

**STATE UNIVERSITY OF NEW YORK
AT
NEW PALTZ**

**INSTITUTIONAL REVIEW BOARD
APPLICATION MANUAL**

IRB Manual

Table of Contents

Purpose of Handbook	1
Instructions for Completing the Application for Research Proposal Review	2
Brief Description of Proposed Research.....	2
Description of Subjects/Participants.....	3
Procedures	5
Risks to Participants	7
Anticipated Benefits to Participants	8
Consent Procedures	9
Privacy and Confidentiality Procedures	12
Justification of Request for Exempt or Expedited Review Process	13
Justification of Request for Waiver of Informed Consent Process and/or Documentation... ..	13
Appendix A – Categories of Research That May Be Reviewed by the Institutional Review Board for Consideration as Exempt	14
Appendix B – Categories of Research That May Be Reviewed by the Institutional Review Board through an Expedited Review Procedure.....	15
Appendix C – Informed Consent Template.....	18
Appendix D – Application for Research Proposal Review.....	21
Appendix E – Application for Survey Research Exemption	26
Appendix F – Application for Modification Approval	30
Appendix G – Application for Continued Approval/Final Report.....	31
Appendix H - International Research	35
Appendix I - Internet Research	36
Appendix J - Policy and Procedures on the Use of Surrogates in Decision	38
Making Capacity to Provide Consent for Research (including Research Involving Subjects with Diminished Capacity)	
Appendix K - Research Proposal Checklist.....	41
Appendix L - Survey Research Proposal Checklist	44

**STATE UNIVERSITY OF NEW YORK AT NEW PALTZ
HUMAN RESEARCH HANDBOOK**

Purpose of Handbook

- To assist researchers in deliberations concerning how they can maximize benefits and minimize risks for participants in their research studies.
- To guide researchers in preparing human subject research applications for the Institutional Review Board (IRB).
- To clarify for researchers the decisions, which the IRB is required by federal regulation to make relative to human subject research applications.
- To facilitate the IRB approval process so that the time from submission of your application to the final approval of the application is reduced.

The regulations which guide the practice of research with human subjects in the U.S. are based upon three basic ethical principles: respect for persons, beneficence and justice. “Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.... Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.... It is commonly said that benefits and risks must be ‘balanced’ and shown to be ‘in a favorable ratio.’ The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, non-arbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research and to consider alternatives systematically.... Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible...” (Belmont Report, 1979).

“Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects. Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only ‘undesirable’ persons for risky research. Social justice requires that distinctions be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons...” (Belmont Report, 1979).

The legal codification of these ethical principles is found in the Final Common Rule. The Common Rule refers to the acceptance of 45CFR46 from the Department of Health and Human Services by all agencies of the U.S. Government. Each agency has different title and part numbers, but the same regulations. For purposes of readability, all cites in this handbook are referenced according to 45CFR46. The other applicable codes are as follows:

Authority: 5 U.S.C. 301; Sec. 474(a), 88 Stat. 352 (42 U.S.C. 2891-3(a)).

Note: As revised, Subpart A of the DHHS regulations incorporates the Common Rule (Federal Policy) for the Protection of Human Subjects (56 FR 28003). Subpart D of the HHS regulations has been amended at Section 46.401(b) to reference the revised Subpart A.

The Common Rule (Federal Policy) is also codified at:

7 CFR Part 1c	Department of Agriculture	24 CFR Part 60	Department of Housing and Urban Development
10 CFR Part 745	Department of Energy	28 CFR Part 46	Department of Justice
14 CFR Part 1230	National Aeronautics and Space Administration	32 CFR Part 219	Department of Defense
15 CFR Part 27	Department of Commerce	34 CFR Part 97	Department of Education
16 CFR Part 1028	Consumer Product Safety Commission	38 CFR Part 16	Department of Veterans Affairs
22 CFR Part 225	International Development Cooperation Agency	40 CFR Part 26	Environmental Protection Agency
		45 CFR Part 690	National Science Foundation
		49 CFR Part 11	Department of Transportation

Information about the regulations may be accessed at: <http://ohrp.osophs.dhhs.gov/>. This website has links to many areas concerning regulations and guidance memoranda for human subject research.

Instructions for Completing the Application for Research Proposal Review

Note: *The application for Research Proposal Review is included as Appendix D.*

Your research proposal will be reviewed initially by the IRB with procedures designated in the regulations according to the category of research for which you are requesting review, i.e., exempt, expedited review or full review. Appendix A and Appendix B list the criteria by which you may apply for exempt status or expedited review. These reviews are performed ordinarily by one member of the IRB. Any studies, which do not meet the criteria for exemption or expedited review, are reviewed by the full board at convened meetings. It is possible that a reviewer of an application for exemption or expedited review considers the study to meet requirements of full review as originally written. If the reviewer considers full board review necessary, the study is submitted for full review. For reasons of timeliness, you may choose to submit 10 copies of the application initially. Otherwise, you need to submit only four (4) copies for exempt and expedited applications. All applications are distributed at convened meetings to assure that members receive copies for review in a timely fashion. A schedule of convened meetings for each semester may be obtained from the Office of Sponsored Programs.

General Considerations:

There may be some questions on this form which you consider do not apply to your application. For those questions, state “Does not apply” if it is clear that it does not apply. If it might be subject to question, then give a rationale for why you do not believe this question pertains to your study. If you leave a question unanswered, the IRB will consider that you forgot to answer the question and will return your application with the request for further information.

Title Page:

Complete the information requested on the title page including your signature on the assurance of your compliance. Email addresses are optional and will be used to notify you that your official approval document and stamped consent form are available for pickup in the Office of Sponsored Programs.

Category A: Brief Description of Proposed Research:

This information is the basis for decisions of the IRB relative to your proposed research. It is used to assess the risk/benefit ratio and to determine if the significance of the research justifies human subject participation (45 CFR 46.111).

Question 1: State the purpose of your research

The statement of purpose is a concise statement of the reason(s) for conducting this particular research study. For data-based research, this statement is closely related to the hypothesis/hypotheses. For ethnographic, historical and qualitative research, this statement is closely related to the question(s) or aims of the research. It may be possible to write only one sentence and explain the purpose of the study. For other studies, more sentences or paragraphs may be necessary for the reviewers to understand the reasons for your study.

Question 2: State the major hypotheses, research question and/or the aims of your study.

In this section, you need only state the hypotheses or the research question(s). If you do not have hypotheses or a specific research question due to the type of research you are proposing, then state the aims of your study.

The design of your experiment or study will determine how you answer this item. For example, you would state a null hypothesis if you were testing it. However, you would state only alternate hypotheses if you are working with them solely. The statement of hypotheses or question(s) is important because all aspects of your proposal are judged in relation to them. Will the procedures, study design and data analyses techniques you outline produce information that will answer your question or support your hypothesis? Is the information to be gleaned appropriate to the risk to which you are exposing subjects/participants? Will information from this study provide benefit?

The specific aims are statements of what you hope to accomplish within the framework of this particular research study. For example, if you “focus” on a research question/issue, then where will the information possibly lead? Will it lead to the development of _____, or to understanding of _____, etc? In other words, why have you targeted these

subjects/participants or this situation to answer your research question?

Question 3: Provide brief review of literature including citations.

Your discussion of the relationship of the research crystallizes the importance of the research in terms of the research of others and the benefits to be derived from this study. **You must include citations and a literature review for studies cited.**

Category B: Description of Subjects/Participants:

Your description of the subjects/participants in your research is at the heart of the decisions which the IRB makes about the proposal. The IRB is charged with protecting human subjects from research risk. In order to assure justice in the selection of subjects, the federal government requires the IRB to review the following items: the approximate number of subjects, their age range, sex, ethnic background, the criteria for inclusion or exclusion from the study, procedures for recruitment, and the rationale for the use or exclusion of vulnerable subjects such as pregnant women, children, prisoners, mentally or physically handicapped persons, or the economically or educationally disadvantaged (45 CFR 46.111; see also http://www.nih.gov/grants/oprr/irb/irb_chapter3.htm and http://www.nih.gov/grants/oprr/irb/irb_chapter6.htm)

A “human subject” is defined as “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” [45 CFR 46.102 (f)].

Special considerations are necessary in your proposal if you hope to use subjects with whom you have a professional relationship. “Easy availability, compromised position, and susceptibility to manipulation overlap. For example, psychology students are readily available for psychological research, medical students available for medical research.... Subjects selected from these populations are also compromised to the extent that their jobs, promotions, grades, etc. are dependent upon those who might be recruiting them for research. This circumstance makes them susceptible to manipulation” (http://www.nih.gov/grants/oprr/irb/irb_chapter3.htm). In order to avoid undue influence or coercion, consider alternative recruitment procedures, an alternative subject pool or other procedural safeguards.

Prisoners constitute a unique subject pool. “On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to ‘volunteer’ or to ‘protect’ them presents a dilemma” (Belmont Report, 1979). Subpart C of 45CFR46 provides special protections to prisoners in research. Requirements for review of projects involving prisoners are very difficult and time-consuming. At the present time, the IRB is not able to consider any proposal for inclusion of prisoners as subjects for research projects.

