actions taken by the Full Board.

### Timing of Reviews

Exempt and expedited protocols should be submitted at a minimum of two weeks in advance for review. Full board reviews must be submitted at least four-to-six weeks in advance to distribute protocol information in advance of the IRB meeting. The full board is scheduled to meet monthly only when full board applications are received for review.

## Executing the Research Activity

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OHRP has identified the following responsibilities of all investigators, including faculty sponsors of student led research:

1. Investigators have the primary responsibility for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of their institution's Assurance.
2. Investigators are expected to be knowledgeable about the requirements of the HHS regulations, applicable state law, their institution's Assurance, and institutional policies and procedures for the protection of human subjects.

3. Investigators are to conduct research according to the IRB-approved protocol and complying with all IRB determinations.
4. Investigators are to obtain and document the informed consent of each subject or each subject's legally authorized representative, unless the IRB has waived these requirements. Informed consent refers to the voluntary choice of an individual to participate in research based on an accurate and complete understanding of, among other things, its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate. For more information about writing legally effective informed consent refer to:
  - Informed Consent Checklist: <http://www.hhs.gov/ohrp/policy/consentckls.html>
  - Informed Consent, Legally Effective and Prospectively Obtained: <http://www.hhs.gov/ohrp/policy/hsdc93-03.html>
  - Informed Consent, Non-English Speakers: <http://www.hhs.gov/ohrp/policy/ic-non-e.html>
  - Certificates of Confidentiality: <http://www.hhs.gov/ohrp/policy/certconf.html>
5. Ensuring that each potential subject understands the nature of the research and participation.
6. Providing a copy of the IRB-approved informed consent document to each subject or the subject's legally authorized representative at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained for at least 3 years after the completion of the research and according to institutional policy.
7. Promptly reporting proposed changes in previously approved human subject research activities to the IRB (at [irb@cortland.edu](mailto:irb@cortland.edu)). The proposed changes may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. To ensure review, proposed changes are to be submitted 7-10 working days in advance of planned execution for exempt and expedited and 4 weeks for full review.
8. Reporting progress of approved research to the IRB as often as, and in the manner, prescribed by the IRB.
9. Report to the IRB ([irb@cortland.edu](mailto:irb@cortland.edu)), within three working days, a detailed description of any undesirable event or incident that may have negatively affected a participant or others, whether that event or incident is directly or indirectly related to participation in the research. This could include any new information coming to light that changes the level of risk, any adverse event, unanticipated problems, or harm to participants (causing physical, psychological, economic, or social loss); this reporting should occur immediately upon discovery (no later than three working days after discovery).
10. Promptly reporting to the IRB ([irb@cortland.edu](mailto:irb@cortland.edu)), within three working days, any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with the HHS regulations or determination of the IRB.
11. If a physician affiliated with SUNY Cortland engages in HSR, that physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by federal, state, or local law. However, such activities may not be considered research nor may the data be used in support of research, except to the extent required by FDA regulations. Investigators should consult with the IRB to ensure that activities that meet the regulatory definition of non-exempt human subject research undergo IRB review and approval prior to the initiation of the activities.

12. Unless specifically authorized by the IRB, no investigator may involve a human being as a subject in research covered by the HHS regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

### Submission of Protocol Changes (Modifications)

Substantive changes to a research project must be submitted to the IRB as a *modification request*. Investigators are not permitted to implement protocol changes without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects. The IRB must be given sufficient time to review and make determinations concerning protocol changes (7-10 working days for exempt and expedited, 4-6 weeks for full review). Investigators are asked to revise the original application and/or supporting documents. After IRB approval, each revision to a research protocol is to be sent to the IRB by email ([irb@cortland.edu](mailto:irb@cortland.edu)). The changes submitted will be appended to the original protocol, effectively incorporating all protocol changes into the original written protocol. This practice ensures that there is only one complete protocol, with the revision dates noted.

### Review of Exempt and Expedited Protocol Changes

Proposed changes to exempt and expedited protocols that do not increase risk or decrease benefits will be reviewed using exempt or expedited procedures, consistent with the initial submission. If the proposed change alters the risk-to-benefit ratio (raising risk or decreasing benefits), the study will be reviewed at the level appropriate to the protocol change.

### Requirement for Review of Proposed Protocol Changes by the Full IRB Board

In accordance with HHS regulations [CFR §46.108\(b\)](#), review of proposed protocol changes must be conducted by the IRB at Full Board meetings at which a majority of the members of the IRB are present. The quorum must include a nonscientist, and any other members needed for review (e.g., member or consultant familiar with the local research context; scientist or consultant knowledgeable in the investigator's area of research).

The Full Board can designate times when minor changes to full review protocols can be reviewed at the expedited level and reported to the Full Board IRB at the next meeting [CFR §46.110\(b\)\(2\)](#). Examples of minor changes include:

- correcting non-substantive typographical errors in materials to be presented to participants;
- requesting permission to add recruitment sites similar to those previously approved (e.g., approved for SUNY Cortland undergraduates and is now requesting to extend approval to collect data from SUNY Brockport undergraduates);
- adding procedures, advertisements, brochures, or published, standardized measurement instruments normally classified as minimal risk or less than minimal risk; which, in and of themselves, would be reviewed at the exempt or expedited levels; or,
- removing procedures, surveys, or measurement instruments that would not cause a reduction to the potential benefits of the study.

The primary reviewer makes the determination if a protocol change can be reviewed at the expedited level. The primary reviewer can seek consultation from the IRB Chair or another experienced IRB member. The reviewer can seek consultation from other experienced IRB members or IRB administrators at other SUNY institutions familiar with the local research context to aid in their review.

