

**State University of New York
Potsdam
Policy on the Use of Human Subjects in Research**

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STATE UNIVERSITY OF NEW YORK

POTSDAM

POLICY ON THE USE OF HUMAN SUBJECTS IN RESEARCH

The State University of New York at Potsdam has established the Institutional Review Board (IRB) to develop and implement procedures for the protection of human subjects in research. In order to protect the rights, well-being and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of SUNY Potsdam and its faculty, staff, students and other persons acting under its auspices, the policies and procedures described below have been established for the conduct of research involving human subjects.

PART I: STATEMENT OF PRINCIPLES

The State University of New York at Potsdam acknowledges and accepts its responsibility for protecting the rights and welfare of human subjects of research. Since the conduct of research with human beings may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and non-funded projects, or between projects carried out by students, faculty, staff, agents, or affiliate researchers (on-campus or off-campus). SUNY Potsdam is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, (The "Belmont Report"). SUNY Potsdam complies with Federal laws requiring the protection of human research subjects. **Notations occurring in the State University of New York at Potsdam Policy on the Use of Human Subjects in Research are taken from Title 45, Code of Federal Regulations, Part 46 (45 CFR 46) unless otherwise indicated.**

The IRB will ensure that all human subject research, regardless of funding source, for which the IRB provides review and oversight, complies with 45 CFR 46 and all of its subparts (A, B, C, and D). All Federally supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All Federally supported human subject research will comply with any human subject regulations and policies of any relevant regulatory Department or Agency. The State University of New York at Potsdam will not conduct FDA regulated research.

The following principles apply equally to all research involving human beings, whether carried out with university resources or with the assistance of outside funds. SUNY Potsdam assumes responsibility for communicating and explaining these principles to faculty, personnel and students and for providing procedural guidelines to effectuate them. All faculty members, staff, students, agents and affiliate researchers who anticipate conducting research projects (on or off campus) involving human subjects are responsible for familiarizing themselves and complying with the guidelines.

- A. The State University of New York at Potsdam and the individual members of its faculty, staff and student body acknowledge and accept their responsibilities for protecting the rights and welfare of human subjects of research. This policy covers ALL research involving human subjects conducted under the auspices of SUNY Potsdam or to be used by current faculty or staff in any professional activity or publication in which the individual claims an affiliation with the institution. This policy includes both individual and institutional research conducted on or off campus whether externally funded or not.
- B. SUNY Potsdam becomes engaged in human subject research whenever (a) the institution's employees or agents intervene or interact with living individuals for purposes of research; (b) the institution's employees or agents obtain, release or access individually identifiable private information for purposes of research; or (c) the institution receives a direct Federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.
 1. Research is defined as a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this

definition constitute "research" for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

2. For the purpose of this policy, data collection procedures that are part of a program or service evaluation and are intended SOLELY for the purpose of monitoring or improving the effectiveness or quality of the program or service being evaluated and NOT for the purpose of contributing to generalizable knowledge about such programs or services are not research and, therefore, are not subject to the requirements of this policy, as long as the collection of data poses no more than minimal risk to participants and it does not involve vulnerable subjects. Minimal risk will be defined here in keeping with campus IRB regulations (See Part IV of this policy). For example, a survey that gathers confidential information, sensitive personal matters or illegal behavior involves more than minimal risk and would require IRB approval. In addition, a project collecting data to be reported to SUNY System Administration or accrediting or regulatory bodies is subject to IRB review if that data will then be used outside of the SUNY System or accrediting or regulatory process.
 - i. For example, some data collection activities conducted by the institution are NOT defined as research and are, therefore, not subject to the requirements outlined in this policy as long as they pose no more than minimal risk to participants. These "institutional research" activities include the following
 1. Collecting data regarding student perceptions of, satisfaction with or suggestions for improvement of instruction and services they receive from SUNY Potsdam, provided that the data collected will be used solely for evaluating, improving or reporting to campus departments, SUNY System Administration, or accrediting or regulatory bodies, about the quality of the instruction or services.
 2. Collecting data about student interest in programs or services that SUNY Potsdam might offer, unless the data collected will be used for anything other than planning for, developing or reporting to SUNY System Administrations, or accrediting or regulatory bodies about such programs or services.
 3. Collecting data from students about other issues, if the data will be used for the sole purpose of evaluating, improving, planning for, developing or reporting to SUNY System Administration or accrediting or regulatory bodies regarding programs, courses, or services for students.
 4. Gathering information from faculty or staff members, alumni, or other college constituents for the purposes of ascertaining satisfaction with policies or procedures, needs assessment or other program review, unless the data collected will be used for anything other than evaluating or improving policies, procedures or programs or reporting to campus departments, SUNY System Administration or accrediting or regulatory bodies.
 - ii. To be excluded from the requirements of this policy, data collection must be approved as meeting the definition of "institutional research" described in this policy (Section I.B.2.i) by the IRB Chair in consultation with the appropriate department head. For the purpose of this policy, designated department heads include:
 1. The Director of Institutional Research and Assessment
 2. Deans of the School of Arts and Sciences, School of Education and Professional Studies, and the Crane School of Music.
 3. The Vice President for Business Affairs
 4. The Vice President for Advancement
 5. The Director of the Libraries
 6. The Director of Computing and Technology Services
 7. The Director of the Center for Lifelong Education and Recreation
 8. The Director of Extended Education
 - iii. Individuals in departments that do not report to one of these department heads should consult with the IRB Chair.

- iv. Each of these individuals will consult with the IRB Chair when new projects arise that may be considered institutional research and confer annually with the IRB Chair to review the projects defined as institutional research in their areas.
3. Activities that are specifically deemed NOT to be research by the revised Common Rule are journalism, oral history, and public health surveillance criminal justice or criminal investigative activities; and activities in support of intelligence, homeland security, defense, or other national security missions
- C. It is the policy of SUNY Potsdam that the responsibility for review of all research involving human subjects' lies with the IRB. The IRB has the responsibility and authority to review, prospectively approve, disapprove, grant exemptions (46.101,b,1-6), require changes in and exercise continuing oversight of research activities involving human subjects.
 - D. No individual involved in the conduct and/or supervision of a specific research project shall participate in IRB review, except to provide information.
 - E. SUNY Potsdam will provide the IRB with resources, professional staff and support staff sufficient to carry out its responsibilities efficiently and effectively. SUNY Potsdam will provide meeting space and staff support for IRB reviews and documentation.
 - F. All activities involving humans as research subjects must provide for the safety, health, and welfare of every individual. Rights, including the right to privacy, must not be infringed. Researchers must take all steps possible within a study to reduce risk to research subjects to no more than minimal risk (i.e., risk no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests). However, in some cases, even when all possible measures to minimize risk are taken in a study, the risk to which subjects are exposed will exceed minimal risk. The IRB shall determine whether or not (1) the researcher has taken all possible steps to minimize risks to subjects, (2) the potential benefits of the study outweigh those risks and (3) the informed consent materials clearly and adequately describe all risks.
 - G. The direct or potential benefits to the subject, or the importance of the knowledge to be gained, must not preclude consideration of the inherent risks to the individual.
 - H. Participation in projects must be voluntary. Written informed consent must be obtained from all subjects for all expedited review projects and full board review projects, unless the IRB waives this requirement. Methods in accordance with the requirements of 45 CFR 46.116 and 46.117, appropriate to the risks of the research, must be used to obtain the subjects' informed consent.
 - I. Consent should be obtained whenever possible from the participants themselves. In research involving subjects with diminished capacity, surrogates may be used in the consent process in accordance with the policy in Part III.D.3.
 - J. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety, and harassment.
 - K. In research involving more than minimal risk or substantial stress or discomfort, such risk, stress, or discomfort shall be carefully explained to the subject before his or her participation; the investigator shall be satisfied that the explanation has been understood by the subject; and the written consent of the subject, such consent containing the substance of the explanation, shall be obtained and kept as a matter of record for a period of no less than three (3) years.
 - L. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of all applicable laws and regulations.

- M. SUNY Potsdam requires more stringent safeguards for certain research activities and for subjects likely to be vulnerable to coercion or undue influence such as:
1. pregnant women
 2. children (under the age of 18)
 3. decisionally-impaired persons
 4. economically or educationally disadvantaged persons
 5. other potentially vulnerable groups
 6. activities involving fetuses and human in vitro fertilization, and
 7. activities involving cooperative research projects (projects that involve other institutions or agencies)
 8. prisoners
- N. Safeguarding the well-being of and information about an individual is a primary responsibility of the investigator. When the investigator is a student, responsibility for the conduct of the research and the supervision of human subjects lies with both the student and the faculty sponsor.
- O. SUNY Potsdam will assure that the IRB Chairperson, IRB members, IRB staff, and human subject investigators will complete appropriate, initial and continuing education related to the protection of human subjects before reviewing or conducting human subject research.
- P. SUNY Potsdam will ensure that all institutions and investigators (including subcontractors and sub grantees) collaborating in its federally supported human subjects research operate under an OHRP-approved Assurance of Protection for Human Subjects.
- Q. SUNY Potsdam will exercise appropriate administrative oversight to ensure that practices and procedures designed for the protection of the rights and welfare of human subjects are being effected and are in compliance with the requirements of 46.103 and this policy. A copy of this policy will be posted on the SUNY Potsdam IRB web site and will be sent to faculty/staff requesting copies. SUNY Potsdam encourages and promotes constructive communication among research investigators, the IRB, SUNY Potsdam administration, and human subjects as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
- R. No involvement of human subjects in research is permitted until the IRB has reviewed and approved the research protocol, the Institutional Official (The Provost and Vice President for Academic Affairs) has approved the protocol and legally effective informed consent has been obtained. It is the responsibility of the investigator to obtain clearance from the IRB prior to the initiation of any research involving the use of human subjects.