One of the common errors that occurs in applications concerns the identification of only one pool of subjects when in fact there are two pools of subjects. For example, a researcher may be studying student learning. S/he may carefully describe all procedures related to the learners and neglect to describe procedures related to their teachers who are also part of the study. **If there are two pools of subjects in your study, then you need to develop separate responses to all questions beginning with Question 4 (the Description of Subjects) and continuing through Question 35.**

Question 4: State the source of the participant population

From what pool of individuals will your subjects be recruited? Are all participants students at SUNY at New Paltz? Are all subjects residents of a single skilled care facility? For International Research studies, refer to Appendix H. For Internet studies, refer to Appendix I.

Question 5: State the approximate number of subjects.

Give the approximate **maximum** number of subjects involved at any time in the study. If you initially are screening participants for exclusionary criteria, then include those participants in your maximum number of persons involved even if they will be excluded from the study at a later time. Be sure that you have the number of subjects necessary for your data analysis procedures. (Note: If you exceed your maximum number of subjects, it is necessary to file an amendment to your protocol.)

Question 6: Discuss the characteristics of participants as individuals and as a pool (including age, gender, student status, disease conditions, behavioral abnormalities and affiliations or memberships)

Describe the participants as completely as possible including whether they might be members of classes considered as vulnerable, e.g., minors, patients with dementia, etc. Explain why this group of people could be considered a population/pool for your research. If there is a diversity in ages of participants, then state an age range. If a characteristic such as gender and/or ethnic background is not an issue in your research, then state either that you expect representation similar to the institution or facility at which you will be conducting the research and give statistics on that population if they are available, or state why gender and ethnic background are not issues in your research. On the other hand, if a characteristic such as gender is a determining qualification for your pool, you must explain why you are excluding a class of people. This is also true for exclusion of children under 18 years old. “If one gender and/or minorities are excluded or inadequately represented in the research, ...a clear compelling rationale for exclusion or inadequate representation should be provided” (IRB Guidebook, Chapter VI, p. 8). (Convenience to the investigator is not an appropriate rationale for inclusionary or exclusionary practices.) Note for International Studies: This question is particularly important for you to address. Give background on specific cultural characteristics pertinent to the study.

Question 7: If your research involves non-English speaking subjects or subjects from a foreign culture, include contact information for someone who can act as a cultural consultant for your study, i.e., name, address, telephone number, and email. (The cultural consultant should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.)

Special considerations are necessary in research involving non-English speaking participants or participants from a foreign culture. The investigator is responsible for recommending to the IRB a consultant knowledgeable about cultural, political, economic and/or social issues within the foreign country. The Chair of the IRB or the Chair’s designee will contact the consultant relative to questions of the IRB regarding the study.

In addition, the investigator is responsible for authoritative documentation of equivalence in translation of all materials. An additional consultant, or the cultural consultant, if fluent in the language of the participants, must verify that translated documents are the equivalent of the English version of documents submitted. This documentation must be provided at the time of application submission.

For each consultant, include contact information, i.e., name, address, telephone number and email.

Question 8: State criteria for including subjects in the study or excluding subjects from the study.

In that the IRB is charged with assuring equitable selection of subjects in research [45CFR46.111 (a) (3)], these criteria are key. On what basis will you include or exclude subjects from your pool. For example, if the basis is responses to a questionnaire, then you must include the questionnaire and describe which items on the questionnaire will result in subjects being either included or excluded from the study. If you intend to accept all persons applying for inclusion, then state that. You may realize that some subjects will need to be removed from the study after they have begun a treatment. If so, state what the theoretical basis for that might be.

Question 9: Provide a rationale for the inclusion or exclusion of vulnerable subjects.

The federal requirement of a rationale for the use of vulnerable subjects in the research application is not meant as an exclusionary vehicle. The recognition evident in a subject’s inclusion in one of the categories which have been defined by the federal government as “vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons” is meant to assure that the IRB has reviewed the study and warrants that “additional safeguards have been included in the study to protect the rights and welfare of these subjects” (45CFR46.111 (7)(b)). The IRB attempts to balance issues that may be construed as paternalism with protections necessary due to vulnerabilities (45CFR46, Subparts B, C and D). It is not the intent of the IRB to preclude vulnerable subjects from participating in research studies solely on the basis of their vulnerability. It is the intent of the IRB to assure safeguards are in place so that decisions of all participants are voluntary and informed, even with subjects with impaired or limited decision-making capacity.

(See: <http://grants.nih.gov/grants/policy/questionablecapacity.htm>).

Question 10: Describe how you will recruit subjects for the study. Include all relevant materials, e.g., advertisements, fliers, scripts, translations, psychology pool sign-up sheets, etc.

How will you find participants for your study? State exactly what you will do to recruit subjects. If you use several means, explain each of them. All descriptions of procedures for recruitment must include scripts of what you or another person will be saying to subjects or announcing to subjects by way of posters, advertisements, letters, telephone calls, etc. Additionally, information concerning how access to subjects will be achieved must be addressed. (If you are setting up a website to collect data, how will you draw respondents to your website? If your research concerns patients with a given diagnosis, how will you access that information? If you are conducting ethnographic research, explain recruit procedures related community groups to their spokespersons?) The IRB must assure the confidentiality of private information so the procedural descriptions need to state how confidentiality will be maintained. This is especially true for children and health-impaired subjects. Recruitment of subjects may not begin before IRB approval has been granted.

Additionally, the IRB is charged with insuring that there is no coercion, undue influence or unjustifiable pressures to subjects to participate. If you are recruiting among your students or patients, consider alternatives to avoid conflicts of function and interest. It may be that students in another class or patients at a facility at which you are not employed would be more appropriate subjects.

Recruitment materials must state that the research is from SUNY at New Paltz and have contact information relative to the study. Recruitment materials are not marketing ploys; do not begin an advertisement with a dollar amount for participation.

Question 11: Discuss other matters pertinent to human participants.

The last question in each category is a “catch - all” question where you are free to add any information you consider important to the IRB’s understanding of your research. If you have excluded a class of subjects from your research and have not included a rationale elsewhere, include a “compelling” rationale for exclusion of classes of subjects. If there are no other pertinent considerations relative to your subjects, write, “Does not apply.”

Category C: Procedures

The procedural section of your application should include descriptions of all aspects of the research procedures. In weighing the risks and benefits of your research study, the IRB considers your methodology as well. “The value of research depends upon the integrity of study results. One of the ethical justifications for research involving human subjects is the social value of advancing scientific understanding and promoting human welfare by improving health care. But if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even to inconvenience them through participation in such a study”

http://www.nih.gov/grants/oprr/irb/irb_chapter4.htm - (See also: 45CFR46.109, 45CFR.111 & 45CFR46.116).

Question 12: Specify location of study.

Specify where the study will be done. For studies to be conducted at external sites, preliminary approval must be obtained from the IRB prior to obtaining external site approval. Such external site approval must be provided by appropriate authorities.

Note: If this is an international research study, special considerations apply. (Refer to Appendix H for additional procedural requirements. For further information on review procedures, contact the Chair.)

Question 13: List all variables to be studied.

State all the variables you will be examining. Analysis of these variables should allow you to answer your research question. Ask yourself if you need to collect all of the information you are collecting in order to answer your question. For example, if you are collecting demographic information in a survey, is it necessary to include a category called, “Eskimo.” For reasons of privacy and respect for persons, it is best not to collect unnecessary information.

Question 14: Describe the methods of data collection, record keeping and data analysis. (Attach copies of surveys, interview guides, questionnaires, instruments, stimuli-such as words, etc.) Document authorization of use or permission to modify a copyrighted instrument, or document access in the public domain of non-copyrighted instruments.

Describe the procedures you will use to collect data on all variables. Include surveys, copies of data collection instruments, interview guides, questionnaires, stimuli (such as words), etc. If you are using an instrument you did not develop, document authorization for use or permission to modify copyrighted instruments, or document access in the public domain. Sojourner Truth Library has several resources available to investigators for documentation purposes in the Reference Section. These include: *Tests in Print*, *The Mental Measurements Yearbook*, and *the Directory of Unpublished experimental Mental Measurers*. For information related to this question, you may review information on APA Online at <http://www.apa.org/science/faq-findtests.html>. If you are videotaping, audio taping or storing data on computer disks, explain how you will store them during the experiment and what will be done with them after the study is complete.

Describe how you will analyze your data. What is the design of your study? What statistics are you envisioning using? What process will you follow to code responses to questions? What data will be linked?

Question 15: Describe all activities involving participants, including frequency and duration of each activity and of the total time commitment.

This information is collected to evaluate the extent of varied activities subjects will experience and to assess risks, which may be associated with the activities. What is the subject going to be asked to do, e.g., participate in a focus group, exercise, weigh themselves, etc.? Each activity should be described extensively. The IRB makes a value judgement relative to the risks/benefits of participation in the study and must have exact information to make that decision. If there any costs to the participant, they should be included as well, e.g., equipment or travel.

Time is important to all of us; most of us have begun to answer a questionnaire online and been horrified at how more questions kept popping up. Parameters on the time necessary for each procedure involved in your study need to be reported. If you ask a subject to complete a questionnaire, there should be a realistic estimate of the time involved, similarly in the interview setting. If you are not doing timed trials, you should give a “best estimate” of the time involved (and follow that “best estimate”). You also need to total the time over all encounters so that the subject can realistically estimate what his or her commitment would be.

