



SUNY Oswego Human Subjects Committee (HSC) Policies and Procedures Manual

Ver. 2.11

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Introduction

Consistent with the mission of our comprehensive college, SUNY Oswego supports and fosters research in order to advance scientific knowledge, promote scholarship, and serve the interest of the public. The results of research, scholarship, and intellectual activities conducted at SUNY Oswego 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) for SUNY Oswego reviews the research proposal prior to data collection. SUNY Oswego refers to its IRB as the Human Subjects Committee (HSC). 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 by SUNY Oswego. The purpose of this manual is to provide the operational details of SUNY Oswego IRB process and outline its major functions. Questions, concerns, and suggestions, are to be directed to the HSC, by email at hsc-admin@oswego.edu.

The SUNY Oswego Institutional Official (IO) is William Bowers, Ph.D., Associate Provost for Research Compliance and Administration. SUNY Oswego's compliance officer for IRB is Marcus Durso, Research Committee Coordinator.

William Bowers, Ph.D., Associate Provost for Research Compliance and Administration, is the signing authority for SUNY Oswego. The Provost provides institutional, facilities, and material support required to maintain the official federal wide assurance (State University of New York at Oswego: FWA00001143) and the registration of the IRB (SUNY - Oswego IRB #1: IRB00001676).

Part I

Information for Investigators: IRB Review and Research Conducted at SUNY Oswego

IRB Procedural Overview

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

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

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

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities;

Human subject

A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Generalizable knowledge (contributing to) is when:

- conclusions are drawn from particular instances, and
- the information from the investigation is to be disseminated beyond the SUNY Oswego campus.

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

Minimal risk

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 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 <https://www.hhs.gov/ohrp/>). SUNY Oswego possesses a federal wide assurance, meaning that we have 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 Oswego appears in the table below.

IRB Procedures to be followed by all researchers at SUNY Oswego

Training	<ul style="list-style-type: none"> • Complete the appropriate CITI Program modules associated with the type of research that is being conducted. This training will assist with understanding The Belmont Report and becoming familiar with the definitions used by OHRP and all IRBs. 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). • Read this Policies and Procedures Manual.
Protocol Preparation	<ul style="list-style-type: none"> • Complete the protocol form that can be found on the HSC webpage. Be sure to include all requested information if it is pertinent to your project. Even if you feel as though your project may be considered exempt, a protocol form must be submitted and reviewed by the HSC. If your research is deemed to be exempt, you will be notified as such in writing. • Develop a proposed legally effective informed consent written at a level that the research population can comprehend; include assent when children are participants; include recruitment materials, advertisements, and letters to potential participants as all of these are viewed as part of the consent process. A sample of this form can be found on the HSC webpage. • Prepare all surveys and measures; include information about all tools, supplies, and equipment or apparatus used for the research activity. • 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. • Contact the HSC if you have any questions or need assistance developing your protocol (email: hsc-admin@oswego.edu)
Protocol Submission	<ul style="list-style-type: none"> • Submit the application and all supporting materials electronically through the Google Form located on the HSC webpage. This form is maintained by ORSP to ensure a secure submission for each protocol.

HSC Review	<ul style="list-style-type: none"> • Protocols confirmed as exempt and expedited are normally reviewed by the HSC Chair. • Protocols for which a full review is required are to be placed on the next available opening on the HSC agenda; copies of all materials are made available to the HSC members. • HSC meetings will be held monthly. • At all levels of review, the HSC notifies investigators of the outcome of the review and provides details regarding any revisions or clarifications required.
Investigator Responsibility	<p>If the HSC approves an application and if the project is undertaken, all investigators agree:</p> <ul style="list-style-type: none"> • The information provided in the application is accurate and complete. • All named individuals on the project have read and understand the procedures outlined in the protocol. • All named individuals on the project, paid assistants, and any other students working on the project have completed the appropriate CITI Course based on the project. The lead investigator assures that all individuals working on the project understand the principles of the aforementioned documents as well as SUNY Oswego's policies and procedures; associated with • All recruitment, experiments, and procedures involving human subjects will be performed under the lead investigator's supervision or that of another qualified professional listed on the protocol; • The lead researcher will submit to the HSC any and all modifications and/or changes to the approved protocol and will promptly provide the HSC with any future information requested. All research personnel agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following: <ul style="list-style-type: none"> - Providing legally effective informed consent to all human subjects or their legally authorized representatives; assent will be provided to minors; - Documenting the legally effective informed consent/assent (unless documentation of consent is waived by the HSC. • Assuring the appropriate administration and/or documentation of federally mandated forms other than informed consent such as Health Insurance Portability and Accountability Act (HIPPA) forms or Material Safety Data Sheets (MSDS). • Refraining from any advertisement, recruitment, or data collection until all requests for information or documents are satisfied and HSC approval has been obtained; • Promptly and completely complying with an HSC decision to suspend data collection or withdraw its approval for the project; • Obtaining continuing review through a re-submission of the protocol prior to the date of protocol expiration (1 year). The exemption to this policy is research that was approved through expedited or limited IRB review. Notify the HSC of any substantive changes to the documents or procedures before they are implemented (referred to as "modifications to existing research").

