



HUMAN SUBJECTS COMMITTEE

**for the
Protection of Human Subjects in
Research and
Research Related Activities
at
West Chester University of PA**

Policy and Procedures

**Human Subjects Committee
West Chester University of PA
Office of Sponsored Research
Old Library
West Chester, PA 19383**

**The electronic version of this Policy is located on the WCU
Office of Sponsored Research**

Permission to adapt the Policy and Procedures for the Protection of Human Subjects in Research & Related Activities was obtained from Ms. Donna Stremke, Office of Research and Sponsored Programs, Florida Gulf Coast University on February 2, 2008.

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I. BACKGROUND

The need for the IRB/HSC arose from a world-wide development of public opinion during the years 1945-1970, and from commitments made by the United States Federal Government toward the end of this period to meet certain international standards widely agreed as appropriate when research involving human subjects is conducted. West Chester University of Pennsylvania (WCU) has made a commitment to abide by relevant laws of the country, through documents approved by government agencies. This commitment and the principles outlined in the Belmont Report guide the HSC in its role of protecting the interests of human subjects participating in research.

The HSC is a committee of volunteers, appointed by the President of West Chester University of Pennsylvania (WCU) and provided administrative support by the Office of Sponsored Research (OSR). The Committee's members are drawn from the WCU faculty and staff and at least one non-University representative. Meetings are open to investigators and to the public. Investigators are encouraged to be present when their applications are scheduled for review to address questions from the board. Investigators are requested to notify the OSR ahead of time if they plan to attend an HSC meeting.

Applications are required to conform to a standard format, and review is of format first, and then of content. Only when format is correct is content considered. Guidance on format for submission of applications is included in this document. Further information can be obtained from the OSR.

The primary duty of the HSC is to ensure protection of human subjects. In most cases, human subjects cannot be fully protected if they are not fully informed. When consent forms are necessary, they must be clear and concise, in most cases in language understandable by a person with no more than an 8th grade education. In particular, unambiguous identification of procedure, objectives and risks is an absolute requirement. Consent to participate in research must be considered as an ongoing process. The subject is invited and is kept informed throughout the course of the study.

HSC correspondence should be addressed to:

Human Subjects Committee
Office of Sponsored Research
Old Library
West Chester University
West Chester, PA 19383

The HSC works in collaboration with the OSR. The OSR provides administrative support to the HSC and is located in Old Library. The Chair of the HSC is Dr. Paul K. Smith. Questions pertaining to meetings and/or application forms should be directed to OSR at 610-436-3557 or Research@wcupa.edu, or Dr. Paul K. Smith, HSC chair at 610-436-2764 psmith@wcupa.edu.

II. STATEMENT OF ETHICAL PRINCIPLES

West Chester University of PA (WCU) is committed to excellence in teaching, scholarly activity, and public service, and to the conduct of these activities with the highest possible ethical standards. For projects involving humans as subjects of research and research-related projects, WCU is guided by the ethical principles regarding all research involving humans as subjects as set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, **Ethical Principles and Guidelines for the Protection of Human Subjects of Research: The Belmont Report**. In addition, the requirements set forth in Title 45, Part 46 of the **Code of Federal Regulations** will be followed for all applicable Department of Health and Human Services (DHHS) funded research and, except for the requirements for reporting information to DHHS, for all other research without regard to source of funding. These publications are available in the Office of Research and Sponsored Programs for detailed review.

The participation of humans in research and training projects may raise fundamental ethical and civil rights questions. The following broad principles are the basis for development of WCU's policies concerning review of research involving humans:

1. No distinctions in the approval and monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on-campus or off-campus.
2. All activities involving humans as subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be unduly infringed upon.
3. The direct or potential benefits to the subject, and/or the importance of the knowledge gained, must outweigh the inherent risks to the individual.
4. Participation in projects must be voluntary and informed consent must be obtained from all subjects, unless this requirement is waived by the HSC.
5. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or may refuse to participate without loss of benefits to which the subject would be otherwise entitled.
6. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator.

III. DEFINITIONS

Human Subjects Research is a systematic investigation designed to develop or contribute to general knowledge, which involves the collection of data from or about living human beings. Activities which meet this definition constitute "research," whether or not they are supported or funded under a program that is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities. It does not include research utilizing published or publicly available documents or research on elected or appointed public officials or candidates for public office.