Question 16: Describe all equipment used with participants, e.g., experimental instrument, cameras, video-audiotapes, microphones, etc.

Your description of the equipment will be used to analyze risk to participants. Be sure to disclose any risks associated with the equipment. In some cases, mechanical drawings will clarify questions IRB members may have. The equipment should be designed for human use and/or approved for use with human subjects.

Question 17: Specify what factors will lead to cessation of procedures causing physical or emotional stress. Outline procedures for stopping or interrupting the protocol.

State the conditions under which you would stop or interrupt your experimental or research procedure because the participant is showing distress or revealing information, which could be personally damaging. When would you stop an interview? An exercise program? A videotape? What procedural safeguards have you developed for this possibility? What would you say to a participant about discontinuing his/her participation in the research?

Question 18: Describe biological samples to be taken, the method for their handling and the qualifications of individuals taking samples.

State what you are sampling in what amounts and at what frequency. Describe how the samples will be handled and by whom. What is the participant expected to do? At what times of day? How are samples transferred? Who transfers samples? If the procedure is biomedical, what are the qualifications of the individuals taking the samples? If an abnormality is noted, how will this be handled?

Question 19: Provide debriefing method, rationale for deception (if applicable) and debriefing protocol.

Subjects appreciate knowing what knowledge was gained from a study in which they participated. Investigators may describe the outcome of a study and/or the subject's results if it is appropriate to do so. Debriefing is a courtesy with some studies and a requirement for others. If any deception or concealment was employed, you must schedule a debriefing to explain to the participant the true intent of the research. If you have employed deception or concealment, it is appropriate at the time of debriefing if the subject is upset to ask whether s/he would like to delete the data associated with his/her participation in the study. Your rationale for utilizing deception must be provided. The debriefing protocol must be described.

Question 20: Discuss any other aspects of the procedures.

You may add any information here that you consider pertinent to the discussion of procedures. If you feel that you have covered all areas concerning procedures, write "Does not apply."

Category D: Risks to Participants

"The term 'risk' refers to a possibility that harm may occur. However, when expressions such as 'small risk' or 'high risk' are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.... Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies" (Belmont Report, 1979).

In order to approve an application, the IRB must assure that: "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" [45CFR46.111 (a) (1)]. Most studies on our campus qualify for approval under a determination by the IRB of minimal risk. "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" [45CFR46.102 (i)].

In your discussion of risks, you should list potential adverse effects/events if there is a foreseeable possibility of their occurrence. An adverse effect is "an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy)" (http://www.nih.gov/grants/oprr/irb/irb_glossary.htm). Common risks associated with typical procedures include: breach of confidentiality by participants in focus groups; fatigue, boredom, muscle soreness, heart abnormalities, etc., from exercise testing; psychological discomfort or worry from induction of psychological stress; and emotional distress from a breach in confidentiality related to information on questionnaires.

Subpart D of 45CFR46 provides additional protections for children involved as research subjects. To assure protections for children, the IRB must classify a study into one of four categories and analyze the risk/benefit relationship in terms of that category. The categories are: research not involving greater than minimal risk (45CFR46.404), research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual subject (45CFR46.405), research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (45CFR46.406), and research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45CFR46.407).

If research involves greater than minimal risk for children, then the IRB must find that "(a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in Sec. 46.408" (45CFR46.405). For research involving greater than minimal risk for children and no prospect of direct benefit, there must be the likelihood of the study yielding generalizable knowledge about the subject's disorder or condition (45CFR46.406).

Certain research is considered "sensitive" and requires additional protections for subjects. This research involves "the collection of information falling into any of the following categories: (a) Information relating to sexual attitudes, preferences, or practices; (b) Information relating to the use of alcohol, drugs, or other addictive products; (c) Information relating to illegal

conduct; (d) Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community; (e) Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination; (f) Information pertaining to an individual's psychological well-being or mental health" [Public Health Service Act, Sec. 301 (d)]. In very unusual circumstances, a researcher may apply for a Certificate of Confidentiality, which would provide protection against federal subpoenas and certain state subpoenas. (It is not clear at this time, whether the State of New York would recognize a federal Certificate of Confidentiality.) If you are considering collecting data under any of these categories, you must show why it is necessary to collect the data, what benefit would accrue, and what safeguards you have developed to protect the privacy of participants. If a researcher is collecting data concerning "illegal or stigmatizing activities...which are not eligible for...statutory shields against subpoena, careful attention should be given to a series of decisions related to confidentiality: (1) whether the researcher will record subject identifiers at all (including consent forms); (2) if identifiers are to be collected, whether they will be retained after the data are coded; (3) if identifiers are not destroyed, how are they to be maintained; and (4) what subjects should be told about these matters as part of the informed consent process" (<http://www.nih.gov/grants/oprr/irb/irbchapter3.htm>).

Question 21: Describe potential risks and assess the likelihood, severity, duration and effects of each. (Note "no known risks" if none are anticipated. Consider risks of physical injury, psychological trauma or stress, social/economic harm, legal risks and loss of confidentiality.)

Give the IRB members a description of potential risks arising from your research. Consider risks of physical, psychological, social and economic harms, as well as legal risks and loss of confidentiality. Participants may be facing risks to reputation or insurability because of the design of the study. Discuss the risks which can be reasonably foreseen in terms of how likely they are to occur, how serious they might be, for how long the subject would still be subject to the risks and what the effects of each of these might be. It is not necessary to list remote possibilities of risks. (This information becomes especially important if you are working with subjects who are also students or patients of yours.)

Question 22: Describe methods for minimizing risks. For example, document how potential psychological distress will be addressed, by whom, and with what credentials.

For each risk identified in Question 20, discuss what procedures you will use to minimize risks to participants. Ask yourself whether it is truly necessary to collect information or to perform procedures, which may place subjects at risk. Consider alternative procedures. What procedures will be employed if an adverse event occurs? Who will pay the cost for those procedures, e.g., psychologist's services, medical services, etc.?

Question 23: Describe other methods, if any, that were considered alternatively and why they will not be used.

Other than participating in the research, what alternatives (treatment, medication, etc.) are available to the subjects and how is participation in the research justified in relation to those alternatives? In addition, can the data be collected anonymously rather than in an identifiable format? What are the risks associated with the alternative procedures? Can certain questions be deleted from a questionnaire without jeopardizing the validity of your study? What is your rationale for not employing a procedure involving less risk to subjects?

Question 24: State any other matters relative to risk to participants.

Is there any additional information relative to risk that you could provide for members of the IRB as they make their decision based upon the particulars of your study? Are there other studies in this area in which subjects experienced adverse events? How do your procedures for managing risk compare to other literature in this area?

Category E: Anticipated Benefits to Participants

In that the IRB must make a decision assessing whether the risks to participants are reasonable in terms of the anticipated benefits which may accrue to the participant directly or to others as generalizable knowledge [45CFR46.111 (a) (2)], your statements about anticipated benefits to participants must be clearly identifiable and comprehensible. A benefit is "a valued or desired outcome; an advantage" (http://www.nih.gov/grants/oprr/irb/irb_glossary.htm). Items such as remuneration or extra credit options for participation are considered as incentives, not benefits. They are extraneous to the research question and procedures. Be careful not to overstate the anticipated benefits to subjects of experimental procedures. After all, they are being tested.

The ratio of risk to anticipated benefit, which is assessed by the IRB, allows for multiple possibilities related to benefits. If the category of risk is less than minimal, it may be acceptable to state that there is “no known benefit.” As was discussed in Category D: Risks to Participants, in research with greater than minimal risk, children ordinarily must receive direct benefit.

Question 25: Describe the anticipated direct benefits to these participants because of their participation.

This question asks what, if any, direct benefits may accrue to the participant as a result of participation.

Question 26: Describe the anticipated benefits accruing to the class of participants these individuals represent.

This question has two parts which you need to address. The first part entails discussion of potential benefits for the class the subjects represent. The second part requires that you show why these individuals are representative of the class which will be receiving the benefit. (The IRB is to assure that certain classes of individuals do not bear the burden of research simply due to their availability to the researcher [45CFR46.111 (a) (3)]).

Question 27: Describe the anticipated benefits accruing to society-at-large or other.

Does your research offer hope to a larger population than the participant pool? If so, please describe those benefits.

Question 28: State any other aspects of anticipated benefits to participants.

State any ideas related to benefit that you consider important in your study which you have not already delineated.

Category F: Consent Procedures

“Consent is not a single event; rather it is a process. Since subjects always retain the right to withdraw from a research project, their continuing consent is important” (http://www.nih.gov/grants/opr/irb/irb_chapter3.htm). “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.... There is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness....

Informed consent requires conditions free of coercion and undue influence” as well as “...unjustifiable pressures” (Belmont Report, 1979). The informed consent form that you develop merely documents the ongoing process of informing the subject of all that will be asked of him/her concerning protocols, risks, benefits and alternative procedures and assures that the subject understands what you have told him/her and voluntarily agrees to all procedures.

“The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment” (Nuremberg Code, 1949).

