# Table of Contents

Introduction ........................................................................................................................................ 5  

**Part I—Information for Investigators: IRB Review and Research Conducted at SUNY Cortland** .......................................................................................................................... 6

IRB Procedural Overview ..................................................................................................................... 7

  Sequential Outline of IRB Procedures at SUNY Cortland ................................................................. 7

Human Participant Training Requirements ......................................................................................... 8

  Human Participant Program Ethics Training Requirements at SUNY Cortland .............................. 8

  Investigators, co-investigators, undergraduate/graduate training requirements ............................. 8

  Training Required for Administrators and IRB Members ............................................................... 9

Preparation of IRB Protocols .............................................................................................................. 9

Levels of IRB Review .......................................................................................................................... 9

  Category I — Exempt Review ........................................................................................................ 10

  Category II — Expedited Review .................................................................................................. 10

  Category III — Full Review ........................................................................................................... 10

IRB Applications, Appendices, and Other Required Documents ...................................................... 10

Legally Effective Informed Consent is Required ............................................................................... 11

  Research Involving Children: Parental Consent and Child Assent .............................................. 12

  Waivers of Consent ....................................................................................................................... 13

Institutional Permission Letters ......................................................................................................... 13

Miscellaneous Issues to Consider Before Submission ........................................................................ 13

Protocol Submission .......................................................................................................................... 14

Summary of IRB Review Process ....................................................................................................... 14

Executing the Research Activity ......................................................................................................... 15

  Submission of Protocol Changes (Modifications) ........................................................................ 16

  Documentation of Protocol Changes ............................................................................................. 16

  Review of Exempt and Expedited Protocol Changes .................................................................. 16

  Requirement for Review of Proposed Protocol Changes by the Full IRB Board ........................... 16

Requests to Continue Research .......................................................................................................... 17

  Timeline for Continuing Review .................................................................................................. 17

  Expedited research continuation requests .................................................................................. 17

  Full review research continuation requests ................................................................................ 17

  Information required for continuing review, expedited and full review ...................................... 17

**Part II—Special Topics of Interest** .................................................................................................. 19

Internet Data Collection .................................................................................................................... 20

Reimbursement and Remuneration ..................................................................................................... 20

Requirements for Program Evaluation ............................................................................................... 22

International Research ....................................................................................................................... 23
Institutional Review Board Responsibilities ................................................................. 42
IRB Responsibilities in the Institutional Context .......................................................... 42
Membership of the IRB ................................................................................................. 43
Appointment to the IRB ............................................................................................... 43
IRB Membership Lists, Qualifications, and Affiliations ............................................. 44
Training of IRB Members ............................................................................................. 44
IRB Communication Policy .......................................................................................... 44
Principles of Discussion and Decision Making ............................................................ 44

Part VI—References, Index, and Acknowledgements ..................................................... 45
Regulatory Requirements Index ................................................................................... 46
References and Acknowledgements .............................................................................. 46
Introduction

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 Administrator, by email at irb@cortland.edu.

The SUNY Cortland IRB chair is Mark Prus, Ph.D., Provost for Academic Affairs, Dr. Prus can be reached by visiting Miller Building Room 4048A by telephone at (607) 753-2207, or by email at irb@cortland.edu or Mark.Prus@cortland.edu. SUNY Cortland’s institutional official for the IRB is Ms. Amy Henderson-Harr, Assistant Vice President for Research and Sponsored Programs (RSPO). Amy Henderson-Harr serves as the Provost’s Designee for IRB institutional compliance, of which the IRB reports to. She may be reached by visiting Miller Building Room 402 by telephone at (607) 753-2511, or by email at irb@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 federalwide assurance (State U of New York College at Cortland: FWA00009541) and the registration of the IRB (SUNY - Cortland IRB #1: IRB00004790).

Revised December 10, 2008
Respectfully submitted by Dr. Leslie Eaton; approved by the SUNY Cortland IRB Full Board on December 10, 2008
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.

Nearly all scholarly 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, a few teaching activities meet this definition; for example, studies of teaching effectiveness to be published, communicated, or disseminated off-campus require IRB review. Many undergraduate research activities and undergraduate thesis projects require IRB review (when the intent of the activity is the creation of generalizable knowledge).

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 federalwide 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.

### Sequential Outline of IRB Procedures at SUNY Cortland

<table>
<thead>
<tr>
<th>Training</th>
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<tbody>
<tr>
<td><em>Complete the CITI Program</em> 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)</td>
</tr>
<tr>
<td><em>Read this Policies and Procedures Manual</em></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Protocol Preparation</th>
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<tbody>
<tr>
<td><em>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); include Appendix B, when applicable. Applications/appendices, instructions, examples and help files for protocol preparation are available at <a href="http://www.cortland.edu/irb">http://www.cortland.edu/irb</a></em></td>
</tr>
<tr>
<td><em>Prepare a proposed legally effective informed consent written at a level the population to be recruited 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</em></td>
</tr>
<tr>
<td><em>Prepare copies of surveys and measures; gather for submission information about all tools, supplies, and equipment or apparatus used for the research activity</em></td>
</tr>
<tr>
<td><em>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</em></td>
</tr>
<tr>
<td><em>Contact the IRB Administrator if you have any questions or need assistance (email: <a href="mailto:irb@cortland.edu">irb@cortland.edu</a>)</em></td>
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</tbody>
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<table>
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<tr>
<th>Protocol Submission</th>
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<tbody>
<tr>
<td><em>Submit the application and all supporting materials to the IRB Administrator (primary reviewer); all documents are to be submitted electronically, as email attachments to <a href="mailto:irb@cortland.edu">irb@cortland.edu</a>; Appendix A (signature page) can be sent by campus mail, fax, or email (as a PDF file); original signed permission letters (and MOUs) must be sent through US or campus mail to the IRB Administrator</em></td>
</tr>
</tbody>
</table>
IRB Review

- At primary review, protocols confirmed as exempt and expedited are normally reviewed by the IRB Administrator.
- 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.
- The IRB Chair notifies investigators of the date/time of their IRB review.
- At all levels of review, the IRB Administrator notifies investigators of the outcome of the review and provides details regarding any revisions or clarifications required.

