ALL COLLEGE REVIEW BOARD

FOR

HUMAN SUBJECTS RESEARCH

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POLICIES AND PROCEDURES

AND

GUIDELINES FOR INVESTIGATORS

As contained in the Ithaca College Policy Manual, Volume II, Section 21

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Terms that appear in bold type appear in Appendix A: Operational Definitions

All related materials for Human Subjects Research are located at the Center for Faculty Excellence website.

1. INTRODUCTION

The mission of Ithaca College to blend professional and liberal arts education is enhanced by the conduct of **research** where faculty and students share in projects which question and expand the body of knowledge in their fields. In order to study some phenomena, it is often necessary to involve human beings as subjects in research projects.

Since 1979 procedures for the involvement of **human subjects** in research has followed the principles set forth by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. These principles, contained in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report"), include respect, beneficence, and justice. These principles guide specific research procedures such as the voluntary and informed participation of subjects, adequate assessment of **risks** and **benefits** of the research, and just and non-coercive measures for the selection of subjects.

All participants must be able to enter into participation on a voluntary basis, with knowledge of what will be expected of their participation and how the information they provide will be used, and must be permitted to terminate their participation at anytime. Except where permitted by Federal or State regulations (see 4.3.4 below), all research participants must indicate that they have been provided with information necessary to make autonomous decisions regarding their involvement in research. In addition, the College supports a very comprehensive and inclusive concept of risk as it applies to the potential harm to human subjects. Any risk - physical, psychological, economic, social, or legal - is weighed carefully to assure that it has been minimized as much as possible in the project protocol. The College also seeks to ensure that appropriately qualified supervision will be available throughout the subjects' participation and afterwards, if needed. Finally, researchers should take care to avoid reinforcing social inequalities in their selection of subjects for research, and must exercise due diligence when involving members of **protected populations** in their work.

Review and approval by the All College Review Board for Human Subjects Research (HSR) is meant to aid both the subjects and the investigators by bringing scrutiny to projects by a group of peers who can objectively assess efforts to conduct research according to these principles.

2. ALL COLLEGE REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

2.1 Charge

The mechanism for protection of human subjects is prescribed by federal and state law and includes the establishment of an Institutional Review Board for Human Subjects Research. At Ithaca College this body is the All-College Review Board for Human Subjects Research and is appointed by the Provost and Vice President for Educational Affairs. "HSR," as it is commonly known, has the responsibility for fulfilling all federal and state regulations pertaining to human subjects research. Statutory responsibility of HSR can be found in the United States Code (5USC301, 42USC289, and 42USC300v-l(b)) and in Public Laws 99-158 and 103-43. Regulatory guidelines appear in the Code of Federal Regulations, Title 45, Part 46, Subpart A, Protection of Human Subjects (45CFR46). Additional statutory responsibility is contained in the Consolidated Laws of the State of New York, Public Health Law Article 24-A. Portions of the Health Insurance Portability and Accountability Act (HIPAA), known as the Privacy Rule and codified under 42USC1320d-2 and 1320d-4 and Public Law 104-191, and appearing in 45CFR164 Subpart E: Privacy of Individually Identifiable Health Information, applies directly to the use of **Protected Health Information** (PHI) in the conduct of research. These statutory regulations must be met for any human subjects research for which external funds are sought. The Provost and Vice President for Educational Affairs extends this statutory responsibility to encompass all research involving human subjects, regardless of the source of support.

Further, the Provost and Vice President for Educational Affairs has charged all faculty to rigorously scrutinize all projects involving human subjects to ensure that the subjects are properly protected. HSR assumes responsibility for assuring that, in projects involving human subjects that fall outside the scope of the regulations indicated above, the subjects are also accorded proper and adequate protection. This goal is achieved through its educational efforts and by encouraging all who oversee research-like activities involving human subjects (see 3.1.2) to use the principles and procedures set forth in this document.

Finally, HSR advises the Provost and Vice President for Educational Affairs as necessary to ensure the currency of these guidelines as changes occur to the above-mentioned regulations, and to facilitate the maintenance of the College's Federal-wide Assurance, issued through the Office of Human Research Protections, Department of Health and Human Services.

2.2 Composition

Membership of the All-College Review Board for Human Subjects Research shall be:

- at least four faculty or professional staff members from areas/disciplines actively engaged in research involving human subjects,
- one physician,
- one community member whose primary concern is in a nonscientific area and who is not a member of the immediate family of any person affiliated with the College, and
- the Associate Provost or designee.

Members are appointed for two-year terms and, at the discretion of the Provost and Vice President for Educational Affairs, may be reappointed. Members will recommend a chairperson to the Provost and Vice President for Educational Affairs. The term of the Chairperson also will be two years. A list of current board members and their area of expertise and/or degrees or certifications is available on the Board's website or by contacting the Office of the Provost.

3. POLICIES APPLICABLE TO HUMAN SUBJECTS RESEARCH

All projects involving human subjects must be scrutinized rigorously by the investigator(s) responsible to assure that all participants are properly protected. Although the need to safeguard academic freedom is recognized, primary accountability must be for the safety and protection of human subjects**.**

3.1 Activities Covered by These Policies

3.1.1 Definition of Human Subjects Research: Formal HSR responsibility applies only to projects that can be characterized as human subjects research under 45CFR46. Human subjects are living persons from or about whom **personally identifiable information** is sought, whether or not there is direct **interaction** with those persons. A human subject may also be the target of some form of **intervention** about which information (e.g. the outcome of the intervention) is recorded. A person is engaged in research whenever she or he engages in the systematic investigation of some phenomenon, designed to develop or contribute to generalizable knowledge (45CFR46.1 02(d)). Such activities include:

- Projects that are components of a course but are conducted outside of the classroom, laboratory, studio, etc. and that use persons not enrolled in the course as subjects. For example, individual or group assignments carried out by students outside regular class times and locations, or individual projects undertaken in fulfillment of a program requirement, such as a senior project, independent study, or thesis.
- Individual, collaborative, or cooperative research by faculty, administrators, or staff undertaken for professional purposes. This is any project an individual carries out in affiliation with Ithaca College or using Ithaca College facilities**.**

3.1.2. Activities Not Covered by These Guidelines: Activities that involve human subjects, but that are not covered by the definition above, should be reviewed by an appropriate administrator or his or her designee. Persons who may act in this review capacity (or appoint a designee) include the deans of each school or division, the Senior Associate Vice President for Student Affairs and Campus Life, the Vice President for Finance and Administration, the Vice President and College Counsel, or the Vice President for Institutional Advancement. For projects that, if they were defined as research (see 3.1.1) would require approval of a Request for Standard Review to proceed (that is, are not exempt and are considered to involve more than **minimal risk** and therefore not eligible for Expedited Review), the Associate Provost or designee must be consulted prior to approval of the activity.

The "Researcher Responsibilities" included below (Section 4) should serve as a guide for reviewers when assessing any project not covered by 3.1.1, above. Additionally, the remaining guidelines included in this section (including those listed under 3.9 Ongoing Oversight) should be used to guide the creation and retention of necessary records relating to the project, and the oversight and suspension of research (if applicable). If **adverse events** are reported, or the project is suspended (see 3.9.5), the Provost and Vice President for Educational Affairs must be notified.

Activities that typically involve human subjects, but for which HSR has no direct oversight except as provided in 3.1.2 above, include:

- Clinical procedures that are administered by a qualified staff member or a student(s) under the supervision of qualified faculty, for the purpose of diagnosis, prevention, or treatment of a medical condition and which may directly benefit the patient.
- Activities, such as demonstrations, which are contained within regularly scheduled class session or laboratory instructional process, or exclusively with students enrolled in a given session of a particular course, and are designed to instruct students in technique, methodology, or procedure.