PART II: GENERAL PROCEDURES OF THE IRB

The following are general IRB procedures. Please refer to Part III for specific procedures.

A. Responsibilities of Research Investigators

It is the responsibility of each investigator (faculty, staff, student and affiliate researchers) to bring **ALL proposed research activity involving the use of human subjects or involving data collection from, or related to, human subjects** to the attention of State University of New York at Potsdam IRB for review and approval. This includes, but is not limited to:

- historical, educational and business related research,
- research using survey and interview procedures,
- classroom projects (defined below),
- student research activities,
- thesis research
- research projects that may qualify for exemption
- cooperative research projects (defined below)

- research involving clinical and experimental techniques.

1. IRB review of class projects, activities and assignments that involve data collection from human subjects within or outside of the classroom

Instructors may conduct activities or make assignments in a variety of courses that involve students in the collection of data from or about people. For example, students in a biology lab may be asked to take one another's pulse or blood pressure when standing and sitting or students in a sociology course may be given an assignment that involves asking people about their experiences with various organizations. These types of assignments, whether they are in-class activities or out-of-class work, can provide students with valuable experiences with the research process and insight into the discipline being studied.

However, there is the potential for these types of activities to cause harm to the subjects from or about whom data are collected. In addition, there is the possibility that some such data collection activities are subject to federal regulations governing the use of human subjects in research and must, therefore, be reviewed by the IRB.

The following are guidelines for use in determining whether or not a class data collection project, activity or assignment must be submitted for IRB review.

- (a) If **ALL** of the following are TRUE, the project does NOT need to be reviewed by the IRB. The IRB Chair is available to assist instructors in determining whether or not a specific project meets all of these criteria.
 - 1.) **Results NOT intended to be generalizable or published.** The project is done purely as a pedagogical exercise, to teach students about the research process or discipline. The project is not intended to contribute to the discipline, address a theoretical issue or otherwise contribute to generalizable knowledge. The results of the project will NOT be published or distributed outside of the class
 - 2.) **NO more than minimal risk.** Subjects are exposed to no more than minimal risk (i.e., the level of risk that they would typically encounter in their daily lives).
 - a. Subjects are NOT asked about sensitive, personal, incriminating or private information or issues, nor is such information collected about them (this includes information about sexual behavior or attitudes, immigration status, drug use, criminal activity, medical history or conditions, grades, or other information that could stigmatize the subject).
 - b. No information is collected that could harm the subject's reputation, employability, or financial standing or that could place the subject at risk for criminal or civil liability.
 - c. The project will NOT manipulate the behavior of subjects beyond the range of their typical daily life.
 - d. The project will NOT involve physically or psychologically invasive contact with subjects.
 - e. The project will NOT involve deception of subjects. Subjects are fully informed and given the opportunity to voluntarily consent to participation
 - 3.) **NO vulnerable subjects.** Subjects are adult (i.e. age 18 or older) members of the general population and NOT members of vulnerable populations (e.g., children, women who are pregnant, persons with cognitive impairments, persons who are socially, economically or educationally disadvantaged, persons with disabilities, prisoners, persons with significant health problems, etc.). Potential participants are informed that they may not participate if they are not 18 years of age.
- (b) **If any ONE of the above is NOT true of the project/assignment/activity**, then the instructor must submit an application for the use of human subjects in research. Application forms are available on the IRB website (www.potsdam.edu/rspo -- select "Institutional Review Board").

2. **Department-level review of class projects, activities and assignments that involve data collection from human subjects within or outside of the classroom**

Student research may be reviewed at the Department level if it is done solely as a classroom exercise. This activity meets one or two criteria of the federal definition of research (participants are living, and the project is a systematic investigation), but not the third criteria: it is not designed to contribute to generalizable knowledge.

Each department may designate an IRB representative, who will be CITI Training certified *or* will have read the Belmont Report. The IRB representative will review the proposed classroom exercise according to a checklist available on the IRB website. Records will be kept in the Department, but must be available to be examined by the IRB upon request.

In order to be eligible for department-level review, the classroom activity must satisfy all the following conditions:

1. Results NOT intended to be generalizable or published. The project is done purely as a pedagogical exercise, to teach students about the research process or discipline. The project is not intended to contribute to the discipline, address a theoretical issue or otherwise contribute to generalizable knowledge. The results of the project will NOT be published or distributed outside of the class (Example: a classroom presentation or a paper written for a class would qualify, whereas research presented at the Learning and Research Fair, a Presidential Scholar's project or a Kilmer project would not).

2. NO more than minimal risk. Subjects are exposed to no more than minimal risk (i.e., the level of risk that they would typically encounter in their daily lives).

a) Subjects are NOT asked about sensitive, personal, incriminating or private information or issues, nor is such information collected about them (this includes information about sexual behavior or attitudes, immigration status, drug use, criminal activity, medical history or conditions, grades, or other information that could stigmatize the subject, etc.).

b) No information is collected that could harm the subject's reputation, employability, or financial standing or that could place the subject at risk for criminal or civil liability.

c) The project will NOT manipulate the behavior of subjects beyond the range of their typical daily life.

d) The project will NOT involve physically or psychologically invasive contact with subjects.

e) The project will NOT involve deception of subjects. Subjects are fully informed and given the opportunity to voluntarily consent to participation

3. NO vulnerable subjects. Subjects are adult (i.e. age 18 or older) members of the general population and NOT members of vulnerable populations (e.g., children, women who are pregnant, persons with cognitive impairments, persons who are socially, economically or educationally disadvantaged, persons with disabilities, prisoners, persons with significant health problems, etc.). Please note that **"research" with children is not eligible for Department-level review, even if it is not intended to contribute to generalizable knowledge.**

3. **NO cooperating organizations.** The activity will be conducted within the SUNY Potsdam community. Data may also be collected from relatives or acquaintances of members of the SUNY Potsdam community, but no other institution can be involved in the classroom exercise.

4. If any ONE of the above is NOT true of the project/assignment/activity, then the instructor must submit an application for the use of human subjects in research. The application will be reviewed at the Exempt, Expedited, or Full Board level.

NOTE regarding internships, student teaching and other clinical and field experiences:

Data collection activities that take place during student teaching, internships and other clinical and field experience courses are typically excluded from IRB review because they are part of the host organization's normal operations (or initiated by the host organization and consistent with the host organization's normal operations) and do not meet the IRB's definition of research. However, in

student teaching, internship or clinical/field experience courses, any project that involves data collection from or about people that is not part of the host organization's normal operations is considered a class project and is subject to this policy.

Instructors' responsibilities when assigning data-collection activities and projects

Regardless of whether or not IRB review is required for a classroom project, activity or assignment, the instructor is responsible for:

- (a) Carefully considering whether or not the project meets the criteria above and consulting with the IRB Chair if there is any ambiguity.
- (b) Insuring that students are familiar with and follow ethical guidelines related to collecting data from human subjects. This includes obtaining voluntary, informed consent from all subjects and protecting the confidentiality of the information collected from or about subjects.
- (c) Reviewing and approving all data collection instruments, methods, procedures and consent forms PRIOR TO their use.
- (d) Insuring that students do not expose subjects to any more than minimal risk AND that students do not collect data from or about vulnerable subjects.
- (e) Insuring that students obtain appropriate permission to gain access to other organizations or institutions they wish to involve in their projects
- (f) Supervising the student researchers

NOTE: IRB approval for class projects, activities and assignments are instructor specific. If the instructor for the course changes, the new instructor must apply for a new IRB approval.

Examples of projects that do NOT require IRB review (assuming that they are not intended to produce results that are generalizable or will be published):

- (a) assignment in which students conduct a survey of faculty about whether they walk or drive to work
- (b) students in class interviewing one another about their favorite teachers in elementary school
- (c) lab in which students examine one another's fingernail clippings or saliva under a microscope
- (d) assignment in which students engage in an innocuous, public violation of a social norm (e.g., standing backwards in an elevator or wearing pajamas to class) and then mentally note and report to the class how others react
- (e) student intern assisting with a needs assessment that the host agency is conducting
- (f) student teacher reviewing spelling words with the class one week using a whole-class game format and the next week using a student-partner format and then comparing students' scores on their weekly spelling tests to determine which review strategy works better for the class

Examples of projects that DO require IRB review:

- (a) assignment in which students conduct a survey of students regarding their condom use or experiences with drugs
- (b) assignment in which students conduct focus group asking adults about their experiences being victimized via domestic violence or other crimes
- (c) lab in which students are engaged in data collection that involves vigorous physical activity
- (d) assignment involving collection of data via hidden camera or covert observation in non-public areas
- (e) student teacher conducting interviews of elementary school students about their favorite cartoon characters

- (f) student intern conducting a survey (that is not part of the agency's routine practice) of an emergency food assistance agency's clients about their criminal or delinquent behavior

Length of Approval:

Approval for classroom activities will be granted for up to a 12-month period after review and approval by the IRB and the Provost. The instructor may apply for two one-year renewals. A new application must be submitted before the second renewal expires if the instructor plans to continue using the assignment.