### Requests to Continue Research

SUNY Cortland is obligated to conduct continuing review of approved research at intervals appropriate to the

degree of risk, but not less than once per year, and has the authority to observe or ask a third party to observe the consent process and the research [CFR §46.109(e)]. The investigator must plan ahead to meet required continuing review dates. When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. OHRP indicates that, when an investigator has failed to provide continuing review information to the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval. The information must be received by the IRB with sufficient time to review the request, because if the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop.

If data collection is completed and investigators are only analyzing unidentifiable data, requesting a continuation from the IRB is not required. However, investigators must be certain to maintain the data as specified in the informed consent and application protocol, allowing only those individuals listed in the informed consent access to the data.

### Timeline for Continuing Review

Assuming that there are no changes to the research, its procedures, and its documents (e.g., consent form, measures, surveys, MOUs), **exempt research does not require continuation requests**; the SUNY Cortland IRB only requests annual email notification (to: [irb@cortland.edu](mailto:irb@cortland.edu)) indicating that the research continues. The purpose of the continuation notification, at the exempt level, is to alert the IRB that the records of the original IRB approval must remain available. Unlimited continuations can be registered for exempt research under federal and SUNY Cortland IRB guidelines.

**Expedited research continuation requests** are reevaluated by the IRB using expedited procedures, not less than once a year for a total of three years. After three years, a new protocol must be submitted.

**Full review research continuation requests** are reevaluated by the Full Board, using full review procedures, at intervals appropriate to the degree of risk, but not less than once a year for a total of three years.

### Information required for continuing review, expedited and full review

Email requests for continuing review are to be sent to [irb@cortland.edu](mailto:irb@cortland.edu). Investigators are to include information identified by OHRP as important to continuing review, which includes:

1. the number of subjects accrued;
2. a summary of adverse events and any unanticipated problems involving risks to subjects or others\*;
3. any withdrawal of subjects from the research;
4. any complaints about the research since the last IRB review\*;
5. a summary of any relevant recent literature;
6. preliminary or interim findings (published or unpublished);
7. planned amendments or modifications to the research since the last review;
8. any relevant multi-center trial reports (if applicable);
9. any other relevant information, especially information about risks associated with the research;
10. copy of the current informed consent document and any newly proposed consent document; and
11. copies of new measures, materials, apparatus, or any other materials that may assist the IRB in their review.

*\* This information should be submitted at the time the incident occurs. If the information was not forwarded to the IRB at that time, the investigator is obligated to provide that information at the time of continuing review.*

All new information and supporting documents for continuing review are to be forwarded to the IRB.

# Part II

## Special Topics of Interest

### Internet Data Collection

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Internet data collection is quickly replacing mailed questionnaires as a cost effective method for collecting data from large numbers of participants. No matter what URL houses the survey, IRB approval is required just as it would be for any other kind of research.

The CITI Course IRB training program provides an excellent presentation of the ethical issues and obstacles faced by those who administer informed consent and conduct research procedures over the internet. The IRB suggests that investigators using the internet for research complete this optional CITI Training module.

- Researchers are advised that internet research is bound by the same regulations (federal, state, local) as any other kind of research.
  - Most internet research conducted at SUNY Cortland involves the administration of an anonymous survey to students, faculty, or staff. The topics of these surveys tend to focus on routine daily life activities and are noncontroversial. This research is classified as exempt and a waiver request for documentation of informed consent is routinely granted, because to obtain signed consent poses more risk to participants (e.g., confidentiality risk) than the anonymous questionnaire.
  - Additionally, some internet research involves assessing learning outcomes, use of campus technology, or use of student services. If the intent of the research is to produce generalizable knowledge through publication or presentations outside of the SUNY Cortland community, the research requires IRB review, normally fitting exempt or expedited categories.

### Reimbursement and Remuneration

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The SUNY Cortland IRB has adopted the policies concerning reimbursement and remuneration for research participation.

There are two separate issues involved when asking people to participate in research:

1. Will the participants incur any expenses to be involved in the study? If so, should those expenses be outlined and shared with participants for their information. Ideally, participants should incur expenses that are not paid for or reimbursed. If the participant is to be reimbursed for subject expenses, the process for reimbursement should be described in the consent form.
2. The researcher should ask themselves if remuneration is appropriate. In other words, should participants be paid or compensated in some way for their participation? This is a more difficult issue, from an ethics standpoint, and the remainder of the discussion will be focused on this issue.

Because researchers sometimes feel that adequate compensation (to demonstrate appreciation for the participant's time and effort, if nothing else) is appropriate. Participants also sometimes expect something back from the researchers in return for their cooperation. The expectation may be even stronger when a study is funded. When participants are members of the community, the need to show appreciation may be important for a number of reasons.

In general, SUNY Cortland asks researchers to consider whether remuneration is appropriate for their study. In all cases, regardless of remuneration, researchers must minimize the possibility of coercion or undue influence by recruiting participants using open, written invitation rather than by personal solicitation. The IRB will base assessment of remuneration on the participant population and the prevailing payment practices within SUNY Cortland and the general locale.

The NIH Department of Bioethics has written extensively on this topic and has offered various formulas for computing participant payment (for more information, visit <http://www.bioethics.nih.gov/research/recruit.shtml>). Volunteers are often compensated for their participation according to an established fee schedule, based upon the complexity of the study, the type and number of procedures to be performed, the time involved, and the anticipated discomfort or inconvenience. Although society generally accepts the premise that those assuming risk deserve reward, the application of this rule in establishing payment for subjects in biomedical and behavioral experiments is still being debated. Although the researchers at NIH tend to write to a biomedical/clinical audience, their ethical principles are easily adapted for social-behavioral research.