Incident Reports	Immediately upon discovery, report to the HSC (hsc-admin@oswego.edu), a detailed description of any undesirable events or incidents that may have negatively affected a research participant or others. A report should be made whether these events or incidents are directly or indirectly related to participation in research. This could include any new information coming to light that changes the level of risk, any adverse event, unanticipated problems, or harm to participants (causing physical, psychological, economic, or social loss).
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Requirements for Program Evaluation

Program evaluation (or quality improvement activities as it is termed by OHRP), as a rule, do not constitute human subjects research and does not require HSC review. The requirement for IRB review lies within intent. If the researcher's intent is to gather assessment data to improve practice, the evaluation does not require HSC approval. However, if the researcher intends to gather assessment data to improve practice and contribute to *generalizable* knowledge through publication or presentation, the evaluation falls within and under the jurisdiction of the IRB.

Routine Program Evaluation

Most simply defined, program evaluation is *research that is conducted in order to determine the effectiveness of a program*. Program evaluation is for internal use only. Collecting and reporting data required by SUNY or participation in federal assessment initiatives, as most activities conducted by the office of Institutional Research and Assessment do not require IRB review. The data is collected by SUNY, funded by SUNY, and is intended only to inform SUNY and local administration, faculty, and staff who manage and deliver the programs. Nonetheless, by SUNY policy, when program evaluations do not require IRB review, procedures should conform to human subject's rules and regulations (federal, state, and local) in particular informed consent, voluntary participation, and right to withdraw with information maintained as confidential.

Human Participant Training Requirements at SUNY Oswego

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

Investigators, co-investigators, undergraduate/graduate training requirements

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

Training Required for Administrators and HSC Members

HSC members are required to complete the CITI "IRB Members" course. In addition, HSC members should complete all optional modules before reviewing protocols in those areas. The HSC Chair, IO and primary reviewers are also required to complete [OHRP Assurance Training](#) Modules 1 through 3.

Preparation of HSC Protocols

Levels of IRB Review

Research projects are reviewed at one of four levels, depending upon the investigator(s) and HSC's understanding of the target population to be sampled, the risk to participants posed by the recruitment, procedures, data retention, and dissemination plans; and the federal guidelines that define the categories of HSC 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 HSC 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 are in place to protect the rights and welfare of these participants. The categories for review are summarized below:

Category I – Exempt Review

The HSC has adopted the Department of Health and Human Services (HHS) procedure for identifying exemptions. 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. All of the examples of exempt research can be found in the [Code of Federal Regulations \(CFR\) 46.104](#).

Even if a researcher feels as though their research is exempt, a protocol must be submitted and a letter of exemption from the HSC will be provided, if said research is deemed exempt.

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 accordance with HHS regulations [CFR 46.110](#).

Under the expedited review procedures, the review may be carried out by the HSC chairperson and/or a designated HSC reviewer. In assessing the research, the reviewers may exercise all of the authorities of the HSC except that the reviewers may not disapprove the research. Disapproved research may only occur at convened meetings of the HSC with a quorum present, including at least one member whose primary concerns are in non-scientific areas. Investigators are notified in writing and provided an opportunity to respond in writing should their protocol be disapproved.

Category III – Limited IRB Review

Limited IRB review is a process that is required only for certain exemptions, and does not require an IRB to consider all of the IRB approval criteria in [CFR 46.111](#). In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced HSC member designated by the Chair (although it can also be conducted by the full HSC). Continuing review is not required.

