BINGHAMTON UNIVERSITY
HUMAN SUBJECTS RESEARCH REVIEW OFFICE

INVESTIGATORS GUIDELINES
Introduction

Binghamton University, State University of New York, investigators and their research staff, and the Human Subjects Research Office, must share a collaborative responsibility and commitment to maintain the highest ethical standards in our research endeavors.

Throughout history scientific research has produced substantial social benefits versus troubling ethical questions. Reported abuses first received public attention during the Second World War, Nuremberg War Crimes Trials. Federal Regulations have been passed that reflect the issues brought up in these trials, as well as, other trials that have brought into question ethical treatment of human subjects.

In 1974 the National Research Act (Pub. L. 93-348) was made into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Nation Commission for the Protection of Human Subjects completed their study and review and published the Belmont Report in 1979. This report details ethical principles and applications to ensure that research is conducted in an ethical manner. The Code of Federal Regulations Title 45 Part 46 contains rules that all Internal Review Boards must follow. Binghamton University incorporates both documents in their review and assessment of risk in human subject’s research.

Binghamton University offers these guidelines to investigators to educate all researchers on policies and procedures that incorporate the ethical standards in conducting human subject’s research. This includes all research conducted at Binghamton University and research involving university faculty, staff or students. Research at Binghamton University adheres to all local, state, federal and, when warranted, international guidelines.

This manual also assists investigators planning to conduct research involving human subjects in designing their research and submitting it for approval. Investigators are urged to read this manual carefully in order to avoid unnecessary delay in obtaining approval for their research. Below are listed some frequently asked questions concerning human subjects research along with brief answers.

Frequently Asked Questions

What is human subject’s research?

Research involving human subjects” means any activity that either:

- Meets the Department of Health and Human Services (DHHS) definition of “research” and involves “human subjects” as defined by DHHS; or
- Meets the Food and Drug Administration (FDA) definition of “research” and involves “human subjects” as defined by FDA.

DHHS Definitions:

Research: a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge [45 CFR 46.102(d)]
**Human Subject:** a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. [45 CFR 46.102(f)]

- “Intervention” as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. [45 CFR 46.102(f)]
- “Interaction” as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]
- “Private information” as defined by DHHS regulations means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). [45 CFR 46.102(f)]
- “Identifiable information” as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

**FDA Definitions**

**Research** - any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations [21 CFR 50.3(c), 21 CFR 56.102(c)]

- “Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act” means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
- “Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act” means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
- “Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]”

**Human Subject** means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g), 21 CFR 56.102(e)] A human subject includes an individual on whose specimen a medical device is used. [21 CFR 812.3(p)]
Some research on specimens derived from living individuals may be considered human subjects research under both the DHHS and FDA regulations.

**WHY must it be reviewed?**

It is University policy to ensure that the rights and welfare of human subjects are adequately protected in research conducted under its auspices. Federal and state laws require this protection. In order for the University to fulfill its responsibility, all human subjects research conducted under University auspices must receive appropriate review and approval.

**WHO reviews it?**

The University has established the Human Subjects Research Review Committee (HSRRC) as the institutional review board (IRB) responsible for the institution’s obligations to review research involving human subjects. The HSRRC is composed of individuals of diverse backgrounds, which include a non-scientists, a community advocate, a clergy member, a physician, an attorney and other scientific members who have expertise in the areas of research that are conducted at Binghamton University.

**WHO must submit it?**

Binghamton University’s policy requires all research projects involving human subjects conducted by University faculty, staff and students or done under the sponsorship and auspices of the institution must be reviewed and approved by the HSRRC.

**HOW is it submitted?**

Human subject’s research projects are submitted via a completed Human Subjects Review Form. The form is available on-line: [http://humansubjects.binghamton.edu/](http://humansubjects.binghamton.edu/)

**WHEN does it have to be submitted?**

When submitting projects, sufficient time should be allowed for adequate review. The HSRRC meets monthly during the academic year, and as needed at other times. For projects requiring full review, proposals must be submitted ten days preceding a meeting to be included on the agenda for that meeting. Projects eligible for exempt or expedited review may submit their protocol at any time and will generally be reviewed within three to five days. Please contact the HSRR Office for scheduled meetings.

**HOW will it be reviewed?**

The review of human subjects research includes reviewing the procedures affecting the rights and welfare of human subjects. The review also focuses on such issues as risk to subjects, voluntary participation, informed consent, and confidentiality. Evaluation is also made of the content or scientific merit of research projects that submit subjects to an increased level of risk. In this case, the risk/benefit ratio of the project will be reviewed.
WHERE can I get assistance?

The Human Subjects Research Review Office Staff, at 777-3818 or hsrrc@binghamton.edu

Planning a Research Project

When an investigator plans to conduct research involving human subjects, he/she would be advised to read through the Investigators Guidelines and contact the Human Subjects Research Review (HSRR) Office at (607) 777-3818 or hsrrc@binghamton.edu if you have any additional questions. Aspects of the project that may be problematic can be discussed and alternative procedures suggested. At this point, the research often can be designed in a way that will facilitate approval.

Educational Requirements

ALL investigators, research personnel, faculty supervisors, and all other individuals involved in human participant's research must complete a Human Subjects Research Training Program. Investigators submitting new protocols, as well as those who may be continuing previously HSRRC approved research, must complete the course. The course can be found on our website: http://humansubjects.binghamton.edu. The training program should be completed prior to the submission of your protocol.

Re-certification is required every three years.

Determining Human Subjects Involvement

Principal Investigators should contact the Human Subjects Research Review Office if they are unsure if their research actually involves "Human Subjects". All research projects involving human subjects conducted by University faculty, staff and students or done under the sponsorship or auspices of the institution must be reviewed and approved by the Human Subjects Research Review Committee (HSRRC). This includes research involving subjects from outside the university and research which is not funded. This includes the following types of research, (this is not an exhausted list)

- All surveys and questionnaires distributed on-campus for research purposes
- Behavioral and social science research
- Clinical research
- Human genetic research
- Pilot studies

Once it has been determined that an activity is to be considered human subjects research, it will be reviewed under one of three categories: Exempt, Expedited or Full Board Review. The review procedures for each of these are described below.

Final authority for making this determination rests with the HSRRC.
Exempt Research Criteria and Guidelines

Federal Regulation 45 CFR 46.101(b) allow certain research to be exempt from Federal Policy. The exemption status does not apply when the research activities include any of the following:

- prisoners;
- surveys or interviews which include children as participants

Exempt Research

Binghamton University grants exemption determinations to research activities in which in which the only involvement of human subjects will be in one or more of the following categories.

45CFR46.101(b)(1) Educational Strategies, Curricula or Classroom Management Methods
- Research conducted in established or commonly accepted educational settings
- Research involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Subjects (or their parents) should be provided with overview of project that contains basic elements of informed consent, but no formal written consent is obtained

45CFR46.101(b)(2) Tests, Surveys, Interviews, Observations
- Studies involving children as subjects, only educational tests and/or passive observation of behavior is permitted; investigators cannot interact with child subjects
- Studies involving adults as subjects, test, surveys, interviews or behavioral observations can be included if the following conditions are met
  - participation is completely anonymous
  - participation is not anonymous, and the information that will be gathered would not place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation
- Studies involving interviews or focus groups (of individuals age 18 or over) provided that the data collected (or topics discussed) would be unlikely to place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation
- Studies involving the observation of public behavior

45CFR46.101(b)(3) Tests, Surveys, Interviews, Observations
- Human subjects are elected or appointed public officials or candidates for public office; or
- Federal statue(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
45CFR46.101(b)(4) Existing Data, Documents, Records, Pathological Specimens, or Diagnostic Specimens

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. • All data is currently in existence and stripped of any direct identifiers or indirect identifiers • All data is publicly available • Medical records to be accessed for study are currently in existence • Medical records data is recorded in such a way that the respective patient cannot be identified • Specimens may include tissue, blood, or bodily fluid • Specimens were obtained independent of this research project • All specimens and corresponding data are recorded anonymously • Data are recorded in such a way that researchers cannot identify subjects

45CFR46.101(b)(5) Studies which are designed to study, evaluate, or otherwise examine existing programs

- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads (Federal Agencies), and which are designed to study, evaluate, or otherwise examine:
  (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

The Office for Protection from Research Risks (OPRR) has determined that the following criteria (see 48 FR 9266-9270, March 4, 1983) must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs" as specified under Department of Health and Human Services (HHS) regulations at 45 CFR 46.101(b)(5):

1. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
2. The research or demonstration project must be conducted pursuant to specific federal statutory authority.
3. There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).
4. The project must not involve significant physical invasions or intrusions upon the privacy of participants.

Institutions should consult with the HHS funding agency regarding the above conditions before invoking this exemption.
45CFR46.101(b)(6) Taste and Food Quality Evaluation and Consumer Acceptance Studies

- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Research Criteria and Guidelines

Federal Regulations allow certain low risk research to be exempt from Federal Policy. 45 CFR 46.110 and 21 CFR 56.110.

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

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

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

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

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

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

Expedited Research Categories

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

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretiography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular
strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(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.

**Full Board Review Research Criteria and Guidelines**

By regulation, action on protocols that require full HSRRC review may be taken only at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it must receive the approval of a majority of those members present. In the event a quorum is lost during a meeting, the HSRRC cannot take votes until it is restored. Below is a list of materials made available to and reviewed by all of the members present at the meeting of the HSRRC.