2. Cooperative Research

- (a) Cooperative research projects are those projects covered by this policy which involve more than one institution or that involve an outside agency.
- (b) In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.
- (c) When the other agencies involved in the cooperative research project will be providing information or data, will be a source of subjects or a location for subject recruitment or play some similar role in the research project (e.g., hospital, public school, clinic), the SUNY Potsdam IRB requires written approval from the appropriate administrative official within the agency prior to final approval of the project by the IRB.
- (d) When the other institution(s) involved in the cooperative research project has an IRB, the SUNY Potsdam IRB requires documentation of approval of the cooperative research project by the IRB of the other institution(s) involved.

3. Training

All investigators (principal investigators as well as student researchers) submitting an application to the IRB must be trained in the protection of human participants in research before a project can be approved. Other research staff must also be trained before they can begin working on the project. Training will be provided through the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org; training received through other programs will not be accepted in place of the CITI training. The modules investigators are required to complete will be determined by the IRB and identified on the CITI website. Investigators who have completed the CITI training will be required to renew their certification every two years by completing update modules, which will be selected by the IRB and identified on the CITI website. Completion and renewal records will be maintained by the Office of Research and Sponsored Programs. CITI Training for researchers and staff should show up in every application submitted through IRB-PACS. If training did not show in the online application, researchers must upload a copy of their CITI Training certificate with the rest of application materials. Failure to complete scheduled training updates or to train research staff may result in suspension or termination of IRB approval of a research project.

4. Preparation of Application

- a. Research investigators shall prepare the Application for Permission to Involve Human Subjects in Research for all research projects involving human subjects (including those that may be exempt). In the application, research investigators shall make provision for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.
- b. Research investigators shall submit all of the information requested in the application, including but not limited to the following:
 - 1. The purpose of the research activity
 - 2. The risks involved for participants in the research activity

3. A description of who the proposed participants are, the process by which participants will be recruited and the expected number of participants
4. A description of the procedures to be used in the research activity, e.g., any interventions, measurements, etc.
5. A description of how confidentiality will be insured
6. The applicable proposed informed voluntary consent and assent form(s), processes and/or scripts
7. Copies of any research instruments, e.g., interview guides, questionnaires, curricula
8. Solicitation materials and documents, e.g., letters to subjects
9. A description of the manner and location in which consent and assent forms will be stored for a minimum of three years following completion of the project.
10. Letters granting permission to conduct the research activity from the administration of any other agency involved in the project
11. Evidence of approval by the IRB of any other institution involved in the project
12. Date on which the most recent CITI training or update was completed

5. Submission of application to the IRB

It is the responsibility of each investigator (faculty, staff, student and affiliate researchers) to bring all proposed research activity involving the use of human subjects or activity involving data collection from, or related to, human subjects to the attention of the State University of New York at Potsdam IRB for review and approval. All IRB submissions must be completed using IRB-PACS.

6. Reporting changes in the research

- a. Research investigators are responsible for submitting to the IRB proposed changes in a research activity prior to implementing the changes.
- b. Changes in research during the period for which IRB approval has already been given shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.
- c. Examples of protocol changes:
 - The original protocol proposed to involve human subjects but some activities previously had only indefinite plans; plans are now definite.
 - The original protocol had no plans for the involvement of human subjects, and their involvement is now proposed.
 - It is now proposed to change the involvement of human subjects to something different from that which was initially approved by the IRB.
 - It is now proposed to change the informed consent document or procedure.
- a. An application for revision includes the submission of all proposed changes with a rationale for each proposed change.
- b. Applications for revisions should be submitted electronically to the IRB Chair. Applications for revisions from protocols submitted prior to August 2018 can be sent by email to the IRB Chair. Applications for revisions from protocols submitted on or after August 2018 must be submitted through IRB-PACS.

7. Apprising subjects of findings that may affect participation.

Research investigators are responsible for reporting both to subjects and to the IRB significant new findings developed during the course of the research that may relate to the subjects' willingness to

continue participation.

8. Complying with IRB decisions

Research investigators shall be responsible for complying with all IRB decisions, conditions and requirements.

9. Retention of signed consent documents

Research investigators are responsible for placing the consent documents signed by human research subjects in a repository approved by the IRB. Principal investigators are to keep all records for three (3) years following completion of the research activity. Undergraduate and graduate student investigators are to submit all consent documents to the faculty member sponsoring the research activity. The faculty member is to keep all records for three (3) years following completion of the research activity. However, if another institution is unwilling to release signed consent forms for reasons of confidentiality, an agreement may be developed if the cooperating institution agrees to appropriately retain for three years the IRB consent documents. These records must be available for IRB review or the review of authorized supporting department/agency representatives.

10. Submission of progress reports and requests for continuation of approval

For studies approved prior to January 2019: Research investigators are responsible for reporting the progress of the research to the IRB, as often as and in the manner prescribed by the IRB but no less than once per year. Prior to the anniversary of IRB approval, a request for continuation of research that has not been completed must be submitted to and approved by the IRB. Continuation can be granted for up to one year and can be requested twice. A final report must be submitted when the research is completed or the approval has expired at the end of the third year.

Both requests for continuation and final reports should include at least the following information:

- a. The number of subjects accrued
- b. A summary of any adverse events or any unanticipated problems involving risk to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review
- c. A summary of any relevant recent literature, interim findings and amendments or modifications to the research since the last review
- d. Any relevant multi-center trial reports
- e. Any other relevant information, especially information about risks associated with the research
- f. A copy of the current informed consent document and any newly proposed consent document
- g. For continuation requests, an explanation of why a renewal is needed (i.e., a description of additional or continuing work needs to be completed for the extension period)

Requests for continuation of approval and final reports should be submitted with original signatures by mail and electronically to the IRB Chair.

Principal Investigators who fail to submit appropriate completion reports for any project may have their approval suspended or terminated. Principal Investigators whose IRB approvals have been terminated due to failure to submit the appropriate completion form and/or report for any project will be required to submit the appropriate completion form(s) and/or report(s) before approval for any new project will be granted.

For studies approved after January 2019: For studies governed by the 2019 revised Common Rule, annual renewal of Exempt and Limited Review studies is no longer required. Expedited studies with minimal risk approved after January 20, 2019 will not need annual review, unless an IRB reviewer justifies why continuing review would enhance the protection of research subjects. Studies approved by Full Board review must comply with the annual review requirement described above.

11. Submission of injury reports and reports of unanticipated problems involving risks.
 - a. Research investigators are responsible for reporting within 24 hours to the IRB any injuries to human subjects using the Report of Unanticipated Problems form available on the IRB website. The IRB will be immediately convened to consider the situation.
 - b. Research investigators are responsible for reporting within 10 days to the IRB any unanticipated problems that involve minimal risks to the human research subjects or others using the Report of Unanticipated Problems form available on the IRB website. The IRB Chair or the Chair's designee serves as primary reviewer.
 - c. Research investigators are responsible for reporting immediately to the IRB any unanticipated problems that involve above minimal risks to the human research subjects or others using the Report of Unanticipated Problems form available on the IRB website.
12. Reporting of noncompliance

Research investigators are responsible for reporting to the IRB any serious or continuing noncompliance with 45 CFR 46, the requirements of this policy or the determinations of the IRB.
13. Attending IRB meetings

To facilitate the review of research and the protection of the rights and welfare of human subjects, research investigators are encouraged to attend IRB meetings concerning their research activities.

B. IRB Structure

1. IRB membership requirements
 - a. The IRB shall be composed of at least five members from diverse disciplinary backgrounds to promote complete and adequate review of research activities commonly conducted by SUNY Potsdam. Additional members may be appointed to enhance the diversity of the committee, with a maximum committee size of ten.
 - b. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes and issues related to vulnerable populations, to promote respect for its advice and counsel safeguarding the rights and welfare of human subjects.
 - c. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice and shall, therefore, include persons knowledgeable in these areas.
 - d. The IRB shall include qualified persons of both sexes so long as no selection is made solely on the basis of gender.
 - e. The IRB shall include at least one member whose primary concerns are in a non-scientific area and one member whose primary concerns are in a scientific area.
 - f. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with SUNY Potsdam.
 - g. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the

IRB.

- h. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.
- i. IRB members will be required to complete specialized training regarding IRB operations and related policies and laws such as that offered through the Collaborative Institutional Training Initiative (CITI).

2. IRB appointment

- a. The Provost makes appointments to the IRB for terms of three years.
- b. The Provost also appoints the IRB Chair for a three-year term. The chair must have previous IRB experience.

3. Summer IRB

The summer IRB shall be an entity separate from the IRB that functions during the academic year. Members of the summer IRB will be appointed by the Provost. Summer IRB appointment is for one term of three months (June 1 to August 30). Summer IRB appointments will be made with attention to the issues outlined in section II B (1) a-f of this policy. Untenured faculty will not be appointed to the summer IRB. The summer IRB will follow the same policies and procedures as the IRB that functions during the academic year.