Category IV – Full Review

Any research that does not fit Categories 1-3 will be submitted to the HSC for full review. Additionally, any feature of a research project could prompt a full review; these include recruitment, sampling, participant characteristics, method/procedure, measures, storage plan, or dissemination. Examples of full review research includes:

1. Research which may put research participants at risk *greater than minimal risk*;
2. Research involving psychological or physiological intervention or non-curricular, interactive research;

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

HSC Applications, Appendices, and Other Required Documents

The HSC protocol review form is available online at www.oswego.edu/human-subjects-committee. HHS regulations ([CFR 46.111](#)) sets forth the criteria for the HSC to approve research.

The investigator is responsible for providing to the HSC 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
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 review form and legally effective informed consent (assent). Other materials may be required, when applicable to the research. For example, research falling under the National Institutes of Health (NIH) requires investigators to submit a complete copy of their grant proposal in addition to IRB protocol forms for the institution so that HSC members can cross reference research procedures outlined in the NIH proposal with SUNY Oswego's HSC forms and policies.

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

Legally effective informed consent

HSC review requires that HSC members focus on the research, from the perspective of the participant. Legally effective informed consent is one of the central protections provided to human research participants under the HHS regulations ([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”. 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 specific elements that will be provided to each subject in a written form.

The consent form may be either of the following:

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

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

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

Requests for a waiver of informed consent should be adequately justified in the HSC application, in accordance with the requirements of [CFR 46.116](#) or [CFR 46.117](#). For assistance requesting a waiver, contact the HSC. In cases in which the documentation requirement is waived, the HSC may require the investigator to provide subjects with a written statement regarding the research.

The consent form and any other information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any 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 recruitment materials and consent documents, unless this requirement is waived by the HSC.

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

Informed consent is **not** a single document that researchers ask participants to sign. Informed consent is best described as an active, ongoing process of sharing information between the investigator and the prospective subject. The exchange of information between the investigator and prospective subject(s) can occur via any type of communication medium. The informed consent process should ensure that all

critical information about a study is completely disclosed, and that prospective subjects or their legally authorized representatives adequately understand the provisions of consent and the research procedures so that they can make informed choices.

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

Research Involving Children: Parental Consent and Child Assent

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

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

By regulatory definition, children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" ([45 CFR 46.402\(a\)](#)). In the United States, the legal age of adulthood is a matter of state and local law; in a large majority of states, as in New York, 18 years of age is the legal age of adulthood, but this is not true in every state, locality, or territory. Multisite research and international research must respect the laws applicable to the site where the data is collected. State law also may address specific circumstances in which a person younger than the age of adulthood is legally authorized to consent to medical procedures: for example, some states allow children younger than the legal age of adulthood to consent to the provision of contraceptive services. Certain states provide a mechanism for the emancipation of minors through which a child younger than the legal age of adulthood may gain certain civil rights, which might include the legal ability to consent to research participation.

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

Institutional Permissions

HSC approval should not be confused with other institutional approvals required for the use of college facilities or resources. Investigators seeking the use of campus facilities or resources (e.g. access to institutional lists serves for recruitment, datasets, or the administration of institutional surveys), requires the prior approval of the authorizing official responsible for the activity. Questions about who should be contacted for prior approvals can be submitted to the HSC Chair for investigator assistance. Research

conducted at a site other than SUNY Oswego, also requires prior approval from the authorizing official of that site(s) to assure adequate protections and communications about the research.

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 principal investigator and all co-investigators, and the department chair or immediate supervisor, have signed Appendix A – Investigator Assurance (signature page); and,
3. the HSC 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 application materials should be submitted through Google Forms. Correspondence at all levels of review are to be addressed to hsc-admin@oswego.edu.

Summary of HSC Review Process

Once a protocol is submitted, the HSC Chair conducts an in-depth examination of all information and documents. Specifically, the HSC Chair confirms the classification of the research (exempt, expedited, limited, full review) and ensures that the HSC has enough information in sufficient detail to meet HHS regulations at [CFR 46.111](#). Next, HSC Chair also examines the proposed consent/assent document(s), and is available (upon request) to assist the researcher in making changes until each form (consent or assent) is legally effective. Should the HSC Chair find that revisions are required or further documentation is needed, he/she will contact the lead investigator with details concerning the request. All additional documents or information is to be sent to hsc-admin@oswego.edu. HSC review is suspended until the requests have been satisfied by the investigator. By having the HSC Chair review these documents, in no way, implies that the protocol will be approved upon official review.