The federal regulations are very specific about the information that must be provided to participants in research studies in an ongoing manner [45CFR46.116(a)]. In order to assure understanding of the procedures to which subjects are consenting, researchers (or their designated assistants) are to speak with the participants, to present the participants with written information about the research in the form of an Informed Consent Form, and to give participants a copy of the signed Informed Consent Form. For certain studies, the IRB may be required “to observe, or have a third party observe, the consent process and the research itself” [45CFR46.109 (e)]. The following information must be communicated and comprehended:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to

the subject;

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

The regulations further provide that the following additional information be provided to subjects, where appropriate [45CFR46.116 (b)]:

- (1) 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;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) 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
- (6) the approximate number of subjects involved in the study.

In addition to requirements relative to the information presented in the process of informed consent, there are requirements that language be understandable and that no exculpatory language be used. "If English is not the subject population's primary language, the explanations and the forms should be translated into the subjects' native language" (http://www.nih.gov/grants/oprr/irb/irb_chapter3.htm).

In most instances, informed consent must be documented with an informed consent form which includes all required information and is written so that subjects can understand the information [45CFR46.117 (a) and (b)]. Exceptions to the requirement of written informed consent documentation are listed at 45CFR46.117 (c). "An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

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

(Note:) 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."

Consent processes with children involve a process allowing for assent of the child and permission of the child's parent(s) [45CFR46.408]. Language appropriate to the age and maturity of the child is key. For example, written language is not appropriate for a child who has not learned to read yet. According to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in their report entitled *Research Involving Children* (1977), a child with normal cognitive development becomes capable of meaningful assent at about seven years of age. The "rule of sevens" holds

that there is an increasing need for agreement from children as they become more mature. From birth to seven, the questionable capacity to consent affects whether there is a need for assent. From 7-14, a minimal level of assent should be obtained as the child is considered to have a minimal capacity for consent. From 14 to the age of consent in a given state, there should be a greater role for assent as the child is maturing to full capacity for consent. Issues relative to developmental age (as opposed to chronological age) also affect the assent process. Permission of one or both parents is required for research participation according to the category of risk to the child [45CFR46.408 (b)]. Children who are wards of the State or any other agency, institution, or entity can be included only in research approved under certain conditions [45CFR46.409]. Additionally, the State of New York Legislature is considering further requirements for research with children.

Consent processes with persons with limited capacity for consent vary according to the capacity of the individual and the complexity of the research study. Procedures should accommodate the potential for fluctuating states of cognizance or awareness with subjects with certain diagnoses. They should also promote voluntariness through special procedures to assure that the participant understands that s/he has the choice to participate or not at all times throughout the research study.

See: <http://grants.nih.gov/grants/policy/questionablecapacity.htm>

If you are considering working with veterans in a Veterans' Administration facility or on referral at another facility, be aware that there are special protections for veterans. It may be necessary for the IRB to monitor the informed consent process. (Due to major violations of rights in several VA Hospitals, the VA has imposed additional requirements for IRB review of research proposals and the studies themselves.) Consult the VHA HK Handbook 1200.5 to assure protections for veterans. (See <http://www.va.gov/publ/direc/health/handbook/1200-shk7-15-03.pdf>).

Ethnographic Research constitutes a special instance: In many cases it is appropriate first to request permission for general participation in community or group activities. Such permission should follow adequate public disclosure to and discussion with members of the group. Authorized spokespersons or the group or community as a whole may grant permission. (Hunn & Rhodes, Anthropology News, April, 2002, p.22).

Question 29: Describe how potential participants will be informed about the project activities.

This question asks you to explain all of the procedures you will use to assure informed consent and assent, if applicable. Who will administer the consent/assent process? What procedures will you use to let participants know what they will be doing and you will be doing as part of the research? How will you encourage their questions about the research? What procedures have you developed to assure their ongoing consent/assent (if that is an issue)? When will you (or your designee) give the participants a copy of the informed consent form? Are alternative procedures needed, e.g., translations or modifications for persons with handicapping conditions?

Question 30: Attach the consent form and assent form/script, if appropriate. (Use reading level and terminology understandable to participants. If participants are non-English speaking, include translations of all consent/assent documents and certification of the equivalence of the translation in relation to the English language documents. See Question 7.)

A consent template appears in Appendix C. You should adapt this to your project by adding specific information about your research. The language level you use should be appropriate to your subject pool. It is estimated that the average American reads at a level between the sixth and eighth grade levels. If participants are non-English speaking, the investigator is responsible for verification of translation.

Assent forms present complex issues. They should include all informational elements of consent, but in a way that will be understandable to the participant. These will vary according to the chronological and developmental ages of the participant. Depending upon the reading ability of the participant, you may choose to develop a script, which you will read and ask for assent. (see a sample assent form at the IRB website: http://newpaltz.edu/sponsored_programs)

Approved consent forms will be available for researchers to review in the Office of Sponsored Programs after January 1, 2002.

Question 31: Other aspects of the consent process.

Depending upon your population, you may see the need to develop alternative procedures for some subjects. For example, for confused subjects or interviewees, you may develop a process at the beginning of each session for assuring ongoing consent. If you have not listed the procedures elsewhere, you should include them here.

Category G: Privacy and Confidentiality Procedures

“Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure” (http://www.nih.gov/grants/oprr/irb/irb_chapter_3.htm). Privacy and confidentiality issues although related require investigators to consider different issues concerning personally identifiable information. Invasions of privacy occur when an investigator either accesses or releases personally identifiable or private information without the consent of the subject. Studies involving deception, incomplete disclosure, covert observation or participant observation techniques, need to address issues related to invasion of privacy. Breaches of confidentiality occur when information about subjects is divulged improperly. The information may be divulged by the investigator, a research assistant, a transcriber, another subject (in a group setting), or a hacker (for web-based studies). Procedures need to be developed to ensure protection of personal and private information in each setting according to the potential for breach of confidentiality. This includes training of assistants and research staff, as well as security measures, e.g., locked file cabinets, coding of data, use of pseudonyms, etc. The principle of beneficence requires investigators to protect the confidentiality of information of participants in their research.

Question 32: Describe the method(s) used to protect the identity of individual participants.

What procedures will you follow to protect the identities of participants? Will your procedures be anonymous or merely confidential? Ordinarily, no names should appear on data. If there is an overriding reason for their inclusion, then be sure to state that. Will you record identifiers? If so, what protections will you employ? (Remember identifiers can be more than names. They may often be found in demographics lists. How many Eskimos are students at SUNY at New Paltz?) Consider whether it is essential in your research to record identifiers. (The best way to protect the identity of participants is not to record it.) If you feel that the recording of identifiers is essential to your study, consider coding options and include details on how the master list linking names and codes will be handled. Do not record social security numbers. Who will transcribe any audiotapes and what are their credentials?

Question 33: Describe your plans for maintaining data after the study is complete.

If your data must be maintained for at least three years following completion of the study due to requirements of funding agencies or journal submission policies, you need to inform participants of this. Some researchers do not destroy their data. The decision to keep or destroy data relates to the type of data you might retain and what issues in privacy and confidentiality would result from your keeping that data. Describe your plans for data storage and access to that data which assures privacy and confidentiality to participants. (If you keep your data and then want to do a secondary analysis of it, you must complete a new research proposal application. Ordinarily, the proposals will be handled by expedited or exempt review procedures.)

Question 34: Describe how the federal requirement for consent forms to be retained for three years following the conclusion of the project will be met. If an organization requires retention of consent forms on site, then the investigator may request a waiver of this requirement.

Describe how the forms will be stored during the required time period. It is important that the original forms be kept at SUNY-New Paltz as the college has the responsibility to make them available for federal or state audits.

Question 35: If you are audiotaping, videotaping or photographing, specify tape/film storage, use, and when and how disposition of the tapes will take place.

Audiotapes, videotapes and photographs of subjects or their signed work contain personal identifiers. These procedures must be discussed with participants prior to their occurrence. Participants have the right to know of the procedure, how the tapes/film will be stored and what the disposition of the tapes will be. Describe how you will protect the confidentiality of participants in terms of storing the tapes or film and using the tapes or film for data analysis and any other purposes, e.g., conference presentations, contribution to an historical archive, etc. Describe when and how you are going to dispose of the tapes or film.

There are situations such as oral histories of public figures in which both the researcher and the participant do not want to

maintain confidentiality in the traditional sense. These constitute special cases. You should create a list of options which you see for the participant in terms of disposition of the tapes or film and allow a space for the participant to set contingencies upon their release to the public, e.g., a specified time delay in the release of the tapes or film, or specific use categories.

Question 36: Discuss any other aspects of confidentiality.

Discuss any other information or issues related to confidentiality. There may be issues between collaborating agencies. There may be issues related to aggregate data collected in small groups by which members can be identified. Describe how you would handle these issues.

Category H: Justification of Request for Exempt or Expedited Review Processes

Question 37: Give a full justification for an exemption or expedited review request.

Include the category of exemption (Appendix A) or expedited review (Appendix B) you are requesting and discuss the relationship of your study to the criteria for the specified exemption/expedited review category.

Category I: Justification for Request for Waiver of Informed Consent Process and/or Documentation

Question 38: Give a full justification for a request for waiver of the informed consent process.

Note: A consent procedure may be approved which does not include, or which alters, some or all of the elements of informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Question 39: Give a full justification for a request for waiver of documentation of the informed consent process.