An equally compelling reason for offering remuneration is the strong expectation known as *the norm of reciprocity*. This norm would indicate that researchers should feel uncomfortable if they ask participants to volunteer without providing adequate compensation (to show appreciation for the participant time and effort, if nothing else). It also indicates that participants likely expect something back in return for their cooperation, directly from the researchers.

When participation entails minimal time and effort, SUNY Cortland researchers have given Red Dragon pencils or stickers to children, provided in-service instruction to teachers or a free lecture to the community, and framed certificates of appreciation to school administrators or others who have granted permission to use facilities. Introductory Psychology professors offer extra credit, on an hourly basis, to students who wish to participate in psychology experiments. For more complex studies and those that are funded, researchers have offered cash payment (minimum wage is often used as a guide for hourly rates of remuneration for minimal risk studies.)

Clear cases of coercion (i.e., actual threats) are readily identifiable; it is more difficult to recognize undue inducement. Any offer one could not refuse is essentially coercive (or "undue"). Undue inducements may be troublesome because: (1) offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment; and (2) they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling or continuing as participants in a research project. For example, a large bonus payment for completing multi-session or longitudinal research is a practice that will likely substantially decrease the number of participants who withdraw from a study. However, this practice is controversial for the same reason it is effective (undue influence). Similarly, researchers have offered door prizes in the form of gifts; however, to avoid undue influence, they ensure that they give a large number of small prizes given to many, as opposed to one expensive prize given to only one participant.

The type of remuneration (monetary versus non-monetary) is less important than its appropriateness and the need to disclose the terms and conditions of remuneration in all advertisements and the informed consent document. If a researcher proposes to provide remuneration, the SUNY Cortland IRB will review the study, in the attempt to ensure that all advertisements and the consent document contain a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (for

example, what will happen if they withdraw part way through the research). Advertisements and other recruitment materials should not read like an advertisement for a commercial product and should not emphasize participant payment. The advertisement should simply state, “Volunteers will be asked to participate in three sessions, and will be receive \$10.00 payment at each session.” Note that the researcher must, be prepared to pay all participants who appear for the session, even if they do not complete the session (participants’ right to withdraw without penalty).

The IRB will ask four questions when reviewing the research:

1. Are all conditions in keeping with standards for voluntary and informed consent?
2. Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the particular subject population?
3. Are there special standards that the IRB ought to apply to the review of research in which volunteers are asked to assume significant risk?
4. Should the IRB monitor subject recruitment to determine whether coercion or undue influence is a problem?

## International Research

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International research can be time consuming. The IRB process should begin early and involve the IRB before a protocol is written. Researchers who plan to conduct research in another country should complete the CITI Course optional international research modules before proceeding (see §46.101(h) and [International Issues](#)). International research, including class projects conducted in another country, may require additional approval from an IRB (or similar body) in that country. Copies of the translation of the informed consent document(s) and any survey or interview questions, including back-translations may be required.

## Guidance for SUNY Cortland Student Participation in Research/Experimental Activity

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Certain courses routinely involve students in a number of in-class experiments. If the research activity is both a classroom activity and human subject research, IRB review is required. For courses requiring or allowing students to volunteer in human subjects research projects for credit or extra credit (studies under the purview of the IRB), SUNY Cortland’s IRB requires the following protective steps:

1. Assure that students understand that they will be offered research alternatives that would fulfill the same requirement/credit as the research. The alternatives must be neither more onerous nor more time-consuming than participation in the research project.
2. Avoid, whenever possible, seeking consent in physical settings in which participants may feel coerced or unduly influenced to participate. This often requires that the study be advertised, in advance, ideally with data collection occurring at a time and location outside of the normal class hours. A less desirable, but sometimes permissible approach, is allowing students who elect not to participate to miss class (to complete the alternate assignment at that time) or come to class late, after the research activity.
3. All participants must be eighteen years of age. Otherwise, parental consent is required, in addition to student consent.

Academic Affairs is responsible for all research activities that do not fall under the authority of the IRB. In this regard, SUNY Cortland's primary concerns are the safety and welfare of students and the security of the information they provide.

Before beginning an experimental activity, legally effective informed consent from the student participants should be obtained. Instructors are asked to ensure that the classroom project(s) involves no more than minimal risk to participants, and they are strongly encouraged to assign and discuss with their students *The Belmont Report*. Instructors are asked to inform students about consent/disclosure as well as safeguarding privacy and maintaining confidentiality.

In typical research studies, participants have the right to refuse to participate or to withdraw from the study without penalty. However, the practice of this right becomes complicated when considering research conducted for the purpose of class demonstration/education. OHRP's recommendation of alternative assignments is an excellent reference to help guide instructors when the classroom research/demonstration activity is not human subjects research. In any case, the course syllabus should contain a clear statement about whether participation in the classroom research is voluntary and/or how the participation is related to the goals/objectives of the course and how it might influence the final grade. The instructor should be mindful of the types of situations that may occur if the student is uncomfortable with participating and should be prepared with an alternative assignment.

The SUNY Cortland IRB defends and protects the academic freedom of faculty and students. The American Association of University Professors (AAUP) recommends that instructors with any concerns about procedures, topics, or risks involved in classroom activities should discuss concerns with colleagues in their field (on or off campus), their Department Chair, or Dean. Risk to student researchers or participants of such activities should not exceed those present in normal daily activities and normal educational practices for that particular course in that particular academic discipline otherwise the instructor must be prepared to provide strong justification. The IRB will play a consultative role when asked for assistance. If the IRB receives a complaint about classroom activities or research instruction that is not under the purview of the IRB, that complaint will be immediately referred to the Instructor, Department Chair, School Dean and/or Provost, depending on the nature of the complaint. When anonymity is requested, all efforts to maintain the confidentiality of the individual making the complaint will be honored by the IRB. However, students or others filing a complaint should be aware that anonymity may limit the actions administration can take to address concerns.