4. IRB membership lists and qualifications

The names, qualifications and affiliations of the members of the IRB will be reported as required under the institution's Federal wide Assurance of Protection for Human Subjects.

C. IRB Authority and Responsibilities

1. IRB functions and operations

- a. The IRB shall follow written policies and procedures of the State University of New York at Potsdam for the protection of human research subjects which are in compliance with applicable Federal law.
- b. SUNY Potsdam meets the exemption from NYS law pertaining to research with human subjects as provided in Laws of New York 1975, Chapter 450, Article 24-A, Protection of Human Subjects.

2. Confidentiality

All proposals submitted to the IRB and discussions of proposals by the IRB are confidential, and there should be no discussion of submitted proposals or committee decisions by any member of the board outside of the IRB. The IRB may find it necessary to discuss proposals, decision-making, IRB recommendations, and the conduct of particular studies with appropriate college administrators and federal agencies that oversee human subjects protections. In addition, other university or state offices (e.g. the Research Foundation) may need to consult with the IRB on a particular study or review IRB activities. In cases such as these, the chair of the IRB or a designated member of the IRB board will, with the knowledge of the IRB, meet with college administrators who have a legitimate interest. The importance of confidentiality to the Institutional Review process cannot be overstated. Failure to observe confidentiality threatens the operation of

the IRB.

2) IRB Research Review Responsibilities

- a. The IRB will have at least two regularly scheduled meetings each semester and at least one additional meeting during the summer if needed. These regularly scheduled meetings will be announced in the Reporter and posted on the IRB website. These regular meetings will serve to handle relevant issues, address member concerns, and discuss IRB applications requiring full-board review. Deadlines for receipt of proposals requiring full-board review for discussion at each regularly scheduled meeting will also be announced in the Reporter and posted on the IRB website.

Additional meetings will be scheduled as necessary.

- b. The IRB shall have the responsibility to review and the authority to approve, require modifications in (to secure approval), or disapprove all research activities or proposed changes in previously approved activities covered by this policy.
- c. The IRB shall require that information given to subjects as part of informed consent is in accordance with 46.116. The IRB may require that information, in addition to that specifically mentioned in 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- d. The IRB shall require documentation of informed consent or may waive documentation in accordance with 46.117.
- e. The IRB shall notify investigators and the institution (the Provost) in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- f. The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. Based on the degree of risk to human subjects, the Board may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. The IRB shall have authority to observe or have a third party observe the consent process and the research.

4. Proposal Submission Processes

a. Training

Investigators are required to complete a training program prior to IRB review of their research. Training for investigators and research staff will be provided through the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org; training received through other programs will not be accepted in place of the CITI training. The modules investigators are required to complete will be determined by the IRB and identified on the CITI website. Investigators who have completed the CITI training will be required to renew their certification every two years by completing update modules, which will be selected by the IRB and identified on the CITI website. Completion and renewal records will be maintained by the Office of Research and Sponsored Programs. Failure to complete scheduled training updates or to train research staff may result in suspension or termination of IRB approval of a research project.

b. Materials

Application forms for submission of a proposal to the IRB are available through the Office of Research and Sponsored Programs and from the IRB Chair. Forms will also be available in electronic form from the IRB website, which will be maintained by the Office of Research and

Sponsored Programs.

c. Submission

Two copies of the completed applications should be submitted to the Chair of the IRB. One complete paper copy with original signatures should be mailed to the IRB Chair. One complete electronic copy should be emailed to the IRB Chair.

d. Review of Funding

Or both initial and continuing review, protocols that also involve grant applications to external agencies, the Chair or Chair's designee will review the entire grant application as well as the protocol.

e. Determination of the Type of Review Required

When a proposal is received, the IRB Chair determines the type of review required: review for certification of exemption, expedited review or full-board review. For a detailed description of each type of review, go to Part III of this policy.

f. Notification of Decision

The research investigators shall be notified in writing of the IRB's decisions regarding project approval. Also, the IRB shall provide to the investigator reasons for the IRB's decision to disapprove a research protocol and an opportunity for the investigator to respond. Similarly, the Office of the Provost will be notified of approvals, and disapprovals in writing.

- (a) The IRB chair will notify the researcher in writing of the IRB's action on a proposal that is being reviewed through the expedited or full-board review process. After the IRB approves a proposal, the proposal will be sent to the Provost for final approval. Once the Provost has approved the proposal, the IRB chair will communicate the approval to the researcher in writing. Only at this point is the researcher free to proceed with the study.
- (b) The IRB chair will also notify the researcher in writing of the IRB's action on a proposal for which exemption was requested. Only if the exemption is granted can the researcher proceed with the study. If the exemption is not granted, then the proposal must be approved via expedited or full-board review before the researcher can proceed with the study.
- (c) The IRB Chair or designee will report on all exempted projects and expedited reviews at the IRB meeting following the review decision.

g. Duration of Research Approval

Approval of proposed research is usually granted for a period of 12 months commencing on the date approval is granted by the Provost. Classroom Projects are also approved for a 12-month period provided they remain under the direction of the Instructor who submitted the project to the IRB for review. Based on the degree of risk to human subjects the Board may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. Proposals funded by contract or grant will be approved for a period of up to one year that coincides with the contract or grant.

h. Application for continuation (renewal) of approval

Continuation of projects past the approval period requires submission of the Application for Continued Approval/Final Report form to the Board. It is the responsibility of the investigator to submit the application form and obtain approval for project continuation from the IRB prior to expiration of the approved period. Continuation can be granted for 12 months at a time. Approval for project continuation can be requested twice. It is also the responsibility of the investigator to submit

the Application for Continued Approval/Final Report at the conclusion of the project. Investigators will be notified of the need for renewal 60 days prior and again 30 days prior to the end date of the IRB approval period. If a completed renewal request has not been received by the renewal date, IRB approval of the project will be suspended. The investigator will be notified of the suspension in writing. If the completed renewal request is not received within 30 days after the suspension, IRB approval will be terminated. If the researcher wishes to continue the project, a new proposal must be submitted to the IRB. Principal Investigators whose IRB approvals have been terminated due to failure to submit the appropriate completion form and/or report for any project will be required to submit the appropriate completion form(s) and/or report(s) before approval for any new project will be granted.

i. Projects for which the IRB will require verification from sources other than the investigator that no material changes have occurred are:

- a. Those involving high risk to human subjects, or
- b. Those directed by investigators who have previously been found in non-compliance with institutional and Federal policy.
- c. Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

j. Conflict of Interest

The IRB may not have a member participating 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.

5. Criteria for IRB approval of research

a. In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- (1) Risks to subjects are minimized:
 - (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result:
 - (i) In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
 - (ii) The IRB will not consider long range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- (3) Selection of subjects is equitable.

- (i) Selection criteria should consider all populations which might potentially benefit from the research. Utilization of populations based solely upon ready availability should be avoided.
 - (ii) The IRB will take into account the purposes of the research and the setting in which the research will be conducted.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative or surrogate as per the "Policy and Procedure on the Use of Surrogates in Decision Making," Part III, E.3. of this policy, and will be appropriately documented, in accordance with, and to the extent required by 46.116 and 46.117.
- (5) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (6) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (7) When appropriate, the IRB will ensure sufficient knowledge of the local research context through proper representation on the Board and/or the use of external consultants.
- b. When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, decisionally-impaired persons, or economically or educationally disadvantaged persons) additional safeguards must be included in the study to protect the rights and welfare of these subjects.

6. Review by Institutional Official

- a. Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Provost, who serves as the institutional official.
- b. However, the Provost may not approve the research if it has not been approved by the IRB.

7. Suspension or termination of IRB approval of research

- a. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. In instances of serious unanticipated problems involving risks to subjects or others or serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB, the IRB Chair and the Provost each have the authority to immediately suspend approval of the research.

This decision is subject to review by the full IRB at its next convened meeting. The IRB may choose to terminate approval of the research.

- b. Any suspension or termination of approval other than those indicated in c below, shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and to the Provost. The Provost shall inform immediately other appropriate institutional officials, and subsequently OHRP and department and agency heads if federally funded.

- c. Any suspension or termination of approval resulting from non-submission of Application for Continued Approval/Final Report, expiration of training certification, failure to train new research staff or non-submission of minor modifications to an approved protocol shall be reported to the investigator, the Provost, and the IRB. The Provost shall inform other institutional officials if deemed necessary.

1. Principal Investigators who fail to submit appropriate completion reports for any project may have their approval suspended or terminated. Principal Investigators whose IRB approvals have been terminated due to failure to submit the appropriate completion form and/or report for any project will be required to submit the appropriate completion form(s) and/or report(s) before approval for any new project will be granted.

- d. If an instance of i) unanticipated problems involving above minimal risks to subjects or others or ii) any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB come to the attention of any IRB member, that individual will report them immediately to the IRB Chair and the Provost.

- e. If an instance of i) unanticipated problems involving above minimal risks to subjects or others or ii) any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB come to the attention of the IRB Chair, that individual will report them immediately to the Provost and subsequently to the IRB.

