LEHIGH UNIVERSITY

Policy on the Protection of

Human Subjects in Research

Revised January 1993
Recent Revision: May 8, 2007

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Lehigh University
Human Subjects Policy

Mandatory training requirements!!!!

Lehigh University has adopted the federal standards for the protection of human subjects in research. The federal standards recently changed and now require training in the protection of human subjects. Any individual working with human subjects in research must complete an on-line tutorial offered by the National Institutes of Health. The tutorial takes about 30-45 minutes to complete. At the beginning of the tutorial, you are asked to establish a username and password to allow you to interrupt the tutorial at any time and return to the same place at a later time. Upon completion of the tutorial, a certificate will appear on your screen. Please print the certificate and submit it with your human subjects protocol or shortly thereafter. **The tutorial must be completed before your study/protocol can be approved.** It is recommended that you do the tutorial before completing the human subjects questionnaire - the tutorial should make the process easier.

The tutorial is found at:

http://phrp.nihtraining.com/users/login.php

Remember to print the completion certificate and submit it to the Office of Research and Sponsored Programs with your protocol or shortly thereafter!

Note: You can send the completion certificate as an e-mail attachment if you print screen and paste the screen into a Word document. While the certificate is displayed, press the "Shift", "Alt" and "Print Scrn" keys simultaneously; go to a new Word document; right click on your mouse and "paste" the screen print in the Word document. Send the Word document as an e-mail attachment to the Office of Research and Sponsored Programs at "inors@lehigh.edu".

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HUMAN SUBJECTS POLICY

All research and experimental activities that are conducted by Lehigh University and in which people are involved as subjects must be approved by Lehigh University's Institutional Review Board (IRB) prior to the involvement of the subjects and prior to the distribution of any information or written materials that require IRB approval. This applies to all sponsored and unsponsored research, continuing education and instructional projects and activities conducted by University faculty, students, and staff. The IRB also reserves the right to review research and experimental activities involving human subjects when a University faculty or staff member or student is actively involved in the recruitment of subjects, whether in person or through the use of University resources (e.g., e-mail, telephone, campus postings, etc.), or is actively involved in the conduct of such research even though the research is not being conducted by the University.

Lehigh University's policy on the protection of human subjects in research was developed in accordance with the Federal Policy for the Protection of Human Subjects, published in the Federal Register on June 18, 1991, as a final common rule for participating federal agencies. The policy is designed to safeguard the rights and well-being of human subjects and to ensure that the principles of respect for persons, beneficence, and justice are met by proposed activities involving human subjects.

DEFINITIONS

As defined in the federal policy, research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information. Intervention includes 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. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information is individually identifiable when the identity of the subject is or may readily be ascertained by the investigator or associated with the information. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The principle of respect for persons requires that researchers recognize that each individual's judgments and choices about participation in research must be respected. For those not capable of self-determination, special protection measures must be used. To meet this principle, unless the IRB determines to the contrary, human subjects in research, or their legal representative, must sign an informed consent form detailing the research to be performed, the potential risks and hazards and any feature which may influence their decision to participate. The IRB reviews all protocols to ensure that participation of subjects is voluntary and the information provided to gain subject consent is adequate and appropriate.

Beneficence refers to the resulting benefit of the research to the participant and society. All research should be designed to minimize risks. The IRB will review all proposed research to determine if the risks to the subject are so outweighed by the potential benefits to the subject or the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.

The benefits and the burdens of participation in research must be distributed fairly among all populations to ensure justice. Researchers must take care not to select already burdened or vulnerable groups who might be more easily coerced to participate. These include prisoners, children, residents or clients of institutions for the mentally ill and mentally retarded and persons subject to military discipline. The IRB will ensure that subjects are selected fairly within a specific project and among all University research so that no unjust patterns emerge.

Under University policy, the principal investigator has the primary responsibility for protecting the welfare and the right of privacy of the individual subject in a research project. The responsibility is shared by the University as an institution and by the sponsor when outside support is provided for the project. It is the policy of the University that all research proposals and projects involving human subjects include as principal investigator or co-principal investigator at least one person holding the academic rank of Professor, Associate Professor, or Assistant Professor. (Professors of Practice, Research Engineers or Research Scientists holding an appointment from an academic department or research center of the University may also serve as a principal investigator or co-principal investigator with the written approval of the chair of the academic department or director of the research center in which he/she holds an appointment.) Research involving human subjects must be proposed and conducted within a regular academic department of the University or through the cooperation of multiple academic departments or through a research center. A research proposal may be submitted by an individual who does not qualify as a principal investigator under this policy, or by a non-academic department of the University on the following conditions: (a) the individual proposing to conduct the research is a full-time University employee with the requisite qualifications and research experience necessary to conduct such research; and (b) the research proposal has been approved in writing by the Vice President or Dean to whom such individual or department reports, with such approval (i) indicating that such research is in furtherance of University objectives, and (ii) accepting responsibility for ensuring that such research will be conducted in compliance with University research policies and procedures.