Once a protocol file is complete, the action the HSC Chair takes depends upon the level of review. Exempt, expedited and limited review protocols are reviewed by the HSC chair or a chair-designated primary reviewer. All other protocols are reviewed by the HSC (with quorum) at its next scheduled meeting to allow the HSC time for questioning or clarifications concerning the protocol. Full review applications are placed on the agenda for the next available committee meeting. After the protocol review, the HSC Chair will notify the investigator of the actions taken by the HSC.

Timing of Reviews

All protocols should be submitted at least two (2) weeks in advance of the next scheduled HSC meeting. The dates for these meetings can be found on the [HSC website](#). The full board meets monthly. In many cases, protocols that are exempt or fall under expedited or limited review, will be reviewed within two weeks.

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 HSC-approved protocol and complying with all HSC determinations.
4. Investigators are to obtain and document the informed consent of each subject or each subject's legally authorized representative, unless the HSC 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.
5. Ensuring that each potential subject understands the nature of the research and participation.
6. Providing a copy of the HSC-approved informed consent document to each subject or the subject's legally authorized representative at the time of consent, unless the HSC has specifically waived this requirement. All signed consent documents are to be retained for at least 3 years after the completion of the research ([CFR 46.115](#)).
7. Promptly reporting proposed changes in previously approved human subject research activities to the HSC (at hsc-admin@oswego.edu). The proposed changes may not be initiated without prior HSC review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. To ensure review, proposed changes are to be submitted at least two (2) weeks in advance of planned execution for review.
8. Reporting progress of approved research to the HSC as often as, and in the manner, prescribed by the HSC.
9. Report to the HSC (hsc-admin@oswego.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 HSC (hsc-admin@oswego.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 HSC.
11. If a physician affiliated with SUNY Oswego engages in human subject resuscitation, that physician may provide emergency medical care to a patient without prior HSC 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 HSC to ensure that activities that meet the regulatory definition of non-exempt human subject research undergo HSC review and approval prior to the initiation of the activities.
12. Unless specifically authorized by the HSC, no investigator may involve a human being as a subject in research covered by the HHS regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Submission of Protocol Changes (Modifications)

Substantive changes to a research project must be submitted to the HSC as a *modification request*. Investigators are not permitted to implement protocol changes without prior HSC review and approval, except when necessary to eliminate apparent immediate hazards to subjects. The HSC must be given sufficient time to review and make determinations concerning protocol changes (two weeks). Investigators are asked to revise the original application and/or supporting documents. After HSC approval, each revision to a research protocol is to be sent to the HSC by email ([hsc-](#)

admin@oswego.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. Any approved revisions do not extend the expiration date for the original protocol.

Review of Exempt, Limited and Expedited Protocol Changes

Proposed changes to exempt, expedited and limited review protocols that do not increase risk or decrease benefits will be reviewed using exempt, expedited or limited 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 modification.

Requirement for Review of Proposed Protocol Changes by the Full Board HSC

In accordance with HHS regulations [CFR 46.108\(b\)](#), review of proposed protocol changes that are not exempt, expedited or limited, must be conducted by the HSC at Full Board meetings at which a majority of the members of the HSC 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 HSC at the next meeting [45 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 Oswego 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 HSC Chair makes the determination if a protocol change can be reviewed at the expedited level. The HSC Chair can seek consultation from the IRB Administrator or another experienced HSC member. The HSC Chair 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 as well.

Requests to Continue Research

SUNY Oswego is obligated to conduct continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year, and has the authority to observe or ask a third party to observe the consent process and the research [\[45 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 HSC (one year), HSC 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 HSC approval. The information must be received by the HSC with sufficient time to review the request, because if the HSC has not reviewed and approved a research study by the continuing review date specified by the HSC, the research must stop.

If data collection is completed and investigators are only analyzing unidentifiable data, requesting a continuation from the HSC 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 procedure or document (e.g., consent form, measures, surveys, MOUs) changes associated with the research project, exempt research does not require continuation requests; the SUNY Oswego HSC only requests annual email notification (to: hsc-admin@oswego.edu) indicating that the research continues. The purpose of the continuation notification, at the exempt level, is to alert the HSC that the records of the original HSC approval must remain available. Unlimited continuations can be registered for exempt research under federal and SUNY Oswego HSC guidelines.