Research Activity

During the execution of the research activity, investigators must

- Notify the IRB of any changes to the documents or procedures before they are implemented (referred to as “modifications to existing research”);
- Report to the IRB (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).
- Apply for continuing review at intervals appropriate to the original level of review, usually once annually for expedited and full review research, usually once every three years for exempt research. The IRB can request review at more frequent time intervals, depending on the level of risk posed to participants and others.

Human Participant Training Requirements

Proper training in human subjects research ethics is the cornerstone of SUNY Cortland’s Human Participant Program (HPP). In recognition of the importance of training and in response to strong calls for federal action concerning education of all individuals involved with human subjects research (e.g., OIG, 1998), several groups (e.g., NIH, OHRP) enacted training requirements or recommendations. These policies were aimed at helping to ensure that institutions, IRB members, and investigators, are adequately educated about human participant protections (HPP) (NIH, 2000) so that they can meet the obligations of their respective roles. Although recommendations and requirements varied somewhat across federal agencies, most institutions adopted the October 2000 NIH requirements, mandating that all key personnel receive HPP ethics training. In the context of a research project, key personnel include “all individuals responsible for the design and conduct of research studies involving human participants.”

Human Participant Program Ethics Training Requirements at SUNY Cortland

To satisfy multiagency training requirements, SUNY Cortland has subscribed to the CITI Program, Collaborative Institutional Training Initiative. 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 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 (research using the internet, international research, research involving children, biomedical research). Key personnel (investigators, co-investigators, and some research assistants) are to be familiar with the policies presented in this Manual.

Investigators, co-investigators, undergraduate/graduate training requirements

Key personnel can include faculty, staff, students, or administrators. Anyone who is involved in research design, participant recruitment, or the gathering of information from participants is to be considered key personnel. Key personnel also include individuals whose data management responsibilities, analysis tasks, and dissemination activities require direct access to participants or private information provided by participants.
All key personnel are required to complete the basic modules of the CITI Program and all optional modules applicable to the research. The CITI Program is continuously adding modules to satisfy multiagency demands and emerging research methods. Refer to the CITI Course menu for a current list of modules. At this time, the CITI modules that are required or optional for social and behavioral sciences key personnel appear in the following table.

<table>
<thead>
<tr>
<th>Required Basic Course Modules</th>
<th>Optional Modules – (required when applicable to the research)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Belmont Report (ID: 1127)</td>
<td>Research with Prisoners - SBR (ID: 506)</td>
</tr>
<tr>
<td>Students in Research - SBR (ID: 1321)</td>
<td>Research with Children - SBR (ID: 507)</td>
</tr>
<tr>
<td>History and Ethical Principles - SBR (ID: 490)</td>
<td>Research in Public Elementary and Secondary Schools - SBR (ID: 508)</td>
</tr>
<tr>
<td>Defining Research with Human Subjects - SBR (ID: 491)</td>
<td>International Research - SBR (ID: 509)</td>
</tr>
<tr>
<td>The Regulations and The Social and Behavioral Sciences - SBR (ID: 502)</td>
<td>Internet Research - SBR (ID: 510)</td>
</tr>
<tr>
<td>Assessing Risk in Social and Behavioral Sciences - SBR (ID: 503)</td>
<td>International Research (ID: 971)</td>
</tr>
<tr>
<td>Informed Consent - SBR (ID: 504)</td>
<td>Human Subjects Research at the VA (ID: 13)</td>
</tr>
<tr>
<td>Privacy and Confidentiality - SBR (ID: 505)</td>
<td>HIPAA and Human Subjects Research (ID: 14)</td>
</tr>
</tbody>
</table>

Recently, multiagency concern has been expressed about noncompliance that may be attributed to a lack of training, including investigators’ misunderstanding of the federal regulations and breakdowns in implementation during the design and execution of human subjects research (OHRP, 2008). The SUNY Cortland IRB ensures, to the greatest extent possible, that principle investigators receive proper training. We ask that faculty sponsors and research methods instructors likewise ensure that graduate and undergraduate students working with human research participants complete appropriate training and that they fully understand their duties under federal and state laws and regulations.

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 IRB Administrator must complete OHRP assurance training Modules 1 through 3.

Preparation of IRB Protocols

Levels of IRB Review
Research projects are reviewed at one of three levels, depending upon the investigator(s) and IRB’s understanding of

1. the target population to be sampled;
2. the risk to participants posed by the recruitment, procedures, data retention, and dissemination plans; and,
3. 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 primary reviewer (IRB Administrator) will make the final determination. Any irresolvable matter or dispute between an investigator and the IRB Administrator is brought before the Full Board. 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 (see 45 CFR §46.101(b) or [http://www.cortland.edu/irb/Applications/exempt.html](http://www.cortland.edu/irb/Applications/exempt.html)).

**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 (see federal register), 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.cortland.edu/irb/Applications/exp.html](http://www.cortland.edu/irb/Applications/exp.html).

**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 in schools;
3. Research involving deception;
4. Interviews or surveys relating to topics the Cortland community would define as being sensitive (e.g., sexual activity, alcohol or drug use, illegal behavior), particularly if identifiers are used or confidentiality could be compromised;
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 supervised classroom project affiliated with course objectives;
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](http://www.cortland.edu/irb/app.html). HHS regulations (CFR §46.111) set forth the criteria that must be satisfied in order 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. These include copies of a grant/fellowship proposal, copies of surveys, measures, apparatus, and materials are to be submitted. References for published measures that are widely used (e.g., Wechsler Adult Intelligence Test) can be submitted in lieu of materials. Photographs of apparatus and equipment can be helpful, particularly images demonstrating how the apparatus/equipment would be used by the researcher and participants. Appendix B, listing co-investigators, research staff, and research assistants are to be submitted when applicable. Submission of any other documents, photographs, or materials that will assist with IRB review may also be required. Should a SUNY Cortland investigator become involved in HHS-supported multicenter clinical trials, the IRB should receive and review a copy of the HHS-approved sample informed consent document and the complete HHS-approved protocol.

