

STATE UNIVERSITY OF NEW YORK

NEW PALTZ

POLICY ON THE USE OF HUMAN SUBJECTS IN RESEARCH

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POLICY ON THE USE OF HUMAN SUBJECTS IN RESEARCH

The State University of New York at New Paltz 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 New Paltz 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 New Paltz 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 New Paltz 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 New Paltz complies with Federal laws requiring the protection of human research subjects. **Notations occurring in the State University of New York at New Paltz 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, 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 New Paltz will not conduct FDA regulated research or research with prisoners.

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 New Paltz assumes responsibility for communicating and explaining these principles to personnel and students and for providing procedural guidelines to effect their observance. 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 New Paltz, 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 New Paltz 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 includes both individual and institutional research conducted on or off campus whether externally funded or not.

- B. SUNY New Paltz 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.
- C. It is the policy of SUNY New Paltz that 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. No individual involved in the conduct and/or supervision of a specific project shall participate in IRB review, except to provide information.
- D. SUNY New Paltz will provide the IRB with resources, professional staff and support staff sufficient to carry out its responsibilities efficiently and effectively.
- E. 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.
- 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. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
- G. 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.
- H. 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.
- I. 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 the law.
- J. Participation in projects must be voluntary. Written informed consent must be obtained from all subjects, unless this requirement is specifically waived by the IRB. Methods in accordance with the requirements of 46.116 and 46.117, appropriate to the risks of the research, must be used to obtain the subjects' informed consent.
- 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.
- L. 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, E1.

- M. SUNY New Paltz 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. prisoners
 3. children
 4. physically or mentally handicapped persons
 5. economically or educationally disadvantaged persons
 6. other potentially vulnerable groups
 7. activities involving fetuses and human invitro fertilization, and
 8. activities involving cooperative research projects.
- 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. Meeting space and staff support are provided by SUNY New Paltz for IRB reviews and documentation.
- P. SUNY New Paltz 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.
- Q. SUNY New Paltz requires that all institutions and investigators (including subcontractors and subgrantees) collaborating in its human subjects research operate under an OHRP-approved Assurance of Protection for Human Subjects.
- R. SUNY New Paltz will exercise appropriate administrative overview 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 New Paltz Office of Sponsored Programs web site and will be sent to faculty/staff requesting copies. The Chair of the IRB will send copies of all correspondence between the IRB and investigators to the Provost/Vice President for Academic Affairs.
- S. SUNY New Paltz encourages and promotes constructive communication among research investigators, the IRB, SUNY New Paltz 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.
- T. No involvement of human subjects in research is permitted until the IRB has reviewed and approved the research 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 activity involving data collection from, or related to, human subjects** to the attention of State University of New York at New Paltz IRB for review and approval. This includes, for example, historical, educational and business related research, survey and interview procedures, as well as research involving clinical and experimental techniques.

1. Application for exempt status

Research activities in which the only involvement of human subjects are in one or more of the following categories may be reviewed for exempt status by the IRB. (See a.-f. below.) **No exemption categories apply to research involving prisoners, 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).** If after consulting these sections, it is not clear whether the research meets the criteria for certification of exemption, it is the responsibility of the investigator to follow the procedures and to allow sufficient time for full IRB review.

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Please note that research on classroom management methods in special education will not qualify for exempt certification.)

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Please note that research using survey, interview or observational procedures with vulnerable populations (including children) is not exempt.

c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph b above if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (At present the only statutes that meet this criterion are 42 USC 3789g governing research conducted or supported by the Department of Justice and 20 USC 1221 e-1 governing research conducted or supported by the National Center for Education Statistics of the Department of Education.)

d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

e. Research or demonstration projects which are conducted by or subject to the approval of federal department or agency heads and which are designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs,

(ii) procedures for obtaining services or benefits under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

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.

2. Student research activities

Student research activity means research exercises involving human subjects conducted by students in completion of coursework requirements. These will be considered classroom activities and not scientific research and therefore do not require IRB approval if the following conditions are met:

a. the results will never be submitted for publication or presented in a public forum; and

b. the raw data will be destroyed immediately upon completion of course requirements.

Note that **thesis research** remains subject to IRB review, since the completed theses are routinely bound and placed in the library.