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

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

Information required for continuing review, expedited and full review

Email requests for continuing review are to be sent to hsc-admin@oswego.edu. Investigators are to include information identified by OHRP as important to continuing review, which includes:

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

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

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

Part II

Special Topics of Interest

Internet Data Collection

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

The CITI training program (Social & Behavioral Research) 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 HSC suggests that investigators using the internet for research complete this optional CITI Training module.

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

Reimbursement and Remuneration

The SUNY Oswego HSC has adopted the policies concerning reimbursement and remuneration for research participation.

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

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

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

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

prevailing payment practices within SUNY Oswego and the general locale.

The NIH Department of Bioethics has written extensively on this topic and has offered various formulas for computing participant payment (for more information, visit <http://www.bioethics.nih.gov/research/recruit.shtml>).

Volunteers are often compensated for their participation according to an established fee schedule, based upon the complexity of the study, the type and number of procedures to be performed, the time involved, and the anticipated discomfort or inconvenience. Although society generally accepts the premise that those assuming risk deserve reward, the application of this rule in establishing payment for subjects in biomedical and behavioral experiments is still being debated. Although the researchers at NIH tend to write to a biomedical/clinical audience, their ethical principles are easily adapted for social-behavioral research.

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

When participation entails minimal time and effort, SUNY Oswego researchers have given Oswego pencils or stickers to children, provided in-service instruction to teachers or a free lecture to the community, and framed certificates of appreciation to school administrators or others who have granted permission to use facilities.

Introductory Psychology professors offer extra credit, on an hourly basis, to students who wish to participate in psychology experiments. For more complex studies and those that are funded, researchers have offered cash payment (minimum wage is often used as a guide for hourly rates of remuneration for minimal risk studies).

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

The type of remuneration (monetary versus non-monetary) is less important than its appropriateness and the need to disclose the terms and conditions of remuneration in all advertisements and the informed consent document. If a researcher proposes to provide remuneration, the SUNY Oswego HSC will review the study, in the attempt to ensure that all advertisements and the consent document contain a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (for example, what will happen if they withdraw part way through the research). Advertisements and other recruitment materials should not read like an advertisement for a commercial product and should not emphasize participant payment. The advertisement should simply state, "Volunteers will be asked to participate in three sessions, and will be receive \$10.00 payment at each session." Note that the researcher must, be prepared to pay all participants who appear for the session, even if they do not complete the session (participants' right to withdraw without penalty).

The HSC 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 HSC ought to apply to the review of research in which volunteers are asked to assume significant risk?
4. Should the HSC monitor subject recruitment to determine whether coercion or undue influence is a problem?

International Research

International research can be time consuming, and in areas of Europe, a separate compliance topic of General Data Protection Regulation (GDPR) must be considered. The HSC process should begin early and involve the HSC before a protocol is written. Researchers who plan to conduct research in another country should complete the optional international research CITI Course modules before proceeding (see [45 CFR 46.101\(h\)](#) and [International Issues](#)). When conducting international research, a separate HSC protocol **must** be submitted even if approval has been granted by the international institution. The only case in which HSC can accept an international IRB approval is if the institution is accredited through the Office of Human Research Protections and has a Federal Wide Assurance number.

Guidance for SUNY Oswego Student Participation in 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 subject research, HSC review is required. For courses requiring or allowing students to volunteer in human subjects research projects for credit or extra credit (studies under the purview of the HSC), SUNY Oswego's HSC requires the following protective steps:

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

The Office of Institutional Research and the Division of Academic Affairs are responsible for all research activities that do not fall under the authority of the HSC. In this regard, SUNY Oswego's primary concerns are the safety and welfare of students and the security of the information they provide.

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

In typical research studies, participants have the right to refuse to participate or to withdraw from the study without penalty. However, the practice of this right becomes complicated when considering research conducted for the purpose of class demonstration/education. OHRP's recommendation of alternative assignments is an excellent reference to help guide instructors when the classroom

research/demonstration activity is not human subjects research. In any case, the course syllabus should contain a clear statement about whether participation in the classroom research is voluntary and/or how the participation is related to the goals/objectives of the course and how it might influence the final grade. The instructor should be mindful of the types of situations that may occur if the student is uncomfortable with participating and should be prepared with an alternative assignment.

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

Research Conducted by Non-SUNY Oswego Investigators

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

Part III

Operational Details of the SUNY Oswego Human Subjects Committee (HSC)

HSC Operational Details

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

When a protocol is submitted, the HSC Chair conducts an in-depth review, verifying that sufficient documentation has been received to meet requirements for review ([CFR 46.111](#)), determining that the information justifies an exemption, expedited or Full Board review. The IRB Chair 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 HSC Chair conducts a primary review. At exempt and expedited levels, the HSC Chair performs initial review, continuing review, and review of protocol changes.