- Projects undertaken at the request of an outside agency or department involving evaluations or assessments, when performed by faculty, staff, or student(s) acting under the supervision of qualified faculty. To be considered non-research activity, these evaluations must be intended to produce information used only by that agency or department. However, when participation in research activity could place a subject at risk for criminal or civil liability, or be damaging to one's financial standing, employability, insurability, or reputation if his or her identity were known, the necessity of **confidentiality** is paramount. Where confidentiality cannot reasonably be assured (due to small sample sizes, for example), a Request for Review must be submitted to HSR.
- Projects undertaken for institutional purposes, such as opinion polls, administrative surveys, and alumni follow-up studies, but only when methods assuring confidentiality are included in the project design. Where confidentiality cannot reasonably be assured, a Request for Review or Application for Exemption (as appropriate) should be submitted to HSR.

The Board recommends that even when projects are not covered by these guidelines, all projects should be designed with the belief that data or results could be shared some time in the future. Wherever possible, therefore, data should be collected anonymously or in such a way that separation between identifying information and research data can be maintained. In addition, all research should engage only participants who have been fully informed regarding why the research is being conducted, what is expected of their participation, that participation is voluntary, the possible risks associated with their participation, and information about how to contact the researcher for further information**.**

3.2. General Information about HSR Procedures

Once a researcher has determined that a project qualifies as research (see 3.1), the researcher should next:

- Determine whether or not the project should be exempt from ongoing HSR oversight (see Appendix B). If so, follow the procedures outlined in Section3.4.
- If the project does not qualify for exemption from ongoing oversight, the researcher should determine next if the project qualifies for expedited review, using the criteria in Appendix C. If so, the researcher should submit a Request for Review, following the directions for expedited review (see Section 3.5).
- If the project does not qualify for expedited review, the researcher should submit a Request for Review, following the directions for standard review (see section 3.6).

Instructors who supervise multiple research projects performed by students enrolled in research methods classes should refer to the procedures described for Requesting Delegated Review (see 3.7).

3.2.1. General Criteria: In assessing applications and requests, HSR examines the thoroughness with which the investigator has identified potential harms to subjects (risk), procedures developed to minimize the risk, if aspects of risk are necessary to successfully complete the study, and if the risks to the subjects significantly outweigh the benefits to the subjects or the benefits of the study in general. In making this assessment, HSR must assure that the rights and welfare of each human subject are adequately protected, that voluntary and legally effective **informed consent** will be obtained in an appropriate manner, and that the person(s) conducting the research is appropriately competent and qualified. Correspondence and project documentation that is poorly written or incomplete signals a lack of general competence.

3.2.2. Terminology: Keeping in mind that HSR is composed of both non-academic and academic persons from many different disciplines, all correspondence, forms, or other documentation should be written in such a way as to be understandable by persons outside of the specific field in which the research is conducted. If specific terminology is used (e.g., in descriptions of tests, procedures, equipment) then the terms should be explained or a glossary attached. HSR cannot make competent judgments about risk if the exact nature of the procedures is not clear. Technical terminology often confuses the issue.

3.2.3. Meetings of the Board: In advance of each semester, HSR publishes a schedule of general meetings to be held that semester. These meetings are held as indicated whenever there are Requests for Standard Review to be considered. Each request is discussed in turn, concluding with a vote regarding the disposition of the request (see 3.7.2). A minimum of one-half the regular number of members, including a member who is a non-scientist, is necessary for the Board to take action on any Request. No member of HSR may participate in the deliberation about or cast a vote on any request for which he or she may have a conflict of interest.

3.3 Necessity of Approval or Certification

Projects that qualify as research (see 3.1.1) can be undertaken only after approval of a Request for Review by HSR (see 3.5 and 3.6), or upon receipt of Certification of Exemption (see 3.4). Approval or certification of Exemption is required by Title 45 of the Code of Federal Regulations, Part 46, and/or the New York State Public Health Law, Article 24-A, and/or the Provost and Vice President for Educational Affair's charge to HSR. Any breach of this requirement may result in a Notice of Suspension (see 3.9.5). Incomplete applications or requests for review will delay the process.

3.4 Applications for Exemption from Ongoing HSR Oversight

Certain research activities are considered **exempt activities** under 45CFR46.101. These activities are listed in Appendix B. Although such activities are therefore not subject to ongoing HSR oversight (as defined in Section 3.9 of these guidelines), only the Chairperson of HSR or his/her designee can certify whether or not the activities associated with the research adequately meet the provisions of 45CFR46.101 and that the protocol otherwise includes adequate subject protections.

In order to secure assurance that activities are indeed exempt from ongoing review, researchers should file an Application for Exemption from Institutional Oversight. Applications can be filed at any time. The applicant should submit an Application for Exemption found online or deliver an application to the Office of the Provost to initiate action on the application.

If the activities described within the application support the interpretation of exempt activities, a letter that certifies as much will be provided for the researchers' use. The letter may also include recommendations intended to assist the researcher in improving the quality of the research (see 3.8.2 (C). If the activities are not considered to be "exempt activities," researchers may subsequently complete the recommended form of a Request for Review (see 3.5 and 3.6, below). Researchers can expect to receive notification of the disposition of their application (including reasons for rejection, if applicable) within seven days of submission.

3.5 Requests for Expedited Review

For those projects that are subject to ongoing HSR oversight (i.e. are not covered by the criteria of Appendix B), a Request for Review must be submitted and approved before the project can begin. Certain projects may qualify for expedited review, wherein only the HSR Chairperson (or designee) and one or more other members of HSR review the request. Expedited review may be requested for research "involving no more than minimal risk, and for minor changes in approved research" (45CFR46.110). A complete list of research activities that may qualify for expedited review is listed

in Appendix C.

Researchers who believe that their projects qualify for expedited review should file a "Request for Expedited Review Proposal" – templates are provided at on the HSR website. Requests can be submitted at any time. The applicant should submit an online Expedited Review Application, and as well as appendices and attachments or deliver an application to the Office of the Provost to initiate action on the application.

The outcome of the review (see 3.8.2) will be reported by email and corresponding letter to the researcher within ten days of submission.

EXCEPTION: A Request for Expedited Review must be remanded to the full board at the next convened meeting if either of the reviewers disapproves the request (see 3.8.1). This will obviously require additional time.

NOTE: Requests for Expedited Review can be submitted for studies in which **anonymity** is not assured but which use the research methods specified in Appendix C, item 7. However, if the procedures specified to ensure confidentiality are considered inadequate to minimize the risk of exposing a subject to criminal or civil liability, or do not minimize risk to the subject's employability, financial standing, or reputation, the request will not be approved.

3.6 Requests for Standard Review

For research activities that do not meet the criteria for exemption, and which cannot be reviewed under expedited procedures, researchers must submit a "Request for Review" following the instructions for standard review (templates are on the HSR website). The applicant should submit an online Standard Review Application, and as well as appendices and attachments or deliver an application to the Office of Provost seven business days before a scheduled HSR meeting to be considered at that meeting. A schedule of HSR meetings (and appropriate deadlines) is published each semester on the HSR website). Researchers will receive notice of the outcome of the Board's deliberations (see 3.8.2) in the form of an email and corresponding letter within five *business* days of the meeting at which the request is considered.

If a proposal is found before the meeting to be generally sound but needing clarification prior to approval, the **principal investigator** may be invited to appear to speak on items in need of clarification during the HSR meeting. This process is meant to facilitate more rapid review of the request. However, it should not be expected to eliminate all follow-up questions or **stipulations**. The discussion of proposals often brings to light questions or concerns that were not recognized in advance.