It is the obligation of the principal investigator to bring any proposed research projects involving the use of human subjects to the attention of the IRB via the Office of Research and Sponsored Programs. At any stage of the review process, the application may be referred to the initiating principal investigator for clarification or for alteration and resubmission. Approval of a proposed investigation is granted for a period of one year.

It is the responsibility of the principal investigator to submit *the Human Subjects Progress Report (see Appendix C)* for a continuing review if the activity is ongoing or if the investigator is analyzing and reporting on the data. If at any time there are changes in the plan of research, the principal investigator must resubmit the project to the IRB for review and further action.

INSTITUTIONAL RESEARCH

Institutional research or internal research is the gathering of data from or about Lehigh students, faculty, or staff members by university offices or organizations, with the intent of using the data solely for internal informational purposes or for required data-collection purposes. Examples would include surveys or other data-collection instruments designed to: improve university services or procedures; ascertain the opinions, experiences, or preferences of the university community; or provide necessary information to characterize the university community. This kind of data collection does not require review by the IRB except in instances where the information deals with sensitive aspects of the subject's own behavior, with the result that any disclosure of the responses outside the context of the research could place the subject at risk of criminal or civil liability or be damaging to the subject's reputation, employability, or financial standing. Examples would include information on subjects' drug use, alcohol use, sexual behavior, or illegal conduct.

CLASS-RELATED AND STUDENT-CONDUCTED RESEARCH

Student research and training activities involving human subjects may range from activities taking place entirely within the classroom to independent dissertation research. In these instances, the faculty instructor or faculty advisor is the principal investigator and is ultimately responsible for the protection of human subjects, for the training and supervision of student investigators, and for ensuring that student-related projects have been reviewed by the IRB, if required, and meet any departmental review or approval requirements.

A. Activities Requiring IRB Review

1. All doctoral dissertations and master's theses involving human subjects.

2. Class-related research involving human subjects who are not members of the class, including:

   a) Instructor-led class projects designed to teach research procedures and design, including projects for which the instructor provides a research design and protocol or when the class designs and generates the research projects as a class assignment.

   b) Student-generated research projects, including independent study projects, honors papers or theses, or other individual or small-group student-initiated projects.

      The informal collection of information by students from respondents (for example, informally interviewing friends or relatives for purposes of class discussion or assignments) does not require IRB review. IRB review is required if students intend to undertake a systematic investigation, produce a design or protocol for the research, sample a population, report findings, etc.

B. Activities to be Overseen by Departmental Procedures

1. Class research activities in which the human subjects are members of the class and the activities involve minimal risk, including: gathering of data by the instructor or students with the intent of illustrating or teaching course material or methods.

2. Student clinical training, under close faculty supervision, including: activities in which the student functions primarily as a practitioner, rather than as a researcher, and the primary purpose of the activities is the student's delivery of services to a client or group of clients. Although evaluation of intervention effects may be a component of the activities, the focus is on the quality of clinical service provided by the student, rather than on any findings obtained.

TYPES OF REVIEW

There are three categories of review: expedited, limited and full committee review. Research proposals requesting or receiving funding from agencies of the Department of Health and Human Services (HHS) are required by the agencies to receive full committee review if they are not eligible for expedited review.

A. Expedited Review

Proposals are exempt from more detailed review if the research described poses minimal risks to subjects and proper procedures are used to implement ethical principles for the protection of human subjects.

The chair of the IRB determines whether a research project will undergo an expedited review. As necessary, the chair will consult with other IRB members when making this decision.

The following types of research may fall into the expedited category:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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

   (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

   Note: Research involving subjects under the age of 18 may not be reviewed on an expedited basis if it involves: (i) survey procedures; (ii) interview procedures; or (iii) observation of public behavior if the investigator is a participant in the activities being observed.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

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

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

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

   i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies if: (i) wholesome foods without additives are consumed; or (ii) 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.

Note: *If the research involves the collection of data in a school (or other institutional) setting,* a letter of approval from the principal or superintendent of the school must be submitted to the IRB before final approval can be granted for the study.

B. Limited Review

The limited review category is used for certain types of research involving no more than minimal risk and minor changes to research previously approved by the full committee, during the period for which approval has been authorized. Proposals are reviewed by three members of the University's IRB. Agreement of all reviewers is needed for approval. Reviewers may refer the proposal to the full committee. The principal investigator will be informed in writing whether the proposed research has been approved or referred for full committee review. All members of the IRB will receive written notification from the Executive Secretary of research activities that have been approved by limited review.