Full review protocols are submitted to the HSC, with the HSC Chair providing initial review before the Full Board convenes. The purpose of the HSC Chair review is to determine that all materials have been submitted in the correct form. The Chair can name a primary or secondary reviewer to lead the discussion on certain protocols that align with a particular member's expertise. The IRB Administrator forwards a copy of the complete protocol and supplementary materials electronically to each member.

Expedited Review Procedure

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

Review of Research by the HSC at Full Board Meetings

In accordance with HHS regulations at [45 CFR §46.108\(b\)](#), initial and continuing reviews of level III research must be conducted by the HSC at convened meetings at which a majority of the members of the HSC 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. 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 non-scientist member), the HSC may not take further actions or votes unless the quorum can be restored.

Expedited and full review research is reconsidered by the HSC 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 Oswego.

Documents Distributed to the Full Board HSC

OHRP guidelines indicate that continuing review of research must be substantive and meaningful for the institution and remain in compliance with the Federal Wide Assurance. 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 HSC a minimum of five working days prior to HSC Full Board meetings. The SUNY Oswego HSC uses a secure Google 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 HSC meeting minutes are stored in this location for review by the Full Board. HSC 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 Oswego HSC members have been carefully chosen to represent the anticipated scope of research activities conducted at SUNY Oswego, 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 Oswego, the primary area of expertise of the HSC lies mostly in the area of social and behavioral sciences. The volume, scope, and complexity of research activities at SUNY Oswego are adequately managed by the current administrative structure and composition of the HSC. Consequently, the SUNY Oswego HSC 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 HSC Full Board. In the event this should occur, most likely in the case when a biomedical protocol has been submitted, IRB colleagues at other SUNY Colleges/Universities could be assembled to serve as a subcommittee for that protocol. These individuals would be approached for the initial review of the protocol and/or serve as consultants to the current Full Board IRB. The same approach would be used to develop a pool of consultants appropriate to conduct continuing review, review of protocol changes, reports of unanticipated problems, or cases of serious or continuing noncompliance.

Procedures for Continuation Requests

Expiration of HSC Approval

For nearly all protocols submitted at SUNY Oswego, research may begin on the date of HSC 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 HSC may determine that a protocol requires review more often than annually. The HSC 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 HSC determines that more frequent review is necessary at the time of initial approval, at each continuation review the investigator can ask the HSC to revisit the timetable for continuing review, in the event that no problems or issues of noncompliance have occurred.

Continuing Review and Audit of Approved Research

The HSC must receive a continuation request before the expiration date of a previously approved HSC protocol. The HSC is permitted to accept continuation notification indefinitely for exempt research, provided that there have been no substantive changes to the protocol (recruitment, procedures, measures, consent, purpose, risk-benefits, and so on). Expedited continuation requests can be submitted, for two years after the initial protocol expiration. For expedited and Full Board continuations, researchers must submit a continuation request in accordance with the directions on the HSC website. 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.

Similar regulations for expedited continuation apply to full review research. When continuing reviews

are conducted at the full review level, the HSC Chair 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 HSC to date, and the minutes from the meetings when the protocol was previously reviewed. HSC members have access to the complete protocol file and relevant HSC meeting minutes prior to the convened HSC meeting through the HSC Google Drive.

The HSC determines which projects need verification from sources other than the investigators to ensure that no material changes have occurred since previous HSC 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; and (d) projects where concern about possible material changes occurring without HSC approval have been raised based upon information provided in continuing review reports or from other sources.

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

Range of Possible Actions Taken by the HSC

The HSC Chair and/or designated experienced members of the HSC can approve 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

Investigators are prohibited from advertising, recruiting, or collecting any information from prospective subjects or volunteers until HSC 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.

Avoiding Deferred Reviews

SUNY Oswego's Full Board HSC 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 HSC Chair or primary reviewer to answer questions and make appropriate modifications.

When an investigator chooses to attend meetings with the HSC, 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.

Disapproval of Protocols

On occasion, the Full Board HSC will disapprove a protocol. This action is taken only when the HSC

determines the protocol cannot be altered or modified to meet federal, state, and local guidelines for human subject research. Under federal guidelines, there is no appeal process. Institutional officials (President, Provost, Deans, Department Chairs) may not approve the research if it has been disapproved by the IRB ([CFR 46.112](#)).