3.7 Requests for Delegated Review

Instructors of research methods courses (or similar) in which multiple student projects are completed in a semester may request permission from HSR to review those projects on the Board's behalf.

The following are types of projects that can be reviewed under delegated review:

- Anonymous pencil and paper questionnaires, participants age 18 or older
- Anonymous online surveys, participants age 18 or older
- Face to face interviews in which is no greater than minimal risk, participants age 18 or older
- Observational studies in which there is no greater than minimal risk, participants age 18 or older

The following types of projects cannot be approved via delegated review:

- Studies of protected populations (those under age 18, the mentally ill, prisoners, etc.)

- Studies in which physical, psychological, economic, social or legal risks are more than minimal (i.e., questions that may introduce substantial emotional strain, questions that involve reporting of illegal behavior)
- Experiments

To request this permission, instructors should complete a "Request for Delegated Review" to the Office of the Provost and Vice President for Educational Affairs seven business days before a scheduled HSR meeting to be considered at that meeting. A template is provided on the HSR website.

Initial approval to perform delegated review will be granted by the Board and evaluated using the process applied to standard reviews. Delegated Review approval will be given only for the time period stated in the approval letter (not to exceed one year). Subsequent approval of Delegated Review can be processed through expedited review protocols, contingent on the submission of the previously approved application with the following statement appended to the project title "Application for Renewal of Previously Approved Delegated Review, No Changes Integrated in Re-application." If changes are made to the application for Delegated Review, the re-application will be evaluated using the process applied to standard reviews.
Collaborative Institutional Training Initiative (CITI) certification is also required in the initial submission. A refresher course is required every three years. CITI information can be found on the HSR website.

A schedule of HSR meetings (and appropriate deadlines) is published each semester on the HSR website. Researchers will receive notice of the outcome of the Board's deliberations (see 3.8.2) in the form of a letter within five business days of the meeting at which the request is considered.

3.8 Review Outcomes

3.8.1 Criteria for Approval: The following considerations are specifically required by 45CFR46.lll before approval can be granted by HSR. These are considered minimum requirements for all research projects subject to HSR oversight. No project may be approved unless:

- Risks to **s**ubjects have been minimized through sound research design and/or by using data provided through treatment or diagnostic procedures in which the subject is already taking part.
- Risks are considered reasonable in relation to anticipated benefits to the subjects, and the knowledge that can be reasonably expected to result from the research itself. The potential for long-range application of the knowledge to be gained cannot be considered.
- The selection of subjects is equitable and just. If research is to involve "children, prisoners, pregnant [or nursing] women, mentally disabled persons, or [economically or] educationally disadvantaged persons," (45CFR46.111(a)(3), special care must be taken.
- Informed consent is sought (and **documented informed consent** is solicited) in accordance with guidelines included herein (see 4.3) or a waiver of documented informed consent has been granted under the provisions of 45CFR46.117(c) and described below (see 4.3.4).
- Adequate provisions are made for monitoring data to ensure the safety of subjects where appropriate.
- Adequate provisions are made to protect the confidentiality (or privacy) of all data provided by subjects, unless specific authorization to the contrary has been granted by the subject.
- Safeguards are included to reduce subjects' vulnerability to coercion in the recruitment process.

3.8.2 Disposition Letters: Following review, the HSR Review Board, through the Associate Provost or designee, will provide the researcher(s) (including faculty advisor, where applicable) with the result of its review in the form of a letter. The letter will specify:

A. the disposition of the proposal into one of the four categories:

- approved
- approved with stipulations
- tabled until stipulations are met and HSR has reviewed the revised proposal
- disapproved

B. the reasons for the action above with stipulations specified, if applicable; and
C. consultative comments and suggestions.

If the proposal is approved, the researcher(s) may begin the study immediately.

If the proposal is approved with stipulations, the investigator must resubmit a revised proposal before the study can begin. Revisions of proposals that have been approved with stipulations should be sent to hsrlog@ithaca.edu or delivered to the Office of the Provost. If these revisions are found to be satisfactory by the Associate Provost or his/her designee, notification of approval will be provided to the investigator(s) and the study may begin. If the revisions are not satisfactory, the letter will include a revised disposition, and the process will be repeated.

In cases where the proposal is tabled with stipulations, a revised proposal should be submitted. Review of revised proposals will be undertaken by the HSR Chair and, at minimum, one other member of HSR. If these revisions are found to satisfy the original stipulations, notification of approval will be provided to the researcher and the study may begin. If the revisions area not satisfactory, the letter will include a revised disposition, and the process will be repeated.

If a proposal has been disapproved, a revised proposal may be submitted without prejudice after it has been modified to eliminate the concerns of HSR related to safety of human subjects. In some cases, HSR will disapprove Requests for Expedited Review but encourage the researcher to resubmit the proposal with a Request for Standard Review.

Regarding item C above: in a spirit of collegiality and peer review, HSR may provide comments and suggestions which are intended to strengthen and improve the methodology and outcomes of projects. There is no requirement that investigators comply with these suggestions, as they will not affect the safety of human subjects. Members of HSR are experienced researchers and/or reviewers who believe that peer review and interaction is one of the most significant advantages of membership in an academic community. HSR members represent various disciplines of the academic community and can bring to proposal review objective and fresh viewpoints. It would be unfortunate for an investigator not to have the benefit of their observations.

3.9. Ongoing Oversight

HSR or a designated third party may be involved in the oversight of research activities it has approved.

3.9.1. Periodic Review: If HSR finds more than minimal risk is involved, but approves the activity, it will review the conduct of the activity at timely intervals, but no less frequent than once per year. The process for this review will be determined on an individual basis to meet the unique needs of the project.

3.9.2. Approval of Changes: Approval will be given only for the specific research plans contained in the Request for Review. Changes in the research procedures must not be undertaken without approval of HSR. Changes will be considered upon receipt of a Request for Review (Expedited), and will follow the same review procedures as specified in section 3.5, above.

3.9.3. Reporting Adverse Events: A researcher must immediately suspend a project if an adverse change in the health or behavior of a subject is observed which is, or may be, attributable to the research. The researcher should promptly report the matter to HSR by submitting a letter to the

Associate Provost detailing the observation. No part of the project shall be resumed without the specific approval of HSR and the Provost and Vice President for Educational Affairs.

3.9.4. Requests for Continuation: Approval will be given only for the time period stated in the Request for Review (not to exceed one year). Should an extension of time beyond the approved period be necessary, an email or letter explaining the reason or reasons for the extension must be submitted to the Office of the Provost via email or delivery. The maximum length of an extension on a proposal is five years. HSR may approve these requests only if the request is submitted before the approval period expires. If the approval period has expired and the request for continuation has not been submitted prior to the expiration date, the investigator(s) should follow the procedures for submitting a Request for Review (Expedited).

3.9.5. Suspension of Research Activities: Any breach of safety measures in approved procedures will result in suspension of the project by HSR, and a Notice of Suspension will be sent immediately to the Principal Investigator and to the Provost and Vice President for Educational Affairs. The Provost and Vice President for Educational Affairs may report any violation to the New York State Commissioner of Health or the Department of Health and Human Services. Additionally, if HSR observes harm to the general rights or welfare of subjects that was not anticipated in the review process, becomes aware of research being undertaken without its review (or issuance of a Certification of Exemption), or has received a written complaint regarding research procedures, a Notice of Suspension may be issued. Researchers must cease all research activities upon receipt of the Notice, and may not resume any research activity until the matter has been adequately resolved. HSR may terminate the research prior to the expiration of the approval period.