**Legally Effective Informed Consent is Required**

IRB review demands that IRB members focus on the research, from the perspective of the participant. The primary reviewer begins his/her protocol review by reading recruitment materials and the consent form, using the OHRP consent form checklist to ensure that the participants obtain all required information (see OHRP or Cortland IRB websites). Then the primary reviewer proceeds to read the materials and protocol (IRB application). Investigators are urged to keep information consistent across these documents, using the informed consent (assent) as the key document. 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 identified as critical to a participant’s understanding of research. All applicable elements [at minimum, CFR §46.116 (a through f)] must appear in every informed consent and every child assent. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. 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. The approval date
for each document and the expiration date for the research protocol are to appear on all recruitment materials and consent documents, unless this requirement is explicitly waived by the Full Board.

Consent must be documented; that is, participants must sign a consent form, and 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.

OHRP recognizes recruitment/advertisement activities as part of the informed consent process. Nearly every imaginable type of communication about a study must be pre-approved by the IRB. Examples of recruitment materials include a research brochure, flyer, newspaper advertisement, press release, email, or news-related story about the study that contains contact information for the researcher. Public relations stories, press releases, and other forms of news/journalism about research are subject to IRB review 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. Prospective subjects should be provided with ample opportunity to ask questions and seek clarification from the investigator. The prospective subjects should be in a position decide freely whether to initially enroll in the research, or later to withdraw or continue participating in the research.

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

Although the regulations state that children are unable to provide legally effective informed consent to participate in research, 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 accord with CFR §46.116 and CFR §46.408(a).

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.
The definition of children also takes into account the particular interventions or interactions involved in the proposed research (e.g., surveys, blood tests). For example, in some places individuals who are 16 years of age may legally consent to certain clinical interventions or interactions. If the involvement of human subjects in a proposed research activity consists of these interventions or interactions, then those individuals may be considered as adults for that purpose. If a proposed activity includes an intervention or interaction for which the subject has not yet reached the legal age of consent, however, that person must be considered a child.

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.

Waivers of Consent
Sometimes an investigator will request a waiver to document informed consent. When this waiver is granted, the researcher provides the participant with a written consent statement, but the participant does not sign a consent form. This waiver is appropriate under some limited circumstances (CFR §46.117), most commonly when the principal risk would be potential harm resulting from a breach of confidentiality.

In a few specific and more unusual circumstances, a researcher may find that the study procedures require a consent process which does not include, or which alters, some or all of the elements of informed consent (e.g., unobtrusive observation of public behavior; use of deception to preserve the scientific integrity of a manipulation). Under some circumstances, defined at CFR §46.116 (d), the IRB can waive providing some or all of the elements of informed consent. This type of waiver requires full review by the convened Full Board, even if the research is otherwise low risk. When a volunteer’s participation in the study has concluded, full consent is administered as part of a debriefing process.

Requests for either type of waiver 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 Administrator.

Institutional Permission Letters
Permission letters must be submitted for all off-site locations (e.g., schools, businesses, institutions) where facilities or resources will be used to place advertisements, engage in recruitment activities, and collect data. When an institution’s facilities or materials will be used for the research (e.g., a room, telephones, email, photocopy machines, internal/external mail), a Memorandum of Understanding (MOU) should be sought, giving the investigator permission to use specific facilities, assets, or resources for the research. Negotiating the terms of a MOU, explicated within a permission letter, is critical when advertising, recruitment, data collection, analysis, or dissemination will occur at any off-campus location.

IRB approval only indicates that the research meets federal, state, and local ethical guidelines. IRB approval should not be confused with institutional approval to use facilities or resources. If institutional facilities or resources are required from SUNY Cortland, institutional approval is to be sought from the President’s Office, in addition to IRB approval. For example, if an investigator plans to advertise the study through campus email, the IRB will need to approve the text of the email message to ensure that the language of the text is consistent with federal guidelines. However, IRB approval does not grant permission to use the campus email resources. Permission to use campus email to advertise the study must be obtained from the appropriate individual or groups in SUNY Cortland administration.

Miscellaneous Issues to Consider Before Submission
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).

The HHS-OHRP regulations do not affect any applicable state or local laws or regulations, which provide additional protections for human subjects [CFR 46.110[f]]. New York State Department of Health regulations apply to human subjects research at SUNY Cortland (click here). The SUNY General Counsel has recommended that all SUNY employees be familiar with these requirements and follow the Common Rule when conducting all kinds of research-related activities. As SUNY employees and students, we are advised to remain in compliance with all applicable federal, state, and local laws, regulations, and rules regardless of the nature of the activities (whether engaged in teaching/learning, scholarship, or service).

Protocol Submission

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 the primary reviewer (IRB Administrator) by email: irb@cortland.edu. Appendix A, original permission letters, and other signed documents are to be sent by intercampus mail addressed to 134-B Old Main; through US Mail: IRB Administrator, SUNY Cortland, P.O. Box 2000, Cortland, NY 13045 (or by fax).

Summary of IRB Review Process

SUNY Cortland uses a primary reviewer system. After submission to irb@cortland.edu, the primary reviewer (IRB Administrator) conducts an in-depth examination of all information and documents. At this stage, the IRB Administrator 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 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, in writing, with details concerning the request. All additional documents or information is to be sent to 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 IRB Administrator takes depends upon the level of review. Exempt protocols are reviewed by the IRB Administrator only; expedited protocols are reviewed by the IRB Administrator, audited by a second member of the Full Board (normally the IRB Chair), and a summary is reviewed by the Full Board. Full review applications are forwarded to the IRB Chair and will be placed on the agenda for the next available Full Board Meeting. The IRB Chair will notify the investigator of the location, date, and time of the protocol review. After the protocol review, the IRB Administrator will notify the investigator of the actions taken by the Full Board.
Executing the Research Activity

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://hhs.gov/ohrp/humansubjects/assurance/consentckls.htm
   - Informed Consent, Legally Effective and Prospectively Obtained
     http://hhs.gov/ohrp/humansubjects/guidance/hsdc93-03.htm
   - Informed Consent, Non-English Speakers
     http://hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm
   - Certificates of Confidentiality
     http://hhs.gov/ohrp/humansubjects/guidance/certconf.pdf

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). 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), 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]), 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)
All changes to a research project must be submitted to the IRB as a modification request. Investigators are not permitted to implement any 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 weeks for full review). OHRP specifically directs IRBs to take actions to ensure that investigators submit protocol changes, which might be addressed through training programs and materials for investigators, specific directives included in approval letters to all investigators, information provided on the SUNY Cortland IRB internet site, and random audits of research records (for example).