Procedures for Communicating Actions Taken by the HSC

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 HSC 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: Research Committee Coordinator
 Office of Research and Sponsored Programs
 225 Hewitt Union
 Oswego NY, 13126

EMAIL: hsc-admin@oswego.edu

Communication with Campus Administration

The HSC Chair incorporates an overall review of HSC activity within their Annual Report at the end of each academic year. This report is submitted to the IO. Included is summary information about HSC activities.

When there is a report of an unanticipated problem or of harm to any participant, or when there is a report of a circumstance that raises risk to unacceptable levels (those exceeding the tolerance of the local research context), the issue is discussed by the Full Board at their next regularly scheduled meeting. If the circumstance is time urgent, the HSC Chair will call an emergency meeting of the Full Board. In all cases, regardless of the findings, the HSC Chair will prepare an incident report that is submitted as soon as possible to the Office of Research and Sponsored Programs. This report includes a summary of the circumstance, the HSC's discussion and findings, and the HSC's suggested actions to remedy. In such cases, HSC actions could range from recommendation of additional training and auditing research records on a frequent basis (appropriate to the rate of data collection) to suspending or stopping the research. The Office of Research and Sponsored Programs may take further action, consistent with union agreements, human resource policies and procedures, and external funding agencies. 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 Office of Research and Sponsored Programs, in consultation with the HSC Chair and Full Board, reports to OHRP unanticipated problems, any serious or continuing noncompliance with 45 CFR Part 46, and any suspension or termination of IRB approval. The Office of Research and Sponsored Programs will comply with OHRP timelines for reporting, upon completion of an independent investigation into the allegations.

Offices Responsible for Further Institutional Review

HSC review is limited to issues relevant to human subjects' ethics (applications of respect for persons, beneficence, and justice). HSC approval indicates that the research plan appears to be within the ethical boundaries of federal, state, and local human participant regulations. HSC 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 ([45 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 HSC 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, additional approvals may be required. Investigators are urged to contact the HSC Chair, before an application is submitted, if they require the use of institutional resources. The HSC Chair will help to identify the groups that should review the research in addition to the HSC. However, institutional approval cannot substitute for HSC 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 HSC.

HSC 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 [[CFR 46.103\(b\)](#)]. 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

HSC personnel are trained to be sensitive to conflict of interest, as it is defined by federal regulations and NY State law. When the HSC Chair, primary reviewers, or member has a protocol under consideration, that individual will not participate in any HSC activities concerning that project whatsoever; rather, that individual will act only in the role of an investigator, providing information as requested by the HSC 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 HSC Chair, primary reviewers, or member is a co-investigator or consultant on a study under consideration; when she/he are an individual or member of any group that will be advanced by or otherwise benefit financially from the study being approved; or when she/he are a member of a group funding any portion of the study. Actions to remedy conflict of interest are prescribed by HHS regulations 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." OHRP suggests that IRB members with a conflict of interest, when possible, choose to be absent for discussion and votes on full review protocols. If the HSC Chair or primary review is in direct conflict of this proposal that is being reviewed, that individual will recuse themselves from the meeting entirely. If an HSC Chair has been recused from the meeting, an ad hoc chair will be named and will carry out the duties of the chair for that discussion of that protocol.

Part IV

HSC Records and Documentation

HSC Protocol Records

The Research Committee Coordinator prepares and maintains documentation of research activities as stipulated by HHS regulations at [CFR 46.115](#), 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;
2. Records of continuing review activities;
3. Copies of all correspondence between the HSC and the investigators; and,
4. Statements of significant new findings provided to subjects, when required.

These records and documents are stored in the HSC Google Drive, housed on a password-protected SUNY Oswego 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 HSC. Access will be granted, upon request, to other authorized representatives at SUNY Oswego (e.g., Provost, President) for copying and/or inspection. All materials related to a protocol, including notes from meetings with investigators, are to be documented in writing and stored electronically in the HSC Drive.