3.10. Records Retention

3.10.1. By Researchers: The Principal Investigator is responsible for keeping records related to the project, if approved, for a period of five years. Records include all correspondence with HSR (including the complete, approved Request for Review or Application for Exemption), all documentation of informed consent, and any lists used in assigning codes or other **identifiers** to participants. Researchers may keep, at their discretion, completed data collection instruments provided they continue to be protected in the manner specified in the Request for Review or Application for Exemption and as described to the subjects in the process of obtaining informed consent. If Protected Health Information (PHI) is included in the data, all identifiers linked to the data must be destroyed at "the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is required by law" (National Institutes of Health, 2003, p. 4).

3.10.2. By HSR: HSR will maintain a record of all projects it reviews (including all relevant correspondence and requests for continuation), and the decision made on each project or request. Where approval is not given, the record must include the reasons for the negative decision. Disapproved Requests for Review will be maintained for a minimum of one academic year after rejection. If the project or request is approved, the records will be maintained for a minimum of three years after the project is complete. HSR also will maintain Notices of Cooperative Research for a minimum of three years after the project is complete.

HSR will also maintain records of reports of injuries or adverse events and Notices of Suspension. These records will be maintained indefinitely. Minutes of meetings which include a record of attendance, the outcome of votes taken (including number of members voting for, against, or abstaining), and summaries of controversial issues discussed will also be maintained indefinitely.

3.11. Guidelines for Cooperative Projects

HSR recognizes that many successful projects result from the efforts of a team of researchers representing multiple institutions. To avoid duplication of effort, a researcher who is affiliated with Ithaca College should submit an Application for Exemption or Request for Review whenever he or she is the Principal Investigator on the project for which Certification of Exemption or approval is sought. When a researcher is affiliated with Ithaca College, but serves in some capacity on the research team other than Principal Investigator, he or she should submit a Notice of Cooperative Research. The notice must include a copy of the approved research protocol from the Principal Investigator's home institution or agency. Please note the following, however:

- When the Principal Investigator is not affiliated with Ithaca College, but is affiliated with an institution or agency that does not possess a federal-wide assurance issued by the Office of Human Research Protections, Department of Health and Human Services, the researcher who is affiliated with Ithaca College should submit an Application for Exemption or Request for Review as indicated by the nature of the project.
- For projects undertaken by Ithaca College students, faculty, or staff at the University of Rochester, special rules apply. Please see Appendix D for more information.

3.12. Letters of Acknowledgement for Externally Funded Research

From time to time, researchers seek external funding for research projects "with the knowledge that subjects may be involved within the period of support, but [for which] definite plans [have not been]set forth in the application" (4SCFR46.118). In these instances, a letter of acknowledgement indicating HSR's awareness of an impending Request for Review (or Application for Exemption) can be provided upon request. To request such a letter, submit copies of all relevant documents (including a copy of the grant application) to the Associate Provost, or designee, along with details as to why the research procedures are yet to be decided. The request should also include information about to whom the letter should be addressed.

NOTE: Receipt of this letter does not release the investigator(s) from normal HSR procedures. Investigators are prohibited from undertaking the actual research until a Request for Review has been approved (or Certification of Exemption provided).

4. RESEARCHER RESPONSIBILITIES

This section is intended to provide additional guidance relevant to the criteria for approval included in 3.7.1, above. Researchers should consult it as they design studies, particularly those for which an Application for Exemption will be filed. Concerns not explained herein (or procedures not recommended herein) may still be considered by HSR in the process of review and in its exercise of responsibility to ensure that all human subjects of research are protected. In determining the nature of the risks and the extent to which the benefits of the study justify exposing the subjects to risk, HSR will consider the following:

4.1 Adequate Identification of Risks

Researchers are responsible for identifying all possible physical, social and/or psychological risks for the subject as a result of his/her participation in the study. Virtually all research involves some risk even though it may be very slight, e.g., embarrassment over one's performance on a task or slight discomfort in answering personal questions about oneself. HSR will consider the extent to which the researchers have identified the potential risks to the subject, and the extent to which those risks have been minimized as much as possible without interfering with the **validity** of the research itself. Some common risks include:

4.1.1 **Deception** - In some types of research it is necessary to withhold information from the subject or even to purposely deceive the subject about the nature of the study to ensure that the subject does

not alter behavior while being observed. If deception is used in a study, **debriefing** will be required (see 4.2.3). In general, withholding information about the purpose of the study is more acceptable than actively misleading subjects. In all cases the subjects must be told how long their participation will take, what types of activities they will be asked to do, and any possible risks resulting from participation.

4.1.2 Inducement to Participate/Coercion - Subjects are frequently offered some form of **incentive**, inducement, or reward for their participation (e.g., earning extra credit points from their professor, small gifts or prizes, a chance to win money in a lottery). In general, such inducements are allowable as long as they are minimal and are not more attractive to some subjects than to others. The primary ethical issue involves the extent to which an incentive might be substantial enough to cloud the person's judgment about whether or not participation in the study is in her of his own best interest. This is of particular concern when conducting research with members of protected populations. In cases where students may earn extra credit points from their professor, other options to earn extra credit besides research participation must be available.

A second issue involves the extent to which subjects can reasonably choose not to participate, especially in cases where subjects are approached in a large group (e.g., a class) and asked to participate *en masse*. In such cases, potential subjects may feel that they cannot refuse to participate without standing apart from their peers. This is particularly a problem if participation involves a sensitive issue. In such cases, the researcher/recruiter would need to demonstrate that this concern has been recognized and addressed (e.g., by providing a means for all potential subjects to appear as if they are participating even if they are not).

4.1.3 Disclosure of Personal Information - Research involving human subjects in which anonymous participation is impossible amplifies the importance of assuring the subjects of the confidentiality of their responses as well as reasonably conceal the fact that persons are participating in the study. This is especially important in cases where the study involves asking the subjects personal questions about themselves or obtaining other information that might put the subject at risk if the information, or the fact of their participation, was made public. Such risks might be psychological (a subject might be embarrassed if his or her responses were made public, the subject might be stigmatized), or economic (a subjects' income from employment or other social services could be affected). Total anonymity (i.e., where the subject's name or face is never associated with his/her responses, even to the researcher) is preferable, especially in the case of extremely sensitive or personal information. Specific research processes that prohibit the possibility of anonymous participation include:

- Records of Participation – Both printed and electronic records related to a study, including data collection instruments and informed consent (where required), as well as certain recruitment procedures, can make subjects' responses or identities known. The secure storage of Protected Health Information is of particular importance. See section 4.2.1 for suggestions regarding how to decrease the risk of public identification of participants and/or their responses, and section 4.4 for guidance on the use of PHI.
- Videotaping/Audiotaping/Photography – Videotaping, audiotaping, and photography (in both traditional and digital formats) most certainly raise the possibility of risk of the subject being identified. As such, additional procedures related to these activities must be followed in the process of obtaining documentation of a subject's informed consent. See section 4.2.2 for more detail.

4.2 Development of Procedures to Reduce Risks

Researchers are responsible for devising procedures to reduce risks inherent in the research design and for explaining those procedures to both the HSR Review Board and to any participants. In general, researchers can reduce risks (short and long term) by developing procedures to ensure confidentiality (or anonymity), securely storing all research materials and records of the study, providing for a debriefing

activity, and/or providing **compensatory follow-up.** While the informed consent process ensures that subjects are alerted to the possibility of the risks of their participation, it does not *reduce* those risks and is therefore treated separately (see Section 4.3).

4.2.1 Anonymity/Confidentiality/Privacy – For research data to be truly anonymous, data collection procedures must ensure that neither the researcher(s) nor other subjects in the research can at any time connect specific data to the individual participant who provided them. For this to occur, the subject must be able to provide information (or not) privately and to submit the information in such a way that it is indistinguishable from a record of other subjects' data before they are retrieved by the researcher (e.g., putting a questionnaire into a "drop box").