## Research Conducted by Non-SUNY Cortland Investigators

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The IRB requires any non-SUNY Cortland investigator(s) to have approval from a department or faculty/staff member who agrees to serve as a campus contact for the facilitation or assistance required by the external research in the recruitment of subjects, administration or organization of research activity. The IRB is not responsible for assisting researchers in participant recruitment, advertising, coordinating research rooms for interviews, etc. As such, the IRB requires non-SUNY Cortland investigators to secure an institutional affiliate to help them navigate SUNY Cortland procedures, protocols, culture and ancillary research needs. The originating department or faculty/staff member agreeing to help the investigator is responsible for forwarding a copy of the Federal Wide Assurance number and approved protocol of the investigator to the IRB Chair or primary reviewer. Guest investigators will receive written authorization from the IRB Chair granting approval to conduct the study at SUNY Cortland once sponsorship is obtained.

## Part III

# Operational Details of the SUNY Cortland Institutional Review Board

### IRB Operational Details

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In the sections that follow, details regarding the operations and procedures of the SUNY Cortland IRB are explicated. The operational details of the SUNY Cortland IRB represent our commitment to OHRP (through compliance with the terms and conditions of our Federal Wide Assurance) and our commitment to research participants.

#### **Primary Reviewer System**

The SUNY Cortland IRB uses a primary reviewer system for applications for initial review, continuing review, review of protocol changes, and/or review of reports of unanticipated problems or of serious or continuing noncompliance. At SUNY Cortland, the role of the primary reviewers are to serve as the liaisons to the IRB, managing day-to-day protocol reviews and questions to assure that SUNY Cortland's Federal Wide Assurance standards are met. Ultimately, the primary reviewers take action on exempt and expedited protocols, and forwards documents/information to the appropriate individual(s) or groups in accordance with the federal regulations. The primary reviewer for each School is responsible for communicating the IRB decisions for their School.

At SUNY Cortland, the primary reviewers serves as the direct contact with researchers, unless away from campus or there is a possible or real conflict of interest. Each primary reviewer is assigned a secondary reviewer within their School who serves as backup. In those situations when both a primary reviewer and secondary reviewer are absent, the IRB Chair shall serve as primary reviewer. The IRB Chair may appoint at his/her discretion another experienced member (or members) of the IRB to serve as primary reviewer(s) in addition to, or in the place of, the Chair.

When a protocol is submitted, the primary reviewer conducts an in-depth review, verifying that sufficient documentation has been received to meet requirements for review ([CFR §46.111](#)), determining that the protocol was submitted for the appropriate level and specific category of review, and documenting the information justifying exemption or expedited review. The primary reviewer consults with applicants to gather incomplete or missing documents and assists with application, recruitment/advertising, and consent/assent revisions.

When all requested materials have been received, the primary reviewer conducts a primary review. At exempt and expedited levels, the primary reviewer performs initial review, continuing review, and review of protocol changes.

Full review protocols are submitted to the IRB, with the IRB Chair providing initial review before the Full Board convenes. The purpose of the Chair review is to determine that all materials have been submitted in the correct form. The IRB Secretary forwards a copy of the complete protocol and supplementary materials electronically to each member.

### **Expedited Review Procedure**

The Primary Reviewer System, as previously described, is used to review expedited protocols. Normally, the primary reviewer conducts the reviews. The IRB Chair may serve as second reviewer/auditor. Alternatively, secondary reviewers may serve as back up for primary reviewers or even the Chair.

All documents related to an expedited protocol are made available to the Full Board for review in the electronic drop-box. The IRB Board members may discuss the determinations of expedited review approvals at the next convened Full Board meeting. It should be noted that in conducting expedited review, the IRB primary reviewers may exercise all of the authorities of the Full Board IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b).

### **Review of Research by the IRB at Full Board Meetings**

In accordance with HHS regulations at [CFR §46.108\(b\)](#), initial and continuing reviews of level III research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present. Among the members present, the quorum must include at least one member whose primary concerns are in non-scientific areas, except when approved expedited protocols are audited. In accordance with the federal regulations and guidance documents, under some circumstances, a representative from the local research context will be required to review the research. Approval of full review research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.

Expedited and full review research is reconsidered by the IRB annually. The Full Board may set a shorter approval period for high-risk protocols, investigators found to have serious or continuing noncompliance, and protocols with a high potential risk-to-benefit ratio. Any of these conditions are rare, given the scope and nature of human subjects research at SUNY Cortland.

### **Documents Distributed to the Primary Reviewer and IRB Full Board**

OHRP guidelines indicate that continuing review of research must be substantive and meaningful for the institution and remain in compliance with the Federal Wide Assurance (FWA). Meaningful review is facilitated by an open and complete sharing of information about proposed or continuing research. Documents are distributed electronically to the members of the IRB Full Board a minimum of seven working days prior to IRB Full Board meetings. The SUNY Cortland IRB uses a secure password, protected electronic drop-box to store protocols and other materials submitted for review at all levels. Copies of crucial email communications relevant to a protocol, agendas, and IRB meeting minutes are stored in this location for review by the Full Board. IRB members have continuous access to these materials, information, and documents for all initial reviews, continuing reviews, review of protocol changes, and review of reports of unanticipated problems or of serious or continuing noncompliance.

### Subcommittee Procedure and Use of Consultants

The SUNY Cortland IRB members have been carefully chosen to represent the anticipated scope of research activities conducted at SUNY Cortland, the size and complexity of the institution, and the types of subject populations likely to be involved in activities (as researchers and participants). Consistent with the mission, schools, and academic departments at SUNY Cortland, the primary area of expertise of the IRB lies mostly in the area of social and behavioral sciences. The volume, scope, and complexity of research activities at SUNY Cortland are adequately managed by the current administrative structure and composition of the IRB. Consequently, the SUNY Cortland IRB does not require any subcommittee procedure for reviewing protocols, reports of problems, or noncompliance.