Note: A consent procedure may be approved which does not include a signed consent form/document for some or all subjects, if the IRB finds either:

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

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

Appendix A

**Categories of Research That May Be Reviewed by the Institutional Review Board (IRB)
for Consideration as Exempt**

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 1-4 below). **No exemption categories apply to research involving prisoners, fetuses, pregnant women or human invitro fertilization. Only certain exemptions pertain to children (see items 1 and 2 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.

45 CFR 46.101(b):

(1) 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.)**

(2) 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.**

(3) 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 (2) of this section, if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
- (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

- (i) public benefit or service programs;
- (ii) procedures for obtaining benefits or services 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.

(6) 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.

Appendix B

**Categories of Research That May Be Reviewed by the Institutional Review Board (IRB)
Through an Expedited Review Procedure¹**

Applicability

(A) 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 and 21 CFR 56.110. 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.

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

(C) 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.

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

(E) IRBs are reminded that 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.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(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 children², 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.

(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 gumbase 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 subgingival 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. 45CFR 46.101 (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.

¹ An expedited 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.

² 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 46.402(a).

[Source: 63 FR 60364-60367, November 9, 1998.](#)

Appendix C

Informed Consent Template

Note: This template is based upon a template by Cancer Trials, a service of the National Cancer Institute.

NOTE:

- Model text is in **bold**.
- Instructions are in *[italics]*.
- _____ Indicates that the investigator should fill in the appropriate information.

State University of New York at New Paltz – Informed Consent**Study Title:****Name Of Principal Investigator:****Department:****Position:***[If Applicable:]* **Name Of Co-Investigator:****Department:****Position:****Contact Name And Phone Number For Questions/Problems:***[If Applicable:]* **Sponsor Of Project:** (Funding Agency Or Company)

This is a _____ (TYPE OF: historical, educational, psychological, etc.) research study. This research study includes only participants who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. You are being asked to take part in this study because _____ (State reason for inclusion in population pool.)

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to _____.
This research is being done because _____. *[Explain in one or two sentences. Examples are: “We do not know which of these two commonly used strategies is better.” “Currently, there is minimal information on this topic.”*

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About _____ people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

[Provide simplified schema and/or calendar.]

[For randomized studies:]

You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an _____ (EQUAL/ONE IN THREE/ ETC.) chance of being placed in any group.

[For nonrandomized and randomized studies:]

If you take part in this study, you will have the following tests and procedures:

[List procedures and their frequency under the categories below. Identify experimental procedures as such. For randomized studies, list the study groups and under each describe categories of procedures. Include where a subject will be, e.g., at home, at school, at a hospital, etc. If the research question(s) or aims include a comparison of interventions, list all procedures, even those considered standard.]

- Procedures that are part of your regular care/education/etc. and may be done even if you do not join the study.
- Standard procedures being done because you are in this study.
- Procedures that are being tested in this study.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for _____ (MONTHS, WEEKS, OR UNTIL A CERTAIN EVENT).

[Where appropriate, state that the study will involve long-term follow-up.]

The researcher may decide to take you off this study if _____.

[List circumstances, such as in the participant's medical best interest, funding is stopped, subject is distressed, inappropriate information is being revealed, new information is available, etc.]

You can stop participating at any time. [If applicable:] However, if you decide to stop participating in the study, we encourage you to talk to the researcher (and your regular doctor, psychologist, teacher, etc., first.)

[Describe any serious consequences of sudden withdrawal from the study.] **WHAT ARE THE RISKS OF THE STUDY?**

While in the study, you are at risk in these ways. _____

[List all reasonably foreseeable risks or discomforts to the subject. Separate risks into categories such as "very likely" or "less likely but serious."]

For more information about risks, ask the researcher or contact _____.

[Reference and attach any materials relevant to specific risks to participants.]

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this research, there may or may not be direct benefit to you.

[List any direct and anticipated benefits to participants. If the experimental design involves randomization, discuss anticipated benefits in terms of that.]

We hope the information learned from this research will benefit _____ (Describe population pool or others who may benefit.)

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this research study, you have these options: _____

[List alternatives including commonly used treatments or techniques.]

[If appropriate (for non-investigational treatments):]

You may get _____ (OTHER ITEMS RELATED TO STUDY PROCEDURES AT THIS FACILITY AND OTHER FACILITIES) even if you do not take part in the study.

Please talk to your regular _____ (Professional) about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. *[Provide a description of how confidentiality will be maintained.]*

We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. *[If appropriate:] Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: [List relevant agencies such as study sponsors, funding agencies, etc.]*

WHAT ARE THE COSTS?

[If appropriate:] Taking part in this study may lead to added costs to you. _____
(DESCRIBE ALL ADDITIONAL COSTS.)

You will receive (NO) payment (CREDIT) for taking part in this study. _____
(DESCRIBE ANY REMUNERATION OR INCENTIVES.)

[If the level of risk is more than minimal:] I understand that should emergency medical care become necessary during my actual participation in research activities that: (1) the research staff will make every effort to contact the Rescue Squad or appropriate emergency medical services if necessary; (2) I will be responsible for the cost of such care, either personally or through my medical insurance or other form of medical coverage; (3) no compensation for injuries which may occur as a result of this project will be paid to me by the State University of New York at New Paltz.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose not to take part, may leave the study at any time, or not answer research questions, which you consider inappropriate. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your welfare or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher(s),

_____ at _____
Name(s) Phone

For questions about your rights as a research participant, contact the State University of New York at New Paltz Institutional Review Board (which is a group of people who review the research to protect your rights) at 845-257-3282.

OTHER INFORMATION:

The Institutional Review Board of the State University of New York at New Paltz has determined that this research meets the criteria for human subjects according to Federal guidelines. - You will get a copy of this form.

CONSENT:

I have read or have had read to me the preceding information describing the study. All my questions have been answered to my satisfaction and this form is being signed voluntarily by me indicating my desire to participate in this study. I am not waiving any of my legal rights by signing this form. I understand I will receive a copy of this consent form.

Printed Name of Participant Signature of Participant Date

PERMISSION:

I am the parent/legal guardian of _____ and I voluntarily approve of his/her participation.

Printed Name of Parent/Guardian Signature of Parent/Guardian Date

Printed Name of Person Obtaining Consent Signature of Person Obtaining Consent Date

Is this project expected to continue for more than one year? Yes No Anticipated completion date _____

Approval for projects is valid for one year only. Investigators must request a continuation of the approval yearly if the activity is ongoing for more than one year. The *Application for Continued Approval/Final Report* in Appendix G of the Institutional Review Board Manual is to be used for this purpose. The same form is to be used for your final report upon completion of the project.

Signature of Principal Investigator (PI)

Signature certifies that the information in this application is correct and that the research will be conducted in full compliance with SUNY New Paltz policies and federal regulations. The period of approval is determined by the IRB and continuing review is required in order to maintain approval status. The PI must submit progress reports for this review. Adverse events must be reported to the IRB according to the guidelines and changes in the study must be approved by the IRB prior to implementation.

Signature of Principal Investigator

Date

Statement of Assurance for Investigators Applying for Full or Expedited Review

Principal Investigator(s) and Faculty Sponsor (if a student investigator) must sign the following Statement of Assurance if the research proposal is being submitted for Full or Expedited Review Procedures.

The proposed investigation involves the use of human subjects. I am (we are) submitting this form with a description of the project prepared in accordance with institutional policy for the protection of human subjects participating in research

_____ **I (We) understand the SUNY New Paltz policy concerning research involving human subjects and agree to:**

1. Accept responsibility for the scientific conduct of this project.
2. Assure that the information in this application is correct;
3. Obtain informed consent of all subjects, provide subjects with copies of consent forms and maintain consent forms for the required three years, unless these procedures are waived by the IRB. (Faculty sponsors will keep consent forms on file for student investigators below the thesis level.)
4. Assure that all key personnel have completed the SUNY New Paltz educational requirements for human subject research prior to assuming duties;
5. Use only an IRB approved and stamped copy of the consent form.
6. Obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form and utilize only the revised, stamped copy of the consent form.
7. Maintain research data and consent documents under appropriately secure conditions in order to protect subject confidentiality.
8. Report promptly to the IRB any injuries to human subjects or any problems which involve risks to the human subjects or others, which become apparent during the course of or as a result of experimentation and any actions taken.
9. Cooperate with the IRB with the continuing review of this project including submission of the Application for Continued Approval/Final Report.
10. Report promptly, both to subjects and the IRB, significant new findings developed during the course of the research which may relate to the subjects' willingness to continue participation.
11. Comply with all IRB decisions, conditions and requirements.
12. Report to the IRB any serious or continuing noncompliance with the requirements of the SUNY New Paltz human subjects policy or determinations of the IRB.
13. Train and supervise study personnel who are obtaining consent.

Printed Name of Investigator	Signature of Investigator	Date
Printed Name of Faculty Sponsor	Signature/Approval of Faculty Sponsor	Date

Statement of Assurance for Requests for Certification of Exempt Status

Principal Investigator(s) and Faculty Sponsor (if a student investigator) must sign the following Statement of Assurance.