- f. The possible actions to be taken by the IRB in response to reports of unanticipated problems involving above minimal risks to subjects or others or of serious or continuous noncompliance are (1) inquiry into the nature of the problem, (2) immediate suspension by Chair with subsequent IRB review, (3) immediate termination of approval of the research by the IRB, (4) reinstatement of approval of the research after suspension or inquiry, (5) requirement for more frequent continuing review, (6) partial suspension of approval for research activities, e.g., recruitment of new subjects or cessation of a particular procedure, (7) requirement for protocol changes to eliminate apparent immediate hazards to subjects.

- g. Notification to investigators

Investigators are apprised of IRB's authority to suspend or terminate approval of research in letters of notification of initial approval and reminders for submission of continuing approval/final report form. Upon suspension or termination of approval, the IRB Chair writes an individualized letter to the principal investigator explaining violations. A copy of the letter will be given to the Provost.

8. Review of Unanticipated Problems Involving Risk to Subjects or Others

- a. The Chair will act as primary reviewer determining risk level and will refer all those above minimal risk for full IRB review.
- b. For those problems at or below minimal risk, the Chair will submit a report of the unanticipated problem to the IRB at its next convened meeting and of any protocol modifications required to address the problem.

9. Review of Allegations of Noncompliance

The IRB Chair has the authority to determine the level of risk or seriousness of noncompliance. Given a determination of above minimal risk or serious noncompliance, the Chair is authorized to suspend approval of research activities and will refer the allegation for Full IRB Review. Given a determination of level of risk as minimal or below, the Chair will present the complaint for discussion along with a report of the investigation and any actions taken by the Chair at the next IRB meeting.

The IRB will decide upon procedures relative to protections of subjects from research risk. These decisions are binding upon the principal investigators and research project staff. All decisions of the IRB are reported to the Provost as the institutional official. If the IRB determines that further investigation is appropriate, the IRB will make a recommendation to the Provost. In cases of serious or continuing noncompliance, the institutional official will report within SUNY and to the Office for Human Research Protections as required.

10. Appeal Process

Investigators may appeal decisions of the IRB to the IRB for review. To do so, the investigators should submit a written appeal (including an electronic copy and a paper copy with original signature(s)) to the IRB Chair by the proposal deadline for the next scheduled IRB meeting, which is posted in the IRB website. The letter of appeal and the proposal for which the IRB's decision is being appealed will be distributed to the IRB members and will be discussed at the next scheduled meeting of the IRB.

At meetings in which decision appeals are made, the investigator(s) may wish to include a representative(s), such as a member of the Faculty Senate, an academic administrator, etc. The investigator will be given an opportunity to present the appeal and to respond to questions from IRB members. The IRB will then vote on the appeal via paper ballot. The investigator(s) will receive a report of the vote. Neither investigator(s) nor representatives may be present during the voting process.

A two-thirds or greater majority of the IRB members voting in favor of the appeal is needed for the IRB to reconsider the proposal. If two-thirds or more of the IRB members vote to reconsider the proposal, then the proposal will go through full-board review.

11. IRB Records

- a. The institution, or when appropriate the IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:
 - (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
 - (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and documentation of determinations the IRB is required to make.
 - (3) Records of continuing review activities.
 - (4) Copies of all correspondence between the IRB and the investigators regarding proposal exemption, review modifications or approval/disapproval.
 - (5) A list of IRB members in the same detail as described in 46.103(b)
 - (6) Written procedures for the IRB in the same detail as described in 46.103(b) (4) and (5).
 - (7) Statements of significant new findings provided to subjects, as required by 46.116(b) (5).
- b. Proposals and all relevant correspondence will be stored by the Office of Research and Sponsored Programs and will be available for review by the members of the IRB, the Office of Research and Sponsored Programs, and the Provost's Office.

The records required by this policy shall be retained for at least three years, and records relating to research which was conducted shall be retained for at least three years after completion of the research. These records must be appropriately secured. All records shall be accessible for inspection and copying by authorized representatives of Federal departments or agencies that conduct, support or regulate the research at reasonable times and in a reasonable manner.

12. Resources

- a. The IRB will endeavor to ensure that it is provided with resources, professional staff, and support staff appropriate to the nature and volume of the research for which it is responsible.
- b. The IRB Chair will meet with the Provost at least annually to discuss resource and staff allocation requirements.

D. General Requirements for Informed Consent

1. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
 - a. Research investigators are responsible for obtaining legally effective informed consent, and for ensuring that no human subject will be involved in the research prior to obtaining consent.
 - b. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
 - c. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative;
 - d. No informed consent whether oral or written, may include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.
2. Providing basic elements of informed consent

Unless otherwise authorized by the IRB (see Sections D.4 and D.5 below for exceptions), research investigators at a minimum shall provide the following information in writing to each subject:

- a. A statement that the study involves research, an explanation of the purposes of the research, the approximate number of subjects participating, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- b. A description of any reasonably foreseeable risks or discomforts to the subjects;
- c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
- d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

- f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3. Providing additional elements of informed consent

When appropriate, the research investigator shall provide one or more of the following additional elements of information to each subject:

- a. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- b. anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;
- c. any additional costs to the subject that result from participation in the research;
- d. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- e. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

4. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that (see also Sections E.4 and E.5, below):

- a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - (1) Public benefit or service programs;
 - (2) Procedures for obtaining benefits or services under those programs;
 - (3) Possible changes in or alternatives to those programs or procedures; or
 - (4) Possible changes in methods or levels or payment for benefits or services under those programs; and
- b. The research could not practicably be carried out without the waiver or alteration.

5. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that (see also Sections E.4 and E.5 below):

- a) The research involves no more than minimal risk to the subjects;
- b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

- c) The research could not practicably be carried out without the waiver or alteration; and
 - d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
6. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
 7. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.
 8. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
 - a. 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
 - b. 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.
 9. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

E. Documentation of Informed Consent

1. Research investigators shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative or surrogate as per "Policy and Procedure on the Use of Surrogates in Decision Making," Part III, E, 3 of this policy, unless this requirement is specifically waived by the IRB. (See Section 4 below for conditions of waiver.)
2. Research investigators shall ensure that each person signing the written consent form is given a copy of that form.
3. The State University of New York at Potsdam Informed Consent Template

Except as provided in Section 4 below, research investigators are to use the State University of New York at Potsdam Informed Consent Template (available on the IRB website) as a model to develop their consent forms. The State University of New York at Potsdam Informed Consent Template embodies the elements of informed consent as required by 46.116.

 - a. The consent form may be read to the subject or the subject's legally authorized representative or surrogate as per "Policy and Procedure on the Use of Surrogates in Decision Making," Part III, E, 3 of this policy, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
 - b. A "short form" written consent document stating the elements of informed consent required by 46.116 may be presented orally to the subject or the subject's legally authorized representative or surrogate as per "Policy and Procedure on the Use of Surrogates in Decision Making," Part III, E, 3 of this policy.
 - (1) When this method is used, there shall be a witness to the oral presentation.
 - (2) The IRB shall approve a written summary of what is to be said to the subject or

the representative.

- (3) The subject or the representative shall sign the short form.
- (4) The witness shall sign both the short form and a copy of the summary.
- (5) The person actually obtaining consent shall sign a copy of the summary.
- (6) A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

F. Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by the IRB before an award may be made.

However, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by SUNY Potsdam, to the funding agency as required.

G. Research Undertaken without the Intention of Involving Human Subjects

In the event research is undertaken without the intention of involving of human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by the IRB, as provided in this policy, a certification submitted, by SUNY Potsdam, to the funding agency, if required, and final approval given to the proposed change by the agency.

PART III. SPECIFIC REVIEW PROCEDURES AND SPECIAL CONSIDERATIONS

All human subjects research activities must be submitted to the IRB for review.

The IRB authorizes three (3) levels of review based on the type of research activity. These levels are: (a) full-board review by the IRB, (b) expedited review by the IRB and (c) IRB certification of exempt status. For all three levels of review, investigators should submit the Application for Permission to Involve Human Subjects in Research to the Chair of the IRB. The IRB Chair shall determine whether the research protocol meets the criteria for exemption from review or expedited review or requires full-board review.

A. Full-Board Review by Institutional Review Board

1. Full-board review by the IRB is required for all protocols, except those meeting exempt, limited review, or expedited review criteria (See sections III B and C below).
2. For all research, investigators shall submit two copies of the Application for Permission to Involve Human Subjects in Research to the Institutional Review Board through IRB PACS.. Proposals must be submitted by the deadline (announced in the reporter and posted on the IRB website) for discussion at the next regularly scheduled meeting of the IRB. Forms are available on the IRB web site or from the Chair of the IRB.
3. Proposals not meeting exempt, limited review, or expedited review criteria will be sent to IRB members for review. The proposal will be discussed at the next scheduled meeting of the IRB.
4. Attendance of the investigator at the IRB review meeting in which his or her research activity is scheduled for discussion is encouraged.
5. Voting

Members will vote on proposals requiring full-board review via a written ballot.

Members will submit their ballots to the IRB chair within three days of the meeting during which the proposal was discussed.