Nonetheless, it is possible that a faculty or staff member could submit a protocol outside the area of the current membership of the IRB Full Board. In the event this should occur, most likely in the case when a biomedical protocol has been submitted, IRB colleagues at other SUNY Colleges/Universities could be assembled to serve as a subcommittee for that protocol. These individuals would be approached for the initial review of the protocol and/or serve as consultants to the current Full Board IRB. The same approach would be used to develop a pool of consultants appropriate to conduct continuing review, review of protocol changes, reports of unanticipated problems, or cases of serious or continuing noncompliance.

## Procedures for Continuation Requests

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### Expiration of IRB Approval

For nearly all protocols submitted at SUNY Cortland, research may begin on the date of IRB approval and must end **one year** thereafter (For more information, refer to the procedures for requesting approval to continue the research.) However, in rare cases, the IRB may determine that a protocol requires review more often than annually. The IRB will make this determination when the protocol possesses high risk or a high risk- to- benefit ratio, when unanticipated problems arise, or when continuing or serious noncompliance is an issue. If the IRB determines that more frequent review is necessary at the time of initial approval, at each continuation review the investigator can ask the IRB to revisit the timetable for continuing review, in the event that no problems or issues of noncompliance have occurred.

### Continuing Review and Audit of Approved Research

The IRB must receive a continuation request **before** the expiration date of a previously approved IRB protocol. The IRB is permitted to accept continuation notification indefinitely for exempt research, provided that there have been no substantive changes to the protocol (recruitment, procedures, measures, consent, purpose, risk-benefits, and so on). Expedited continuation requests can be submitted, extending the research for up to three years. For expedited and Full Board continuations, researchers must submit a continuation request in accordance with the directions on the IRB website and outlined on page 19 and 20 of this manual. Allowing sufficient time for a new review prior to the three-year anniversary of the original IRB approval, the investigator must submit a new application to the IRB to continue the research.

The same regulations for expedited continuation apply to full review research. When continuing reviews are conducted at the full review level, the primary reviewer will review the continuation request, and will provide to the Full Board (online and at the meeting) a copy of the original complete protocol, including any modifications approved by the IRB to date, and the minutes from the meetings when the protocol was previously reviewed. IRB members have access to the complete protocol file and relevant IRB meeting minutes prior to the convened IRB meeting through the IRB drop-box.

The IRB Full Board determines which projects need verification from sources other than the investigators to ensure that no material changes have occurred since previous IRB review. Criteria used to make these determinations could include some or all of the following: (a) randomly selected projects; (b) complex projects involving unusual levels or types of risk to subjects; (c) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and (d) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

The IRB Full Board determines which steps are appropriate to ensure that investigators do not implement any protocol changes without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects. These issues are addressed proactively by semiannual training programs, online educational materials for investigators (CITI Program and SUNY Cortland IRB web site), specific directives included in approval letters to investigators, and random audits of research records.

## Range of Possible Actions Taken by the IRB

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The primary reviewer and/or designated experienced members of the IRB approves an exempt or expedited protocol, requests modifications, or refers the protocol to the Full Board for review. Any point(s) of disagreement between a primary reviewer and an investigator results in the reclassification of the protocol to full review, and a resolution for the dispute is formulated by the Full Board. Requests for exceptions to any of the policies and procedures outlined in this manual result in the reclassification of the protocol to full review, and the Full Board determines if an exception to policies and procedures is appropriate. The Full Board can request full review of any application previously classified and approved under expedited procedures. The Full Board may approve the protocol, approve the protocol contingent upon revision, or disapprove the research, using the procedures described in the following sections.

### Approval of the Protocol: Full & Contingent (Conditional)

Investigators are prohibited from advertising, recruiting, or collecting any information from prospective subjects or volunteers until IRB approval and institutional approval (if applicable) has been obtained. When the protocol is approved unconditionally, the investigators can begin recruitment and data collection immediately. Alternatively, investigators may receive a contingent approval.

### Contingent (Conditional) Approval

The IRB often sets conditions under which a protocol can be approved. If the clarifications or modifications are minor, the IRB can conditionally approve the research. OHRP refers to this process as *contingent approval of research*.

OHRP places some limits on contingent approval of research, stating that: “*When the IRB requests substantive changes or requests clarifications that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be **deferred**, pending subsequent review by the convened IRB of [the investigator’s] responsive material.*”

### Contingent approval can be granted

- only when minor modifications are required by the IRB. For example, the IRB asks the investigator use synonyms for words in measures, child assent, or adult consent forms to ensure that all participants will understand the words and phrases contained in research documents (e.g., asking the investigator to change the word “fastidious” to the phrase “picky, choosy, and hard to please”); or,

- questions are raised by an IRB member that require minor clarifications to be submitted by the investigator. These tend to be issues requiring the investigator to simply confirm the IRB's understanding of a procedural feature of a protocol. The IRB cannot make any assumptions about the intent of the investigator, as expressed in a research protocol and supporting documents. For example, in a true experiment, research volunteers are randomly assigned to an experimental condition and a control condition (at minimum). If the researcher indicates that a true experiment is to be conducted, but omits information about how participants are assigned to groups when they arrive to the laboratory, the IRB would ask for clarification. An investigator being asked to confirm that participants are randomly assigned to groups is defined as a request for a minor clarification.