The proposed investigation involves the use of human subjects. I am (we are) submitting this form with a description of the project prepared in accordance with institutional policy for the protection of human subjects participating in research. **I have ensured that all items on the Research Proposal Checklist are included.**

___ **I (We) understand the College's policy concerning research involving human subjects and agree to:**

1. Accept responsibility for the scientific conduct of this research;
2. Assure that the information in this application is correct
3. Assure that all key personnel have completed the SUNY at New Paltz educational requirements for human subject research prior to assuming any duties;
4. Obtain parental permission for all subjects (if required) and maintain permission forms for the required three years, unless these procedures are waived by the IRB. (Faculty Sponsors will keep permission forms on file for Student Investigators below the thesis level.).
5. Maintain research data and permission documents under appropriately secure conditions in order to protect subject confidentiality;
6. Report to the IRB any unanticipated effects on subjects which become apparent during the course or as a result of experimentation and any actions taken;
7. Obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form.
8. Comply with all IRB decisions, conditions and requirements.

Signature of Investigator	Date
Approval/Signature of Faculty Sponsor	Date

Completing the Application for Research Proposal Review

General Considerations:

There may be some questions on this form, which you consider do not apply to your application. For those questions, state, "Does not apply" if it is clear that it does not apply. If it might be subject to question, then give a rationale for why you do not believe this question pertains to your study. If you leave a question unanswered, the IRB will consider that you forgot to answer the question and will return your application with the request for further information. Refer to pages 2-12 for instructions pertaining to the questions below.

Category A: Brief Description of Proposed Research:

Question 1: State the purpose of your research.

Question 2: State the major hypotheses, research question and/or the aims of your study.

Question 3: Provide a brief review of literature including citations.

Category B: Description of Subjects/Participants

Question 4: State the source of the participant population. (For international or internet studies, refer to the IRB Manual, pp. 3 & 4.)

Question 5: State the approximate number of subjects.

Question 6: Discuss the characteristics of participants as individuals and as a pool (including age, gender, student status, disease conditions, behavioral abnormalities and affiliations or memberships).

Question 7: If your research involves non-English speaking subjects or subjects from a foreign culture, include contact information for someone who can act as a cultural consultant for your study, i.e., name, address, telephone number, and email. (The cultural consultant should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.)

Question 8: State criteria for including subjects in the study or excluding them from the study.

Question 9: Provide a rationale for the inclusion or exclusion of vulnerable subjects.

Question 10: Describe how you will recruit subjects for the study. Include all relevant materials, e.g., advertisements, fliers, scripts, translations, psychology pool sign-up sheets, etc.

Question 11: Discuss other matters pertinent to human participants.

Category C: Procedures

Question 12: Specify the location of the study.

Question 13: List all variables to be studied.

Question 14: Describe the methods of data collection, record-keeping and data analysis. (Attach copies of surveys, interview guides, questionnaires, instruments, stimuli (such as words), etc. Document authorization of use or permission to modify a copyrighted instrument, or document access in the public domain of non-copyrighted instruments.)

Question 15: Describe all activities involving participants, including frequency and duration of each activity and of the total time commitment.

Question 16: Describe all equipment used with participants, if any.

Question 17: Specify what factors will lead to cessation of procedures causing physical or emotional stress. Outline procedures for stopping or interrupting the protocol.

Question 18: Describe biological samples to be taken, the method for their handling and the qualifications of individuals taking samples.

Question 19: Provide debriefing method, rationale for deception (if applicable) and debriefing protocol.

Question 20: Discuss any other aspects of the procedures.

Category D: Risks to Participants

Question 21: Describe potential risks and assess the likelihood, severity, duration and effects of each. (Consider risks of physical injury, psychological trauma or stress, social/economic harm, legal risks and loss of confidentiality. Note "no known risks" if none are anticipated.)

Question 22: Describe methods for minimizing risks. For example, document how potential psychological distress will be addressed, by whom, and with what credentials.

Question 23: Describe other methods, if any, that were considered alternatively and why they will not be used.

Question 24: State any other matters relative to risk to participants.

Category E: Anticipated Benefits to Participants

Question 25: Describe the anticipated direct benefits to these participants because of their participation.

Question 26: Describe the anticipated benefits accruing to the class of participants these individuals represent.

Question 27: Describe the anticipated benefits accruing to society-at-large or other.

Question 28: State any other aspects of anticipated benefits to participants.

Category F: Consent Procedures

Question 29: Describe how potential participants will be informed about the project activities.

Question 30: Attach consent form and assent form/script, if appropriate. (Use reading level and terminology understandable to participants. If participants are non-English speaking, include translations of all consent/assent documents and certification of the validity and reliability of the translation to the English language documents. See Question 7.)

Question 31: Discuss any other aspects of the consent process.

Category G: Privacy and Confidentiality Procedures

Question 32: Describe the method(s) used to protect the identity of individual participants.

Question 33: Describe your plans for maintaining data after the study is complete.

Question 34: Describe how the federal requirement for consent forms to be retained for three years following the conclusion of the project will be met. (If an institution/organization requires retention of consent forms on site, then the investigator may request a waiver of this requirement.)

Question 35: If you are audiotaping, videotaping or photographing, specify tape/film storage, use, and when and how disposition of the tapes/film will take place.

Question 36: Discuss any other aspects of confidentiality.

Category H: Justification of Request for Exempt or Expedited Review Processes

Question 37: Give a full justification for an exemption or expedited review request. (Refer to p. 13 in Manual.) Include the category of exemption (Appendix A) or expedited review (Appendix B) you are requesting and discuss the relationship of your study to the criteria for the specified exemption/expedited review category.

Category I: Justification for Request for Waiver of Informed Consent Process and/or Documentation

Question 38: Give a full justification for a request for waiver of the informed consent process. (Refer to p. 13 in Manual)

Question 39: Give a full justification for a request for waiver of documentation of the informed consent process. (Refer to p. 13 in Manual)

Appendix E**STATE UNIVERSITY OF NEW YORK
AT NEW PALTZ****Institutional Review Board****Protocol #****Approval Date:****APPLICATION FOR SURVEY RESEARCH EXEMPTION**

Note: Incomplete applications will be returned. Refer to IRB guidelines & policies available on the web at www.newpaltz.edu/sponsored_programs/humansubs.html

This application may be completed only for survey research with adults which meets the criteria at 45CFR46.101(b)(2). "Research involving the use of survey procedures, 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. In order to qualify for this exemption, the level of risk to participants may not exceed minimal risk (physical, psychological, social, undue stress and/or invasion of privacy.) **Do not use this form if your research involves any activities other than survey completion.**

For survey research with vulnerable subjects (including children) or on sensitive topics, investigators are to complete the Application for Research Proposal Review (Appendix D of the Institutional Review Board Manual). Research which is considered "sensitive" requires additional protections for subjects. This research involves "the collection of information falling into any of the following categories: (a) Information relating to sexual attitudes, preferences, or practices; (b) Information relating to the use of alcohol, drugs, or other addictive products; (c) Information relating to illegal conduct; (d) Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community; (e) Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination; (f) Information pertaining to an individual's psychological well-being or mental health" [Public Health Service Act, Sec. 301 (d)].

Please type all pages. Submit 4 copies with relevant materials, i.e., surveys, recruitment materials, Psychology Pool Sign-up Sheet, if applicable, etc., to the Institutional Review Board, c/o Office of Sponsored Programs, HAB 805. Submit two copies of grant/contract proposals, if any. Applications will be distributed for review at convened meetings. Depending upon the number of proposals to be reviewed, the IRB will review your proposal within two weeks of receipt by members. (There are certain periods of the year, e.g., mid-terms, finals, and holidays, in which the proposals cannot be reviewed within two weeks.)

Title of Study:**Date of Submission:****Principal Investigator****Name:**

Specify: ___ Faculty/Staff ___ Graduate Student ___ Undergraduate Student

Faculty Sponsor if student: _____ Dept. _____ Telephone _____

Mailing address: _____**Department:** **Division:** **Phone:** **Fax #:** **email:**

To complete required CITI human subjects training program, go to www.miami.edu/citireg. This training must be completed prior to submission of application.

Principal Investigator : CITI completed? Yes No

Study Team: List all individuals who assist the PI in the design or conduct of the study. **Attach additional pages as needed.**

Name:	Department:	CITI completed? Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	Department:	CITI completed? Yes <input type="checkbox"/> No <input type="checkbox"/>
Name:	Department:	CITI completed? Yes <input type="checkbox"/> No <input type="checkbox"/>

Funding Source(s) and Application Deadline(s) (if applicable):

Agency/Organization: _____ Application Date: _____

Is this project expected to continue for more than one year? Yes No Anticipated completion date _____

Principal Investigator(s) and Faculty Sponsor (if a student investigator) must sign the following Statement of Assurance.

The proposed investigation involves the use of human subjects. I am (we are) submitting this form with a description of the project prepared in accordance with institutional policy for the protection of human subjects participating in research.

___ **I (We) understand the SUNY at New Paltz policy concerning research involving human subjects and agree to:**

9. Accept responsibility for the scientific conduct of this research;
10. Assure that all key personnel have completed the SUNY at New Paltz educational requirements for human subject research prior to assuming any duties;
11. Maintain research data under appropriately secure conditions in order to protect subject confidentiality, if applicable due to use of identifiers;
12. Report to the IRB any unanticipated effects on subjects and which involve risks to subjects or others and which become apparent during the course of administration of the survey or as a result of any actions taken;
13. Obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes;
14. Comply with all IRB decisions, conditions and requirements.