Minutes of HSC Meetings

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

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

1. For research approved by the convened HSC, all required findings are fully documented in the minutes of the HSC meeting, including *protocol-specific* information justifying each HSC finding. These circumstances include:
 - (a) approving a procedure which waives the requirement for obtaining a signed consent form [\[CFR 46.117\]](#);
 - (b) approving research involving pregnant women, human fetuses, or neonates [\[CFR 46.204-207\]](#);
 - (c) approving research involving prisoners [\[CFR 46.301-306\]](#); or
 - (d) approving research involving children [\[CFR 46.401-409\]](#).
2. Research that was reviewed under an expedited review procedure,
3. Details about HSC recommendations and required modifications/revisions;
4. Rationale for requiring continuing review more often than annually, as appropriate to the degree of risk [\[CFR 46.109\(e\)\]](#). The minutes of IRB meetings will clearly reflect these determinations regarding risk and approval period.

5. The vote on all IRB actions including the number of members voting for, against, and abstaining. Following OHRP format, votes are recorded in the minutes using the following format: Total = 15; Vote: For - 14, Opposed - 0, Abstained - 1.

HSC Records

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

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings that are in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of raised issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members in the same detail as described in [CFR 46.107](#)
6. Statements of significant new findings provided to subjects, as required by [CFR 46.116\(b\)\(5\)](#).

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

Part V

Organizational Structure, Charge and Duties of the IRB at SUNY Oswego

Statement of Institutional Principles

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

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

The institution encourages and promotes constructive communication among the research administrators, department heads, research investigators, HSC, 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 HSC members are available, upon request, to assist investigators with applications and preparing for full review. The results of Full Board meetings are communicated to the lead investigator by the IRB Chair within three working days of the meeting.

The SUNY Oswego HSC is committed to ensuring a culture of compliance at SUNY Oswego, by working with individual investigators, conducting outreach, training, and educational opportunities. If you would like the HSC to speak with your department or research group about human subject protections and the HSC application process, please call to schedule a meeting date. You can reach the HSC at 315-312-2885 or at hsc-admin@oswego.edu.

Human Research Protections Program Administration

Institutional Official (IO) Responsibilities

The Institutional Official (Associate Provost for Research Development and Administration) is the individual authorized to act for the institution. On behalf of the institution, the IO obligates the institution to the Terms of the Federal Wide Assurance.

Administratively, the IO is responsible for:

1. Designating members of an IRB that will review research covered by the institution's FWA.
2. Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties.
3. Providing training and educational opportunities for the IRB and investigators.

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

IRB Compliance Officer Responsibilities

The IRB Compliance Officer at SUNY Oswego is the Research Committee Coordinator, and serves as the institution's primary OHRP contact. Administrative responsibilities fall into three general areas: IRB oversight as designated by the Institutional Official, communication and supporting education, record keeping and reporting. The Research Compliance Officer may also serve as a primary or secondary reviewer, having authority to review and approve exempt and expedited protocols.

HSC Chair Responsibilities

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

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 [CFR 46.108](#) - [CFR 46.115](#). The IRB at SUNY Oswego is referred to as the Human Subjects Committee (HSC).

The HSC has the authority to approve, require modifications (to secure approval), or disapprove all human subject research activities at SUNY Oswego. The goal of the HSC is not only to guarantee

compliance with existing laws and regulations but also to assist campus researchers in the planning and implementation of their projects.

Membership and Appointment to the HSC

Appointments to the HSC are made in accordance with the federal requirements ([CFR 46.107](#)). In addition to possessing the professional competence necessary to review specific research activities, the HSC shall be able to establish 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 HSC shall therefore include persons knowledgeable in these areas and meet the specific criteria set forth by OHRP for membership and reviewing protocols involving protected classes (children, prisoners, pregnant women, or handicapped or mentally disabled persons).

The Associate Provost for Research Development and Administration shall make appointments to the HSC for three-year terms that begin at the start of the academic year. All HSC personnel are asked to be available for consultation or meetings throughout the year to facilitate the review of time urgent matters. Due to the extensive time commitment, training requirements, and qualifications of HSC personnel, all HSC appointments are renewable.

HSC Membership Lists, Qualifications, and Affiliations

The names, qualifications, and affiliations of the members of the HSC 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 membership are reported to OHRP as appropriate.

Part VI

References, Index, and Acknowledgements

Regulatory Requirements Index

HHS regulations require that institutions have written IRB (HSC) 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 Summer 2019.

The foundation for this document of policies and procedures is a similar document graciously provided by the Institutional Review Board of SUNY Cortland.

The policies referenced in this document can be found through each of the links provided or at:

<https://www.hhs.gov/ohrp>