#### **Contingent approval cannot be granted**

- when the issues cannot directly involve information/clarifications/modifications to risk, the risk/benefit ratio, selection of subjects for participation in the study, informed consent documents or child assent, provisions for monitoring data collection, or provisions to protect the privacy and confidentiality of participants (those items directly required under [45 CFR 46.111](#)); and
- when the investigator's response to IRB's questions or modifications change the IRB's understanding of the study's risk, the risk/benefit ratio, selection of subjects for participation in the study, informed consent documents or child assent, provisions for monitoring data collection, or provisions to protect the privacy and confidentiality of participants (those items directly required under [45 CFR 46.111](#)).

#### **Avoiding Contingent Approval or Deferred Reviews**

SUNY Cortland's Full Board IRB has adopted an optional procedure inviting investigators to present and answer questions about their research plans at the Full Board meeting when their protocol will be discussed. Likewise, for exempt and expedited protocols, investigators have the opportunity to meet with the primary reviewer to answer questions and make appropriate modifications.

When an investigator chooses to attend meetings with the IRB, the investigator can provide immediate clarifications, thereby avoiding delays in the process. Modifications are often made to the protocol and supporting documents, in real time, during a meeting with the primary reviewer or at the convened meeting of the Full Board. This timesaving procedure greatly reduces the probability that approval must be *deferred* until the next month's regular IRB meeting.

#### **Communication Concerning Approval Contingencies and Receipt of New and Revised Documents**

After the IRB has determined contingent approval is appropriate, the primary reviewer (usually the primary reviewer) communicates to the investigator the terms of contingent approval. Information is forwarded, in writing, within five working days after the Full Board meeting. The primary reviewers, IRB Chair, or any member of the Full Board is available upon request to assist investigators with compiling responsive materials.

When responsive materials have been received, the primary reviewer examines the documents, using expedited review procedures, verifying that all required modifications and IRB requests have been satisfied. Under expedited procedures, the primary reviewer acts upon an investigator's submission of responsive material on behalf of the Full Board. The IRB Full Board is provided all revised documentation about the study in the electronic drop-box, and members are notified when the documents are available for their independent or secondary review.

#### **Disapproval of Protocols**

On occasion, the IRB will disapprove a protocol. This action is taken only when the IRB determines the protocol cannot be altered or modified to meet federal, state, and local guidelines for human subject research. Under

federal guidelines, there is no appeal process. Institutional officials (President, Provost, Deans, Department Chairs) may not approve the research if it has been disapproved by the IRB (CFR §46.112).

## Procedures for Communicating Actions Taken by the IRB

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### Communication with Investigators

Investigators are primarily and ultimately responsible for complying with federal, state, and local human subjects rules and regulations. Investigators are responsible for responding to communications from the IRB and are responsible for providing information/documents when they are requested. Except for originally signed documents, which should be sent through intercampus mail or faxed, all documents and information are to be sent via email. Email is the preferred method of communication, as OHRP requires documentation in writing.

**ADDRESS:** IRB, RESEARCH AND SPONSORED PROGRAMS, 402 MILLER, P.O. BOX 2000, CORTLAND, NY 13045

**EMAIL:** [irb@cortland.edu](mailto:irb@cortland.edu)

### Communication with Campus Administration

The IRB Chair incorporates an overall review of IRB activity within his/her Annual Report at the end of each academic year. This report is submitted to his/her direct supervisor, and in this case, the Provost's Office. Included is summary information about IRB activities.

When there is a report of an unanticipated problem or of harm to any participant, or when there is a report of a circumstance that raises risk to unacceptable levels (those exceeding the tolerance of the local research context), the issue is discussed by the Full Board at their next regularly scheduled meeting. If the circumstance is time urgent, the IRB Chair will call an emergency meeting of the Full Board. In all cases, regardless of the findings, the IRB Chair will prepare an incidence report that is hand-delivered immediately to the Provost's Office. This report includes a summary of the circumstance, the IRB's discussion and findings, and the IRB's suggested actions to remedy. In such cases, IRB actions could range from education and auditing research records on a frequent basis (appropriate to the rate of data collection) to suspending the research, to stopping the research. The Provost's Office may take further action, consistent with union agreements and human resource policies and procedures. In compliance with federal, state, and local human subjects' regulations, the Provost's Office will allocate resources appropriately to rectify and remedy any harm to participants.

The Provost's Office, in consultation with the IRB Chair and Full Board, reports to OHRP unanticipated problems, any serious or continuing noncompliance with 45 CFR Part 46, or the requirements or determinations of the IRB, and any suspension or termination of IRB approval. The Provost's Office will comply with OHRP timelines for reporting, upon completion of an independent investigation into the allegations.

## Offices Responsible for Further Institutional Review

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IRB review is limited to issues germane to human subjects' ethics (applications of respect for persons, beneficence, and justice). IRB approval indicates that the research plan appears to be within the ethical boundaries of federal, state, and local human participant regulations. IRB approval does not obligate the institution to provide the resources (facilities or material) that may be required to conduct the research. Therefore, research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution (CFR §46.112). All departments, groups, or organizations that may be affected by the research (stakeholders) are to be consulted, and written permission is to be obtained and submitted to the IRB at the time of application. Under most circumstances, the Department Chair or immediate Supervisor should be consulted

first about using institutional resources. In some cases, other approvals may be required. Investigators are urged to contact the IRB Chair, before an application is submitted, if they require the use of institutional resources. The IRB Chair will help to identify the groups that should review the research in addition to the IRB. Institutional approval cannot substitute for IRB approval. Institutional officials (e.g., President, Provost, Vice Presidents, Deans, Directors, Department Chairs) may not approve the research if it has not been approved by the IRB.