6. IRB members who feel that they have a conflict of interest may excuse themselves from voting on particular proposals.
7. The formal actions taken by the IRB will consist of approval of the proposal, modifications required to secure “approved” determination, or disapproval of the proposal.
 - (a) Approval: A proposal requiring full-board review will be approved by a simple majority of the active voting members of the IRB. Once approved, the protocol will be sent to the Provost, as Institutional Official, for approval. Approval by the IRB and the Provost means that the researcher may begin data collection and the project meets the IRB standards for human subject research.
 - (b) Modifications required to secure “approved” determination: A proposal requiring full-board review may be granted deferred approval pending minor modifications or receipt of specific pieces of information (e.g., letter from an organization that will be involved in the research, approval by the IRB at another institution where a collaborator is employed, evidence that the researcher successfully completed any required training, etc.) by a simple majority of the active voting members of the IRB. Research may not begin until the requested modifications have been submitted to and approved by the IRB and the Provost.

Protocol modifications and additional information should be submitted to the Chair within 60 days of the meeting at which the proposal was discussed. The minor modifications or information submitted in response to a deferred approval may be subject

to expedited review at the discretion of the Chair. Once all modifications and additional information requested by the IRB have been received and approved, the protocol will be sent to the Provost for approval.

The Board may also request Major Revisions. In this case, approval by the Board has been withheld as the proposed research does not meet SUNY Potsdam and federal guidelines for the protection of human subjects. A resubmission with major revisions can be required by a simple majority of the active voting members of the IRB. The research activity may not be undertaken, and will not be endorsed by the institution, unless the investigator significantly revises the original application. A revised proposal should be submitted to the IRB Chair within 60 days of the IRB meeting at which the proposal was discussed. The revised proposal will be subject to full-board review.

- (c) Disapproval - indicates the proposed research does not meet SUNY Potsdam and federal guidelines for the protection of human subjects. A proposal is disapproved by a simple majority vote of the active voting members of the IRB. The research activity may not be undertaken, and will not be afforded institutional endorsement. The investigator shall have the opportunity to respond in person or in writing to the Board.

8. Research protocols scheduled for full-board review shall be distributed to all members of the IRB at least one week prior to the meeting.
9. When it is determined that consultants or experts will be required to advise the IRB in its review, the research protocol or appropriate sections shall also be distributed to the consultants or experts prior to the meeting if determined by Chair to be necessary. These individuals may not vote with the IRB.
10. A majority of the membership of the IRB constitutes a quorum and is required in order to convene a meeting for the full-board review of research protocols. (Members on official leaves of absence, e.g. medical, sabbatical, summer, etc., will not be considered as active members in the determination of quorum.)
11. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the IRB can conduct its review of research.
12. The IRB may not have a member participating 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. If quorum is at risk, the member with the conflict of interest will leave the room for discussion and will return for a secret ballot vote in which that member submits a signed abstention.

B. Expedited Review Procedures

1. The only categories of research for which the IRB may use an initial expedited review procedure are those which are specified in Part III B 12-c below.
2. The research investigator seeking expedited review is to submit this/her application through SUNY PACS.
3. The application must provide full justification to support expedited review in relation to the appropriate category listed in Part III, B 12-c below
4. Applications may be submitted at any time. However, if the investigator has any questions about the applicability of the expedited review status, s/he should submit the application by the deadline posted in the IRB website to allow for full-board review at the next regularly scheduled IRB meeting, if necessary.
5. The IRB Chair determines whether or not a proposal meets the criteria for expedited review.
6. Under an expedited review procedure, the review may be carried out by the IRB chairperson and/or by one or more experienced reviewers designated by the chairperson from among members of the IRB. Any requests for clarifications or modifications made by board members will be forwarded to the researcher by the IRB Chair. Subsequent modifications of the proposal will also be subject to expedited review unless

they result in the project no longer meeting the criteria for expedited review.

7. If there are no objections from board members, the proposal will be submitted to the Provost for approval. If one third or more of the IRB members object to the proposal being reviewed through the expedited review process or being submitted to the Provost, the proposal will be subject to full-board review and will be discussed at the next regularly scheduled meeting of the IRB.
8. Committee members who feel they have a conflict of interest may excuse themselves from responding to particular proposals.
9. When the expedited review procedure is used, the IRB Chair shall inform the full IRB of research protocols which have been approved at the meeting following their approval.
10. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or full-board—utilized by the IRB.
11. Expedited review procedures and categories
 - a. The IRB acknowledges that Federal agency or department heads may restrict, suspend, terminate or choose not to authorize the IRB's use of the expedited review procedure.
 - b. Applicability

In most cases, requests for minor modifications of previously approved protocols will be subject to expedited review. Minor changes include changes to grant contract dates, addition of questions to or changes to questions in a survey that do not change the focus of the survey, changes in project personnel, etc.

Requests for major modifications of protocols previously approved through expedited review will typically be subject to expedited review, unless those changes result in the project no longer being eligible for expedited review. Major changes include changes to informed consent procedures or documents, changes in the scope of work, etc.

The expedited review procedure may NOT be used where any ONE of the following is true:

1. identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
2. There is more than minimal risk of emotional distress or physical harm to subjects
3. Subjects are deceived in the research
4. The research is taking place in another country
5. Subjects are members of protected populations such as children (under 18 years of age) (some research with children may be exemptible, please see section C below for a description of exempt categories)
- 6.

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in this list apply regardless of the age of subjects, except as noted. In

addition, the categories in this list pertain to both initial and continuing IRB review.

c. Expedited review categories include:

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Children are defined in the HHS regulations as “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 46.202 (a).
2. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples:
 - (a) hair and nail clippings in a non-disfiguring manner;
 - (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - (c) permanent teeth if routine patient care indicates a need for extraction;
 - (d) excreta and external secretions (including sweat);
 - (e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
 - (f) placenta removed at delivery;
 - (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - (h) supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - (j) sputum collected after saline mist nebulization.
3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
 - a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;
 - (b) weighing or testing sensory acuity;
 - (c) magnetic resonance imaging;
 - (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
4. Research involving materials (data, documents, records, or specimens) that have been

collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b) (4). This listing refers only to research that is not exempt.)

5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, , focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR46.101 (b) (2) and (b) (3). This listing refers only to research that is not exempt.)

7. Continuing review of research previously approved by full-board review as follows:
 - (a) where
 - (i) the research is permanently closed to the enrollment of new subjects;
 - (ii) all subjects have completed all research-related interventions; and
 - (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis; or
 - (d) where there are no changes to the protocol as it was approved via full-board review and there have been no adverse events
8. Continuing review of a study previously approved by the Expedited procedure, if at the time of the review a reviewer determined that continuing review would enhance the protection of research subjects.

C. Review for Certification of Exemption and Limited IRB Review Procedures

1. The only categories of research that are eligible for exemption from IRB review are listed in Part III Section C8 below.
2. An investigator seeking certification of exemption should submit one complete paper copy with original signatures of the Application for Permission to Involve Human Subjects in Research through IRB-PACS.
3. The application must provide full justification to support exemption in relation to the appropriate category listed in Part III, Section C 8 below.
4. Applications for certification of exemption may be submitted at any time.
5. The IRB Chair determines whether or not a proposal meets the criteria for exemption.
6. The investigator will be notified in writing whether or not the project qualifies for exemption. If the project does not qualify for exemption, the investigator should then submit an Application for Permission to Involve Human Subjects in Research requesting expedited or full-board review to the IRB Chair.
7. If the project does qualify for exemption, the researcher may proceed with the project once the certification of exemption is received.

8. Research activities in which the only involvement of human subjects is in one or more of the categories may be reviewed for exempt status by the IRB. (See a.-f. below.) **No exemption categories apply to research involving fetuses, pregnant women or human in vitro fertilization. Only certain exemptions pertain to children (see items a. and b. below). To qualify for certification of exemption, human subject involvement may not exceed minimal risk (physical, psychological, social, undue stress and/or invasion of privacy).**

a) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Examples of research acceptable in this category include research in colleges with students +18, research with peer educators/administrators in schools. Research with children is NOT eligible for this category of exemption)

b) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

(Research with children involving ONLY educational tests or the observation of public behavior when the investigator(s) do NOT participate in the activities being observed for paragraphs (i) and (ii) is eligible for this category of exemption)

c) Research involving benign behavioral interventions* in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

*For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Research with children is NOT eligible for this category of exemption. Research involving deception is NOT eligible for this category of exemption, unless subjects authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

d) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- i. The identifiable private information or identifiable biospecimens are publicly available;
- ii. Information, which may include information about biospecimens, is recorded by the investigator

in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(Research with secondary data from children is NOT eligible for this category of exemption)

e) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

f) Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, or

ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

9. **Limited IRB Review:** Research that involves no risk or no more than minimal risk to participants and is exemptible but requires that a limited IRB review is conducted to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.

a) Educational Tests, Surveys, Interviews, or Uninfluenced/Unmanipulated Observation of Public Behavior: Research that ONLY includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. (Research with children does NOT qualify for this category of Limited Review)

b) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

D. Special Considerations

1. International Research

Research in foreign countries presents special concerns regarding the rights and welfare of human participants. In general, the IRB accepts the standards of the location in which the research is taking place, unless those standards violate the basic principles of ethical human participants research. Investigators must understand the context of the locality in which they are conducting their research and must communicate that understanding to the IRB in writing. In addition, the following issues apply to international human participants research:

- All human participants research in foreign countries must be reviewed by the full IRB, regardless of the nature of the research.
- All materials, including consent forms, must have English language translations included with the protocol.
- In localities where English is not the primary language, all materials presented to subjects must be understandable to them. An authority in the native language must provide documentation that the translated materials adequately convey the content of the English language version presented to the IRB.
- Documentation of permission from local authorities is generally required before approval can be granted.
- To expedite the review process, the investigator is asked to provide the name of an individual(s) who has knowledge and/or experience in conducting research in the particular location of study.
- Where research involves minimal risk to subjects, the IRB will obtain necessary information related to the research context through written materials from the investigators or others, and/or discussions with appropriate consultants.
- Where research involves greater than minimal risk to subjects, the IRB will obtain the federally required information through written materials, personal knowledge on the part of one or more IRB members, discussions with consultants in person or via electronic means, and in interchange between the IRB and elements of the local research context, etc.
- If the project is federally funded, each site that is engaged in research must have a federal-wide assurance on file with The Office for Human Research Protections.