Documentation of Protocol Changes
Prior to original IRB approval, 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 Administrator by email ([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 at 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 monthly 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 IRB Administrator (primary reviewer) makes the determination if a protocol change can be reviewed at the expedited level. The IRB Administrator can seek consultation from the IRB Chair or another experienced IRB member.

Protocol changes requiring expedited review is assigned to a second reviewer. Ideally, the second reviewer will possess expertise in the investigator’s research area. Either designated 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 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 technically require continuation requests; the SUNY Cortland IRB only requests annual email notification (to irb@cortland.edu) indicating that the research continues. The purpose of the continuation notification, at the exempt level, is to alert the IRB Administrator 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 Administrator using expedited procedures, not less than once a year for a total of three years.

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. 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 by email at irb@cortland.edu or through intercampus mail to Old Main Room 134-B.
Part II

Special Topics of Interest
Internet Data Collection

Internet data collection is becoming extremely common. It 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 for any other kind of research.

Many of the same consent issues present for mailed questionnaires apply to internet data collection. 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 requires that investigators using the internet for research complete this optional CITI Training module, and strongly recommends researchers carefully consider the issues presented. Beyond issues considered during a normal protocol review, these issues will also be seriously considered.

Below is a list of common misconceptions about internet research and requirements specific to SUNY Cortland:

- Internet research always requires IRB review. Even if the survey is completely anonymous and even if it is housed off-campus, investigators are required by federal regulations to apply. A SUNY Cortland IRB application is required for all research that any SUNY Cortland faculty, staff, or student does no matter who collects the data, where the survey is housed, or when the information is/was collected (including the use of publicly available datasets often downloaded from the internet).
  - Internet research is bound by the same regulations (federal, state, local) as any other kind of research. In fact, internet research raises additional concerns, which are outlined below.
  - Most internet research conducted at 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.
  - 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, all of this research requires IRB review, normally fitting exempt or expedited categories.
- At the time of application receipt, researchers will be advised to complete the “Internet Research” CITI Course Module (a maximum of about 20-minutes to read the materials and complete the quiz).

The IRB is concerned about any misunderstandings that could result in noncompliance with federal, state, and local regulations. Noncompliance poses unnecessary risk to individuals and the institution. As research ethicists note, internet data collection adds elements of risk not present in traditional forms and methods of data collection. Investigators must be aware of these issues before embarking on internet data collection. They are summarized in the CITI Training module, based on the scholarly work of Lorna Hicks (Duke University), recognized as a leading expert in this area. As technologies change, IRB concerns will shift to meet the demands for ethical use. The IRB Administrator stays current in this literature and can assist you with current and emerging technologies. Contact the IRB Administrator at irb@cortland.edu

Reimbursement and Remuneration

OHRP requested that local IRBs institute policies concerning reimbursement and remuneration for research participation. After some deliberation, the SUNY Cortland IRB adopted the policies outlined herein.

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 reimbursed? Ideally, participants should not earn that any extra expenses that are not paid for by the researcher or reimbursed (e.g., parking fees, cab fare, mileage, fees for services, postage, babysitting, etc.).

2. Is remuneration 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.

There are no federal regulations that directly govern remuneration or incentives to participate, except to say that no inducement should be offered that could be construed as coercion or undue influence. OHRP has articulated some additional issues that researchers should consider when asking people to participate in research. In summary, OHRP states, "Regardless of the form of remuneration, the issues for IRBs remain the same. IRBs must consider whether paid participants in research are recruited fairly, informed adequately, and paid appropriately. Taking into consideration the subjects' medical, employment, and educational status, and their financial, emotional, and community resources, the IRB must determine whether the rewards offered for participation in research constitute undue inducement." "Although payments are usually monetary, both patients and normal healthy volunteers may be offered other rewards in lieu of or in addition to money. Free medical care, extra vacation time, and academic rewards are examples of alternative rewards." (e.g., At Cortland, extra credit is given to students) (FDA, 1989 cited by OHRP).

In general, SUNY Cortland asks researchers to consider if remuneration is appropriate for their study. In all cases, regardless of remuneration, researchers are to 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 NIH and the general locale. For example, free coercion health care for persons with limited resources and major medical problems may present undue influence (even if the research activity is nontherapeutic).

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 a study is funded, this expectation may be even stronger. When participants are members of the community, the need to show appreciation may be important for a number of reasons.

When participation entails minimal time and effort, SUNY Cortland researchers have given Red Dragon pencils or stickers to kids, provided in-service 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. PSY 101 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: (I) 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. The SUNY Cortland IRB will review the study, trying 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. 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).

Ultimately, according to OHRP recommendations, 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?

Requirements for Program Evaluation

Once rare in higher education, program evaluation and review are now common. Program evaluation (or quality improvement activities as it is called by OHRP), as a rule, does not constitute human subjects research and does not require IRB review (see http://www.hhs.gov/ohrp/qualityfaq.html). However, sometimes investigators may find the IRB Administrator asking that IRB approval be sought. This raises the question, “When does program evaluation require IRB review?” The answer to this question does not lie in the study’s recruitment or procedures. The answer lies in intent: program is always intended to inform someone, so those individuals can improve the quality of their practices. To determine if your study needs IRB approval, ask yourself, “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 “educators across the SUNY system,” “NY State teachers,” “sociology professors,” you hope to publish the results in a teaching journal, you hope to present the results at a conference, or you hope that some other group will benefit (who were not included as part of the original sample), then that research does require 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 never 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).

Program evaluation can serve dual purposes. Sometimes a program evaluation is intended to inform a department or unit, for example, and then will be used later to “sell” a program or service (e.g., quoting student satisfaction statistics). In this case, the program evaluation should receive IRB approval because the results are disseminated off campus. Sometimes program evaluation results will be presented at a conference or included in a publication. In these cases, the program evaluation should be submitted for IRB review. The only time a program evaluation does not require IRB review is when the data will be used for internal purposes only (to improve a program or service, submit to accreditation agencies, or to SUNY).

Because of an increasing need for program evaluation and human subjects research data, some groups are beginning to receive more requests than they can accommodate. To avoid the duplication efforts, the **Office of Institutional Research and Assessment** should be consulted about existing data, before planning new data collection efforts.