The following types of research may fall into the limited review category:

1. Collection of hair and nail clippings, in a nondisfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

2. Collection 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 noninvasive 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 includes 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, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times a week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. 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.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers. The American College of Sports Medicine Guidelines or those of the American Heart Association should be followed.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

C. Full Committee Review

Any research not covered under the expedited or limited review categories is referred to the IRB for full committee review. The principal investigator may be invited to attend the review. The committee will either: (i) approve the research; (ii) approve the research pending modifications that must be verified by committee members; or (iii) not approve the research. The committee will notify the principal investigatorin writing about the committee's decision.

RESEARCHER CERTIFICATION

Lehigh University has adopted the federal standards for the protection of human subjects in research. The federal standards recently changed and now require training in the protection of human subjects. Any individual working with human subjects in research must complete an on-line tutorial offered by the National Institutes of Health. The tutorial takes about 30-45 minutes to complete. At the beginning of the tutorial, the individual is asked to establish a username and password to allow him or her to interrupt the tutorial at any time and return to the same place at a later time. Upon completion of the tutorial, a certificate will appear on the individual's screen. The individual should print the certificate and submit it with his or her human subjects protocol or shortly thereafter. **The tutorial must be completed before the study/protocol can be approved.** It is recommended that the tutorial be completed before the human subjects questionnaire is completed.

The tutorial is found at:

http://phrp.nihtraining.com/users/login.php

An individual should remember to print the completion certificate and submit it to the Office of Research and Sponsored Programs with his or her protocol.

SPECIAL CONSIDERATIONS

A. HIPAA: The Privacy Rule

The Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, regulates the way organizations or businesses handle the individually identifiable health information known as protected health information (PHI)[1]. Researchers must be aware of the Privacy Rule because it establishes the conditions under which PHI can be used or disclosed. Lehigh University is considered a "hybrid entity" under the Rule which means that some of the functions of the University are covered by the Rule.

For the purposes of research involving human subjects, principal investigators must notify subjects of the intended use and disclosure of any information which can be considered PHI.

All research involving human subjects that falls under HIPAA regulations will require written authorization, waiver of authorization or a request that an "exception" from the authorization requirement be given. The authorization is a separate document from the informed consent and is written confirmation that a research subject has voluntarily agreed to permit the use, sharing, copying and release of his or her current and future health information related to a particular research project.

HIPAA authorization requirements do not apply to a project if either: (A) all subject health-related information will be obtained directly from the subject, or (B) no PHI is collected for the project.

The IRB may "except" a project from the HIPAA authorization requirement if one of the following apply: (A) information being used or disclosed is "de-identified"[2] as required by HIPAA, (B) information being used or disclosed constitutes a Limited Data Set[3], (C) all use of PHI is solely for preparation for research and no identifying information will be recorded or removed from the source, (D) all research involves decedents and their information only, or (E) all research involves educational records or student health records.

A "Waiver of HIPAA Authorization" may be granted if all of the following apply: (A) the use or disclosure of information involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements: (1) an adequate plan to protect the identifiers from improper use/disclosure, (2) an adequate plan to destroy the identifiers at the earliest possible time consistent with the research, unless there is a health or research justification for retaining identifiers or is otherwise required by law, and (3) adequate written assurances that individual health information will not be reused/disclosed to any other person or entity, except as required by law, for authorized oversight of the research or for other research, (B) the research could not practicably be conducted without the waiver, and (C) the research could not practicably be conducted without access to and use of the information.

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1 PHI includes the following 18 individual identifiers: names; geographic subdivisions small than State (e.g., cities, streets, counties); all elements of dates (except year) for dates directly related to an individual (e.g., birthday, date of death, date of hospitalization); telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; and any other unique identifying number, characteristic, or code.

2 "De-identified" data have all of the 18 PHI individual identifiers removed.

3 Limited Data Set is defined as information that may include the following direct identifiers: town, city, State and zip code; and all elements of dates directly related to an individual, but may not include any of the other PHI identifiers.

B. Children as Subjects in Research

When children are involved as subjects in research, the range of activities that may be approved by expedited review is reduced. Specifically, research involving survey or interview procedures and research involving the observation of public behavior where the investigator is a participant in the activities being observed (category #2 under Expedited Review above) may not receive expedited review when these activities involve persons under the age of 18 (hereinafter, child or children).