3. Preparation of Application

- a. Research investigators shall prepare the Application for Research Proposal Review. 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 include the proposed informed consent form and copies of any research instruments, e.g., interview guides, questionnaires, curricula, solicitation letters to subjects with the protocol as well as a description of the manner and location in which these forms will be stored for a minimum of three years following completion of the project.

4. 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 New Paltz IRB for review and approval.

5. 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.
- d. In most cases, requests for minor modification will be expedited by chair review. Requests for major modification will be considered at the next scheduled IRB review meeting.
- e. An application for revision includes the submission of all proposed changes with a rationale for each proposed change.

6. Apprising subjects of findings which 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 which may relate to the subjects' willingness to continue participation.

7. Complying with IRB decisions

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

8. 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 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.

9. Submission of progress reports on the research

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. A final report must be submitted when the research is completed. Prior to the anniversary of IRB approval, a request for continuation of research must be submitted to and approved by the IRB. (For both purposes use Application for Approval/Final Report in the IRB Manual appendices.)

10. 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.

b. Research investigators are responsible for reporting within 10 days to the IRB any unanticipated problems which involve minimal risks to the human research subjects or others. 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 which involve above minimal risks to the human research subjects or others.

11. 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.

12. 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 comprised of at least five members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted by SUNY New Paltz.
- 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 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 New Paltz.
- 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.

2. IRB appointment

- a. The Provost/Vice President for Academic Affairs makes appointments to the IRB for terms of three years.
- b. The Provost/Vice President for Academic Affairs also appoints the Chair on an annual basis.

3. 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 Federalwide 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 New Paltz for the protection of human research subjects which are in compliance with applicable Federal law.

b. Except when an exempt or expedited review procedure is applicable, the IRB shall review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

A convened meeting may either take place with members present in one location or may be conducted via telephone conference call provided that each participating IRB member (i) has received all pertinent material prior to the meeting, and (ii) can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance, initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).

c. SUNY New Paltz 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. IRB review of research

a. 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.

b. 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.

c. The IRB shall require documentation of informed consent or may waive documentation in accordance with 46.117.

d. The IRB shall notify investigators and the institution (the Provost/Vice President for Academic Affairs) 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.

e. 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.

3. Expedited review procedures and categories

- a. The IRB will utilize expedited review procedures for research in **categories listed in e. below** involving no more than minimal risk or for minor changes in previously approved research (of one year or less).
- b. The expedited review procedure will be carried out by the IRB Chair or one or more experienced reviewers designated by the Chair from among members of the IRB.
 - (1) In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.
 - (2) A research activity may be disapproved only after review in accordance with the Full Review procedure.
- c. The IRB Chair or designee reviewing the proposal will report on all expedited reviews at the IRB meeting following the review decision.
- d. 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.
- e. Applicability

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.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects 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.

The expedited review procedure may not be used for classified research involving human subjects.

The review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

Categories one (1) through nine (9) pertain to both initial and continuing IRB review.

f. Expedited review categories include:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which:

(i) an investigational device exemption application (21 CFR Part 812) is not required; or

(ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant 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).

3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

(a) hair and nail clippings in a nondisfiguring 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 unstimulated 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.
4. 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.
 5. 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.)
 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR46.101 (b) (2) and (b) (3). This listing refers only to research that is not exempt.)
 8. Continuing review of research previously approved by the convened IRB as follows:
 - (a) where
 - (i) the research is permanently closed to the enrollment of new subjects;
 - (ii) all subjects have completed all research-related interventions; and
 - (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis
 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that

the research involves no greater than minimal risk and no additional risks have been identified.

4. 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., 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, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons) additional safeguards must be included in the study to protect the rights and welfare of these subjects.
5. Review by Institution
- 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/VPAA.
 - b. However, institutional officials may not approve the research if it has not been approved by the IRB.
6. 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 has 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 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/Vice President for Academic Affairs. The Provost/Vice President for Academic Affairs shall inform immediately other appropriate institutional officials, and subsequently OHRP and department and agency heads as required for non-exempt research.
 - c. Any termination of approval resulting from non-submission of Application for Continued Approval/Final Report or of minor modifications to an approved protocol shall be reported to the investigator, the Provost/Vice-President for Academic Affairs, and the Human Protections Administrator. The Provost/Vice-President for Academic Affairs shall inform other institutional officials if deemed necessary.
 - 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 the Human Protections Administrator, that individual will report them immediately to the IRB Chair and the Provost/Vice President of Academic Affairs.
 - 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 Human Protections Administrator and the Provost/Vice President for Academic Affairs 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 of approval, the IRB Chair writes an individualized letter to the principal investigator explaining violations.