Human Subject means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

HSC - the Human Subjects Committee (HSC) of the Institutional Review Board (HSC). This board is appointed to review research involving human subjects for compliance with applicable federal, state, and local regulations. The HSC membership includes WCU faculty and staff from relevant disciplines, as well as member(s) of the local community.

At Risk - to be placed in a position with greater potential for physical, mental, social, or financial harm than would be expected for that individual in his or her normal occupation or daily activities.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Reasonable Risks means the relationship of anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

IV. GENERAL GUIDELINES

It is the policy of West Chester University to safeguard the rights and welfare of human subjects in research and other activities. Safeguarding the rights and welfare of human subjects in research is the responsibility of the Primary Investigator. Any project involving human subjects at WCU is subject to review and approval by the HSC. In order to approve proposed research protocols, the HSC shall determine that all of the following requirements are satisfied:

1. **Risks to subjects are minimized** by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. **Risks to subjects are reasonable** in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the HSC shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in research).

3. **Selection of subjects is equitable.** In making this assessment the HSC shall take into account the purposes of the research and the setting in which the research will be conducted.
4. **Unless waived by the HSC, informed consent will be sought from each prospective subject or the subject's legally authorized representative,** in accordance with, and to the extent required by 45 CFR 46.116.
5. **Unless waived by the HSC, informed consent will be appropriately documented,** in accordance with, and to the extent required by 45 CFR 46.117.
6. **Where appropriate, the safety of subjects will be ensured** through appropriate data monitoring methods provided in the research plan.
7. **Vulnerable populations may require special considerations.** Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards will be included in the study to protect the rights, welfare and privacy of these subjects

Principles that assist the HSC in protecting the rights and welfare of human subjects include the following existing codes:

1. Ethical Principles in the Conduct of Research with Human Participants; adopted by the American Psychological Association, 1973.
2. 45 CFR 46, Code of Federal Regulations, Final Regulations for the Protection of Human Research Subjects; (Revised June 18, 1991 as the Federal Policy for the Protection of Human Subjects; Notices and Rules).
3. The Belmont Report – Ethical Considerations and Principles for the Protection of Human Subjects of Research.

V. HSC AUTHORITY AND STRUCTURE

A. Authority

The HSC has full authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

The President appoints the individuals to the HSC, on a staggered basis, for a minimum of two years (including the Chair). Nominations may be submitted by Deans, Vice Presidents and the Associate Vice President for Sponsored Research.

B. Structure of the HSC

The HSC shall consist of faculty, administrative staff, and individuals with various experiences and skills necessary to evaluate human research and its institutional, legal, scientific and social implications. The HSC shall be sensitive to diversity, including consideration of race, gender, ethnicity, cultural backgrounds and community attitudes, in order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. No member of the HSC shall participate in the HSC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the HSC.

The HSC shall have at least five members with at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person affiliated with the University. When it is deemed necessary by the Chair, or at the request of a member of the committee, the committee may invite a physician to participate in a review as a voting member if a physician is not an HSC member. A physician will be appointed by the President as an on-call committee member and will receive any training provided to the committee.

The HSC works in close relationship with the Associate Vice President for Sponsored Research, who acts as liaison with the University Administration and who is a non-voting member of the HSC.

Duly appointed alternates-at-large will be specifically invited to attend HSC meetings as needed, such as Prisoner Advocates. The OSR will be responsible for determining whether one or more alternates will be needed at meetings and for notifying the alternates.

Absence from twenty percent (20%) of regular meetings without due cause will result in a request by the HSC Chair to the Associate Vice President for Sponsored Research to replace that member. The Associate Vice President for Sponsored Research will take the matter up with the President through the Vice President of Academic Affairs and offer suggestions for replacement.

The chair (a voting member) will call the committee together, preside, and keep records of all actions of the committee. The OSR will assist in supplying space for maintaining the records.

The chair is authorized by the President through the Vice President of Academic Affairs to act on behalf of WCU for exempted projects and expedited review.

The chair may appoint one or more reviewers from among the HSC to review research falling under those categories established by the Public Health Service as expedited categories. Under an expedited review procedure, the review may be carried out by the HSC chairperson or by one or more experienced reviewers designated by the chairperson from among members of the HSC.

The Chair may appoint additional Ad Hoc committees, inviting individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the HSC. These individuals may not vote with the HSC.

There shall be a minimum of one meeting of the HSC in each semester. Meetings shall be scheduled on a monthly basis, but will only be called as need requires. Special meetings may be called by the Chairperson as deemed necessary for the performance of HSC responsibilities.