- Human Subjects Research Review Form – Application for Expedited or Full Board Reviews
- Project Proposal as described in Section G of Human Subjects Research Review Form – Application for Expedited or Full Board Reviews.
- Proposed consent documents.
- The DHHS-approved sample consent document (when one exists).
- The complete DHHS-approved protocol (when one exists).
Scientific Evaluation
All expedited and full board review protocols will be reviewed by the initial reviewer and the Human Subjects Research Review Committee to evaluate all research protocols for scientific or scholarly validity by determining that:

- The research procedures are consistent with sound research design
- The research is likely to achieve its objectives
- The knowledge expected to result has importance

Full Committee Actions
The Full Committee may act on a protocol in one of four ways:

- it may be approved
- it may be approved pending modifications (this may not need to be re-reviewed by the full committee)
  - This option may not be used when the HSRRC requests modifications or clarifications that are directly relevant to the regulatory criteria for approval.
  - For modifications and clarifications that are not relevant to the regulatory criteria for approval will be reviewed by the HSRRC Chair or a HSRRC member designated by the HSRRC Chair.
- it may be tabled, needing substantial revisions or clarifications (such protocols will need to be re-reviewed by the full committee)
- it may be disapproved (in this case, the study may be re-written to address all concerns and re-submitted for full committee review).

The HSRRC will review the Criteria for Approval of Research Form to determine whether the research undergoing initial review can be approved.

Once a project is approved, no protocol or consent form changes, amendments, or addenda may be made without re-review and approval by the HSRRC.

Attached to the standard approval memo is the final approved version of the consent form with the HSRRC approval stamp.

In the event that a Committee member leaves the meeting a quorum is lost during the meeting, the HSRRC cannot take votes until the quorum is restored.

Approved Consent Form
The consent form is stamped with an approval/expiration date and an approval letter is forwarded to the Principal Investigator and Faculty Supervisor.

The expiration date on the stamped consent document is the date that the protocol has expired, i.e. the first date that the protocol is no longer approved.

The expiration date is the date of the convened meeting at which the research was approved or approved with modification plus the approval interval, not to exceed one year. The calculation of the approval period for research is based on the date of the convened meeting at which the HSRRC approved the protocol or approved the protocol with modifications.
Copies of all documents are placed in the Principal Investigators file and in a chronological folder.

**Review Forms**

The HSRRC has developed Human Subjects Research Review Forms for submitting proposals. The forms can be found on-line at [http://humansubjects.binghamton.edu/Forms.htm](http://humansubjects.binghamton.edu/Forms.htm)

The form must be typed or neatly written. Ineligible forms will be returned to investigators without being reviewed. Students submitting materials should ask their faculty sponsor to e-mail the HSRR Office confirming that they have read the materials submitted and are ready to sign off on the application. This e-mail needs to include the student investigator’s name, title of the project and faculty sponsor’s name and position. Student submittals will not be reviewed until this email is received.

**Submission Materials**

The Principal Investigator must provide:

- The Human Subjects Research Review – Application for Expedited or Full Board Review
- Project Proposal as described in Section G of Human Subjects Research Review Form – Application for Expedited or Full Board Reviews.
- Proposed consent documents.
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**Protocol Evaluation**

Applications that qualify for exempt/expedited review are reviewed for approval by the Chair or an experienced member of the HSRRC designated by the Chair. Experience being defined as those committee members who having gained this knowledge of the subject beyond that of an average man through their education, training, skill, or experience.

The Chair will designate experienced HSRRC members by periodically updating a list of experienced HSRRC members designated to conduct review using the expedited procedure and the HSRR staff will select reviewers from the list. If the chairman or designated member of the HSRRC questions the approval of the protocol, they will communicate their questions to the Principal Investigator. Comments, questions and the request for additional information will be returned to the Principal Investigator in writing. All comments, questions and additional information must be addressed by the Principal Investigator before the protocol can be approved.

The Review process includes:

- Initial Review:
  - The reviewers will review all materials that would have been reviewed by the convened HSRRC.
• The reviewers will review Federal Regulations 45 CFR 46.110, 21 CFR 56.110 and 45 CFR 46.101. The reviewers will also complete the Human Subjects Research Review Checklist and the 46 CFR 45 Criteria Form to ensure that the research:
  o Meets all applicability criteria
  o Represents one or more approvable categories of research.

Continuing Review:
• The reviewers will review the initial protocol along with the Continuing Review application and all material that would have been reviewed by the convened HSRRC.
• The reviewers will review Federal Regulations 45 CFR 46.110, 21 CFR 56.110. The reviewers will also complete the Human Subjects Research Review Checklist and the 46 CFR 45 Criteria Form to ensure that the research:
  o Meets all applicability criteria
  o Represents one or more approvable categories of research.

Modifications
• The reviewers will review the initial protocol along with the Modification application and all material that would have been reviewed by the convened HSRRC.
• The reviewers will review Federal Regulations 45 CFR 46.110, The reviewers will also complete the Human Subjects Research Review Checklist and the 46 CFR 45 Criteria Form to ensure that the research:
  o Meets all applicability criteria
  o Represents one or more approvable categories of research.

All expedited research, initial, continuing review and modifications are posted on the agenda and presented to the HSRRC at the next convened meeting.

Review Procedures

Exempt/Expedited Research
If the protocol falls into one or more exemption categories and meets additional ethical criteria, it will be approved as an exempt protocol. If the protocol either (1) meets all applicability criteria for review using the expedited procedure, falls into one or more categories allowing review using the expedited procedure or (2) is a minor change to previously approved research, and in addition meets the regulatory criteria for approval it will be approved as an expedited protocol.

The Principal Investigator will receive an approval memo via e-mail, along with their consent form date stamped - the protocol must note that the research will last longer than one year to receive the stamp.

Full Board Review Research
Written notification of actions taken at the HSRRC meeting is e-mailed to the Principal Investigator after each meeting.
In cases where a study is disapproved - the HSRRC will provide its rationale for the action taken. The investigator may request an appearance before the Committee to present arguments for reversal of the decision or propose a change in the protocol based on the advice and counsel of the Committee.

**Sub-Committee Review**
In the event that the Chair or the Chair designee does not have the expertise required to assess a protocols risk criteria - that protocol will be reviewed by three experienced members of the committee designated by the Chair, one of which will have expertise in the research area. The three members have the option of approving the protocol, approval with revisions or requiring a full board review. The approval options can only occur if all three committee members agree on approval. In one committee member requires full board approval, the protocol will be placed on the agenda for full board review.

**Full Committee Review**
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Student Research

Students conducting classroom assignments which will be gathering information about people through interventions or interactions with those individuals and classroom assignments which will be gathering private identifiable information about people must be reviewed by this office. Please submit a classroom Application for review. The HSRRC Office will make a determination whether the activity is human subject research as defined in the Policy and Procedures Section IX.A or may request additional information to make this determination. You will be notified of this decision via email.

It is the faculty members’ responsibility to ensure that any activity that is “research” involving “human subjects” as defined in the Policy and Procedures Section IX.A, require HSRRC review and approval before the project starts. Federal regulations can be confusing, rather than risk conducting research without HSRRC approval, and be out-of-
compliance, it is strongly suggested that you contact our office for assistance in determining if your activity involves human subjects research.

**Recruiting Study Subjects**

**A. Students** Under the SUNY Board of Trustees policy students may not be required to participate in any research project as a subject as a course requirement or required by faculty member to serve as a subject for pilot testing research instruments. Courses that involve a research requirement must make clear that participation in research, as a subject is one of several options to fulfill the research requirement. A written explanation of all research alternatives is strongly urged. The informed consent for projects proposing to recruit student participants must make clear the voluntary nature of their participation.

**B. Recruiting Subjects over the Internet.** The use of the Internet to recruit subjects presents similar issues as with any other recruiting tool. The HSRR Office needs to review information to be presented to subjects. Not only does the HSRR Office need to review the text of the recruitment, but it also has to examine the context in which the recruitment takes place (e.g., posting a message on a newsgroup or creating a web site to recruit subjects). When the Web is used to recruit subjects, the HSRR Office must see an example of what the prospective subjects will see (i.e., a “screen shot”). The Binghamton University HSRR requires that all recruitment on the Internet be limited to:
1. the name and address of the clinical investigator and/or research facility;
2. the condition under study and/or the purpose of the research;
3. in summary form, the criteria that will be used to determine eligibility for the study;
4. a brief list of participation benefits, if any;
5. the time or other commitment required of the subjects;
6. the location of the research and the person or office to contact for further information;
7. a link to the Human Subjects Research Review Office web site.

**C. Advertising:** Binghamton University considers direct advertising for study subjects to be the start of the informed consent and subject selection process. Advertisement should be reviewed and approved by the HSRR Office as part of the package for initial review. If the clinical investigator decides at a later date to advertise for subjects, the advertising may be considered an amendment to the ongoing study. When such advertisements are easily compared to the approved consent document, the HSRR Chair, or other designated HSRR member, may review and approve by expedited means, as provided by 21 CRF 56.110 (b)(2). When the HSRR reviewer has doubts or other complicating issues are involved, the advertising should be reviewed at a convened meeting of the HSRR.

**Maintaining Records**

Although regulations require that all human subjects’ research records be retained for three years following the completion of the research [45.115(b)], we recommend that records be maintained in the investigator’s files for a minimum of six years or an indefinite period following completion of the study. The investigator must maintain all
research records (including a copy of the entire protocol, consent form, amendments, and copies of signed consent forms for each research participant (if applicable) in the lab or office of the investigator.

If the investigator leaves Binghamton University, the records must be kept at the University in the Human Subjects Research Review office or with a designated investigator. The HSRRC office must be informed of this transfer of records prior to the investigators departure. The records will be accessible for inspection and copying by authorized representatives of the DHHS and FDA and the university.

When a student graduates, or otherwise leaves the University, the faculty advisor is then responsible for retaining the human subject documentation. Students may retain the original, while a copy of all research documentation must be maintained in the areas listed above.

The HSRR Office will retain all records required by the regulations (e.g. minutes, correspondence between the HSRR office and investigators, HSRRC rosters, and written procedures required by regulations) for at least six years, and retains all records relating to research that has been conducted or cancelled for at least six years after completion or cancellation of research.