## IRB Review in Emergency Situations

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HHS regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval (see [45 CFR 46.103\(b\)](#) and [46.116\(f\)](#)) and OHRP guidance at <http://www.hhs.gov/ohrp/policy>. When emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject under 45 CFR Part 46. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a prospectively conceived research activity. When emergency care involves investigational drugs, devices, or biologics, U.S. Food and Drug Administration (FDA) requirements must be satisfied.

## Conflict of Interest

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For the purpose of developing SUNY Cortland IRB Policies and Procedures, conflict of interest is defined by the New York State Public Officers Law, Section 74, 3g (NYS), and actions to remedy conflict of interest are guided by HHS, OHRP regulations [45 CFR §46.107 \(e\)](#) and the [OHRP IRB Guidebook](#) (1993).

IRB personnel are trained to be sensitive to conflict of interest, as it is defined by federal regulations and NY State law. When the IRB Chair, primary reviewers, or member has a protocol under consideration, that individual will not participate in any IRB activities concerning that project whatsoever; rather, that individual will act only in the role of an investigator, providing information as requested by the IRB Full Board. The same policy applies when a spouse, common law partner, or romantic partner has a protocol under consideration. Conflict of interest also includes times when an IRB Chair, primary reviewers, or member is a co-investigator or consultant on a study under consideration; when she/he are an individual or member of any group that will be advanced by or otherwise benefit financially from the study being approved; or when she/he are a member of a group funding any portion of the study. Actions to remedy conflict of interest are prescribed by HHS regulations ([CFR §46.107 \(e\)](#)), which state that: “No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.” The [OHRP IRB Guidebook](#) (1993) suggests that IRB members with a conflict of interest, when possible, choose to be absent for discussion and votes on full review protocols. By necessity, the IRB Chair and primary reviewers may remain present during Full Board discussions, but are to remain silent on a protocol when a conflict exists, except to provide information concerning policy and procedure when required during Full Board discussions.

# Part IV

## IRB Records and Documentation

### IRB Protocol Records

The IRB Secretary prepares and maintains documentation of research activities as stipulated by HHS regulations at [CFR §46.115\(a\)](#), including:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects [CFR §46.115\(a\)\(1\)](#);
2. Records of continuing review activities [CFR §46.115\(a\)\(3\)](#);
3. Copies of all correspondence between the IRB and the investigators [CFR §46.115\(a\)\(4\)](#); and,
4. Statements of significant new findings provided to subjects, when required [CFR §46.115\(a\)\(7\)](#).

These records and documents are stored in the IRB electronic drop-box and/or the IRB email account, housed on a password-protected SUNY Cortland server, and is be retained for at least three years after completion of the research (or three years after a protocol expires). All records are fully accessible for inspection to members of the IRB Full Board. Access will be granted, upon request, to other authorized representatives at SUNY Cortland (e.g., Provost) for copying and/or inspection [[CFR §46.115\(b\)](#)]. All materials related to a protocol, including notes from meetings with investigators, are to be documented in writing and stored electronically in the IRB drop-box.

### Minutes of IRB Meetings

Minutes of IRB meetings are recorded in a manner consistent with the federal regulations ([CFR §46.115](#)) and current guidance documents ([January 15, 2007](#)) addressing IRB Meeting Minutes. SUNY Cortland uses a regular format for meeting minute notes to document protocol discussions.

Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

1. For research approved by the convened IRB, all required findings are fully documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding. These circumstances include:
  - (a) approving a procedure which waives the requirement for obtaining a signed consent form [CFR §46.117(c)];
  - (b) approving research involving pregnant women, human fetuses, or neonates [CFR §46.204-207];
  - (c) approving research involving prisoners [CFR §46.305-306]; or
  - (d) approving research involving children [CFR §46.404-407].
2. For research reviewed under an expedited review procedure, the findings reported to the IRB are documented elsewhere in the IRB record ([irb@cortland.edu](mailto:irb@cortland.edu)).
3. Details about IRB recommendations and required modifications/revisions;
4. Rationale for requiring continuing review more often than annually, as appropriate to the degree of risk [CFR §46.103(b)(4) and §46.109(e)]. The minutes of IRB meetings will clearly reflect these determinations regarding risk and approval period (review interval).
5. The vote on all IRB actions including the number of members voting for, against, and abstaining. Following OHRP format, votes are recorded in the minutes using the following format: Total = 15; Vote: For-14, Opposed-0, Abstained-1.

## IRB Records

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The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings that are in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members in the same detail as described in §46.103(b)(3).
6. Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).
7. Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

# Part V

## Organizational Structure, Charge and Duties of the IRB at SUNY Cortland

### Statement of Institutional Principles

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SUNY Cortland is committed to fulfilling its responsibilities to human research participants and to complying with federal, state, and local laws and regulations. A human participant research conducted under College auspices must receive appropriate review and approval.

In addition, the SUNY Board of Trustees has issued the “General Policy Statement Concerning Procedures for Investigations Involving Human Subjects” which indicates that: *“This policy applies to all research and teaching activities involving human participants. It is designed to protect all participants involved in such activities under the auspices, aegis, or control of the University community. Research and teaching activities are covered even though no sponsored funds are used and would include an activity solely within a learning experiment in the classroom. It applies to all members of the University community including faculty and employees of the University and the Research Foundation instructors, graduate and undergraduate students.”*

The institution encourages and promotes constructive communication among the research administrators, department heads, research investigators, IRB, other institutional officials, and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants.

Our Full Board maintains an open door policy by inviting all lead investigators and/or members of a research team to discuss their plans at the meeting when their protocol is reviewed. The Full Board values cooperative and productive exchanges with researchers. The IRB members are available, upon request, to assist investigators with applications and preparing for full review. The results of Full Board meetings are communicated to the lead investigator by the IRB Chair within three working days of the meeting.