Further information can be found at www.hhs.gov/ohrp.

Please note: Additional time is needed when reviewing international research since the IRB may need to consult with an expert in that area for local context information.

2. Internet Research

The Internet is being used increasingly in conducting human participants research. Research on the Internet presents new concerns to the prevalent human participants issues: risk, consent, participation by minors, and confidentiality. **Investigators must provide technical information on how they address these issues.**

Risk: There are two sources of potential harm to participants from Internet research: harm resulting from participation in the research (e.g., acute emotional reactions to certain questions), and harm resulting from breach of confidentiality. Since there is generally no direct contact with participants in research over the Internet, it may be difficult or impossible to deal with individual participant reactions. **As a result, some sensitive research may not be appropriate for the Internet.** Breach of confidentiality is the primary source of harm in most Internet research and is discussed below.

Consent: Not all research requires the documentation of informed consent (signed consent forms). The IRB can waive the requirement for signed consent when appropriate. Innocuous research on non-sensitive topics conducted over the Internet may not need documentation of consent (NOTE: only the IRB can make that decision). When a signed consent form is not required, investigators can use a “portal”; i.e., where participants must click on a consent page to get to the rest of the research. As it is currently not possible to get a signed consent form over the Internet, where signature is required, investigators can have participants submit a signed consent form and send them a password to gain access to the research pages.

Alternatively, investigators can announce the study, provide the consent form, and have the participants download the consent and then mail it to the investigator. At that time, the investigator could give the participant the password to access the study. In any case, investigators must indicate to the IRB how they plan to obtain consent from participants.

Participation by minors: Ordinarily parental permission is required for participation in research studies. Investigators can use passwords as above. To screen out minors completely from the research, investigators can take advantage of Internet Monitoring Software (such as SafeSurf). Because no system can guarantee that minors are not participating, some research may not be appropriate for the Internet.

Confidentiality: Because it is impossible to guarantee absolute data security over the Internet, some extremely sensitive research may not be appropriate for the Internet. Investigators need to address how they intend to assure confidentiality, keeping in mind that the degree of concern over confidentiality is directly related to the sensitivity of the data. Data transmitted via e-mail cannot be anonymous without the use of additional steps. Almost all forms of e-mail contain the sender's e-mail address. In order to maintain anonymity, the research must use an "anonymizer" – a third party site which strips off the sender's e-mail address. Data submitted over the Web can only be anonymous if software is used to store the information directly in a database without identifiers; otherwise identifiers are attached to the data. Web servers automatically store a great deal of personal information about visitors to a web site, and others can access that information.

When a research project is conducted over the Internet, the following statement must be placed in the introduction of the study: (The statement must be highlighted.) **"This project has been approved by the SUNY at Potsdam Institutional Review Board. Approval of this project only signifies that the procedures adequately protect the rights and welfare of the participants. Please note that absolute confidentiality cannot be guaranteed due to the limited protections of Internet access."**

Three types of research-related activities involve the use of the Internet:

1. Recruiting participants over the Internet
2. Observation of Internet activity
3. Collecting data over the Internet

Recruiting Participants over the Internet: The use of the Internet to recruit participants presents similar issues as with any other recruiting tool. The IRB needs to review information to be presented to participants. Not only does the IRB need to review the text of the recruitment script, but it also has to examine the context in which the recruitment takes place (e.g., posting a message on a newsgroup or creating a web site to recruit participants). When the Web is used to recruit participants, the IRB must see an example of what the prospective participants will see (i.e., a screen shot).

Observation of Internet Activity: Observation of Internet activity usually involves such activities as gathering information about the use of the Internet and/or recording user information or users' comments. Examples include: participant observation of an on-line discussion group, using "cookies" to track web sites visited, or asking visitors to a web site to provide demographic information. The human participants issues involved in this type of research generally involve consent/disclosure issues. Investigators need to indicate to the IRB how they intend to obtain the participants' consent to use this information for research. As with other types of participant observation, investigators generally must disclose their role as a researcher to the group participants.

Gathering Data on the Internet: This type of research generally involves having participants submit data (e.g. survey data) over the Internet, and it presents the most serious human participant's concerns due to the potential limits to confidentiality. As in other types of Internet research, the investigator needs to indicate how the participant's consent will be obtained and his/her confidentiality protected. Of particular concern with this type of research is the participation by minors that must be addressed in their IRB protocol.

For additional information on Internet Research, refer to the following website:
<http://www.aaas.org/spp/sfrl/projects/intres/main.htm>

3. Policy and Procedure on the Use of Surrogates in Decision Making-Capacity to Provide Consent for Research (including Research Involving Subjects with Diminished Capacity)

A. Introduction

An essential part of the consent process is assessing whether the potential subject has the capacity to make a decision about participating in a given research study. The proposed subject population and the inherent risks and benefits of a particular study will determine who should be responsible for assessing the capacity of potential subjects. These factors will also determine the procedures that should be followed if the subject is deemed incapable of providing consent.

An ethical balance must exist between the need to conduct research that asks questions about certain diseases or disorders, and the need to protect the affected, sometimes vulnerable, subject populations whose inclusion in the study can help answer those questions. However, the rights of the potential subject are always preeminent.

This section addresses consent issues in adult subjects only. Consistent with legal requirements on research involving minors, it is generally accepted that minors are not capable of consenting to research activities. This is due to an immaturity in decision-making skills (rather than impairment).

4. Research Involving Prisoners

“Prisoner” is defined by the regulations as “any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals’ detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing”.

“Penal” means relating to the punishment of offenders under the legal system; subject to punishment by law.

When reviewing research involving prisoners, the IRB must also meet the following requirements:

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
- At least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

In addition to all other responsibilities for IRBs the IRB shall review research involving prisoners and approve such research only if it finds that ALL of the following are true:

- The research falls into one of the following permitted categories (45CFR 46.306)
 - Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject;
 - Research on conditions particularly after prisoners as a class.

- Any possible advantages accruing to the prisoner through his or her participation in the research, where compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners; unless the PI provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research project;
- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

5. Research involving students as subjects

To avoid possibility of coercion, faculty pressure or influence on a student's grades, faculty should try to avoid recruiting amongst their students. In order to be able to recruit from their own students, a scientific reason must be explained in the application, other than working with a convenience sample. The IRB may reject an application that does not involve a valid scientific reason. *If* a valid scientific reason is provided, when a faculty member seeks to recruit amongst his/her students, the faculty member **MUST** do at least one of the following:

- a) Have a research assistant who has undergone CITI Training recruit, handle data and consent forms so that the faculty/researcher will not know about the participation of his/her students
- b) Develop a method for collecting data and consent forms that will not reveal participation of a student until grades have been released

Students must be clearly informed of these procedures prior to participating in the research and in the Consent Form. If an extra credit assignment is used as compensation in the research, an alternate assignment with equivalent effort must be provided for those students in the same class who do not wish to participate in the study.

B. IRB Review

1) During the review of a project, the IRB makes an assessment of the risk and therapeutic benefit associated with the study procedures. Risk can be considered minimal, i.e., the level of risk encountered in the subject's daily life, or more than minimal risk. The study may contain no benefit, direct benefit, or indirect benefit (benefit to society, e.g., provides information about the disease in general).

2) Based on this assessment, the IRB will determine what type of review the study can undergo (exempt, expedited, or full committee) and will determine if the proposed subject populations are acceptable for inclusion. Capacity to consent (described below) is one factor that is considered in this determination:

a. Subjects who lack the capacity to consent for themselves can be included in studies only if the IRB confirms that one of the following criteria is met:

risk is minimal (defined in the federal regulations as "the probability and magnitude of harm anticipated in the research are not greater in and of themselves than those encountered in daily life, or during the performance of routine physical or psychological examinations or tests")

OR

risk is more than minimal, but there is a possibility of direct benefit to the subject.

Individuals who lack the capacity to consent for themselves cannot be enrolled in research studies that include more than minimal risk and no direct benefit. These types of studies can enroll individuals who are able to consent for themselves only with added procedural requirements, to be addressed by the IRB.