The HSRR Office makes records accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

**Conditions of Approval**

Approval of a project by the HSRR Office applies only to the procedures submitted in the proposal. No form of recruitment, or any other aspect of the research, may commence until HSRRC approval has been issued. The investigator must secure prior approval from the HSRR Office for any changes in the procedures that will affect the use of human subjects. The investigator must also report to the HSRR Office any problems that arise in connection with the use of human subjects. Approval for projects is valid for no more than one year. See below for the procedures for obtaining a continuation of approval.

**Continuing Review**

The HSRR Office is required to continue to reevaluate research projects at intervals appropriate to the degree of risk but not less than once a year. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the HSRRC will determine the appropriate approval period.

For research with a one-year approval period, investigators must request a continuation for the approval yearly if the activity lasts more than one year. Four (4) continuations will be granted for a given project. After 5 years, the project must be resubmitted.

The following should be submitted to the HSRCRC office for continuing review:
- Human Subjects Continuing Review Form
Human Subjects Research Review Form – Application for Expedited full Board Review

Project Proposal as described in Section G of Human Subjects Research Review Form – Application for Expedited Full Board Review

- Currently approved consent documents
- Any proposed consent documents.

The convened HSRRC will use the Criteria for Approval of Research Form to determine whether the research undergoing continuing review can be approved.

Continuing review must occur on or before the one-year anniversary date of the previous HSRR Office review, even though the research activity may not begin until some time after the HSRR Office has given approval. As a result, the HSRR Office must receive the request for continuation sufficiently in advance of the anniversary date to allow it to conduct its review. Reminders will be sent out several weeks before the anniversary date.

If the Continuing Review application is not provided to the HSRRC or the HSRRC has not approved a protocol by the expiration date:

- The HSRR Office staff will provide written notification to the investigator that:
  - All research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information.
  - If current subjects will be harmed by stopping research procedures that are available outside the research context, then these should be provided on a clinical basis as needed to protect current subjects.
  - If current subjects will be harmed by stopping research procedures that are not available outside the research context, then the investigator should immediately contact the HSRRC Chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping research procedures.
  - When the HSRRC Chair is notified by an investigator that current subjects will be harmed by stopping research procedures that are not available outside the research context, then the HSRRC Chair may allow such procedures to continue when determined to be in the best interest of subjects.
- Under no circumstances may the HSRRC Chair approve enrollment of individuals in an expired research.

NOTE: IF APPROVAL FOR THE PROJECT LAPSES, CONDUCTING THE RESEARCH IS A VIOLATION OF UNIVERSITY POLICY AS WELL AS STATE AND FEDERAL REGULATIONS.

Modifications

Once the HSRRC has approved a project, it must be carried out exactly as planned. Any and all changes (i.e. subject population, recruitment plans, research procedures, study
design, study instruments, study sites, or research personnel), must be approved by the HSRRC prior to implementation.

The HSRRC will review the following documents involving the modification using the Criteria for Approval of Research Form to determine whether modification undergoing review using the expedited procedure can be approved:

- Modification Form
- One marked copy of the document that will be revised (all changes must be highlighted or underlined)
- The Human Subject Research Review Form – Expedited Full Board Review Application
- Project Proposal as described in Section G of Human Subjects Research Review Form – Application for Expedited Full Board Review
- Currently approved consent documents
- Any proposed consent documents, with all changes highlighted or underlined
- One clean copy of the amended consent document for the HSRRC stamp (note: the expiration date remains the same).

Minor protocol/consent changes may be approved by expedited review.

45 CFR 46.110(b)(2) allows for minor modifications to research that required convened review and approval to be approved through expedited procedures during the period of approval.

The HSRRC has determined that the Chair will make the final decision of the revision is considered a “minor modification”. If the Chair is not available, then all modifications will be reviewed by the full board.

The Chair will review the entire protocol and all information and assess whether the modification is minor. Minor changes would be defined as changes that do not adversely alter the overall risk/benefit profile of the study; would not affect the willingness of current subjects to remain in the study; and do not alter the scientific validity of the study design.

The modification will be reviewed using the Criteria for Approval of Research Form to determine whether research undergoing review using the expedited procedure can be approved.

Those modifications that are excluded from expedited review are those that involve more than minimal risk, or do not fall into expedited categories outlined in 45 CFR 46 110(1)-(7).

Unanticipated Problems/Adverse events/Complaints
Principal Investigators or any individual involved in the research must report the following problems to the HSRRC in writing within five (5) business days.
- allegations or findings of non-compliance.
- Adverse events or any harm experienced by a subject or other individual regardless of whether the event meets FDA definition of “serious adverse event”. 
which in the opinion of the investigator are both unexpected and indicate new or increased risks to subjects.

- Information that indicates a change to the risks or potential benefits of the research. For example:
  - An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits might be different from those initially presented to the HSRRC.
  - A paper is published from another study that shows that the risks or potential benefits of the research might be different from those initially presented to the HSRRC.

- Breach of confidentiality
- Change in FDA labeling or withdrawal from marketing a drug, device, or biologic used in a research protocol.
- Change to a protocol taken without HSRRC review to eliminate an apparent immediate hazard to a subject.
- Incarceration of a subject in a protocol not approved to enroll prisoners.
- Event that requires reporting to the sponsor.
- Sponsor imposed suspension for risk.
- Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.
- Protocol violation (meaning an accidental or unintentional change to the HSRRC approved protocol) that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
- Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including supplemental plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
- Any other problem that the investigator considers to be unanticipated and indicates that subjects or others are at increased risk of harm.
- Any problems involving the conduct of the study or patient participation. For example, social and behavioral interviews may deal with sensitive issues - occasionally, research subjects will become upset because of the nature of the questions, this requires reporting.
- Any problems involving the recruitment and/or consent processes require reporting. For example, if a person who is contacted, either in writing or in person, about participating in a study becomes upset about the recruitment process, this should be reported.
- Any deviations from the approved protocol should be reported in writing. Examples of a more serious nature include incidents of a person being enrolled in a study before signed consent has been obtained.

All problems described above must be reported promptly. The Problems form is available on-line at: [http://humansubjects.binghamton.edu/Forms.htm](http://humansubjects.binghamton.edu/Forms.htm)
Definitions:

- **Non-compliance**: Failure to follow the regulations or VHA Handbook 1200.5 and failure to follow the requirements or determinations of the HSRRC.
- **Allegations of non-compliance**: An unproven assertion of non-compliance.
- **Findings of non-compliance**: A proven assertion of non-compliance.
- **Serious non-compliance**: Non-compliance that affects the rights and welfare of participants.
- **Continuing non-compliance**: A repeated pattern of non-compliance likely to recur without intervention.
- **Unanticipated Problem Involving Risks to Participants or Others**: Any problem, event, occurrence or new information that is (1) unanticipated and (2) indicates that participants or others are at increased risk of harm.

Review of Reports
The HSRR Office staff review all reports and ask these three questions:

1. Does this report involve an allegation of non-compliance?
2. Does this report involve a finding of non-compliance?
3. Does this report involve an unanticipated problem involving risks to participants or others? (i.e., is the information

If the answer to question 1 is yes, the report is processed as described in “Allegations of Non-compliance”.

If the answer to question 2 is yes, the report is processed as described in “Findings of Non-compliance”.

If the answer to question 3 is yes, the report is processed as described in “Unanticipated Problems Involving Risks to Participants or Others”.

If the answer to multiple questions are yes, then the multiple corresponding policies and procedures are followed.

If the answer to all questions is no, then no further action is taken.

Allegations of Non-compliance
HSRR Office staff and the HSRR chair evaluate allegations of non-compliance to determine whether it has no basis in fact or is a finding of non-compliance.

- If the basis has a basis in fact, it is handled as described in “Findings of Non-compliance”.
- If the allegation has no basis in fact, no further action is taken under this section of the policy.

Findings of Non-compliance
HSRR Office staff and the HSRR chair evaluate finding of non-compliance to determine whether it is serious or continuing non-compliance.

- If the non-compliance is either serious or continuing, it is handled under the section on “Serious or Continuing Non-compliance”. 


• If the non-compliance is neither serious nor continuing, it is handled under the section on “Non-serious and Non-continuing Non-compliance”.

Non-serious and Non-continuing Non-compliance
• HSRR Office staff and the HSRR chair work with the non-compliant parties to develop an appropriate corrective action plan.
• If the non-compliance parties do not collaborative work with the HSRRC to develop a corrective action plan when asked to do so, the non-compliance is handled as continuing non-compliance under the section “Serious or Continuing Non-compliance”.

Serious or Continuing Non-compliance
All serious or continuing non-compliance is handled by the convened HSRRC under the section on “Convened HSRRC Review of Problems.

Unanticipated Problems Involving Risks to Participants or Others
All unanticipated problems involving risks to participants or others are handled by the convened HSRRC under the section on “Convened HSRRC Review of Problems”

Convened HSRRC Review of Problems
HSRR staff provides all HSRRC members with information about the problem, results of any investigation, supporting documents, and information about the consent and protocol, when the research involves a specific protocol.

The convened HSRRC considers the following actions and may take no action:

1. Suspension of the research.
2. Termination of the research.
3. Notification of participants when information about the non-compliance my affect their willingness to continue participation.
4. Modification of the protocol.
5. Modification of the information disclosed during the consent process.
6. Providing additional information to past subjects.
7. Requiring current subjects to re-consent to participate.
8. Modification of the continuing review schedule.
9. Monitoring of the research.
10. Monitoring of the consent.
11. Referral to other organizational entities.