Where participation can be, at best, confidential, participants must be given opportunities to indicate their willingness to participate (or lack thereof) privately. Researchers should keep all records related to the recruitment of participants securely stored in an appropriate location. Researchers should also allow participants to return blank informed consent forms (where these forms are required) or blank surveys or other instruments as the specific situation permits, so that others do not know that they have opted not to participate.

Subjects must be told who will see their data and specifically how information will be kept confidential (that is, known only to the researcher or research team) or private (known or available only to a limited number of persons). Subjects should be told where data (electronic or otherwise) will be stored. Informed Consent forms or Authorizations for the Release of Individually Identifiable Health Information must also be kept securely in order to preserve the confidentiality of one's participation (see Section 4.3 and 4.4).
Paper forms, surveys, or other data collection instruments should not contain any personally identifying information (e.g. name, student identification number, etc.); instead, identification codes should be used where necessary to track data from individual subjects across time or with respect to multiple instruments. Lists used to correlate names or other personal information with subject identification codes should be securely stored.

4.2.2 Procedures for Videotaping/Audiotaping/Photography – Researchers must specify how and where storage media will be kept, who will have access to them, whether or not they will be put to any public use (e.g. exhibited in class lectures, conference presentations, etc.) and whether (and how) recordings/images will be destroyed after the study is complete. Documentation of the subject's understanding of these conditions must also be included in the general documentation of informed consent.

4.2.3 Debriefing - There are three cases in which debriefing is required: First, when there has been deception involved in the study. Second, when subjects may be left with a misleading or potentially harmful perception or inaccurate information. And, third, when compensatory treatment or follow-up is indicated (see 4.2.4). Debriefing may consist of providing the participant information about the deception and/or correct(ed) information, either in writing or orally. The participant must have an opportunity to ask questions of the researcher at any time following the debriefing. This requires that the participant be reminded that the information can be found in written materials provided during the consent process.

In some cases, such debriefing may not be possible immediately after the study due to concerns about the **internal validity** of the study. In these cases, debriefing statements or descriptions could be offered to the subjects at a later date through the mail or other means. In rare cases, debriefing may in itself pose a psychological risk to the subjects (e.g., it might make them aware of an extremely embarrassing or negative behavior on their part), in which case it may be more desirable to forego the debriefing procedure. This conclusion must be justified in the Request for Review and will be considered very carefully by HSR.

4.2.4 Compensatory Follow-up - In cases where some physical or psychological harm might result from the subjects' participation, plans for compensatory treatment or follow-up **counseling** should be described in the Request for Review. Only subjects who are from the Ithaca College community should be directed to contact the Ithaca College counseling or health centers. Referral to appropriate professionals should also be considered if the researcher, through the course of the research, uncovers a pre-existing condition warranting professional intervention.

4.3 Informed Consent

All subjects must be properly informed about what participation will entail. In all instances, subjects should be provided with information about the study and its purposes, what they should expect in the course of their participation, potential risks (even if minimal), how data will be stored, and how to contact the researcher(s) after the study is complete, if necessary. Additional required information is included in Box 4.3.3. This information can be provided through whatever means is most appropriate to the study although written information provided in a medium that may be kept by the participant is preferred (e.g. a handout, a tear off-cover page for a pen-and-paper survey, a printable landing page prior to an online survey). Where documentation of informed consent is required (see exceptions under 4.3.4), it must include a place for the participant to sign his or her name (and/or for his or her parent or legally authorized representative to sign). A template of an Informed Consent Form is provided on the HSR website.

Provision of this information should be done during the recruitment process, where possible, and again at the beginning of data collection. When documentation of informed consent is required, subjects must read and sign an informed consent form prior to his/her participation in the study (usually just prior to data collection). Researchers must employ consent procedures that provide potential subjects with sufficient opportunity to consider their participation.

4.3.1. Language: The informed consent form, if required, and all other written materials used in the process of recruitment and in seeking informed consent, should be written in language that is geared to the specific subject population for the study. For example, more technical information may be given to subjects who are upper-level majors in that field. When the subjects are children, on the other hand, the language used must be chosen so that the child can understand. As a general rule, written documents distributed to the adult population at large should be written at no more than an 8th grade reading level.

4.3.2. **Legal Consent**: Federal Law stipulates that a person must be I8 years or older in order to give legal consent for his/her own participation in research. In addition, persons who have a diminished capacity to make informed decisions may also be unable to give legal consent for their participation. Such persons, as well as minors, may participate only upon obtaining the signature of a parent or legally authorized representative, who must also be at least I8 years of age. Thus, <u>all</u> projects involving minors (or those with diminished mental capacity) must include procedures for securing <u>documented</u> informed consent. Minors age 14 through 17 must also indicate their **assent** to participate by signing an informed consent form (in addition to obtaining a signature of consent from the minor's parent or legally authorized representative). Generally speaking, children age seven through seventeen should be given the opportunity to review information about the study and to indicate that they have done so prior to participating. In all instances, children should have the information about participation in the research explained to them in language they can understand.

4.3.3. Elements of the Informed Consent Process - Information that must be provided to subjects includes the items listed in Box 4.3.3 (45CFR46. 116-46.117). Additional items, to be included as appropriate to a particular study, include:

- A statement that a particular treatment or procedure may result in risks that are currently unforeseeable..

- A description of any circumstances under which the subject's participation would be terminated by the researcher (with or without her/his consent).
- A statement that the researcher will make available any significant new findings that are developed during the research and that might impact a subject's willingness to continue participation.
- The approximate number of subjects in the study.

Finally, the following guidelines apply specifically to the construction of informed consent forms (required when documentation of informed consent is necessary):

- There must not be any exculpatory language (e.g., "I agree not to hold Ithaca College liable for any injuries."). Subjects may only be asked to sign in indication of their having been provided information about the study and having had a chance to ask questions before participating.
- If the consent form is more than one page in length, there must be a place for subjects to put their initials on the bottom of each page prior to the final one.
- All required signature lines - for a minor's assent, for the consent of the subject or his or her parent or legally authorized representative, for acknowledgement of recording procedures, and for release of information to be used in public settings (presentations, etc.) - should be clearly labeled and must include a place for the signee to indicate the date. See sample Informed Consent Form.
- Subjects must be provided adequate time to review the form in its entirety before signing. This may require more or less time than the researcher may anticipate, depending on the nature and/or capacities of the subject population, or the complexity of the research procedures.
- Subjects must be given a copy of the informed consent form.
- In cases where medical information must be released by the subject (e.g. the subject allows a researcher to have access to his or her medical records), an additional Authorization for the Release of Medical Information must be signed by the subject (form provided on the HSR website.) A copy of this form should be kept along with an informed consent form, and the subject should receive a copy for his or her keeping.

BOX 4.3.3 INFORMATION REQUIRED FOR INFORMED CONSENT

The following information must be provided to anyone asked to participate in research, unless a waiver of some or all of these items has been granted. While providing this information orally is permitted, a written format is preferred. In situations where documentation of informed consent is required, the information must be in writing, and must be followed by space required for signature(s).