The SUNY Cortland IRB is committed to ensuring a culture of compliance at SUNY Cortland, by working with individual investigators, conducting outreach, training, and educational opportunities. If you would like the IRB to speak with your department or research group about human subject protections and the IRB application process, please call to schedule a meeting date. You can reach the IRB at 607-753-2511 or at [irb@cortland.edu](mailto:irb@cortland.edu).

### Human Research Protections Program Administration

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#### Institutional Official Responsibilities

The Institutional Official (Provost) is the individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. Administratively, the Institutional Official is responsible for:

1. Designating one or more IRBs that will review research covered by the institution's FWA;
2. Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties;
3. Providing training and educational opportunities for the IRB and investigators;
4. Setting the "tone" for an institutional culture of respect for human subjects;
5. Ensuring effective institution-wide communication and guidance on human subjects research;
6. Ensuring that investigators fulfill their responsibilities;
7. Encouraging that all staff engaged in the conduct or oversight of human subject research participate in educational activities;
8. Serving as a knowledgeable point of contact for OHRP, or delegating this responsibility to another appropriate individual, in SUNY Cortland's case, the IRB Compliance Officer;
9. Bearing full responsibility for all research involving human subjects covered under its Assurance. For all HHS-conducted or supported research, all of the requirements of the HHS Regulations that apply to vulnerable populations as defined within 45 CFR Part 46, Subpart A, as well as Subparts B through D, must be met;
10. Developing policies and procedures for effective and efficient administration of the Human Research Protections Program (HRPP);
11. Insuring that assurances are in place and certifications of IRB review are submitted to the appropriate authorities for all HHS-sponsored research, not only for themselves, but also for collaborating performance sites for which the institution has agreed to accept oversight responsibility;
12. Implementing appropriate oversight mechanisms to ensure compliance with HHS regulations and effective administration of the human research protections program;
13. Ensuring that all institutions and investigators engaged in its HHS supported human subject research operate under an appropriate OHRP-approved Assurance for the protection of human subjects.

## IRB Compliance Officer Responsibilities

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The IRB Compliance Officer at SUNY Cortland is the Assistant Vice President for Research and Sponsored Program and serves as the institution's primary OHRP contact. Administrative responsibilities fall into three general areas: IRB Oversight as the designated official by the Provost, Communication and Supporting Education, Record Keeping and Reporting. The Research Compliance Officer may also serve as a primary or secondary reviewer, having authority to review and approve exempt and expedited protocols.

## IRB Chair Responsibilities

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The IRB Chair promotes the activities of the IRB on the SUNY Cortland campus, provides training opportunities, and works to facilitate the appropriate and timely review of research. The IRB Chair coordinates the activities of the Full Board, prepares agendas for convened meetings of the IRB, and that a quorum is present before research is reviewed. The IRB Chair ensures that each IRB member has received all pertinent material prior to the meeting. The IRB Chair performs general oversight of the research protocols in collaboration with the primary reviewers of each School.

## Institutional Review Board

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### Authority and Responsibility of the IRB

The Institutional Review Board (IRB) is a committee established to protect the rights and welfare of human research subjects involved in research activities. The IRB implements federal, state, and local laws and regulations requiring the review and monitoring of human participant research in accordance with the policies outlined in [45 CFR §46.108 - 45 CFR §46.115](#).

The IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities at SUNY Cortland. The goal of the IRB is not only to guarantee compliance with existing laws and regulations but also to assist campus researchers in the planning and implementation of their projects.

### Membership and Appointment to the IRB

Appointments to the IRB are made in accordance with the federal requirements ([45 CFR §46.107](#)). In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of the community at large, the research context, institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The Provost shall make appointments to the IRB for three- year terms that begin at the start of the College's academic year. All IRB personnel are asked to be available for consultation or meetings throughout the year to facilitate the review of time urgent matters. Because of the extensive time commitment, training requirements, and qualifications of IRB personnel, all IRB appointments are renewable.

### IRB Membership Lists, Qualifications, and Affiliations

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 in the office of the IRB Administrator. All changes in IRB membership are reported by the Provost's Designee for IRB Administration and compliance to OHRP as appropriate.

# Part VI

## References, Index, and Acknowledgements

### Regulatory Requirements Index

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HHS regulations at 45 CFR 46.103(b)(4) and (5) require that institutions have written IRB procedures that include seven points. Some information concerning these seven points can be found throughout the manual. This index provides a cross-reference, listing where definitive statements concerning these seven items are located in the manual.

1. the procedures which the IRB will follow for conducting its initial review of research; *(Part I and Part III)*
2. the procedures which the IRB will follow for conducting its continuing review of research; *(Part I and Part III)*
3. the procedures which the IRB will follow for reporting its findings and actions to investigators and the institution; *(Part III)*
4. the procedures which the IRB will follow for determining which projects require review more often than annually; *(Part III)*
5. the procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; *(Part III)*
6. the procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and *(Part I and III)*
7. the procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of:
  - a. any unanticipated problems involving risks to subjects or others (hereinafter referred to as unanticipated problems);
  - b. any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and
  - c. any suspension or termination of IRB approval. *(Part III)*

## References and Acknowledgements

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Substantial revisions made to our policies and procedures during our fall 2008 quality assurance self-study, which were facilitated by OHRP and assisted by members of the SUNY IRB Consortium and members of the SUNY Cortland Institutional Review Board (2008-2009). Dr. Leslie Eaton wrote and compiled this manual and submitted it for approval at the December 10, 2008 IRB Full Board meeting. Further modifications ensued as the IRB transitioned to a primary reviewer system in August 2009 with modifications made by Dr. Jena Curtis, Dr. Joy Mosher, and Ms. Amy Henderson-Harr.