Once the convened HSRRC’s evaluation is completed, the serious or continuing non-compliance, any suspension or termination of HSRRC approval, or unanticipated problems involving risks to participants or others will be reported to organizational officials and appropriate regulatory agencies according to the external reporting policy.
ISSUES OF SPECIAL CONCERN

Audio, Video, Photographic Recordings

Recording the voice and/or image of an individual creates a type of record that requires unique handling and storage, particularly if the content may be considered sensitive.

Research subjects must be informed that such recordings will occur, and be provided with information about the storage, confidentiality, and future use of the recordings. The Human Subjects must be informed of the following:

- Type of recording that will be utilized
- Specific identifiers that will be recorded
- People who will have access to the recordings
- Confidentiality procedures of the recordings
- Indicate when the recordings will be destroyed – or – if they will be kept indefinitely
- Use of the recordings: educational; commercial; analysis by research; unspecified use

The Audio, Video, Photographic Recordings form can be found at the following link: http://humansubjects.binghamton.edu/Forms.htm

Conflict of Interest

Binghamton University’s policy dictates that any real, of perceived, conflict of interest of the HSRRC members or Principal Investigators must be fully disclosed to all parties concerned.

Binghamton University policy prohibits HSRRC members from reviewing, participating in the discussion of, or voting upon any research protocol for which they, their spouse, dependent children, or partner are involved in the design, conduct, or reporting of the research.

Binghamton University policy prohibits HSRRC members from reviewing, participating in the discussion of, or voting upon any research protocol when the committee member, their spouse, dependent children, or partner holds a financial interest, meaning anything of monetary value, including although not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options, or other ownership interest); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights)

Binghamton University HSRRC members with these types of conflicts of interest shall recuse themselves from the final discussion and vote of all such studies. All conflicted members must recuse themselves and leave the room for the vote and are not counted towards quorum. Absences of Committee members, who have a conflict, from the deliberation and the vote are noted in HSRRC minutes.
When a member, or a member’s spouse, relative or partner, is an investigator on a study to be reviewed, HSRRC members must recuse themselves from the review, discussion of, and vote on the protocol.

Consultants are considered to have a conflict of interests when they, their spouse, dependent children, or partner involved in the design, conduct, or reporting of the research.

Consultants are considered to have a conflict of interest when consultant, their spouse, dependent children, or partner holds a financial interest, meaning anything of monetary value, including although not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options, or other ownership interest); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights).

Principal Investigators must fully disclose to all human subject participants, through the informed consent, any financial affiliation or any other monetary influence that the Principal Investigator may have with the research protocol.

Principal Investigators must also include with the initial protocol application the following Conflict of Interest Form:
http://humansubjects.binghamton.edu/Forms/Forms/Conflict%20of%20Interest%20Declaration52.rtf

Binghamton University abides by the following Federal Guidelines conflict of interest requirements: Code of Federal Regulations, Title 42 Part 50 Subpart F.


Deception

Sometimes information must be withheld from subjects or false information provided to them. This may be for substantive reasons (e.g., to distinguish perceptual causes from other causes) or methodological reasons (e.g. to ensure natural reactions or to avoid placebo effects). These circumstances inherently involve a breach of the concept of informed consent. Consequently, several serious concerns must be met before such research can take place.

- Deception cannot be used in any study where there is risk to subjects
- The consent document should 1) never contain anything that is untrue, or be part of the deception, and 2) subjects must be provided with sufficient information for them to decide whether to participate and, as in all other human subjects research, be allowed to withdraw at any point without penalty
- No information can be withheld from subjects that could significantly affect their decision to participate (i.e. the subjects would likely participate anyway if they knew all the information)
• When the deception involves a falsehood told, no information can be provided to subjects that would have a harmful effect on them if the statement were believed.
• Human Subjects need to be informed about the nature of the research in a way that does not invalidate the data.
• All subjects must be debriefed regarding the true nature of the research after their participation.

The debriefing should:

• Explain all truths not revealed and all falsehoods told to subjects.
• Address the reasons the deceptions were necessary.
• Reassure subjects that their reactions to the deceptions were normal.

If having incomplete or erroneous information is not likely to be harmful to subjects, the HSRR Office will consider delaying the debriefing until all subjects have completed their participation. Care should be taken in debriefing to protect the well-being of the subjects.

All debriefings must be submitted as a written text document to the HSRR Office. The debriefing should always be a dialogue. Those conducting the debriefing should be trained to elicit and respond to subject concerns.

Information should not be provided that might damage subjects' self-esteem or hurt their feelings. The use of highly evaluative terms (e.g. "We tricked you." Or "We lied to you.") should be avoided in explaining deceptions to the subjects.

DNA/Genetic Research

All genetic research must be reviewed by the full HSRRC. Genetic research is constantly evolving and more personal information is being obtained. This information can have dire consequences on the human subjects and can affect the subject's insurability and employment opportunities. Genetic studies that generate information about subjects' personal health risks can provoke anxiety and confusion.

The following Binghamton University procedures and NYS laws must be taken into consideration when designing a research protocol that involves the use and storage of human DNA.

Informed Consent

NY Civil Rights Law Section 79-1(4)(d)
Each disclosure or re-disclosure of the (human subjects identified) test results requires the express informed consent of the test subject, and no general waivers are deemed informed consent.

NY Civil Rights Law Section 79-1
While informed consent is required to allow research access to specimens, explicit re-consent is not required once linked identifiers are removed.
For the researchers convenience we provide an informed consent template that addresses all of the issues concerning genetic research:

http://humansubjects.binghamton.edu/Samples/DNA%20Informed%20consent%20sample.doc

Archived specimen repository and bank requirements

1. Laboratory inspection
   - Contact Environmental Health & Safety to schedule:
     - EH&S
     - Biosafety Committee audit

The Archive will require regular inspection (2 times per year) by Environmental Health & Safety Staff. This inspection includes the standard EH&S audit. While scheduling this, you may request that your Biosafety Committee audit is conducted at the same time. The laboratory directors will be required to forward all audit reports and compliance approvals from EH&S and the Biosafety Committee to the Human Subjects Research Review Office. To schedule a lab inspection, EH&S can be contacted at hazwaste@binghamton.edu OR X 7-2211.

2. Laboratory security
   - Provide security measures for the archive
     - Example: key-card access with time-stamped electronic recording of personnel entering lab.

The Archive must be sufficiently secure to prevent theft, loss or destruction of valuable information. The laboratory director should be aware of all individuals with access to archive. Archive rooms should be locked and accessibly to laboratory personnel with key access. We recommend, if not already in place, that the archive be equipped with key-card access via a BU ID, so that there is an electronic time-stamped recording of personnel entering the lab.

3. Data records
   - Storage report
   - Password protected and secure
   - De-identified
   - Key coded or encrypted software
   - Backed up

The protocol must include a detailed description of what type of data has been collected and how all data records are stored and kept secure. All data should be protected and backed-up (on other computers or in file cabinets, etc). All data must be kept in a secure and defined location.

4. Material Transfer Agreement (MTA)
   - MTA through the Division of Research
   - http://research.binghamton.edu/TT/index.htm
In order to function as human biological repository and specimen bank, the Archive will be required to establish an official material transfer and data use agreement for those researchers interested in obtaining samples. The Office of Technology Transfer and Innovative Partnership in the Division of Research will oversee this process. The laboratory directors will be required to forward all MTAs to the Human Subjects Research Review Office.

5. NIH Certificate of Confidentiality
   - Required IF specimens are identifiable
   - Requires IRB approval. Approval can be contingent upon certificate

If the specimens in the Archive are identifiable and belong to living subjects it is a requirement to obtain a Certificate of Confidentiality before sharing information. This certificate can be obtained through the National Institutes of Health. However, if data has been de-identified this may not be required, although advisable.

Please complete the DNA Archive Specimen and Data Storage application for committee review. The forms are available on our website: [http://humansubjects.binghamton.edu/Forms.htm](http://humansubjects.binghamton.edu/Forms.htm)

International Research

Research in foreign countries also presents special concerns regarding the rights and welfare of human subjects. In general, the HSRRC accepts the standards of the location in which the research is taking place, unless those standards grossly violate the basic principles of ethical human subjects’ research. In addition, the following issues apply to international human subjects’ research:

- The review of international research may fall under "exempt" and "expedited" review.
- All materials, including consent forms, must have English language translations included with the protocol.
- OHRP requires that IRB must have knowledge of the local research context – this can be accomplished through an outside consultant who is familiar with the region and provides the committee a summary of the risks to the human subjects in this culture.

Permission to Conduct Research (Social Behavioral)

- Research that receives federal funds and is working with a foreign institution, must receive some form of review, or affirmation of the US review.
- If there are no federal funds, but the research is being done in collaboration with a foreign institution, affirmation that the institution reviewed the research and approves of the protocol.
- If the research is not being conducted with a foreign institution, but within a community, there is no requirement for local review.
Internet Research

It is clear that the Internet will be used more and more in conducting human subjects research. Research on the Internet presents new concerns to the traditional human subjects issues: risk, consent, participation by children, and confidentiality. Investigators are going to have to provide technical information on how they will deal with these issues.

The HSRR Office may require additional information on internet-based research issues. The National Institute of Mental Health has proposed suggestions for addressing such risks: http://humansubjects.binghamton.edu/internet-based-rsch-interventions-chart-may2007.pdf

Internet-Based Issues may include:

- Anonymity or false information
- Information from vulnerable populations
- Monitoring of individuals clinical status
- Lack of in person communication
- Assuring consent was informed
- Delay of appropriate treatment
- Adequate debriefing
- Limits to privacy and confidentiality
- Bias sample selection

Human Subjects Issues

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

Consent. Since it is currently not possible to get a signed consent form over the Internet. Investigators can have subjects submit a signed consent form and send them a password to gain access to the research pages. In any event, investigators must indicate to the HSRR Office how they plan to get consent from subjects.