1. A statement that the person is being asked to participate in research, and a description of the purpose of the study.
2. A brief description of the benefits of the study, both for the subjects and for the broader community (e.g., other individuals, the scientific field, etc.).
3. An explanation of what the subjects will be asked to do, including the amount of time that their participation will take and a description of specific tasks. If alternate procedures are available (e.g. treatments), this information must also be provided.
4. Description of exclusionary criteria if applicable, and detail regarding any pre-testing that will be employed or information that will be gathered in order to determine if a subject qualifies for the study.
5. A clear explanation of any risks (physical, psychological, social, legal, or economic) that may occur as a result of participation. In the case of biomedical or behavioral research that may result in physical injury, information should be provided regarding the availability of emergency medical treatment, and what that treatment would likely be. In the case of social or psychological research that may result in emotional distress, an explanation should be provided as to the availability of counseling or other resources.
6. Information regarding **compensation for injury**, if appropriate. See the statement on the Sample Informed Consent Form.
7. An explanation of how subjects can get more information about the study (e.g., who to ask and how to contact them), before, during, and after their participation.
8. An instruction that subjects are free to withdraw consent and discontinue participation in the project or activity at any time. This includes their right to refuse to answer any questions they feel uncomfortable answering. The researcher should explain that participation is completely voluntary and that refusal to participate or a decision to discontinue participation during the study will not result in penalty or loss of benefits to which the subject is otherwise entitled. Researchers should also indicate what subjects should do if they wish to withdraw during their participation, especially in cases when withdrawing may lead to social embarrassment, or when they are working alone on a task and may not know where to go to find the experimenter.
9. Information regarding how any records identifying the subject will be created, used, and stored so as to assure the confidentiality of the information provided. Where confidentiality cannot be assured, subjects must be told who will see their responses, especially when their responses will be seen by other students assisting in the research. When audio or video tapes or photographs are made of subjects, a statement must be included which describes where tapes or images will be stored, who will have access to them, and whether they will be destroyed at the end of the study. Separate permission is required when material that clearly identifies the subject is to be used for public presentation and/or publication (i.e. "image release").
10. When documentation of informed consent is required, the following statements should appear at the end of the document, above the place provided for the participant's signature: "I have read the above and I understand its contents. 1have had an opportunity to ask questions and those questions were answered to my satisfaction. My signature below indicates my consent to participate in the study described to me. I acknowledge that I am 18 years of age or older." These statements must be followed by a place for the subject to sign his/her name and to put the day's date. (See additional instructions in Section 4.3 for subjects under 18years of age).
11. If subjects will be audiotaped, videotaped, and/or photographed, the following statement is required: "I give my consent to be [insert as appropriate].." If tapes or images will be played in public the following statement is also required: "I consent to the use of tapes or images of me to be used in conference (classroom) presentation. "Each of these statements must be followed by a place for the subject to sign his/her name and to put the day's date. NOTE: This statement alone most likely does not satisfy requirements pertaining to the release of images or recordings for purposes of publication.

4.3.4. When Documentation of Informed Consent is not Required: Signed informed consent forms may not be required when:

- The research is being conducted to study, evaluate or examine public benefit service programs, procedures for obtaining the benefits of those programs, possible changes to those programs, or changes in methods or levels of payment for services under those programs.
- Research cannot practically be carried out without a waiver" of the requirement for documented informed consent (45CFR46.116(c)(2)), and the provision of a waiver will not negatively affect the welfare of the subjects.
- Anonymity is assured and securing documentation of informed consent is the only procedure that makes anonymity impossible (however, if the research requires obtaining an authorization to use private health information (see 4.4), informed consent is required).

Only HSR has the authority to determine whether or not these circumstances apply.

4.4. The Use of Protected Health Information in Research

One of the main components of the Health Information Portability and Accountability Act (HIPAA) of 1996 was the creation of regulations governing the disclosure of individually identifiable health information. These regulations are commonly referred to as the Privacy Rule.
When **covered entities** create or compile individually identifiable health information through the course of their normal operations, this information is referred to as Protected Health Information (a subset of individually identifiable health information). Information created by any entity (individual or organization) that is not a covered entity is not covered by the Privacy Rule.

4.4.1. General Guidance - Researchers who gather data through clinical research, or in the process of conducting research on health care operations (or management), under contract with or supervision by a covered entity, are subject to the requirements of the Privacy Rule. These researchers should follow the guidelines for the use of protected health information in research established by the supervising covered entity.

Other researchers may desire to use some or all of a subject's medical record as part of his/her data, and so may request that information from a covered entity. To obtain this information, the researcher must submit (to the covered entity providing the information) either a) authorization(s) for the Release of Individually Identifiable Health Information signed by each subject in the study, (form provided on the HSR website) or b) evidence that an IRB has reviewed the request for information and has determined that either an authorization is not required (e.g. grants a waiver - in whole or in part - of the requirement) or that the authorization may be altered so as to permit the successful completion of the research.

4.4.2. Valid Authorizations - Valid authorizations must meet the criteria described in 45CFR164.508 (c)(l) (which specifies core elements of the authorization), and (c)(2) (specifying statements that must appear on the form for it to be valid). A sample Authorization, developed by the American Academy of Family Physicians, is provided for reference. In addition, authorizations that have expired, are incomplete, or contain any information that a covered entity knows to be false are also invalid. Please note that HSR is not responsible for reviewing the accuracy or completeness of authorizations. The information here is provided as a courtesy, only.

4.4.3. When Authorizations are not Required - HSR may grant researchers waivers (in whole or in part) with regard to the necessity of Authorizations for a given project, or permit alterations to the standard form of an Authorization. Waivers or alterations may be permitted when:

- The use of the information involves no more than minimal risk (i.e. there is an adequate plan to protect the identifiers from improper use or disclosure and there is a plan to destroy the identifiers at the earliest opportunity). Risk is further minimized by written assurances by the researcher that

the information will not be used or disclosed unless required by law or as necessary for the oversight of the research.
- The research could not be carried out without a waiver (or alteration) and the research cannot be carried out without the protected health information.

Requests for approval of waivers or alterations may be made by submitting (to the Associate Provost) a description of the research (purpose and procedures), the specific reason(s) for the request, information regarding who will have access to the protected health information that will be obtained. HSR will consider the request at a convened meeting of the board, or, if the granting of the request would result in no more than minimal risk to the privacy of the individuals about whom the information is sought, via the board's expedited procedure.

4.4.4. The Use of **Limited Data Sets**: Authorizations are also not required when the researcher requests data in such a form so as to qualify as a limited data set and enters into a data use agreement with the covered entity providing the data. This type of use also does not require a waiver of the Authorization requirement.
- A limited data set is protected health information that excludes direct identifiers of the individual or his or her relatives, employer, or household members.
- Data use agreements must contain: specification of the permitted uses of the data; information regarding person(s) permitted access to the data; assurance that the person(s) will not further disclose any of the information, will develop safeguards against inadvertent disclosure, report any disclosure, and extends the assurance against disclosure to any subcontractors hired by the researcher(s); and an agreement that the researcher will not attempt to identify any of the information.

4.5. Additional Guidance for Online Research

When human subjects research is conducted via the Internet (including through the use of email, bulletin boards, websites, blogs, wikis, multi-user domains, etc.) researchers must develop procedures that take into account the principles of beneficence, justice, and respect described in the introduction. To aid in that process, HSR provides the following guidance.

*Please note: researchers are encouraged to review the definitions of online research and **computer mediated research** (Appendix A) before deciding if these guidelines apply.*

4.5.1. Applicability of Exemption Criteria: Research that would meet the criteria included in Appendix B is also considered exempt when the research occurs online. In particular, research that involves the observation of activity in what otherwise might be considered public space under conditions where subjects can participate confidentially (see 4.5.2, below) is considered exempt. In these cases, researchers should follow the procedures included in section 3.4. To determine the extent to which members of an online community (or individual contributors) consider the space to be "public," researchers should examine "the community's nature and level of accessibility (e.g. is membership required? [Do users need] log-on IDs? [What is the] extent of member profiles?)" ("Guidelines for Internet Research with Human Subjects," ¶ 4, 2005).