7. 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.

8. Review of Allegations of Noncompliance

The 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/terminate 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 study team. All decisions of the IRB are reported to the Provost/Vice President for Academic Affairs as the institutional official. If the IRB determines that further investigation is appropriate, the IRB will make a recommendation to the Provost/Vice President for Academic Affairs. In cases of serious or continuing noncompliance, the institutional official will report within SUNY and to the Office for Human Research Protections as required.

9. Appeal Process

Since the IRB is the final authority on decisions relative to the protections of human subjects from research risk, investigators may only appeal decisions of the IRB to the IRB for review. 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(s) will receive a report of the vote. Neither investigator(s) nor representatives may be present during the voting process.

10. Cooperative Research

- a. Cooperative research projects are those projects covered by this policy which involve more than one institution.

- 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.

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.
 - (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. 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. Training

- a. The IRB will require human protections education of research investigators, IRB members, and other relevant personnel. The IRB will require documentation of such training from research investigators as a condition for conducting human subject research.

13. 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):

- 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.

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, 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 New Paltz Informed Consent Template

Except as provided in Section 4 below, research investigators are to use the State University of New York at New Paltz Informed Consent Template (Refer to the Institutional Review Board Manual, Appendix C) as a model to develop their consent forms. The State University of New York at New Paltz 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, 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.
 - (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."

4. 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.
5. 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.

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 New Paltz, 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 New Paltz, to the funding agency, if required, and final approval given to the proposed change by the agency.

PART III. SPECIFIC REVIEW PROCEDURES

The IRB authorizes three (3) levels of review based on the type of research activity. These levels are: (a) full review by the IRB, (b) expedited review by the IRB for research as specified in II,C.3, and (c) IRB certification of exempt status.

All research activity proposals are to be sent to the attention of the Chair of the IRB, in care of the Office of Sponsored Programs, HAB 805. The IRB Chair shall determine whether the research protocol meets the criteria for exemption from review, expedited review or full review. The research investigators shall be notified in writing of the IRB's decisions, conditions and requirements. 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.

A. Full Review by Institutional Review Board

1. Full review by the IRB is required for all protocols, except those meeting exempt or expedited review criteria. Only certain categories of research involving vulnerable subjects will meet the criteria for exempt or expedited review.

2. For all research, investigators shall submit ten (10) copies of the Application for Research Proposal Review to the Office of Sponsored Programs. (All students should first secure written approval from faculty advisor.) Forms are available on the Sponsored Programs web site.

The application should be submitted to the Office of Sponsored Programs three (3) weeks prior to regularly scheduled Board meetings. The schedule of IRB meetings is on file in the Office of Sponsored Programs and on the Sponsored Programs web site.

3. Attendance of the investigator at the IRB review meeting in which his or her research activity is scheduled for discussion is encouraged.

4. No research involving human subjects in any fashion shall be initiated until approval has been given by the IRB.

5. The formal actions taken by the IRB will consist of:

- a. Approval - indicates the researcher may begin (continue, if request is for continuation of research) data collection and that the project meets the IRB standards for human subject research.

- b. Approval withheld pending revision/external site approval - indicates approval by the Board has been withheld pending revision of specific points or external site approval. Research may not be undertaken until the outlined revisions/site approval are submitted to and approved by the Board or designated member.

- c. Resubmission Recommended: Major Revisions Required - indicates approval by the Board has been withheld as the proposed research does not meet SUNY New Paltz and federal guidelines for the protection of human subjects. The research activity may not be undertaken, and will not be endorsed by the institution, unless the investigator significantly revises the original application.

- d. Disapproval - indicates the proposed research does not meet SUNY New Paltz and federal guidelines for the protection of human subjects. 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.

6. Approval of proposed research is usually granted for a period of 12 months commencing on the date approval is granted by the Board at a convened meeting. 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. 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. 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 approved period. 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.