Confidentiality. Since it is impossible to guarantee absolute data security over the Internet, sensitive research may not be appropriate for the Internet. Investigators need to address how they intend to assure confidentiality, keeping in mind that the degree of concern over confidentiality is directly related to the sensitivity of the data. Data transmitted via e-mail cannot be anonymous without the use of additional steps. Almost all forms of e-mail contain the sender's e-mail address. In order to maintain anonymity the research must use an "anonymizer" - a third party site which strips off the sender's e-mail address. (Form more information on Anonymizer(s) visit: www.anonymizer.com; www.rewebber.com; www.mutemail.com) Data submitted over the Web can only be anonymous if software is used to store the information
directly in a database without identifiers; otherwise identifiers are attached to the data. Web servers automatically store a great deal of personal information about visitors to a web site and that information can be accessed by others. For more information on ethical internet based research, please visit the Association of Internet Researchers.

The Association of Internet Researchers is an academic association dedicated to the advancement of the cross-disciplinary field of Internet studies. It is a member-based support network promoting critical and scholarly Internet research independent from traditional disciplines and existing across academic borders. The association is international in scope. [http://www.aoir.org/reports/ethics.pdf](http://www.aoir.org/reports/ethics.pdf)

**Types of Research on the Internet.**

There are three types of research conducted on the Internet:

- Recruiting Subjects Over the Internet
- Observation of Internet Activity
- Collecting Data Over the Internet

**Recruiting Subjects over the Internet.**

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

**Observation of Internet Activity.**

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

**Collecting Data over the Internet.**

This type of research generally involves having subjects submit data, e.g., survey data, over the Internet and presents the most serious human subjects concerns. As in the other types of Internet research, the investigator needs to indicate how subjects' consent will be obtained and their confidentiality protected. Of particular concern with this type of research is the participation by children and investigators must address this issue in their protocols. The HSRR Office must see an example of what the prospective subjects will see (i.e., a "screen shot").
Investigational New Drugs (IND) and Devices (IDE)

Drugs:
The HSRR office staff will review all documentation submitted by the Principal Investigator to determine that when an investigator proposes to conduct research that involves a drug that one of the following is true:

- The drug has an IND number and the IND number is supported by one of the following: (The Investigator Brochure may not be used for this purpose.)
  - Sponsor protocol imprinted with the IND number.
  - Written communication from the sponsor documenting the IND number.
  - Written communication from the FDA documenting the IND number.
  (Required if the investigator holds the IND.)

- The drug falls into one of the categories of exemption from an IND. [See 21 CFR 312.2(b)]

Devices:
The HSRR office staff will review all documentation submitted by the Principal Investigator to determine that when an investigator proposes to conduct research that involves evaluating the safety of effectiveness of a device that one of the following is true:

- The device has an IDE and the IDE number is supported by one of the following: (The Investigator Brochure may not be used for this purpose.)
  - Sponsor protocol imprinted with the IDE number.
  - Written communication from the sponsor documenting the IDE number.
  - Written communication from the FDA documenting the IDE number.
  (Required if the investigator holds the IDE.)

- The device meets the requirements for an abbreviated IDE. [See 21 CFR 812.2(b)]

FDA Code of Federal Regulations Website
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

Principal Investigators (Researchers) conducting studies in which an investigational device will be used must ensure adequate control of the device. Adequate control and handling of investigational devices include all of the following:

- The investigator must ensure that the investigational device is used in accordance with the HSRR approved protocol, the Occupational Health and Safety report, the Mechanical Report, the investigational plan and applicable FDA regulations.
- The investigator must administer the investigational device only to participants under the investigator’s direct personal supervision or under the supervision of the sub-investigator directly responsible to the investigator who is listed on the Occupational Health and Safety Report as being authorized to use this equipment for the named project.
- The investigator must not supply the investigational device to any person not authorized to receive it.
- The investigator must maintain the following accurate, complete, and current records relating to their participation in the clinical investigation. Specifically, records of receipt, use or disposition of a device that relate to:
The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
- The names of all persons who received, used, or disposed of each device.
- Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

• If the investigation is terminated, suspended, discontinued, or completed, the investigator must return any unused stock of the investigational device to the study sponsor, or otherwise provide for disposition of the unused stock as directed by the sponsor.

Multi-site Study Requirements

Research that is conducted by Binghamton University’s Faculty, Staff or Administrators that works in collaboration with another institution must obtain an IRB approval from the collaborating institution or if an IRB does not exist a letter of collaboration or permission must be obtained from the appropriate official.

If the Principal Investigator is the lead investigator in this multi-site study the Principal Investigator must provide, on a separate sheet of paper, a description of the management of information obtained in multi-site research that might be relevant to the protection of subjects, such as:
- Unanticipated problems involving risks to subjects or others.
- Interim results.
- Protocol modifications.

All modifications, revisions, continuing reviews, adverse events, unanticipated problems, complaints and any other correspondence that is received from the collaborating institution must be forwarded to the HSRRC.

Organizational Research

Often social scientists conduct research on organizations rather than individuals. Since the information gathered in this research is not about individuals, there is often a great deal of confusion about compliance with human subjects requirements. "Organizational research" is defined as research obtaining information only about organizations, not about the individuals in or served by the organizations. Any research which gathers information about individuals (whether identified or not) must meet the human subjects requirements described in this Guidebook.

The human subjects requirements for organizational research depends on the source and nature of the information obtained. There are three categories of organizational research: (1) Information about organizations obtained from publicly available sources, (2) Non-sensitive information obtained through interviews or questionnaires (3) Sensitive information obtained through interviews or questionnaires. Sensitive information is information that might be proprietary or damaging to the organization if divulged.

Please consult the HSRR Office for information concerning organizational research categorization.
Payments to Human Subjects

The HSRRC requires that the Principal Investigators must provide the HSRRC accounting information that indicates the full amount for each subject enrolled full term in the study. Should a modification to the research requesting additional enrollment be submitted – the Principal Investigator must provide an updated accounting.

Payment to subjects must be allocated as outlined by the FDA guidance listed below:


“…Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.”

Questionnaires

The Office has a complete list of all questionnaires that were previously reviewed and approved and also notes the Human Subjects audience that was involved in the research. For a complete list of pre-approved questionnaires, please review this site: http://humansubjects.binghamton.edu/Investigators%20guidelines.htm#21

Questionnaires are the most common research method used in human subjects research at the University. As a result, researchers often overlook some of the human subjects concerns that can hold up approval of a questionnaire study, such as consent and confidentiality.

Consent: Although most questionnaire studies do not require a written consent form, researchers must still ensure that subjects are giving informed consent to participating in the study. All questionnaires must include some form of cover sheet or instructions to subjects which provide subjects with the same information that would be included in a consent form. In particular, subjects need to be informed:
• about the nature of the questions they are going to be asked (especially any questions on sensitive topics);
• that they can skip any question they choose not to answer (subjects should not be instructed to answer every question);
• that they may withdraw at any point without penalty;
• that procedures are in place to protect their confidentiality.

Confidentiality: In even the most innocuous questionnaire research, all research information must be kept strictly confidential. Complete anonymity is the best protection from breaches of confidentiality. Researchers must also be aware that demographic information, in some circumstances, can be an identifier. Anything that allows an individual subject to be identified is an identifier and this information must be protected. The degree of protection depends on the sensitivity of the information.

Another point that is often overlooked is the collection of completed questionnaires. In some circumstances, the individuals collecting the questionnaires can identify who turned in which form. For sensitive information, it would be best if forms were returned in sealed envelopes.

Socially Sensitive Research

In addition to the basic requirements for conducting human subjects research specific research topics present additional concerns relating to the rights and welfare of research subjects. The HSRRC has often delayed or disapproved protocols in these topics until additional information or a Certificate of Confidentiality has been issued

According to the Office for Human Research Protection, Institutional Review Board Guidebook, Chapter 3, Section D. Privacy and Confidentiality, the policy states:

"Where data are being collected about sensitive issues protection of confidentiality consists of more that preventing accidental disclosures. There have been instances where the identities of subjects or research data about particular subjects have been sought by law enforcement agencies, sometimes under subpoena. Researchers can apply for a Certificate of Confidentiality through the Assistant Secretary for Health that will provide protection even against a subpoena for research data. The policy defines sensitive research as involving the collection of information falling into any of the following categories:

(a) Information relating to sexual attitudes, preferences, or practices;
(b) Information relating to the use of alcohol, drugs, or other addictive products;
(c) Information pertaining to illegal conduct;
(d) Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
(e) Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
(f) Information pertaining to an individual's psychological well-being or mental health;

Information in other categories, not listed here, might also be considered sensitive because of specific cultural or other factors".
Risks

Risks associated with socially sensitive information could include:

- Loss of confidentiality about the identity of the volunteers
- Loss of confidentiality about the information given by the volunteers
- Triggering internal conflicts within volunteer-respondents, (e.g., emotional reactions or needs)
- Triggering external conflicts of social, stigmatizing, or physical damage against volunteers, (e.g., assault by abusing partners or legal action by authorities, if subject participation in the study became known)
- In some research (e.g., about fetal alcohol syndrome), the people at risk include not only the subjects of the research, but third parties (e.g., the mothers) as well.

Confidentiality

One of the most important risks in socially sensitive research is the effect of a breach of confidentiality. The researcher must make every effort to try to ensure confidentiality; we suggest relying on anonymity whenever possible.

Anonymity means that no one, not even the investigator, can identify an individual subject. Simply eliminating names and other obvious identifiers does not guarantee anonymity; demographics can sometimes identify subjects as well. Any information or pattern of information that can uniquely identify an individual eliminates anonymity.

When anonymity is not feasible, then the researcher must demonstrate to the HSRR Office how confidentiality can be assured. Depending on the sensitivity of the subject matter, extra care should be taken to ensure that subjects cannot be identified.