Research proposals shall be made available to members for review prior to scheduled meetings.

A simple majority of the voting membership shall constitute a quorum, with at least one member whose primary concern is in non-scientific areas.

VI. HSC RECORDS

The HSC shall prepare and maintain adequate documentation of HSC activities, including the following:

1. Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the protocols, approved sample consent documents, and progress reports submitted by investigators;
2. Minutes of HSC meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the HSC; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving protocols and a written summary of the discussion of the issues and their resolution;
3. Records of continuing review activities;
4. Copies of all correspondence between the HSC and the investigators;
5. A list of HSC members as specified in **49 CFR 11, Section 103.b.3.**
6. Statements of significant new findings provided to subjects.

All records required by this policy shall be retained for at least three (3) years, and records relating to research which is conducted shall be retained for at least three (3) years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. The OSR will house and maintain HSC records.

VII. THE REVIEW PROCESS

This outline is designed to provide an overview of the requirements for research involving human subjects. Please refer to the *Faculty Guidelines*, to the *Belmont Report*, and the *Code of Federal Regulations (45 CFR 46)* for in-depth information.

A. Responsibilities of the Principal Investigator

1. The principal investigator prepares the HSC application which must contain:
 - a) Completed HSC application form (Appendix A in Faculty Guidelines, located on the OSR web site);
 - b) Informed consent documentation (samples are provided in Appendix A of the Faculty Guidelines);
 - c) A copy of the actual survey instrument, questionnaire or data record form to be used in the project;
 - d) Signatures of the principal investigator, faculty sponsor (if student project), chair (if applicable), and dean.
2. The PI submits one original of the complete application packet to the OSR/HSC at least one month prior to the next HSC meeting. Submissions must be hard copy or electronic copy (e-mail attachment of one WORD file) with original or scanned signatures.

B. HSC Receipt of the Application

Upon receipt of the complete application packet, the HSC secretary logs in the application, assigns it a unique identification number, and notifies the PI of the receipt of the HSC application and its identification number.

C. Technical Review

The Chair, or designee, conducts a Technical Review to determine if the HSC application is complete and decides upon one of three actions for the research protocol—exempt, expedited, or full board review.

After review, the HSC Chair, or designee, notifies the applicant of the disposition within two weeks following the HSC meeting, or upon determination of exempt or expedited status.

Note: Incomplete application packets will be returned to the principal investigator, with a memo stating deficiencies. Once corrected, the application may be resubmitted for review.

VIII. TYPES OF HSC REVIEW AND APPROVAL

It is the policy of WCU that the HSC will utilize Department of Health and Human Services criteria for all projects involving human subjects in research when evaluating proposed research protocols. The chairperson or one or more HSC members designated by the chairperson may determine one of three actions: exemption, expedited review, or full board review. The following section elaborates upon the types of HSC reviews.

A. Research Considered Under the “Exempt from Further Review” Category

In order to establish an individual research project as Exempt from Further Review, the principal investigator must complete the “Application for Approval of Investigations Involving the Use of Human Subjects” (located in Appendix A of the Faculty Guidelines) and any appropriate informed consent documents, samples of which are located within the Application. Final determination as to whether a research project is Exempt from Further Review rests with the Chair of the HSC or his/her designee. If the project is certified Exempt from Further Review by the HSC, the principal investigator need not resubmit the project for continuing HSC review as long as there are no modifications in the exempted procedures.

The following categories are considered Exempt from Further Review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special educational instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement) if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interview procedures, *EXCEPT* where all of the following conditions exist:
 - a. responses are recorded in such a manner that the human subject can be identified, directly or through identifiers linked to the subject;
 - b. the subject’s responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability; and
 - c. the research deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
4. Research involving the observation (including observation by participants) of public behavior *EXCEPT* where any of the following conditions exists:
 - a. observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subject;
 - b. the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability; and

- c. the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. 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.
6. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

B. Research Considered Under the "Expedited Review" Category

The principal investigator shall submit the "Application for Approval of Investigations Involving Use of Human Subjects" (Appendix A of the Faculty Guidelines). Research activities involving no more than "minimal risk" to subjects and in which the only involvement of human subjects will be in one or more of the following categories may be reviewed by the HSC Expedited Review Subcommittee:

1. Collection (in a non-disfiguring manner) of hair, nail clippings, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.
2. Collection for analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also include such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays and microwaves).
4. Collection of blood samples by fingerstick or venipuncture, in amounts not exceeding 450 milliliters in an eight-week period, and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant.
5. Voice recordings made for research purposes such as investigations of speech defects.
6. Moderate exercise by healthy volunteers.
7. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
8. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigation does not manipulate subject's behavior and the research will not involve stress to subjects.

9. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

C. Research Considered Under the “Full Board Review” Category

Any research or training project involving the use of human subjects which does not fall into the “Exempt from Review” or the “Expedited Review” categories must be submitted to the HSC for a full board evaluation. The principal investigator must complete and submit the “Application for Approval of Investigations Involving the Use of Human Subjects” found in the Faculty Guidelines.

D. Continuing Reviews

The HSC review body conducts continuing reviews of nonexempt research at intervals appropriate to the degree of risk, but at least once per year.

E. Student Applications

Student applications must reflect faculty sponsorship. The responsibility for complying with the Policy and Procedures is shared by the faculty sponsor and the student.

F. Conditions Under Which HSC Approval is Not Required for Survey Research

Students wanting to collect data from human subjects as part of the requirements **for a specific class** may conduct **opinion research** that is not specific to the behaviors and/or experiences of the interviewees, as long as informants are not identifiable by name or description.

For example, HSC approval is **not required** for a student to survey people’s opinions about topics such as the following:

- a. opinions of political candidates or issues
- b. opinions regarding American made vs. foreign-made products
- c. opinions concerning environmental issues or policies
- d. opinions regarding the subject’s favorite television show, preferred vacation spot, musical preference, etc.

The key factor shared by these examples is that they do not require subjects to reveal anything about their personal experiences, behaviors, and/or identity. Therefore, the subjects are not considered to be placed **at risk** by their participation. Thus, in these cases, HSC approval is not required.

IX. THE INFORMED CONSENT PROCESS

A. Competent Adults

Every potential subject who is a competent adult (at least 18 years of age) must provide consent to participate in research prior to the conduct of any activities that constitute the research encounter.

The investigator must ensure the following:

- the subjects (or their representatives) are provided with sufficient opportunity to consider whether or not to participate.
- the possibility of coercion or undue influence which might be experienced by the subjects is minimized.
- In instances where full *a priori* disclosure of the purpose of the research is not possible because full disclosure could affect research outcome, the PI has the responsibility to attempt to fully debrief the research subject concerning the purpose of the study.

The informed consent document communicates the following to the prospective research subject:

- the study involves research;
- the purpose, procedures, risks and benefits of the study;
- the subject's participation is voluntary;
- the subject's rights in participating in research;
- the name and telephone number of person to contact for questions about research subjects' rights;
- the freedom to decline to participate without any jeopardy;
- the expected duration/frequency of the subject's participation;
- an explanation of any available applicable alternative treatments;
- the identification of any experimental medical treatments or procedures;
- the right to obtain further information and answers to questions related to the study;
- the name and telephone number of person to contact for questions about the research, and name and telephone number of responsible project investigator, if different;
- an explanation of any compensation and, if appropriate, procedures to pro-rate compensation for subjects who withdraw prior to completion of the study;
- the name of person to contact in the event of research-related injury;
- a description of the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- a statement that subjects will receive a copy of the consent form;
- the subject is not waiving any legal rights, including any release of the university or its agents from liability or negligence;

B. More than Minimal Risk Projects

When research involves greater than minimal risk, the subject needs a reasonable enumeration of the risks in order to decide whether or not to participate. The list should not be constructed either to minimize real risks or to overstate them. Projects with risks should also list protection measures used to lower the risk potential or to ensure safety while the subject encounters the

risks. If a project presents one or more risks, an injury clause needs to be included in the consent document. This injury clause should include:

- an explanation of whether any compensation is available if injury occurs;
- an explanation of whether any medical treatments are available if injury occurs, what they are, and where further information may be obtained.

C. Oral Consent

If oral consent is necessary due to limited literacy or language comprehension, the subject or his/her legal representative will be asked to sign a simple form stating that the basic consent form elements have been orally presented. Both the short consent form and the oral presentation must be approved by the HSC. A witness must also be present for this presentation and must sign both the short form and a written summary of the oral presentation. The subject or his/her legal representative must be furnished with a copy of both signed documents.