4.5.2. Anonymity, Confidentiality, and Privacy in **Online Research**: Care should be taken in concealing the identity of research participants given that the information shared online may be recorded and to some degree, accessible to the general public. Since information present on the Internet can be archived and searched, care must be taken in reporting direct quotations or using passages from the messages or postings of specific individuals in the research. The use of pseudonyms for participants (assigned by the researcher or chosen by the participant) may not be sufficient to disguise the participant's identity in this case, especially if the individual who contributed the information also has an easily-located member profile. In cases where information is generally not accessible without a log-in ID, there is a decreased likelihood that the information

is archived in a publicly accessible manner, although if the host site is identified, the confidentiality (or anonymity) of the information may still be compromised.

Additionally, whenever data are recorded by means that would include IP addresses as part of the submission itself or within a log of all submissions related to the project, or includes the defacto gathering other information that could be used in identifying the source of the information (e.g. email addresses), it is impossible to ensure anonymity of the data. When this information is easily accessible by persons outside the research team, it is also impossible to maintain the confidentiality of one's participation.

4.5.3. Informed Consent: While no statutes exist that would govern what constitutes effective informed consent nor the documentation of informed consent in electronic research, the following guidelines have been developed by HSR to assist researchers:

- All information that would normally be provided during the process of informed consent (or that would be required on an informed consent form, see 4.3) must be provided on a single page (e.g. URL) or in a single electronic file, and participants should be encouraged to "print a copy" for their records.
- The informed consent form and/or description of the study, as appropriate, must include information about the potential loss of anonymity, confidentiality, or privacy resulting from the technology used to collect the data.
- In situations where the researcher collects naturalistic materials (e.g. data are gathered via observation, naturalistic interviews, or interpersonal/group interaction that includes the researcher), the informed consent form (or project description) must include detailed information about how data will be recorded in addition to how they will be stored. The researcher should indicate whether he or she will take notes or record short excerpts of what is available online, or if entire posts, messages, threads, or websites will be archived.
- When research is anonymous and all participants are age 18 or over, or any other provisions of 4.3.4 apply, researchers do not need documentation of informed consent. In most cases, the informed consent procedure can be carried out by providing information about the study to participants prior to their completion of research instruments, and by notifying them that their continuation in the study after having read such information implies consent.
- Where documentation of informed consent otherwise would be required, the subject must be provided with a space (on an electronic form) to type in his or her name and the date following the statement "I have been provided with information about the study and I understand what to expect as part of my participation. I have had an opportunity to have any questions about my participation answered by the researchers(s). By providing my name below, I indicate that I agree to participate in the study and that I am 18 years of age or older."
- Participants should be reminded that if they choose to withdraw from the study, they can leave the site and/or exit their browser before completing the study.
- In situations where debriefing or compensatory follow-up may be required by the research design, the researcher should ensure that he/she collects contact information from each participant. This may be included as an additional item on the informed consent form.
- If additional signatures are needed (by minors to indicate assent, to allow for the public use of the information that is recorded), additional statements and places to type in one's name also should be provided.

APPENDIX A
OPERATIONAL DEFINITIONS

Adverse Event

An outcome experienced by a subject that was either not anticipated by the researcher or is of a magnitude greater than was originally anticipated by the researcher.

Anonymity

An assurance that no identifiable private information is being gathered, (i.e., the investigator will not be able to identify subject).

Assent

Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

Benefits

The potential for positive outcomes arising from the research. Benefits may be to the scientific community, in the form of enhanced knowledge about a phenomenon; to the researcher, in the form of increased knowledge of research procedures; or to the subject participants, in the form of a good – tangible or intangible- that arises from their participation. See also, *Incentive to Participate*.

Coercion

Activities that under normal circumstances may create feelings of being compelled by force or threat to participate in research.

Compensation for Injury

Monies of services provided to treat negative physical outcomes caused by participation in research.

Compensatory Follow-up

Activities undertaken in the interest of ensuring equal treatment of all subjects. In "blind" experimental studies, this might involve making a successful treatment available to members of a control group.

Computer Mediated Research

Research conducted with the aid of information and communication technology, most commonly the personal, or desktop computer. When information is stored on the recordable media specific to the device, or transferred solely from the original drive to a drive or disk for permanent storage, such research is not considered "online research".

Confidentiality

An assurance that all-identifiable private information will be kept secret and not be made available to anyone other than the investigator to whom it was entrusted.

Consultative Comments and Suggestions

Statements made by Human Subject Research (HSR) to investigators following HSR review are intended to strengthen and improve the methodology or outcomes of a project. There is no requirement that investigators adhere to these statements as they have no bearing on the safety of human subjects.

Covered Entities

Under the HIPPA Privacy Rule organizations that create, maintain, or transmit identifiable health information as a normal course of business or their business associates.

Counseling

Advice, particularly information that would help a person think or feel differently about themselves or their activities.

Debriefing

Immediately following data collection, subjects should be given clarification for any misconceptions that may have arisen. Subjects should be told the general nature of responses and told who (when and where) to contact if any follow-up is needed, e.g., counseling.

Deception

The engagement of subjects in fraudulent activities, the provision of false information, or the intentional omission of information as necessitated by the research design.

Documented Informed Consent

(see also Informed Consent) A permanent, physical record of information about the research as provided to subjects. Such consent includes the subject's signature (or the signature of the subject's parent or legally authorized representative), or acceptable substitute, indicating that such information has been provided.

Exculpatory Language

Wording that implies a clearing from blame or fault; phrases that could make it appear as if the subject had waived all or part of his or her rights.

Exempt Activities

Research activities included in the descriptions provided in Appendix B are considered to be exempt from the ongoing oversight of the All-College Board for Human Subjects Research. This means that the regulations included in Section 3.9 of these guidelines do not apply. Requests for Certification of Exemption can be submitted, with proper documentation, to the Office of the Provost at any time. Upon receipt of such certification, research may commence.

Human Subject

A person about or from whom an investigator/researcher obtains data or identifiable private information through intervention or interaction.

Identifiers

Information that can be used, alone or in combination, to single out an individual from a group.

Incentive:

(or Inducement) Rewards (goods or monies) provided for participation in research.

Informed Consent

Potential subjects are informed in language appropriate for their level of understanding about all features of the research that may affect their willingness to participate; their questions should be answered; and they should be free to choose to participate or not, and to discontinue participation at any time.

Interaction

Communication or interpersonal contact between investigator and subject.

Internal Validity

In experimental research designs, truthfulness that is ensured by careful control over the conditions of the study.

Intervention

Procedures by which data are gathered through manipulations of the subject or environment that are performed for research purposes.

Legal Consent

Consent to participate in research given by a person 18 or over and who is legally able to act on his or her own behalf.

Limited Data Set

Data that has been de-identified, by removing all information that may be unique to an individual within the subject population (e.g. address, JD numbers, some combination of age+sex+race). Limited Data Sets are not considered PHI.

Minimal Risk

Risks of harm anticipated in the project are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Online Research

Research conducted with the aid of the Internet wherein data are collected or aggregated by, pass through, or are stored on a server (or servers) not owned by Ithaca College, the Principal Investigator, or a member of the research team. For research purposes, the campus' Novell Network is considered remote storage for computers with a permanent network connection, and thus, information transferred from one point on the network to another point on the network is not considered "online research." See also 'Computer Mediated Research'.

Personally Identifiable Information

Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and the information provided for a specific purpose considered to be private. Individuals must be individually identifiable by the investigator to constitute their consideration as subjects falling under these Guidelines.

Principal Investigator

For purposes of the research project, the person who will serve as the main investigator contact for subjects and for the Review Board, and who will be responsible for the storage of records related to the research.