With some research topics, such as sexuality or criminality research, not only is the information sensitive, but the subjects’ presence in the study can be a sensitive piece of information.

Social Risks

If the research concerns illegal behavior, (e.g., a study of HIV and risk factors among prostitutes), the researcher may need to have the cooperation of local legal authorities or a federal Certificate of Confidentiality (see section on Certificates of Confidentiality).

If there is a risk of triggering retribution by others, such as violence by abusing partners, the researcher must ensure that nothing given can identify a person as a respondent.

Risk to the community must be minimized, often by researchers and community agreeing about publication, (e.g., whether to identify the community).

Benefits

Researchers should also maximize benefits of the research each volunteer and community. They must ensure availability of services to the volunteers. For a survey
of fetal alcohol syndrome, for instance, researchers should link to established, or help establish, real services of prevention and treatment. At the very minimum, subjects should be provided with sources of help and support available in the community.

**Coercion**

Research involving emotionally vulnerable subjects should avoid coercion by caregivers. Many patients who are dependent on caregivers' help may feel that refusing to take part in research will lead to loss of the care they need, in spite of the written "non-coercion disclaimer" in consent forms. One way to avoid the problem is to emphasize repeatedly the freedom to refuse. Another is to have at least the consent, and sometimes the research as well, done by people other than the caregivers.

**Mandatory Child Abuse Reporting**

All research that involves children and/or individuals who may divulge acts of abuse must be fully informed that NYS requires mandatory reporting of abuse by those individuals listed below.

According to Section 413 of the Social Services Law, the following persons are mandated child abuse reporters in New York State:

- Physician
- Surgeon
- Intern
- Resident
- Medical Examiner
- Coroner
- Osteopath
- Chiropractor
- Psychiatrist
- Psychologist
- Mental Health Professional
- Dentist
- Dental Hygienist
- Optometrist
- Podiatrist
- Christian Science Practitioner
- Registered Nurse
- Social Service Worker
- Peace Officer
- Police Officer
- School Official
- Day Care Center Worker
- Hospital personnel engaged in the admission, examination, care or treatment of persons
- Employee or volunteer in a Residential Care Facility defined by §412(7).
- Provider of family or group family day care
- Any other Child Care or Foster Care Worker
- District Attorney or Assistant District Attorney
Investigator Employed in the office of the D.A. or other Law Enforcement Official

**Situations in Which Reports Are Required**

Whenever a mandated reporter suspects child abuse or maltreatment while acting in his/her professional capacity as a staff member of a medical or other public or private institution, school, facility, or agency, he or she shall immediately notify the person in charge of that school, facility, institution or his/her designated agent, who will then (also) become responsible for reporting or causing a child abuse report to be made to the county Child Protective Services agency.

It should be noted that Section 413.1 of the Social Services Law does not require more than one report from the institution, school, facility, or agency on any one incident of suspected abuse or maltreatment. The research must be aware that the mandated reporter's obligation is not discharged unless the report is made.

**Subject Coding**

One method commonly used to protect confidentiality is to use subject codes rather than names or other identifiers. Care must be taken to ensure that the code cannot be used as an identifier.

For example, a frequently used code is the last four digits of the subject's social security number. Unless an extremely large number of subjects are being used, this number can still be used to identify an individual subject.

Arbitrary or random codes are much better at protecting confidentiality. On the other hand, when different sets of data for a single subject must be linked, an arbitrary code is usually unsuitable because subjects will forget them. In these cases, the best method is to provide subjects with a formula that they can use to generate a unique code and which will generally result in the same code number each time the subject uses it. The following is an example of a workable formula:

First & Second letter of Your Mother's First Name
First & Second letter of Your Father's First Name
Month You Were Born
Date You Were Born

**FOR EXAMPLE:** If your mother's name was Sally and your father's name was George and you were born on May 1st, you would enter:

SA GE 05 01

**OBTAINING INFORMED CONSENT**

**Definition of Informed Consent**

Informed consent is one of the primary ethical principles governing human subjects research; it assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate.
"Informed consent" means the knowing consent of an individual, or his/her legally authorized representative, who is able to exercise free power of choice without undue inducement or any form of force, fraud, deceit, duress or other form of constraint or coercion.

State and Federal Informed Consent Requirements

**New York State:** defines "Voluntary informed consent" (NY Public Health Law, Article 24-A; Section 2442; March 1998) as the legally effective knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion.

Elements of informed consent

Informed consent will be sought from each prospective participant or the participant’s legally authorized representative in keeping with the criteria outlined below.

The process for obtaining consent must incorporate all of the following:

- The investigator will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative.
- Consent will be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.
- Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence.
- The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.
- The informed consent does not include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights.
- The informed consent does not release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Information that must be provided as part of the interaction with the participant and in the documentation of the consent process, unless waived or altered:

- A statement that the study involves research.
- An explanation of the purposes of the research.
- The expected duration of the participant’s participation.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact for answers to pertinent questions about the research participant’s rights.
• An explanation of whom to contact in the event of a research-related injury to the participant.
• Contact information for the research team for questions, concerns, or complaints.
• Contact information for someone independent of the research team for problems, concerns, questions, information, or input.
• A statement that participation is voluntary.
• A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
• A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

For FDA-regulated research:
• A statement that notes the possibility that the Food and Drug Administration may inspect the records.

For research involving more than minimal risk:
• An explanation as to whether any compensation is available if injury occurs.
• If compensation is available, what it consists of, or where further information may be obtained.
• An explanation as to whether any medical treatments are available if injury occurs.
• If medical treatments are available if injury occurs, what it consists of, or where further information may be obtained.

Additional information, to be provided to each participant, when appropriate:
• A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable.
• A statement that if the participant is or may become pregnant the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable.
• Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.
• Any additional costs to the participant that may result from participation in the research.
• The consequences of a participant’s decision to withdraw from the research.
• Procedures for orderly termination of participation by the participant.
• A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.
• The approximate number of participants involved in the study.
• The amount and schedule of all payments to the participant.

The consent process may be waived or altered under one of two set of conditions:

Most common set of conditions for a waiver or alteration
• The research involves no more than minimal risk to the participants.
• The waiver or alteration will not adversely affect the rights and welfare of the participants.
• The research cannot practicably be carried out without the waiver or alteration.
• Whenever appropriate, the participants will be provided with additional pertinent information after participation.
• The research is not FDA-regulated.

Less common set of conditions for a waiver or alteration -
• The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service.
• programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

Documenting the consent process:
• Informed consent will be documented.

When the long form of documentation is used:
• The consent document embodies the basic and appropriate additional elements of disclosure.
• The participant or the participant’s legally authorized representative will sign (and date for FDA-regulated research) the consent document.
• A copy of the consent document will be given to the person signing the consent document.
• The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

When the short form of documentation is used:
• The consent document states that the elements of disclosure required by regulations had been presented orally to the participant or the participant’s legally authorized representative.
• A written summary embodies the basic and appropriate additional elements of disclosure.
• There will be a witness to the oral presentation.
• For participants who do not speak English, the witness is conversant in both English and the language of the participant.
• The participant or the participant’s legally authorized representative will sign (and date for FDA-regulated research) the consent document.
• The witness will sign both the short form and a copy of the summary.
• The person actually obtaining consent will sign a copy of the summary.
• A copy of the consen short form will be given to the participant or the representative.
• A copy of the summary will be given to the participant or the representative.

The requirement to document the consent process may be waived under one of two sets of conditions:

Condition 1
• The research presents no more than minimal risk of harm to participants.
• The research involves no procedures for which written consent is normally required outside of the research context.
• The oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.
• The IRB has determined whether the participant should be provided written information.

Condition 2
• The only record linking the participant and the research will be the consent document.
• The principal risk will be potential harm resulting from a breach of confidentiality.
• Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern.
• The research is not FDA-regulated.
• The oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.
• The IRB has determined whether the participant should be provided written information.
Proxy Consent
New York State Law states that surrogate consent, other than that of a parent or legal guardian, (a legal guardian is defined as an individual who has obtained legal guardianship through the Surrogate Courts Proceedings Act §1700 ff., Domestic Relations Law §81 and Article Six of the Family Court Act) is not allowable, unless there is a legal document that specifically authorizes another to act on behalf of someone for research purposes (Public Health Law Section 2442). For example, the consent of a friend would not be allowed. Those individuals allowed to give consent to a third party include:
- Persons appointed as health care agents
- Court appointed guardians
- Next of kin in the following order: spouse, adult child, parent, and adult sibling when there is a legal document that specifically authorizes another to act on behalf of someone for research purposes as per Public Health Law Section 2442.

Research conducted outside New York State
- It is the Principle Investigators responsibility to ensure that Federal Guidelines 45.102(c) is followed: (c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. Therefore the Principal Investigator must provide to the HSRRC documentation of State Law, where the research is being conducted, concerning proxy care and these laws must be incorporated in the consent process.

VA requirements regarding informed consent state:
- person must be legally able to give consent. If their legal consent is relinquished, then consent must come from their legal guardian.

Research Involving Deception
Sometimes information must be withheld from subjects or false information provided to them. This may be for substantive reasons (e.g., to distinguish perceptual causes from other causes) or methodological reasons (e.g. to ensure natural reactions or to avoid placebo effects). These circumstances inherently involve a breach of the concept of informed consent. Consequently, several serious concerns must be met before such research can take place.