Signature of Principal Investigator (PI)

Signature certifies that the information in this application is correct and that the research will be conducted in full compliance with SUNY New Paltz policies and federal regulations. Adverse events must be reported to the IRB according to the guidelines and changes in the study must be approved by the IRB prior to implementation.

___ **I (We) believe that the proposed research qualifies for EXEMPTION from human research subject regulations under category 45CFR46.101(b)(2).**

_____ Printed Name of Investigator	_____ Signature of Investigator	_____ Date
_____ Printed Name of Faculty Sponsor	_____ Signature/Approval of Faculty Sponsor	_____ Date

Category A: Brief Description of Proposed Research:

Question 1: State the purpose of your survey research.

Question 2: State the major hypotheses, research question and/or the aims of your study.

Question 3: Provide a brief review of literature including citations.

Category B: Description of Subjects/Participants

Question 4: State the source of the participant population. (For international or internet studies, refer to the IRB Manual pp 3 and 4.)

Question 5: State the approximate number of subjects.

Question 6: Discuss the characteristics of participants as individuals and as a pool (including age, gender, student status, disease conditions, behavioral abnormalities and affiliations or memberships).

Question 7: Describe how you will recruit subjects for the study. (If you are using the Psychology Pool, include a copy of the sign-up sheet and departmental authorization for use of the pool.) Include all relevant materials, e.g., advertisements, fliers, scripts, translations, psychology pool sign-up sheets, etc.

Question 8: State criteria for including subjects in the study or excluding them from the study.

Category C: Procedures

Question 9: Specify the location of the study. (If this is an external site, a letter of cooperation may be necessary for final approval.)

Question 10: List all variables to be studied.

Question 11: Describe the methods of data collection, record-keeping and data analysis. (Attach copy of survey.) Document authorization of use or permission to modify a copyrighted instrument, or document access in the public domain of non-copyrighted instruments.

Question 12: Describe all activities involving participants in the survey, including frequency and duration of each activity and of the total time commitment, e.g., instructional script for administration of survey, estimation of durations of presentation and survey completion time.

Category D: Risks to Participants

Question 13: Describe potential risks and assess the likelihood, severity, duration and effects of each. (Consider risks of physical injury, psychological trauma or stress, social/economic harm, legal risks and loss of confidentiality. Note "no known risks" if none are anticipated.)

Question 14 Describe methods for minimizing risks. For example, document how potential psychological distress will be addressed, by whom, and with what credentials.

Question 15 State any other matters relative to risk to participants.

Category E: Anticipated Benefits to Participants

Question 16 Describe the anticipated direct benefits to these participants because of their participation.

Question 17 Describe the anticipated benefits accruing to the class of participants these individuals represent.

Question 18 Describe the anticipated benefits accruing to society-at-large or other.

Category F: Privacy and Confidentiality Procedures

Question 19 Describe the method(s) used to protect the identity of individual participants, if applicable.

Question 20: Describe your plans for maintaining data after the study is complete.

Question 21: Discuss any other aspects of confidentiality.

Justification for Exempt Status:

Note if any questions below have been answered with a “No” response, then the investigator is to complete the Application for Research Proposal Review.

- Yes__ No__ 1. This survey will be given only to persons 18 years of age or older.
- Yes__ No__ 2. The level of risk to which participants are exposed in this survey is minimal risk or below minimal risk.
- Yes__ No__ 3. There are no activities in this research other than survey administration.
- Yes__ No__ 4. The population surveyed is not considered “vulnerable to coercion.”
- Yes__ No__ 5. This survey has no questions involving information relating to sexual attitudes, preferences, or practices.
- Yes__ No__ 6. This survey has no questions involving information relating to the use of alcohol, drugs, or other addictive products.
- Yes__ No__ 7. This survey has no questions involving information relating to illegal conduct.
- Yes__ No__ 8. This survey has no questions involving information that if released could reasonably be damaging to an individual’s financial standing, employability, or reputation within the community.
- Yes__ No__ 9. This survey has no questions involving information that would normally be recorded in a patient’s medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
- Yes__ No__ 10. This survey has no questions involving information pertaining to the participants’ mental health.

Answer one of the following only, either 11(a) or 11(b):

- Yes__ No__ 11(a). Information about participants in this survey is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the subjects; **OR**
- Yes__ No__ 11(b). Information about participants in this survey is recorded in such a manner that participants can be identified, directly or through identifiers linked to the subjects; however, disclosure of the participant’s responses outside of the research survey could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

Office Use Only
Modification No: _____

APPENDIX F
Application for Modification Approval

Complete this form for all revisions/modifications and return 3 copies to the Office of Sponsored Programs.

Descriptive Title of Revision:

Protocol Number

Protocol Title

PI Name

Statement of request with rationale for change

Statement of whether informed consent procedures and document need to be revised (if so, submit revised Informed Consent Form)

Office Use Only
Received in Office _____

(office use only)
 ___Exempt ___ Expedited ___Full

Appendix G
STATE UNIVERSITY OF NEW YORK AT NEW PALTZ
Institutional Review Board

APPLICATION for CONTINUED APPROVAL/FINAL REPORT

Principal Investigator Name: _____

SECTION 1: PROTOCOL SUMMARY

Provide a brief summary of the initial protocol and all subsequent modifications

SECTION 2: GENERAL INFORMATION

Project Title: _____

A. Investigators:

Principal Investigator:

- Faculty Grad Student*
 Undergrad Student* Staff

Campus Address:

Campus Phone:

E-mail Address:

*Faculty Advisor (if PI is student)

Name:

Campus Fax:

Department:

Co-Investigator:

- Faculty Graduate Undergrad Staff

Co-Investigator:

- Faculty Graduate Undergrad Staff

Co-Investigator:

- Faculty Graduate Undergrad Staff

B. Source of Funding: (If title of grant differs from above, please provide)

Externally Funded

Sponsor (s):

Internally Funded

Seeking Funding

Not Seeking Funding

Sponsor(s):

Sponsor Deadline

SECTION 3: STATUS OF STUDY (check applicable statement)

A. Active Projects with Accrual of Human Subjects:

Accrual and research intervention will continue: Complete Sections 3 and 4 and submit a copy of the current consent/permission /assent form(s) to be used during the upcoming approval period.

Accrual is complete, but research intervention continues with those enrolled: Complete Sections 3 and 4 and submit any consent/permission/assent modifications that may be used during the next approval period.

Accrual and research intervention are complete, but follow-up data collection continues: Complete Sections 3 and 4.

Accrual, research intervention, data collection are complete, but data analysis continues: Complete Sections 3 and 4.

B. Active Projects with No Human Subjects Accrued:

No accrual to date, but recruitment is continuing

If checked, **complete Section 3C**, submit a copy of the current consent/permission/ assent form(s) to be used in the upcoming approval period, and provide reason for no accrual:

C. Completed/Terminated/Withdrawn Studies: **Completed Study** **Terminated Study (ended before completion)** If either of the above are checked, **complete Section 3** as a final report (i.e., include information from the entire duration of the study, not just the past approval period). **Withdrawn Study (project has not and will not be conducted)** If checked, **complete Section 3****SECTION 4: PROGRESS REPORT****A. On-Site Subject Enrollment Since Date of Last IRB Approval and Total:**

	Since Last Approval	Cumulative Total
Number of Males (18 years or older) enrolled:	_____	_____
Number of Males (17 years or younger) enrolled:	_____	_____
Number of Females (18 years or older) enrolled:	_____	_____
Number of Females (17 years or younger) enrolled:	_____	_____
Total:	_____	_____

Estimated percentage of this total that were minorities* _____% _____%

*including American Indians or Alaskan Native, Asian or Pacific Islander, Black (not of Hispanic origin), Hispanic

B. Adverse Events, Complications, Complaints, Subject Withdrawal Since Date of Last IRB Approval:

(For all items in this section, use additional sheets as necessary.)

Were there any adverse events or unanticipated problems involving risks to subjects or others? YES NO

If yes, summarize the reported events, and briefly describe their nature and relationship to the study:

Based on your knowledge of adverse events that have occurred in subjects in this study (including those occurring at other sites, if applicable), do you feel there has been a significant increase in risks to subjects?

 Not applicable (no adverse events have occurred) YES Please explain your assessment: NO Please explain your assessment:

Were any subjects removed from your study without their consent? YES NO

If yes, how many subjects? What was the reason in each case?

Did any subjects withdraw themselves from your study? YES NO

If yes, how many subjects? What was the reason in each case?

Did any problems occur in the process of obtaining and documenting informed consent? YES NO

If yes, please explain the nature of the problem:

Were any complaints about the research received since the last IRB review? YES NO

If yes, please explain the nature of all complaints:

C. Modifications To The Study:

Provide a **brief summary of any changes** that have been made to the project during the last approval period (changes in consent/assent form or process, investigators, protocol amendments). Include copies of approval letters for all modifications. Highlight those changes that resulted in an increased risk to subjects. **If the study was terminated before completion, explain why.** (Use additional sheets as necessary)

D. Study Findings:

Provide a brief summary of the a) goals and b) results (preliminary or final) obtained in the study. If there are no results to report at this time, so state, and explain why. (Use additional sheets as necessary)

E. Additional Required Materials Checklist:

Publications:

Attach a reprint of any publications/abstracts derived from your study since last approval.