Permission is to be obtained from administrative department heads when the recipients of their services will be sampled or affected. For example, the **Director of Advisement and Transition** must grant permission for any study involving students in their programs, including CORIO, orientation, etc.; likewise, the **Educational Opportunity Program** Director must grant permission to recruit EOP students for research. Furthermore, the **Office of Institutional Advancement** must be consulted before sampling alumni for any reason. The directors of administrative offices wish to express that do not want to stop or slow human subjects research, program evaluation, or the development of new programs. Their interest is in ensuring that the research is consistent with the mission of their program and that they have the time and resources to meet the goals of their respective program. The SUNY Cortland IRB will not approve a study that plans to sample from any group of faculty, staff, or students, without the expressed permission of the department head and President’s Office.

Note: When the program evaluation does 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.

**International Research**

International research is time consuming and difficult. The IRB process should begin early and involve the IRB Administrator before a protocol is written. In terms of human subjects protections, if you plan to conduct research in another country 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 Courses with Research/Experimental Activity**

Certain courses routinely involve students in a number of in-class experiments. If the research activity is both a classroom activity and human subjects research, **IRB review is required** and all federal, state, and local requirements apply (without exception). 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, which 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 (see OHRP’s position statement).

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 electing not to participate to miss class (to complete the alternate assignment) or come to class late, after the research activity has concluded.

3. All participants must be eighteen years of age. Otherwise, parental consent as well as consent from the student are required.

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 information they provide. SUNY policy requires that classroom research activities comply with all federal, state, and local human participant protections, even when they do not require IRB approval. SUNY Cortland requires that instructors teaching research-related courses are to complete CITI training so that they are familiar with the federal requirements.

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 required 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, the 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 should be followed, even when the classroom activity is not human subjects research. In any case, the instructor should have a clear statement in the course syllabus about whether participation in the classroom research is voluntary and/or how the participation is related to the goals/objectives of the course or 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 be prepared with an alternative.

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, without the instructor being prepared to provide strong justification for this approach. The IRB will play a consultative role when asked for assistance. If the IRB Administrator or IRB Chair receives a complaint about classroom research 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 Administrator or IRB Chair (But students or others filing a complaint should keep in mind that anonymity may limit the actions administration can take to address concerns.).
Research Conducted by Non-SUNY Cortland Investigators

The IRB requires any non-SUNY Cortland investigators to have a sponsor on campus who is willing to serve as a facilitator for the research. The IRB also requires a copy of the approved IRB protocol from the originating institution of any guest investigators prior to approval of the research on Cortland’s campus. The IRB application and approval letter from the originating institution should be forwarded to the Cortland faculty sponsor for review and submission to Cortland’s IRB. This procedure assures that the research approved adheres to Cortland’s IRB policies. The guest investigators will receive written authorization from the IRB Administrator granting approval to conduct the study at SUNY Cortland.
Part III

Operational Details of the SUNY Cortland Institutional Review Board
IRB Operational Details

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 federalwide assurance) as well as 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 reviewer is to serve as a liaison for the IRB, manages the day-to-day operations of the IRB, and ensures the terms of the federalwide assurance are met. Ultimately, the primary reviewer takes action on exempt and expedited protocols, and forwards documents/information to the appropriate individual(s) or groups in accordance with the federal regulations.

At SUNY Cortland, the IRB Administrator serves as the primary reviewer, unless the IRB Administrator is away from campus or identifies a conflict of interest. In those latter two situations, the IRB Chair is notified. Normally, the IRB Chair will then serve as primary reviewer, but can appoint another experienced member (or members) of the IRB to serve as primary reviewer(s) in addition to, or in place of, the Chair.

When a protocol is submitted, the primary reviewer (IRB Administrator) 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 IRB Administrator 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 IRB Administrator conducts a primary review. At exempt and expedited levels, the IRB Administrator performs initial review, continuing review, and review of protocol changes. Full review protocols are submitted to two sequential reviews, the first conducted by the primary reviewer (IRB Administrator) and the second by the IRB Full Board. Confirmed full review protocols are forwarded to the IRB Chair and Full Board review is scheduled for the next available monthly meeting. The IRB Chair forwards and brings to the Full Board Meeting a copy of the complete protocol and supplementary materials.

Expedited Review Procedure

The Primary Reviewer System, as previously described, is used to review expedited protocols. Normally, the IRB Administrator conducts these reviews, the IRB Chair serves as second reviewer/auditor, and the Full Board provide final approval (by vote at their monthly meeting). Alternatively, the IRB Chair can designate two other experienced member(s) of the Full Board, designating one to serve as the primary reviewer. Expedited reviews of Full Board conditional approvals are reviewed by two experienced members of the IRB, who are designated as reviewers during the protocol discussion. One of these two is normally the IRB Chair, who serves as primary reviewer, collecting revisions and communicating with the second reviewer and investigator. Expedited modification requests and continuations are reviewed by the IRB Administrator (primary reviewer) and IRB Chair (second reviewer, auditor).

Each month, the IRB Administrator prepares and presents reports of expedited protocols to the Full Board, in compliance with federal regulations. The report to the Full Board includes: (a) the specific permissible categories (63 FR 60364-60367) that justified the expedited review; and (b) documentation of the review and action taken by the primary reviewer and any findings required under the HHS regulations.

All documents related to an expedited protocol are made available to the Full Board for review in the electronic drop-box. The IRB Chair or any Board member can audit approved expedited reviews at any time and provide
feedback to Primary Reviewer and the Full Board. The Full Board may approve, approve contingent upon revision, or disapprove expedited protocols at the monthly meeting when the protocols are presented.

**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.

Expeditied 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 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 would be assembled to serve as a subcommittee for that protocol. For example, if SUNY Cortland Student Health Services becomes a site for an FDA regulated multisite clinical drug trial, Christopher Carey (Cortland IRB Member and Physician’s Assistant) would assist the IRB Chair in identifying experienced IRB members at SUNY Upstate Medical Center (Syracuse, NY). 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

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

OHRP indicates that the IRB must receive a continuation request **before** the expiration date of a previously approved IRB protocol. The IRB is permitted to accept continuation requests 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. 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 (IRB Administrator) 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

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 IRB Administrator) communicates to the investigator the terms of contingent approval. Information is forwarded, in writing, within five working days after the Full Board meeting. The IRB Administrator, 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 IRB Administrator acting upon 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 subjects 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).