7. Investigators will be notified in writing and may be notified by telephone of Board action or of the need for modifications required as a condition for IRB approval of the proposed research. The IRB will determine whether the modifications need to be submitted to the full IRB or whether they may be reviewed by the Chair or Chair's designee. The applicant returns the modifications to the Office of Sponsored Programs. They are distributed to the full IRB or the Chair or and the Chair's designee as per the Board's decision. These are examined and either an approval letter is initiated or a request for further modification is made. The Office of the Provost/Vice President for Academic Affairs will be notified of approvals, modification requirements and disapprovals in writing.
8. When the research activity involves an outside agency (e.g., hospital, public school, clinic) the investigator must secure written approval from the appropriate official within the agency prior to receipt of final approval from the IRB. The status of the research project will be "Approval Withheld Pending External Site Approval" until the final approval from the external site is received by the IRB. (Investigators must first secure this project review status before applying for External Site Approval.)
9. If the IRB gives the research proposal an Approval Withheld Pending status, the investigator must contact the Board Chair regarding the required actions within 60 days or the proposal will be withdrawn from further Board action.
10. Research protocols scheduled for review shall be distributed to all members of the IRB at least two weeks prior to the meeting.
11. 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.
12. For both initial and continuing review, protocols that also involve grant applications to external agencies, the Chair or Chair's designee will function as a primary reviewer and will review the entire grant application as well as the protocol.
13. All IRB initial review and continuing review shall be conducted at convened meetings and at timely intervals (Exceptions to this requirement are studies which meet the requirements for expedited continuing review as stated in Appendix B of the Institutional Review Board Manual, F.(8) and F.(9)..
14. A majority of the membership of the IRB constitutes a quorum and is required in order to convene a meeting for the 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.) Members in training will be considered for determination of quorum but are to abstain from voting on research protocols until training is completed.
15. 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.
16. For a research protocol to be approved, it must receive the approval of a majority of those voting members present at the convened meeting.
17. 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 II, C.3.e., or Appendix B of the Institutional Review Board Manual.
 - a. The research investigator is to submit four (4) copies of the Application for Research Proposal Review to the Office of Sponsored Programs. The application must provide full justification to support expedited review in relation to the appropriate category listed in Part II, C.3.e
 - b. 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 at least three (3) weeks prior to scheduled IRB meetings to allow for full review if necessary.
2. Expedited review shall be conducted by the IRB Chair or one or more of the experienced IRB members designated by the Chair to conduct the review. Reviews, checklists and correspondence are to be submitted within 10 school days of receipt.
3. The IRB members conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. The reviewer(s) shall refer any research protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believes that full committee review is warranted.
4. When the expedited review procedure is used, the IRB Chair or member conducting the review shall inform the full IRB of research protocols which have been approved at the meeting following the review.
5. An expedited procedure may also be used to review minor changes in approved research. Expedited review of minor changes may be conducted by the Chair or Chair's designee for all changes except those which would increase risk to subjects above a level of minimal risk.
6. Approval of proposed research is usually granted for a period of 12 months commencing on the date approval is granted by the Board's designee. The Board may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals in instances such as student research projects. Continuation of projects past the approval period requires submission of the Application for Continued Approval/Final Report 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. 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 approved period.

C. Exempt Review Procedures

In the case of applications for certification of exempt status, review shall be conducted by the IRB Chair or by one or more of the experienced IRB members designated by the Chair. To determine whether to apply for exempt status, refer to Part II, A.1, or Appendix A of the Institutional Review Board Manual.

D. Continuing Review Procedures

For continuing review procedures, refer to Full Review Section 6 and Expedited Review Section 6. Actions taken by the IRB relative to continuing review are consistent with other formal actions of the IRB listed at A.5 under Full Review. Determination of the period for continuation is subject to review during this process.

E. 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.
- In certain circumstances, a Memorandum of Cooperation may be required.

Further information can be found on the following web page:

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/ass-intl.htm> and

45CFR46.101 (g) and (h), <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

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 (SafeSurf and RSAQ ratings) or use Adult Check systems. 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 New Paltz 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/sfrr/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. Consonant 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 an impairment).

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 patient to participate in a research study if a patient is incapable of doing so?

Reminder, such patients 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 clinical studies is essential to the research program at SUNY-New Paltz. 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.