- Deception cannot be used in any study where there is risk to subjects
- The consent document should 1) never contain anything that is untrue, or be part of the deception, and 2) subjects must be provided with sufficient information for them to decide whether to participate and, as in all other human subjects research, be allowed to withdraw at any point without penalty
- No information can be withheld from subjects that could significantly affect their decision to participate (i.e. the subjects would likely participate anyway if they knew all the information)
- When the deception involves a falsehood told, no information can be provided to subjects that would have a harmful effect on them if the statement were believed
- Human Subjects need to be informed about the nature of the research in a way that does not invalidate the data
• All subjects must be debriefed regarding the true nature of the research after their participation

The debriefing should:
• Explain all truths not revealed and all falsehoods told to subjects
• Address the reasons the deceptions were necessary
• Reassure subjects that their reactions to the deceptions were normal

If having incomplete or erroneous information is not likely to be harmful to subjects, the HSRR Office will consider delaying the debriefing until all subjects have completed their participation. Care should be taken in debriefing to protect the well being of the subjects.

All debriefings must be submitted as a written text document to the HSRR Office. The debriefing should always be a dialogue. Those conducting the debriefing should be trained to elicit and respond to subject concerns.

Information should not be provided that might damage subjects' self-esteem or hurt their feelings. The use of highly evaluative terms (e.g. "We tricked you.") or "We lied to you.") should be avoided in explaining deceptions to the subjects.

Consent Forms

Documentation of "legally effective informed consent" usually involves the use of a written consent form containing all of the information to be disclosed and signed by the subject or the subject's legal representative. It should be emphasized that the consent form is merely the documentation of informed consent and does not, in and of itself, constitute informed consent. The fact that a subject signed a consent form does not mean that he/she understood what was being agreed to or truly gave their voluntary consent. Informed consent is a process that is documented by a signed consent form.

Consent forms should be designed to meet the needs of the particular research project where it is being used; no one form can be used in every research project. It is recommended that consent forms meet four criteria.

1. Be brief, but have complete basic information. Many potential subjects do not read long consent forms. The longer the form, the fewer the number of people who read it in its entirety, and the smaller the fraction of it that is read by the rest. That is, the quest to be more comprehensive by including more information may actually result in the information transmitted being less comprehensive. Include only the basic information needed by potential subjects ("basic" are the items required by federal regulations) and do not try to answer every conceivable question. "Non-basic information" can be given in a separate handout, perhaps in a Question-and-Answer format. One suggestion is to include a list of questions at the beginning of the handout, to permit each person to go to those questions that most interest him/her.

2. Be readable and understandable to most people. Articles in most popular magazines are at the 8th grade level. Several computer programs estimate readability by the Flesch, Flesch-Kincaid, and FOG measures. Factors that improve readability include the following:
• Technical terms should be replaced with ordinary language
• Use active tense rather than passive tense verbs ("We did" rather than "It was done")
• Write shorter sentences in general
• Make clear the links of logical sequences and of cause-and-effect, even if doing so makes the sentence much longer. ("We will do this, because that happened").

3. Be in a format that helps people comprehend and remember the information. Format can be used to help people comprehend and remember complex material. Good format uses are headings;
• Indents
• bolded type
• lists
• extra spacing between sub-topics
• repetition
• reasonable-size type
• plenty of margins and empty space in general.

These formats help the reader to: A) organize the information; B) recognize, know, and remember the key points; and C) go back later to the consent form and retrieve important information (such as telephone number of the investigator to call with questions).

4. Serve as a script for the face-to-face discussions with the potential subjects
Face-to-face discussions between researcher and potential subject are the most important part of the process of informed consent. These sample forms can be the script for the verbal explanation by the researcher. If the verbal explanation is almost identical to the written consent form, each will reinforce the other and potential inconsistencies will be avoided. One benefit of this approach is that the form/script prompts the researcher to use simple language for the verbal explanation.

Another benefit is that the same form/script can be used for potential subjects who have difficulty reading or low literacy or who need a translation, which also should improve consistency of explanation among all subjects. i.e., researchers need develop only one form/script, not two, to permit people of all literacy levels to be potential subjects.

The script could also be used in videotaping the explanation.

Date Stamping Of Consent Forms

In order to ensure that investigators are using the most currently approved consent forms, the HSRRRC has decided that consent forms will be date stamped by the HSRR Office, with the expiration date of the HSRRRC approval. Investigators using consent forms will submit a clean original to the HSRR Office for date stamping and will make copies from that original. Subjects are to be informed on the consent form not to sign the form without a date stamp or where the expiration date has lapsed.
The expiration date on the stamped consent document is the date that the protocol has expired, i.e. the first date that the protocol is no longer approved.

The expiration date is the date of the convened HSRRC meeting at which the research was approved or approved with modification plus the approval interval, not to exceed one year. The calculation of the approval period for research is based on the date of the convened meeting at which the HSRRC approved the protocol or approved the protocol with modifications.

Anyone not using photocopies, but printing consent forms from a computer can have the stamped informed consent e-mailed to them as an attachment. Contact the HSRR office for more information.

**Vulnerable Populations**

**Research Involving Prisoners**

**Definition**

The purpose of this section is to assist investigators in designing and submitting for approval research involving prisoners as subjects. Federal regulations impose additional safeguards upon research involving prisoners because the constraints of incarceration may affect the prisoners' ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research.

According to federal regulations a "prisoner" is:

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

For purposes of the HSRRC, this would include, for example, individuals held in a prison, county penitentiary, county or city jail, court detention pen, hospital prison ward, police lockup, halfway house, juvenile secure and/or non-secure detention facility, and juvenile residential placement facility, as well as those committed to a host of alternative settings, such as day reporting facilities, youth courts, and drug courts.

**Permitted Research**

45 CFR 46 Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

For prisoners “minimal risk” means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
46.303(c) “Prisoner” means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Research must fall in one or more of the following four (A-D) categories:

(A) study of possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects:

(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects:

(C) research on conditions particularly affecting prisoners as a class.
   - For DHHS funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.
   - For DHHS funded research which require the assignment of prisoners in a manner consistent with protocols approved by the HSRRC to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject
   - For DHHS funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.
   - For DHHS funded research which require the assignment of prisoners in a manner consistent with protocols approved by the HSRRC to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

The following information must be supplied: (please see Research Involving Prisoners Form)
1) Are there any possible advantages accruing to the prisoner through his or her participation in the research, (when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison) that are of such a magnitude that his or her ability to weigh the risk of the research against the value of such advantages in the limited choice environment of the prison is impaired?

2) Do the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?

3) Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? Note: Unless the project director provides to the HHSC justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research project.

4) Is the information presented in language understandable to the subject population?

5) State how you will assure that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole? Is there adequate assurance that parole boards will not take into account a prisoner’s participation in the research in making decision regarding parole?

6) Is each prisoner clearly informed in advance that participation in the research will have no effect on his/her parole? (This must be clearly stated in the consent form)

7) When the research requires follow-up beyond the period of incarceration, have provisions been made for locating the individual. Please discuss these provisions below.

8) Are participants informed of how follow-up will take place if such is required?

HSRRC Convened meeting actions:

The HSRRC must determine that the research falls into one or more categories and that the answers to questions 1-2 and 5-8 are yes.

A majority of the HSRRC (exclusive of prisoner member) have no association with the prison involved, apart from their membership on the HSRRC.

A least one HSRRC member is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity is present at the meeting.

For DHHS funded research the organization has to certify to OHRP that the duties of the HSRRC have been fulfilled.

Issues Related to Consent

In a closed institution such as a prison there may be extraordinary organizational and interpersonal pressures which intrude into the decision whether or not to participate as a subject in research. This may be particularly evident in group situations and classroom environments. Wherever possible, prisoners should be given the opportunity to reflect on the decision to participate in private.
On occasion research will be situated in a prison classroom setting assuring the structured program segment for the day. A prisoner who elects not to participate in such research should be offered an alternative program for the time in question to minimize coercion.

Some prisoners may feel they will lose privileges or be punished if they choose not to participate in research; others may hope for favorable treatment or early release if they do participate. Prisoners must be assured they will be neither punished nor rewarded for their participation, and that they can discontinue their participation at any time without an institutional penalty.

Many adult prisoners are deficient readers, many have an incomplete formal education, and many speak English poorly or not at all. Investigators must use necessary measures to assure that these populations clearly understand the nature of the research and its potential risks.

Issues Related to Confidentiality

Special care should be taken to avoid requesting information in a group setting that could jeopardize the safety of individual prisoners.

In the collection of research data, special care should be taken to assure that confidential materials do not come into possession of prison administrators, guards and correctional officers, or other prisoners.

Prisoners are much more likely than other populations to be associated with sensitive data. This could include, for example, involvement in illegal activity and HIV/AIDS. Appropriate safeguards are necessary regarding the collection, storage, and destruction of such information.

Issues Related to Content

Investigators must be aware that research into certain topical areas within the institution setting can be potentially dangerous for participants. For example, the mere act of interviewing a prisoner about sensitive topics such as gang activity, contraband, and prison prostitution may inadvertently label the respondent as an informant. Great care must be taken to balance the research against protection of the prisoner as subject.

The risk of suicide is an ever present concern in the penal environment. The investigator must assure that debriefing is readily available to the prisoner whenever the subject is questioned about sensitive topics that could evoke self-injury once the prisoner has returned to the privacy of his or her cell.

The Research Involving Prisoners form must be submitted to the HSRR Office, and can be found at the following link: http://humansubjects.binghamton.edu/Forms.htm
Research Involving Children

Introduction

The purpose of this section is to assist investigators in designing and submitting for approval research involving children as subjects. Careful reading of this guide may be helpful in avoiding unnecessary delays in obtaining approval for human subjects research.

45 CFR 46. Subpart D: Additional Protections for Children Involved as Subjects in Research

HSRRC duties:
In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

The IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:
(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:
   (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
   (ii) the research will be conducted in accordance with sound ethical principles;
   (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be
involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

a. Parental Permission cannot be waived for FDA regulated research.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

(1) Related to their status as wards; or
(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

1. School Permissions

Schools do not have the authority to give consent for children to participate in research; only parents or guardians have that authority. Permission from the school district must be obtained before conducting research in schools within the district.