Should this occur, investigators are urged to consult with colleagues in their academic field of study, who have specific expertise in the disapproved area of inquiry. If a colleague can be located on-campus, that individual may agree to become a co-PI and assist with issues, methods, or procedures that are not compliant. Off-campus colleagues can be helpful as well. For off-campus colleagues to serve as effective consultants, they should be presently conducting research in the disapproved area, using similar methods and procedures as those disapproved by the IRB, and should be working at an institution operating under a federalwide assurance. Upon locating qualified colleagues, investigators should seek advice from those colleagues pertaining to modification of research methods and procedures that might be effective in resolving issues, methods, or procedures pertaining to noncompliance.

Should the investigator choose to prepare a new protocol, obtaining letters of support from colleagues would not be of help to the investigator or the IRB. However, the IRB Administrator would find it useful to have the name of the colleague and contact information for the institution before a new protocol is prepared for submission. In some occasions, through discussion, the IRB Administrators together can work through issues and find a reasonable modification or alteration that would allow the research to comply with federal guidelines, given the local research context.

Investigators affiliated with SUNY Cortland (all faculty, staff, and students whether part-time or full-time) are prohibited by the federal regulations from substituting an outside IRB’s review for SUNY Cortland’s IRB review.

**Investigators, faculty sponsors, and/or Department Chairs should not contact an outside IRB (the Administrator, Chair, or any member) about research disapproved or contingently approved by the SUNY Cortland IRB.** This would not be appropriate, given the HPP culture in which IRBs function. Furthermore, the role of the “local research context” in IRB decision-making will prevent external IRBs from having the ability to formulate appropriate determinations about research proposed by individuals affiliated with SUNY Cortland. Rather than contacting outside IRBs, investigators are to speak with the IRB Administrator, IRB Chair, and ultimately the Provost if the investigator believes a problem has arisen during their interactions with the IRB that cannot be resolved with the Full Board.
Procedures for Communicating Actions Taken by the IRB

**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 ADMINISTRATOR  
PO BOX 2000  
CORTLAND, NY 13045  

**EMAIL:** irb@cortland.edu

The IRB Administrator serves as a liaison, facilitating communicating between the IRB and an investigator. The IRB Administrator ensures that all communications among parties are documented in writing and stored in a central location, according to federal regulations (45 CFR 46) and OHRP guidelines. All applications, appendices, proposed consent forms, revisions to protocols, and materials are to be submitted to the IRB Administrator at the address listed above. Forms, documents, and information sent to any other location cannot be considered for review.

When serious or continuing noncompliance comes to the attention of the IRB, these cases are reported to the Provost’s Office, using the same procedure as reports of unanticipated problems, serious or dramatic shifts in risk, or harm to participants.

**Communication with Campus Administration**

The IRB Administrator prepares an Annual Report of IRB activity at the end of each academic year. This report is emailed to the President’s Office, Provost’s Office, and the IRB Chair, and copied to the office of Research and Sponsored Programs. Included is summary information about IRB activities, routine initial reviews, continuing reviews, and reviews of protocol changes at all levels of review.

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 Administrator 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 IRBs 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 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

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, the Provost’s or President’s Office approval may be required. For example, the use of campus email for research requires the approval of the Provost’s Office; requests to survey faculty requires the approval of the President’s Office, in consultation with Human Resources and UUP. Alumni are not to be recruited for research activities without prior written approval from Institutional Advancement. Investigators not affiliated with SUNY Cortland who would like to conduct research at the College or use college resources are to contact Dr. Virginia Levine, Executive Assistant to the President, President’s Office, Miller Building Room 408, telephone: (607) 753-2201, email: virginia.levine@cortland.edu.

Investigators are urged to contact the IRB Administrator, before an application is submitted, if they require the use of institutional resources. The IRB Administrator will identify the groups which 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

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/humansubjects/guidance/hsdc91-01.htm). 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

Several sets of policies and procedures provide guidance with regard to conflicts of interest that are related to IRB matters specifically and to College business in general (HHS, OHRP regulations 45 CFR §46.107 (e); OHRP Guidance Document (May 5, 2004); OHRP IRB Guidebook (1993); New York State Public Officers Law, Section 74, 3g; College Handbook sections 220.10 and 220.11). 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, Administrator, 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, Administrator, 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. Of the more than eleven federal laws, rules, and regulations that explicate conflict of interest, none recognize purported personality conflicts or personal reputation as a basis of conflict of interest. However, if an IRB member feels that his or her discussion or vote could be influenced by an investigator, that individual is to abstain. Finally, it is recognized that when the IRB Chair, Administrator, or member is under consideration for a personnel action (e.g., promotion), that individual should not participate in the review of a protocol when the investigator or co-investigator is a member of their department or sub-school personnel committee.

By definition, it is the responsibility of an IRB member to identify and report a conflict of interest to the Full Board, and the IRB member is to take actions that he/she find appropriate to remedy the conflict as prescribed by HHS regulations. The report of conflict of interest and the steps taken to remedy the conflict will be noted in the IRB Meeting Minutes.

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 IRB Administrator 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. The IRB Chair, IRB Administrator, and IRB members will never vote on any protocol or sign-off on a protocol, at any level of IRB review, where a conflict of interest is presented.
Part IV
IRB Records and Documentation
IRB Protocol Records

The IRB Administrator 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.

The minutes of IRB meetings document, among other things:

1. The meeting agenda;
2. Attendance (IRB members who are present or absent);
3. Dates materials were received, dates materials were distributed to the Full Board, and the locations where the materials are stored;
4. Guests present and details about the deliberations concerning each full review protocol, in order that the protocol is considered;
5. Documents four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent [CFR §46.116(c-d)]
   (a) The research involves no more than minimal risk to the subjects;
   (b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
   (c) The research could not practicably be carried out without the waiver or alteration; and
   (d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
6. When approving such a waiver for research reviewed by the convened IRB, these findings are documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.
7. Similarly, where HHS regulations require specific findings on the part of the IRB, those details are documented in the meeting minutes. 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].