Privacy

Control over the extent, timing, and circumstances of one's participation in research. In general, this means knowing who might have access to identifiable research results in addition to the researcher(s).

Protected Health Information

(PHI) Individually identifiable health information held and maintained by a Health Covered Entity (according to HIPAA, a covered entity is a health care provider or insurer or business associates acting on their behalf). Health information collected (from physical or electronic files or directly from subjects) by researchers in the course of their research does not qualify as PHI unless the researcher is formally affiliated with a covered entity.

Protected Populations

Persons who qualify as research subjects under 45CFR Part 46, Subpart B (Women, Human Fetuses, and Neonates), Subpart C (Prisoners), and Subpart D (Children). While research may still proceed using these persons as subjects, special rules for their protection apply.

Protocol

A defined set of procedures through which data are gathered. A complete protocol includes information about everything from sampling and recruitment to debriefing and follow-up in addition to specifying the data collection process.

Research

Gathering of data by systematic means with the intent of making scientific claims (broadly conceived) about phenomena or in the interest of developing generalizable knowledge. Research is herein defined operationally beginning on p.7 of these guidelines.

Risk

The probability or magnitude of harm. Potential harms can be physical, psychological, social, legal, or economic in nature.

Stipulations

Essential conditions or requirements that must be met in order to receive approval from Human Subjects Research committee to implement the project.

Validity

Generally, the "truthfulness" of the research.

APPENDIX B
Categories of Research that are Exempt from HSR Oversight

The guidelines below apply regardless of the age of the participant, except as noted. No research involving pregnant women, persons involuntarily confined, or those detained in penal institutions is considered exempt at any time.

I. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. Research on regular or special education instructional strategies
   b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless:
   a. Information obtained is recorded in such a manner that human subjects can be identified directly or indirectly through identifiers linked to subjects; and
   b. Any disclosure of human subjects responses may reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing employability, or reputation.

   EXCEPTION: When the research includes researcher participation in the activities being observed, survey procedures, or interviews, and the subjects are minors, the research 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 the above, 2, if:
   a. The subjects are elected or appointed public officials or candidates for public office
   b. Federal statutes require without exception that the confidentiality of personally identifiable information be maintained through the research or 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 recoded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to subjects.

5. Research conducted on behalf of public benefit or service programs and that examines procedures for obtaining services or benefits under those programs, possible changes to those programs, or possible changes in methods or levels of service by or payment for those programs.

6. Taste and food quality evaluation and consumer acceptance studies,
   a. If wholesome foods without additives are consumed or
   b. If a food is consumed that contains a food ingredient at or below the level of use to be found safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA, or approved by the EPA or USDA Food Safety and Inspection Service.

APPENDIX C
Categories of Research Qualifying for Expedited Review

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 HSR through the expedited review procedure authorized by 45 CFR 46.110 (Protection of Human Subjects) and 21 CFR 56.110 (Food and Drug Administration Regulations Pertaining to Institutional Review Boards). 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. Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by HSR.

F. Categories one (1) through seven (7) pertain to both initial and continuing 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; FDA Policy) 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; FDA Policy) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

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; G) 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 nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HSR regulations for the protection of human subjects. See Appendix B, Item #4. This listing refers only to research that is not exempt.)
6) Research that involves the collection of data from voice, video, digital, or still-image recordings.
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 HSR regulations for the protection of human subjects. See Appendix B, Item #2 and Item #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.

APPENDIX D
Procedure for Review of Human Subjects Projects Based on the Rochester Campus Ithaca College Movement Analysis Laboratory

For the Submission of New Protocols:

Research projects that do not involve University of Rochester faculty, students, or patients require approval only from the Ithaca College All-College Review Board for Human Subjects Research (Ithaca College HSR). The usual procedures, as outlined in the Ithaca College Faculty Resource Guide, will be used for this review.

If human subjects research projects involve University of Rochester faculty, students, patients, or if Ithaca College collaborates with the University of Rochester, these projects must be reviewed by the institutional review boards of University of Rochester (Research Subjects Review Board, RSRB) and Ithaca College (All College Review Board for Human Subjects Research). The following procedures will be used.

1. The investigator will complete the Research Subjects Review Board Application and obtain certification of scientific review. The scientific reviewer must be a University of Rochester department chairperson, authorized delegate, or an appointed peer review committee of the University of Rochester investigator's department. The project will be submitted for review to the RSRB in the format prescribed by that board. The RSRB's standard consent form language will be used.

2. Upon approval by the RSRB, the proposal will be submitted for expedited review to Ithaca College HSR. The letter notifying the researcher of University of Rochester approval must be attached to the proposal. It is not necessary for the researcher to rewrite the proposal in the Ithaca College format. The proposal will be reviewed in the format prescribed by the RSRB at the University of Rochester. Upon approval by Ithaca College HSR, the investigator will submit a copy of the approval letter to the RSRB.

3. In the protocol document, under the study title, the following statement should be inserted: "The following application is submitted in accordance with the Ithaca College and University of Rochester agreement." This statement will alert the reviewers that the above procedure is in place.

HIPAA Authorization:

If the study involves the collection of protected health information (PHI), the standard RSRB a HIPAA Authorization for the Release of Protected Health Information must be appended to the consent form if one or more of the study procedures are performed at a UR facility or if an investigator is part of the UR faculty. The HIPAA authorization must specify that both the University of Rochester and Ithaca College may receive study data.

If the study procedures are not performed at a UR facility or if the investigators do not include UR faculty members, the HIPAA Authorization is not needed.

Amendments:

Any amendments (i.e. changes in the protocol design or the consent form) will be submitted to the RSRB for review prior to implementation. Upon approval by the RSRB, the amendment will be submitted for expedited review to Ithaca College HSR. The letter notifying the researcher of the RSRB approval must be attached to the amendment and any applicable study documents. Upon approval by Ithaca College HSR, the investigator will submit a copy of the Ithaca College HSR approval letter to the RSRB.

Continuing Reviews:
The RSRB will send the Principal Investigator a request for progress report three months prior to the study's expiration date. The investigator will submit the progress report to the RSRB in a timely fashion along with any applicable study documents:

For studies in the RSRB paper system:
- Clean copies of all currently approved consent/permission/assent form(s)
- Recruitment materials
- The last signed consent/permission/assent form(s)
- Publications
- Any reports (National Summary Reports, Data Safety Monitoring Board, Audits)
- Adverse event summary sheet

For studies in the RSRB electronic system:
- The last signed consent/permission/assent form(s)
- Publications
- Any reports (National Summary Reports, Data Safety Monitoring Board, Audits)
- Adverse events should be reported in the online system in real time, but will not be reviewed by RSRB until the progress report is submitted.

Upon re-approval by the RSRB, the investigator will submit a copy of the RSRB reapproval letter and progress report to Ithaca College HSR. Once the Ithaca College HSR re-approves the study, the investigator will submit a copy of the Ithaca College HSR approval letter to the RSRB.

Five- Year Reviews:
The RSRB requires that Principal Investigators submit a new application and study protocol every five years. For studies originally approved in the paper system, the five-year review involves converting the study to the new online submission system. If the "Five-Year Review" box is checked on the RSRB progress report, the Principal Investigator must submit the following in addition to the standard materials listed above for continuing reviews:

- New RSRB application (complete with both Principal Investigator and scientific review signatures)
- New study protocol, which includes all amendments since the beginning of the study
- Complete copy of the grant application (if applicable)

Upon approval of the five-year review by the RSRB, the materials listed above will be submitted to the Ithaca College HSR for review. Upon approval by the Ithaca College IRB, the investigator will submit a copy of the approval letter to the RSRB.

REFERENCES

New York State Public Health Law, Article 24-A.