3) As a result of review, any additional safeguards (e.g., type of capacity assessment) required by the IRB will depend on the nature of the study as well as on the time course (temporary, permanent, progressive or fluctuating) and extent of the alteration in capacity. With increasing risk and decreasing benefit, the safeguards imposed on the study will be necessarily more stringent.

C. Required Procedures to be followed by the Person Obtaining Consent for All Studies, All Subjects:

The individual who signs the consent form as the 'Person obtaining consent' is responsible for leading the potential subject through the entire consent process. This means:

- 1) all aspects of the study, as described in the consent form, are first discussed with the potential subject,
- 2) the consent form is thoroughly reviewed with the potential subject and answers to the potential subject's questions are provided
- 3) while reviewing the consent form, the person obtaining consent asks questions designed to assess the potential subject's understanding of the material. The person will specifically state this intent to the potential subject (i.e., the person is making sure the potential subject appreciates what s/he is being asked to do, and why).
- 4) the potential subject is given ample opportunity to decide, without coercion or undue influence, whether or not to be in the study.
- 5) The consent process does not end with the formal signing of the consent document. Rather, it is an ongoing process that continues throughout the subject's participation in the study. The person obtaining consent remains responsible for continued assessments of the subject's understanding of what is happening to him/her, his/her willingness to participate and for providing the subject with any new information that may affect the willingness to participate.

It is the Principal Investigator's responsibility to train and supervise the study personnel who are obtaining consent.

D. What determines a potential subject's capacity to consent to research?

For the purpose of this section, a subject has the capacity to consent to his or her own participation in a research activity if s/he demonstrates an appreciation:

- 1) that the activity is research, not standard treatment
- 2) of the risks and benefits of a study
- 3) of the alternatives that are available if s/he does not participate
- 4) that, if s/he chooses not to participate, this decision will be accepted without penalty, i.e., without jeopardizing clinical care.

In reaching a decision about participation, it is essential for the potential subject to demonstrate an ability to use this information in a rational manner. Thus, in considering risks, benefits, and available alternatives, subjects must show they understand the aspects of these factors that are unique to them as individuals. To

highlight this distinction, a person who is suffering with severe depression may be able to demonstrate an appreciation of a, b, c and d above, but may not care, or may actually want to take risks. Such individuals should not be considered able to provide consent for themselves.

E. What characteristics of research subjects may suggest a diminished capacity to provide consent?

1) Certain individuals, such as those with severe dementia, or severe mental retardation, will have a diminished capacity to provide consent. For these individuals, see the section on 'Surrogate Consent,' below.

2) For other individuals, it will not always be easy to predict whether capacity will be diminished given the following:

- a) Many individuals with psychiatric illnesses have the capacity to provide consent.
- b) Medical illnesses (e.g., cerebral insult) may be accompanied by an impaired capacity to consent.
- c) Upon learning of a serious diagnosis (e.g. cancer), psychological "shock" may temporarily impair a person's capacity to provide consent, although the illness does not affect decisional capacity in and of itself.
- d) Individuals who are intoxicated with alcohol or with drugs may be unable to consent to research until the intoxication resolves.

3) In assessing capacity, it is important to note that capacity is neither a constant nor an absolute. For example:

- a) Stroke victims may not have the capacity to consent to research immediately after the onset of stroke, but may develop capacity as recovery progresses.
- b) Patients in the early stages of Alzheimer's disease may initially have the capacity to consent to research, but as the disease progresses, may lose the ability to decide to continue or withdraw from that research.
- c) Patients with schizophrenia often experience acute psychotic episodes followed by periods of lucidity.
- d) Patients who learn they are terminally ill, often experience an initial short-lived period of emotional shock and denial which impairs their capacity to provide consent

4) The requisite level of capacity will necessarily vary from study to study and will depend on:

- a) the complexity of the information being presented, and
- b) the relative risks and benefits of the study (deciding to participate in a blood drawing protocol is 'easier' than deciding to participate in an experimental drug trial).

Therefore, when developing a research proposal, the investigator must determine whether the study will include any subjects who may not have the capacity to consent to the research, either initially, or at some point during the course of the study. If some or all subjects may have a diminished capacity to consent, the investigator must further determine if the potential impairment is temporary (e.g., 'shock' at the discovery of a medical diagnosis, intoxication), permanent (e.g., severe mental retardation), progressive (e.g., Alzheimer's dementia) or fluctuating (e.g., bipolar disorder).

F. If a study proposes to include a subject population where all or some of the individuals will lack the capacity to consent:

The IRB will make first a determination of risk/benefit category. As addressed above, in order to be considered for inclusion of this population, the study must necessarily involve either minimal risk, or more than minimal risk with the possibility of direct benefit.

If the study can include this subject population, the committee will next make the determination of whether or not a formal attestation/documentation of capacity assessment is required for each subject. An

independent assessment of capacity* may be required in instances where, e.g., the research involves more than minimal risk, or, the research team does not include a physician or mental health professional who could be called upon to make the formal assessment. The above determinations will take into account the psychiatric, medical, and emotional status of the subject population, as well as the inherent risk/benefit ratio of the study design.

If the IRB requires such formal documentation of a subject's capacity, the following statement is added to the end of the consent form:

"My signature below attests to the fact that I am a physician or mental health professional and I have interviewed (name of patient) on _____ (date). I have determined that s/he does _____ does not _____ have the capacity to consent to participation in this research activity, in that s/he is _____ is not _____ capable of appreciating a) that the activity described in this consent document constitutes research, not standard treatment, b) the risks and benefits of this study c) the alternatives that are available if s/he chooses not to participate, and d) that the decision to not participate will be accepted without penalty, i.e., without jeopardizing his/her clinical care."

** (i.e., by an MD or mental health professional not associated with the study, with familiarity with capacity to consent issues in human subjects research)*

G. Who can provide consent for a person to participate in a research study if a person is incapable of doing so?

Reminder, such persons can only be enrolled in minimal risk research, or more than minimal risk research where direct benefit is possible.

1) Individuals who may consent on behalf of the patient include:

- a) Individuals granted legally documented authority to make decisions specifically regarding participation in research activities
- b) Family Member (in order of priority: spouse, adult child, parent, adult sibling).
- c) Individuals named in a health care proxy, only for those research protocols generally recognized in the medical community as offering the optimal treatment choice (e.g., there are few, if any, effective treatments for patients with multiple-recurrent cancer, and those with very rare or highly aggressive cancers. In such circumstances, the medical societies, and the National Cancer Institute, specifically recommend enrollment in a research protocol as the best possible care)

2) For studies in which the patient is able to provide initial consent, but may lose the capacity to decide whether to continue or withdraw consent during the study as a result of disease progression (e.g., Alzheimer's disease), the IRB recommends that the formal designation of a surrogate (via execution of the document presented in #1(a) above) be discussed with the subject early on in the research activity.

3) Individuals who consent on behalf of a patient should be informed that they must make the decision for or against participation based on 'substituted judgment', reflecting views that the potential subject expressed while capable of making their own decision. If the views are not known, the decision should be based on what is believed to be in the best interests of the subject.

4) Individuals who consent on behalf of a patient should receive education about the importance of their role, the study, the health status of the patient, the rights to refuse to participate or to withdraw consent at any time without penalty. This person should be taken through the entire consent process, as described earlier in this section.

5) Assent from the patient should be obtained whenever possible. No subject should ever be enrolled, or continued in a research activity against their will.

6) Further, if an individual consents on the subject's behalf, the subject's capacity should be routinely assessed throughout the study (as reasonable with respect to the subject's disease state or disorder). If the subject regains the capacity to consent, s/he should be presented with the information about the study, as in the initial consent process, and be given the opportunity to decide to continue or withdraw from the study.

H. Conclusion

Obtaining ethically valid consent from all subjects in studies is essential to the research program at SUNY-Potsdam. The IRB hopes that this section will be of assistance to investigators in developing new protocols, and in assuring that current research activities provide maximal protection of human subjects.

PART IV: DEFINITIONS

- (a) "Department or agency head" means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.
- (b) "Institution" means any public or private entity or agency (including federal, state, and other agencies).
- (c) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- (d) "Research" means a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute "research" for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.
- (e) "Research subject to regulation" and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity. It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).
- (f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - 1) Data through intervention or interaction with the individual, or
 - 2) Identifiable private information.

"Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes.

"Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- (g) "Vulnerable subjects" means subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- (h) "IRB" means an institutional review board established in accord with and for the purposes expressed in this policy.
- (i) "IRB approval" means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
- (j) "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.
- (k) "Certification" means the official notification by the institution to the supporting department or agency, in

accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(l)

“Institutional research” means For the purpose of this policy, data collection procedures that are part of a program or service evaluation and are intended SOLELY for the purpose of monitoring or improving the effectiveness or quality of the program or service being evaluated and NOT for the purpose of contributing to generalizable knowledge about such programs or services are not research and, therefore, are not subject to the requirements of this policy, as long as the collection of data poses no more than minimal risk to participants. Minimal risk will be defined here in keeping with campus IRB regulations (See Part IV of this policy). For example, a survey that gathers confidential information, sensitive personal matters or illegal behavior involves more than minimal risk would require IRB approval. In addition, a project collecting data to be reported to SUNY System Administration or accrediting or regulatory bodies is subject to IRB review if that data will then be used outside of the SUNY System or accrediting or regulatory process.