8. For research reviewed under an expedited review procedure, the findings reported to the IRB are documented elsewhere in the IRB record (irb@cortland.edu).

9. Details about IRB recommendations and required modifications/revisions;

10. 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).

11. 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.
Part V
Organizational Structure, Charge and Duties of the IRB at SUNY Cortland
Statement of Institutional Principles

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. For reference, the U.S. Department of Health and Human Services (HHS) federal regulations (45 CFR 46) are available online, and can be downloaded and saved in PDF format.

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 Administrator is 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 Administrator 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 Administrator to speak with your department or research group about human subjects protections and the IRB application process, please contact us to schedule a meeting date. You can reach the IRB Administrator, Dr. Leslie Eaton (Associate Professor of Psychology) by email at irb@cortland.edu. The IRB Chair, Dr. Nancy Aumann (Associate Provost for Academic Affairs) can be reached by email at Nancy.Aumann@cortland.edu.

Human Research Protections Program Administration

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 as detailed in Module 2;
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;
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 at 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 HRPP;

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. In some cases, one institution may operate under an Assurance issued to another institution with the approval of HHS and the institution holding the Assurance.

IRB Administrator Responsibilities

The IRB Administrator at SUNY Cortland serves as the institution’s Human Protections Administrator, the primary contact for investigators and administration at SUNY Cortland, as well as the primary OHRP contact person. Administrative responsibilities fall into three general areas: IRB Communication and Education, Record Keeping and Reporting, and Monitoring and Oversight. Because of the IRB Administrator’s responsibilities, to avoid even the appearance of conflict of interest, this individual may not serve on any committee or group that provides funding to faculty, staff, or students to conduct research at SUNY Cortland.

Communication and Education Responsibilities

- Promoting communication among the research administrators, department heads, investigators, clinical care staff, human subjects, and institutional officials to maintain a high level of awareness regarding the ethical conduct of research and safeguarding the rights and welfare of subjects;

- Maintaining access to the institution's Assurance; copies of pertinent federal regulations, policies, and guidelines related to the involvement of human subjects in research and institutional policies and procedures;

- Educating the members of its research community in order to establish and maintain a culture of compliance with federal regulations and institutional policies relevant to the protection of human subjects.

Record Keeping and Reporting Responsibilities

- Ensuring that IRB records are being maintained per HHS regulations and that the records are accessible, upon request, to authorized HHS officials. For institutions relying on another IRB, records may be retained at the IRB site.

- Maintaining and updating the IRB Policies and Procedures Manual;

- Taking minutes at IRB Full Board meetings;

- Ensuring certification of IRB approval of proposed research to the appropriate HHS agency for HHS-conducted or supported research;
• Ensuring that changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval, except when necessary to eliminate apparent, immediate hazards to the subject;

• Ensuring prompt reporting to the IRB all proposed changes in a research activity;

• Ensuring the prompt reporting to the IRB, appropriate institutional officials, OHRP, and any sponsoring federal department or agency head of:
  o any unanticipated problems involving risks to subjects or others;
  o any serious or continuing noncompliance with the regulations or requirements of the IRB; and
  o any suspension or termination of IRB approval for research.

**Monitoring and Oversight Responsibilities**

• Ensuring that appropriate oversight mechanisms have been implemented to ensure compliance with the determinations of the IRB;

• Ensuring that all cooperating performance sites in HHS-conducted or supported research conducted primarily under the direction of the institution have appropriate OHRP-approved assurances and provide certifications of IRB approval to the appropriate federal authorities;

• Ensuring that cooperative IRB review arrangements are documented in writing, in accordance with OHRP guidance;

• Ensuring that all independent investigators that rely on the institution's IRB have documented, in accordance with OHRP guidance, their commitment to the institution's human subjects protections requirements and to the IRB's determinations.

**IRB Chair Responsibilities**

The IRB Chair coordinates the activities of the Full Board in consultation with the IRB Administrator. The IRB Chair prepares agendas for convened meetings of the IRB in consultation with the IRB Administrator. The IRB Chair ensures 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 sets the tone and directs the convened meetings of the IRB, providing ample opportunities for IRB members and investigators to actively and equally participate in the discussion of all protocols. The IRB Chair performs oversight and audits research reviewed by the IRB Administrator/IRB Chair, or two other experienced member of the Full Board IRB through the expedited review procedure. Because of the IRB Chair's responsibilities, to avoid even the appearance of conflict of interest, this individual should not serve on any committee or group that provides funding to faculty, staff, or students to conduct research at SUNY Cortland.

The IRB Chair along with the IRB Full Board ensures that expedited reviews comply with OHRP requirements, which include insuring that:

• All of the requirements for IRB approval of research apply to expedited review;

• Expedited review should not be viewed as a less rigorous review;

• Under expedited review, the reviewers may exercise all of the authorities of the IRB, except that the reviewers may not disapprove the research;

• Expedited review procedures are used for:
  o research appearing in the published list of eligible research, per HHS regulations, and found by the reviewer to involve no more than minimal risk;
The IRB Administrator and 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.

Institutional Review Board

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.

Institutional Review Board Responsibilities

Review by an IRB is the cornerstone of an institution's program for the protection of human subjects. IRBs are responsible for ensuring that the rights and welfare of the subjects are adequately protected.

- Although in most circumstances the SUNY Cortland IRB will review all research involving individuals affiliated with SUNY Cortland, in some cases the IRB will rely on the IRB of another institution to review the research. Examples include biomedical research that falls outside of the expertise of the SUNY Cortland IRB and research that involves SUNY Cortland only peripherally. When relying on another IRB, the SUNY Cortland IRB Administrator will verify the outside IRB's federalwide assurance and will ensure that the external IRB understands our local research context.

- To approve, require modifications, or disapprove all research activities covered by the HHS regulations. Duties include reviewing proposed changes in ongoing, previously approved human subjects research.

- IRB members shall be familiar with the requirements of the federal regulations, applicable state law, the institution's Assurance, and institutional policies and procedures for the protection of human subjects.

- IRB members shall have effective knowledge of subject populations and other factors that can foreseeably contribute to a determination of risks and benefits to subjects and subjects' informed consent.

- IRBs are to be able to judge the adequacy and accuracy of information in the informed consent document, advertising, and any other materials to be presented to subjects.