Principals and teachers do not have the authority to grant permission for research to be conducted in a school; such permission must come from the school district. Although this permission will usually come from the superintendent, in some districts another individual or committee has been given the authority to grant permission. Investigators should check with the district office to determine the appropriate procedure for obtaining permission.

Permission must be submitted to the HSRRC in writing, and whenever possible, the permission should be on school district letterhead. Provisional approval of the research project can be given by the HSRRC pending receipt of permission by the school district. The research cannot begin until written permission is received by the HSRRC.

The School Permission should address the Family Education Rights and Privacy (FERPA) Act and the Protection of Pupil Rights Amendment (PPRA) if the research involves any forms of data that may be subject to these laws.

2. Minimizing Coercion

In conducting research on children, every attempt must be made to minimize coercion to participate. Researchers must remember that children are in a dependent relationship with adults and special care must be taken to ensure that the decision to participate as research subjects made by children is truly voluntary. The following factors should be taken into account when developing research procedures:

- concrete rewards for participation may be used, but should not be so valuable, within the value system of the child, as to outweigh legitimate reluctance to participate;
- care must be taken to minimize social pressure to participate, particularly peer pressure and fear of ridicule for not participating; and
- care must be taken to minimize the coercion implicit in requests to participate from parents, teachers, or other adult authorities.
In general, researchers should refrain from having teachers or parents request children to participate in research. Researchers should avoid using phrases such as "will you help me" or "we would like your help with this" since children are not likely to refuse to help an adult. Rather, children should simply be asked if they want to participate.

When the investigator is unfamiliar with the population to be studied, he/she should consult experts to determine the degree of coercion in the procedures to be used. Such judgments are inevitably subjective and often result in negotiation between the HSRRC and investigators, who should be prepared to justify questionable procedures.

Family Educational Rights and Privacy Act

The Family Educational Rights and Privacy Act of 1979 (FERPA) is a federal law which states that, "An educational agency or institution shall obtain the written consent of the parent of a student, or the eligible student before disclosing personally identifiable information from educational records of a student, other than directory information....".

Thus, for any research that involves obtaining identifiable information from student records, the investigator must obtain written permission from the parents. Under the law, this permission must specify the information to be released from the records. "Blanket permission" giving access to any information in the records is not acceptable.

Although this is not a human subjects issue, per se, the HSRRC cannot approve a research project unless the procedures for complying with FERPA are acceptable. This is true regardless of the willingness of the school district to release the information without permission. Although this is a school responsibility, the University (and the investigator) would also be liable for any violation of this law.

Protection of Pupil Rights Amendment (PPRA)

The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). PPRA is intended to protect the rights of parents and students in two ways:

- It seeks to ensure that schools and contractors make instructional materials available for inspection by parents if those materials will be used in connection with an ED-funded survey, analysis, or evaluation in which their children participate; and
- It seeks to ensure that schools and contractors obtain written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that reveals information concerning:

  1. Political affiliations;
  2. Mental and psychological problems potentially embarrassing to the student and his/her family;
  3. Sex behavior and attitudes;
  4. Illegal, anti-social, self-incriminating and demeaning behavior;
  5. Critical appraisals of other individuals with whom respondents have
Close family relationships;
6. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or
7. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

Research Involving Cognitively Impaired Subjects

Cognitively impaired persons have a diminished capacity for judgment and reasoning due to psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals, who may be considered decisionally impaired, with limited decision-making ability, are individuals who are also chemically dependent, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical disabilities. Decision making capacity may fluctuate.

The HSRRC shall consider the ethical concern of how the individuals with psychiatric, cognitive, or developmental disorders, or those who are substance abusers have the capacity to understand the information presented and their ability to make a reasoned decision about participation.

Research should involve cognitively impaired subjects where:
• They compromise the only appropriate subject population
• The research question focuses on an issue unique to subjects in this population
• The research involves no more than minimal risk
• Research that involves greater than minimal risk may be acceptable where the purpose of the research is therapeutic with respect to individual subjects and where the risk is commensurate with the degree of expected benefit.

Surrogate Permission with Subjects Judged Incompetent to Consent

A research subject must be competent to give informed consent; otherwise, the consent of the legally authorized representative of the patient must be obtained. In New York State incompetent subjects include children (those individuals under 18 years of age), and the mentally disabled. If competency issues are anticipated for a study, they must be acknowledged in the research proposal and the procedures used to evaluate competency must be described in detail.

New York State Law states that surrogate consent, other than that of a parent or legal guardian, (a legal guardian is defined as an individual who has obtained legal guardianship through the Surrogate Courts Proceedings Act §1700 ff., Domestic Relations Law §81 and Article Six of the Family Court Act) is not allowable, unless there is a legal document that specifically authorizes another to act on behalf of someone for research purposes (Public Health Law Section 2442). For example, the consent of a friend would not be allowed. Those individuals allowed to give consent to a third party include:
• Persons appointed as health care agents
• Court appointed guardians
• Next of kin in the following order: spouse, adult child, parent, and adult sibling

when there is a legal document that specifically authorizes another to act on behalf of someone for research purposes as per Public Health Law Section 2442.

Research conducted outside New York State

It is the Principle Investigators responsibility to determine which individuals are considered “children” or “guardians” outside of New York State to ensure that Federal Guidelines 45.102(c) is followed: (c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. The FDA Regulations 21CFR50.55(e)(1) Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, if consistent with State law, for clinical investigations to be conducted under 50.51 or 50.52. (2) Where clinical investigations are covered by 50.53 or 50.54 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if consistent with State law.

Therefore, the Principal Investigator must provide to the HSRRC documentation of State Law, where the research is being conducted, concerning proxy care and these laws must be incorporated in the consent process.

Research Involving Students and Employees

Employees, students and normal volunteers are also considered vulnerable subjects although the federal regulations do not provide explicit protections for subjects in these categories the IRB Guidebook: Chapter Viii Special classes of subjects offer these guidelines:

Students. Universities, and the association of investigators with them, provide investigators with a ready pool of research subjects: students. Many IRBs have faced the question of whether and in what way students may participate in research. Two questions that have been posed are whether students - medical students, in particular - should be allowed to participate in biomedical research (and whether special protections should be adopted to restrict their participation), and whether participation in research can appropriately be included as a course component for course credit. The latter practice is commonly employed in psychology departments.

The problem with student participation in research conducted at the university is the possibility that their agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming "uncooperative," not part of the scientific community).
Prohibiting all student participation in research may be an over protective reaction. An alternative way to protect against coercion is to require that faculty-investigators advertise for subjects generally (e.g., through notices posted in the school or department) rather than recruit individual students directly. As with any research involving a potentially vulnerable subject population, IRBs should pay special attention to the potential for coercion or undue influence and consider ways in which the possibility of exploitation can be reduced or eliminated.

Requiring participation in research for course credit (or extra credit) is also controversial, though common in the social and behavioral sciences. The justification offered for requiring student participation is educational benefit [Gamble (1982); Cohen (1982)]. Participation of students is seen by faculty-investigators as necessary to the conduct of their research. Grant budgets often do not allow investigators to pay subjects; giving course credit or extra credit is a means of obtaining sufficient participation rates. Again, the issue for IRBs is whether such arrangements for selecting subjects is fair and noncoercive.

Participation in studies might be mandatory or for extra credit. Students in beginning psychology courses, for instance, might be required to serve as subjects for a given number of hours of research or in a given number of research projects. Or they might be given the option of participating for additional grade credit.

Several mechanisms have been suggested for diminishing or eliminating the coercive aspect of student participation for course credit that IRBs might find useful. Gamble (1982) describes a departmental guideline for research involving students where extra credit is offered for participation. Students are to be given other options for fulfilling the research component that were comparable in terms of time, effort, and educational benefit: “for example, short papers, special projects, book reports, and brief quizzes on additional readings” [p. 7]. He raises concerns about the comparability of such alternatives with participating in research (e.g., that if they participate in studies, all they have to do is show up and spend the time, but if they choose to write a paper, it gets graded, and if they do extra readings, they have to be tested on them), and concludes that paying student subjects as researchers would any other subject is the only way to protect students’ freedom of choice to participate.

Cohen (1982) describes a similar policy that seems to meet these concerns. To fulfill the research component, students can either participate in five hours of research, write a brief research paper, or attend faculty research colloquia. The paper is not graded, and students who attend the colloquia have only to show up. If students do choose to participate in studies, the policy seeks to increase the likelihood that participation is freely chosen by requiring: that students be given several studies to choose from and may not be required to volunteer for any particular study; that the studies must not involve more than minimal risk; that students can withdraw from the study at any time without losing the extra credit [p. 11].

Another concern raised by the involvement of students as subjects is confidentiality. As with research involving human subjects generally, IRBs should be aware that research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they
should be made aware and from which they should be protected, to the greatest extent possible. The close environment of the university amplifies this problem.

Where students are likely to be participating in research, IRBs should consider including a student member or consulting with students where appropriate.

**Employees.** The issues with respect to employees as research subjects are essentially identical to those involving students as research subjects: coercion or undue influence, and confidentiality. As medical students have seemed ideal subjects by biomedical researchers, employees of drug companies have been seen by investigators as ideal subjects in some ways, because of their ability to comprehend the protocol and to understand the importance of the research and compliance with the protocol.

Meyers (1979) provides a good summary of the structure of employee volunteer research programs. As student participation raises questions of the ability to exercise free choice because of the possibility that grades or other important factors will be affected by decisions to participate, employee research programs raise the possibility that the decision will affect performance evaluations or job advancement. It may also be difficult to maintain the confidentiality of personal medical information or research data when the subjects are also employees, particularly when the employer is also a medical institution [Meyers (1979)].