Consent/assent forms:

If there has been accrual in the study, **attach a copy of the form** used to enroll subjects **since the last approval date** (redact subject's name and signature to preserve confidentiality).

If you plan to continue accruing subjects over the next approval period, **submit a 'clean' original consent/assent form(s) for review.**

Subject Recruitment Materials

If there will be continued recruitment of subjects, **submit** copies of all materials (advertisements, letters, flyers) to be used to recruit new subjects.

Audit Reports

Attach a copy of any reports from audits/monitoring visits conducted by external organizations (e.g., HHS, sponsors) since last IRB review.

Relevant Recent Literature

Attach a summary of any relevant recent literature if applying for continuation.

Relevant Multi-Center Reports

Attach relevant multi-center reports if applying for continuation.

Other Relevant Information (especially about risks associated with the research)

Attach other relevant information, especially about risks associated with the research if applying for continuation.

SECTION 5 – CERTIFICATIONS

A. Certification of Principal Investigator (and Faculty Advisor if PI is a student):

My signature below certifies that the research described in this application and supporting materials will be conducted in full compliance with SUNY New Paltz policies and Federal regulations governing human subject research.

In addition, my signature certifies that I will:

- conduct all aspects of the project as approved by the IRB,
- promptly report any revisions or amendments to the research activity for review and approval by the IRB prior to commencement of the revised protocol, noting the only exception to this policy being in situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- promptly report any unanticipated problems or adverse events affecting risks to subjects,
- assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials, **and**,
- where consent form(s) have been approved for the research activity, only IRB-approved, stamped consent forms will be used in the consent process.

Signature of Principal Investigator (PI)

Date

Signature of Faculty Advisor (if Student is PI)

Date

B. Approval of the IRB:

IRB Chair

Date

Appendix H 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 regions and 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 involves an international institution that is engaged in research^① the institution must have a federal-wide assurance on file with The Office for Human Research Protections. Otherwise, SUNY New Paltz will not be permitted to conduct research in conjunction with that institution.
- 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.

^① An institution becomes “engaged” in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45CFR46.102(d), (f)]

Appendix I:

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>

Appendix J

Policy and Procedures 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.

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	Chair Approved
	Reviewer approved / _____ date
	Required revisions / _____ date

Appendix K
INSTITUTIONAL REVIEW BOARD
Research Proposal Checklist

Investigator's Name: _____ Date: _____

Protocol Title: _____

A. Descriptions of Proposed Research

Purpose is clear Hypothesis or specific aims are clear Relationship of this to work of others

B. Descriptions of Subjects/Participants

Source of participant population maximum number Characteristics of participants as individuals and as a pool
 Cultural consultant contact information for non-English speaking or foreign subjects criteria for inclusion/exclusion
 Rationale for use of vulnerable subjects (if applicable) Recruitment procedure and related documents Other

Decision: Selection of subjects is equitable. Yes No Dependent on revision(s)

Revisions approved (if applicable) date:

C. Procedures

Specify location List variables studied Description data collection, record-keeping, data analysis
 Copies of surveys, interview guides, questionnaires, instruments, stimuli are attached Documentation of authorization to use/permission to modify instruments, or public domain attached Describe activities involving participants, include frequency and duration, total time commitment Describe equipment used
 Specify factors leading to cessation of procedures causing physical or emotional stress Describe biological samples taken, method for their handling and qualifications of individuals Debriefing method, rationale for deception and debriefing protocol Other

Decision: Research uses procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

Decision: Research uses procedures already being performed on the subject's for diagnostic or treatment purposes
 Yes No Not applicable

D. Risk Statements

Description of risks Description of precautions to minimize risks Statement of any alternative procedures Other

Decision: Risks are minimized. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

Decision: When appropriate, research plan makes adequate provision for monitoring the data collected to ensure safety of subjects. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

Decision: Safeguards are included for vulnerable subjects. Yes No Dependent on revision(s)

Revisions approved (if applicable) date:

Decision: Level of risk is minimal risk or below greater than minimal risk

E. Benefit Statements

Description of anticipated benefits to subjects (if none so state) Description of anticipated benefit to others

Description of anticipated benefits to society at large Other

Decision: Risks are reasonable relative to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

F. Consent Procedures

Description of potential participants and how they are informed Attached consent form and assent form/script Translations and certifications of equivalence Discussion of any other aspects Other

G. Confidentiality Statements: Description of confidentiality insurance procedures

Methods used to protect identity Plans for maintaining data Storage
 Description of how requirement for consent forms will be retained following project Other

Decision: Privacy and confidentiality provisions are adequate. Yes No Dependent on revision(s)
 Revisions approved (if applicable) date:

H. Justification for Exempt or Expedited Status

Justification included Category requested: _____

I. Justification for Waiver of Elements of Informed Consent Process

Decision: The research involves no more than minimal risk to the subjects. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

Decision: The waiver or alteration will not adversely affect the rights and welfare of the subjects Yes No
 Dependent on revision(s) Revisions approved (if applicable) date:

Decision: The research could not practicably be carried out without the waiver or alteration Yes No
 Dependent on revision(s), Revisions approved (if applicable) date: **AND**

Decision: Whenever appropriate, the subjects will be provided with additional pertinent information after participation Yes No Dependent on revision(s) Revisions approved (if applicable) date: Not applicable

J. Justification for Waiver of Informed Consent Signed Documentation

Decision: That the only record linking the subject and the research would be the consent document and the principal risk would be potential 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; Yes No Dependent on revision(s), Revisions approved (if applicable) date: **OR**

Decision: 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. Yes No Dependent on revision(s) Revisions approved (if applicable) date: Not applicable

Decision: Written statement regarding the research is required. Yes No

K. Special Considerations Required: State Category _____

L. Period of Review

Decision: Annually More frequently than annually (Specify) _____

M. Appropriate Signatures

Page 2 of application completed (checked and signed) Other signatures as applicable

N. External IRB Approval

Present if applicable

Decision: Exempt____ Category No. _____
 Expedited _____ Category No. _____
 Needs Full Review _____
 Modifications _____

Decision: Additional CITI Modules needed Yes
 International Res. Vul. Subj. – Women & Fetuses
 HIPAA Vul. Subj. – Group/Community Harms
 Res. using Internet Records Based Research
 Genetics Research VA Research

With revisions listed on the Research Proposal Checklist and the Informed Consent Checklist this would qualify for:

Exempt, Category No. _____ Expedited, Category No. _____ Needs Full Review

Signature of Reviewer: _____ Date: _____

KEY: X = adequate O = missing or not acceptable NA = not applicable

Office Use Only	
_____	Chair Approved
_____	Reviewer approved / _____ date
_____	Required revisions / _____ date

Appendix L
 INSTITUTIONAL REVIEW BOARD
 Survey Research Proposal Checklist

Investigator's Name: _____ Date: _____

Protocol Title & Number: _____

A. Descriptions of Proposed Research

Purpose is clear Hypothesis or specific aims are clear Brief review of literature

B. Descriptions of Subjects/Participants

Source of participant population maximum number Characteristics of participants as individuals and as a pool
 criteria for inclusion/exclusion Recruitment procedure and related documents

Decision: Selection of subjects is equitable. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

C. Procedures

Specify location List variables studied Description data collection, record-keeping, data analysis
 Copy of survey Describe activities involving participants, include frequency and duration, total time commitment

Decision: Research uses procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

Decision: Research uses procedures already being performed on the subject's for diagnostic or treatment purposes
 Yes No Not applicable

D. Risk Statements

Description of risks Description of precautions to minimize risks Other

Decision: Risks are minimized. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

Decision: Safeguards are included for vulnerable subjects. Yes No Dependent on revision(s)
 Revisions approved (if applicable) date: Not applicable

Decision: Level of risk is minimal risk or below greater than minimal risk

E. Benefit Statements

Description of anticipated benefits to subjects (if none so state) Description of anticipated benefit to others
 Description of anticipated benefits to society at large

Decision: Risks are reasonable relative to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. Yes No Dependent on revision(s)

Revisions approved (if applicable) date:

F. Confidentiality Statements: Description of confidentiality insurance procedures

Methods used to protect identity Plans for maintaining data Storage

Decision: Privacy and confidentiality provisions are adequate. Yes No Dependent on revision(s)

Revisions approved (if applicable) date:

G. Justification for Exempt Status as Survey 45CFR46.101(b)(2)

Questions 1-11 answered with "yes".

H. Appropriate Signatures

Page 2 of application completed (checked and signed) Other signatures as applicable

I. External IRB Approval

Present if applicable

Decision: Exempt____ Category No. _____

Needs Other Review_____

Needs Modifications _____

With revisions listed on the Survey Research Proposal Checklist this would qualify for exemption.

Yes No

Signature of Reviewer:_____ Date:_____

KEY: X = adequate
O = missing or not acceptable
NA = not applicable