- For a IRB that regularly reviews research that involves a vulnerable category of subjects such as children, prisoners, pregnant women, or handicapped or disabled persons, membership should include one or more individuals who are knowledgeable about and experienced in working with these subjects.

- IRBs must have the professional competence necessary to review the specific research activities presented for approval.

- IRBs may, at their discretion, invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond, or in addition to, that available on the IRB.

IRB Responsibilities in the Institutional Context

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.

Since the conduct of research with human beings may raise fundamental ethical and civil rights questions, IRB members function with the highest level of professional and personal integrity. IRB review focuses only on the issues outlined by OHRP and 45 CFR §46.111. No distinction in level of review is made between researchers or
research conducted by faculty, staff, students, or other SUNY Cortland personnel. No distinction is made between funded and unfunded research (CFR §46.101). Focusing IRB review on OHRP guidelines ensures that all protocols will be treated fairly and equally, regardless of academic subject or researcher rank.

The responsibility for the protection of human subjects does not rest solely with the IRB. It is a shared responsibility between the Institutional Official, the IRB, and the investigator. Each has a crucial, yet distinct, role. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, institutional officials may not approve the research if it has not been approved by the IRB (CFR §46.112 & CFR §46.114).

Membership of the IRB
The College has established its IRB of eleven members, from diverse backgrounds, in accordance with the stated requirements of CFR §46.107. All of the members of the IRB have experience and knowledge concerning the local research context, including the ability to consider the race, gender, and cultural backgrounds of potential participants. The members of the IRB are sensitive to such issues as community attitudes and are able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

<table>
<thead>
<tr>
<th>SUNY Cortland Institutional Review Board Membership</th>
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<tbody>
<tr>
<td>Mark Prus, Provost and IRB Chair (scientist)</td>
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<tr>
<td>Charles Capanzano, NYS Licensed Psychologist (community member)</td>
</tr>
<tr>
<td>Christopher Carey, Physician Assistant, Student Health Services (biomedical; student services)</td>
</tr>
<tr>
<td>Margaret Anderson, Associate Professor of Psychology (scientist; research methodologist)</td>
</tr>
<tr>
<td>Andrew Fitz-Gibbon, Assistant Professor of Philosophy (non-scientist; ethicist)</td>
</tr>
<tr>
<td>Joseph Governali, Professor of Health (scientist)</td>
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<tr>
<td>Jenna Curtis, Associate Professor of Health (scientist; research methodologist)</td>
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<tr>
<td>Pam Schroder, IRB Administrative Assistant</td>
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<tr>
<td>Joy Hendrick, Professor of Kinesiology (scientist)</td>
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<tr>
<td>Peter McGinnis, Professor of Kinesiology and Assistant Director of Graduate Studies (scientist)</td>
</tr>
<tr>
<td>Joy Mosher, Associate Professor of Childhood and Early Childhood Education and Interim Director of Graduate Studies (scientist)</td>
</tr>
</tbody>
</table>

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 on a 12-month basis to
facilitate the review of time urgent matters. For any academic year, regularly scheduled monthly meetings begin in (September and end in July.) 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.

Training of IRB Members

The Institutional Official (Provost), the Human Protections Administrator (IRB Administrator and primary contact), and IRB Chair are required to complete OHRP’s Human Subjects Assurance Training Modules as identified by OHRP as appropriate to their roles. In addition, the IRB Administrator, IRB Chair, and all IRB Members must complete all modules of the CITI Course for the Protection of Human Subjects. All IRB members are to be familiar with SUNY Cortland Policies and Procedures and the local research context. All training is to be completed before reviewing protocols.

IRB Communication Policy

The Institutional Review Board uses a central email address to facilitate communication between investigators and the IRB. Investigators are to send all correspondence and questions to: irb@cortland.edu. All communication between an investigator and any member of the IRB, the Chair, or Administrative Assistant shall be documented and shared with the Full Board, in accordance with the federal regulations. OHRP requires that every IRB member has full access to all information to ensure that all IRB members can actively and equally participate in the discussion of all protocols.

Principles of Discussion and Decision Making

The IRB maintains its integrity through the diversity of its membership, equal access to information, and each member’s ability to function autonomously free from self-censorship, internal or external influences. Each IRB member functions as an independent reviewer, making individual decisions in accordance with the highest professional and academic principles, free from investigator, sponsor, department, personal, or administrative pressures. Each member of the IRB shall be fully informed; all communication between investigators and the IRB is to be delivered to the investigator and all IRB members in writing (CFR §46.109 (d)). Private, confidential, or undocumented communication between IRB members and investigators is prohibited; such communication is not in the spirit of the federal regulations (CFR §46.109 (d)) and undermine the integrity of the IRB’s decision-making process.

IRB review standards are established in the federal regulations (CFR §46.111) and are followed for the review of all protocols, regardless of the level of risk. During discussions, IRB members freely air objections and doubts without concerns about reprisal or exclusion. Each member is encouraged to discuss the IRB’s interpretations and policies with trusted professionals outside of the group to promote quality assurance. To facilitate open communication and accountability, investigators are invited to attend the IRB meeting at which their protocols are considered. IRB members are to raise questions and concerns with the investigator, permitting him/her time to answer questions and resolve issues. When an ethical or regulatory concern is raised, all effective alternatives are to be examined and communicated to the investigator.
Part VI

References, Index, and Acknowledgements
Regulatory Requirements Index

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

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. Framework for historical reference, particularly information concerning the local research context, was provided by Amy Henderson-Harr and Pamela Schroeder, Research and Sponsored Programs Office (RSPO), SUNY Cortland. We are grateful to RSPO for cooperation and ongoing support. This Policies and Procedures Manual was assembled using guidance documents provided by OHRP *(Guidance on Written IRB Procedures, January 15, 2007).* The SUNY Cortland IRB would like to extend our gratitude to the SUNY IRB Consortium, which lent their expertise and experience, shared their materials, and provided ongoing support. In particular, we would like to acknowledge the assistance received from Marti Benedict (IRB Administrator, SUNY Upstate Medical Center), Colleen Donaldson (IRB Administrator, SUNY Brockport), and Judy Matuk (AVP for Research Compliance, Stony Brook University), who reviewed and provided advice concerning previous versions of our policies and procedures.