D. Minor Subjects

In the case of a minor subject, a simplified version of the consent form signed by the parent or guardian (an assent form written in developmentally appropriate language of the subject) must be signed by those subjects capable of reading and understanding. A copy of this assent form must accompany the parental consent form and the HSC project approval letter. For those subjects who are too young to read an assent form, but who would be capable of understanding an oral explanation of the procedures, a copy of the oral explanation to be given must accompany the request for HSC approval, and be signed by the individual responsible for the oral explanation. The age, maturity, and psychological state of the subjects must be taken into account by the principal investigator when creating an assent form or an oral presentation to obtain oral assent from such subjects. In addition, the child's assent should be positive, that is, not merely lacking of dissent. If the child is old enough to render a signature, investigators are required to obtain a signed assent form.

E. Children Below School Age

For children below school age (e.g., infants, toddlers, and preschoolers) the investigator should give explanations that match the level of understanding. In many instances, the children's nonresistant behavior may be interpreted as assent, but the investigator must use special care to discontinue the participation of children who appear to experience undue stress from the research procedures. A verbal script must be submitted as part of the protocol.

F. Children Who Are Wards of the State

Children who are wards of the state may participate in research only under very limited circumstances with the appointment of an advocate for the child for the duration of the research.

G. Other Types of Especially Vulnerable Subjects

Other types of especially vulnerable subjects for which the researcher should have special concern in obtaining informed consent are the following:

1. **Prisoners: Only certain kinds of research may involve prisoners--basically, studies directly relevant to prisoners, prisons, criminality, etc.--**The research should not provide the prisoners with advantages that would outweigh their ability to weigh the risks involved in the research. The consent form should make it clear to prisoners that participation will have no effect upon their parole or treatment. Additional regulations governing research with prisoners are found in 45CFR46 Subpart C. In addition, when reviewing an application involving prisoners as subjects, at least one HSC member (or consultant) must be a prisoner or a prisoner representative.
2. **Cognitively Impaired Subjects:** All adults, regardless of their diagnosis or condition, should be presume competent unless there is evidence otherwise. Where possible, consent should be obtained from legal guardians. Where appropriate, subject assent should be obtained. The HSC must determine if adequate procedures are proposed to evaluate competence. Consent from surrogates, other than legal guardians, is a waiver of consent and is to be done only when it is appropriate to waive consent.
3. **Fetuses, pregnant women, and human in vitro fertilization:** Regulations require additional safeguards for the conduct of research involving fetuses, pregnant women, and human in vitro fertilization. Among the recommendations are systems for monitoring the acquisition of informed consent as well as other aspects of the research.
4. **Other groups:** Racial minorities, the elderly, the economically disadvantaged, the very sick, and the institutionalized are described as the vulnerable populations by the Belmont Report and are therefore provided similar protection when used as research subjects.

Samples of Informed Consent and Assent forms are provided in the Faculty Guidelines.

H. Anonymous Questionnaires

With anonymous questionnaires (returned by mail or placed in drop-box locations), the researcher may fulfill the requirements of informed consent by providing the subject with a cover letter or set of instructions that includes the following items, as applicable:

1. An explanation of the research project, its purpose and duration of participation time;
2. An offer to answer questions concerning the project and information on how to contact the investigator;
3. A statement indicating anonymity;
4. Indication that the return of the questionnaire will constitute the subject's consent to participate. A statement of voluntariness must be included.

A sample of this kind of consent document is located in the Faculty Guidelines.

I. Retaining and Storing Signed Informed Consent Documents

Signed informed consent forms should be stored in a secured location which is accessible to the University in the event that an inquiry should require an examination of them. Access to these documents should be limited to those authorized persons who have a need to know their contents, ordinarily the investigator (and co-investigators), a representative of the HSC (usually the chair), and the Associate Vice President for Sponsored Research. In compliance with federal regulations consent documents must be retained for a period of three years following the completion of the research. External requests for access to research data and/or document production must be referred to the Associate Vice President for Sponsored Research.

The Application for Approval of Investigations Involving the Use of Human Subjects requires an account of the exact location, the method of storage, and the names or titles of individuals (other than University and federal officials) having access to the consent documents. The HSC cannot approve the continuation of projects which omit this information.

An investigator who leaves the University prior to the end of the three-year retention period for consent forms should notify the HSC of this fact, specifying the new location of the consent documents. If consent documents are maintained by a graduate student or research assistant, they must be turned over to the responsible faculty member after data collection is completed. A change of location within the University that results in a new storage place for consent forms should also be reported to the HSC.