Written permission is required of both parents or the child's guardian for each child under the age of 18 who will be the subject of research. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; or (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child. The requirement for written permission may be waived by the review committee if it is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

Assent: In addition to the written permission required of parents, it is necessary to acquire the assent of children, when they are capable of providing assent. Assent means a child's affirmative agreement to participate in research; mere failure to object should not be construed as assent. Ordinarily for children 14 years and older, written assent is required. For children under 14, verbal assent may be obtained. The Principal Investigator must submit to the IRB the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding whether assent must be obtained and how it will be documented. ***The information given to the children should be in language that is understandable by children. Written materials and a script for verbal descriptions and assent must be submitted for review.***

Children who are wards of the state or of any other entity may be included in research involving greater than minimal risk and no prospect of direct benefit to the individual children only if the research is related to their status as wards or is conducted in schools, camps, hospitals, or other similar settings in which the majority of children involved as subjects are not wards. An individual must be appointed as advocate for the wards; the advocate may not be associated with the research, the investigators, or the guardian organization. The advocate must have the background and experience to act in the best interests of the children for the duration of their participation in the research. The principal investigator should identify a suitable advocate and secure his/ her consent to serve prior to review by the IRB. Advocates for child wards are not required for research involving no more than minimal risk or for research presenting the prospect of direct benefits to the individual children.

C. Research Involving Fetuses, Pregnant Women, or Human In Vitro Fertilization

Additional protection and limitations are placed on research involving pregnant women, fetuses in utero, or fetuses ex utero. Please contact the Executive Secretary of the IRB for additional information.

D. Research Involving Prisoners

Additional protection and limitations are placed on research involving prisoners. Please contact the Executive Secretary of the IRB for additional information.

E. Policy on Informing Those Tested About HIV Serostatus

The Public Health Service (PHS) requires that when HIV testing is conducted or supported by PHS, individuals whose test results can be identified must be informed of their results and provided with the opportunity to receive appropriate counseling. This applies to all intramural and extramural PHS activities, including research and service activities, domestic and foreign. Please contact the Executive Secretary of the IRB for a copy of the PHS policy.

INFORMED CONSENT

A. General Requirements for Informed Consent

Before any research can be undertaken, the investigator must obtain the informed consent of the subject or of the subject's legally authorized representative. An informed consent is knowing consent from the individual (or representative) that has been obtained without coercion or undue influence. The information given to the subject or the representative should be in language understandable to the subject or representative. In addition, the agreement, written or verbal, entered into by the subjects should include no exculpatory language by which the subjects are made to waive, or to appear to waive, any of their legal rights, including any release of the University or its agents from liability for negligence. A copy of the informed consent must be given to every subject.

The informed consent form submitted with the Human Subjects Questionnaire should be the **final** version of the form. If any revisions are made to the informed consent form after approval, **a copy of the revised form must be submitted for expedited review and approval.**

For additional information on the informed consent process, see the informed consent tips offered by the Office of Human Research Protections:

http://www.hhs.gov/ohrp/policy/index.html#informed

The basic elements of informed consent are:

1. An explanation of the purposes of the research, and a description of the procedures to be followed (including an identification of those which are experimental) and of the expected duration of the subject's participation.

2. A description of any attendant discomfort and risks that can reasonably be expected.

3. A description of any benefits that can reasonably be expected.

4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. A statement that participation is voluntary and that the person is free to withdraw his/her consent and to discontinue participation in the project or activity at any time without intimidation or prejudice to the subject.

7. With respect to biomedical or behavioral research which may result in injury, an explanation as to whether medical treatment and/or financial compensation are available if such injury occurs and, if so, of what they consist.

8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury.

When appropriate, any of the following additional elements of informed consent should be included:

1. A statement that the treatment or procedure to be used may involve risks which are currently unforeseeable.

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

7. The use of recording devices for visual or audio images. If visual or audio recordings are to be used, the subjects should be informed of the intended use of the recordings, the methods used to protect the recordings, any uses for the recording beyond data analysis (i.e., publications, training), and when and if the recordings will be destroyed.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably by carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

B. Documentation of Informed Consent

Informed consent is documented by the use of a written consent form, which is approved by the IRB and signed by the subject or his/her legally authorized representative. A copy is given to the person signing the form. *Written informed consent forms should be printed on Lehigh University letterhead or the letterhead of the collaborating institution.* The consent form may be either of the following:

1. a written consent document that embodies the elements of informed consent described above; or

2. a short form written consent document stating that the elements of informed consent described above have been presented orally to the subject or his/her representative.

In addition, when the short form and oral presentation method is used:

1. The review committee must approve a written summary of what is to be said to the subject or to the person authorized to consent for the subject.

2. There shall be a witness to the oral presentation and the witness shall sign both the short form and a copy of the written summary.

3. The person obtaining consent shall sign a copy of the summary.

4. A copy of the written summary shall be given to the subject or the person authorized to consent for the subject, in addition to a copy of the short form.

A sample informed consent form can be found in Appendix B.

C. Waiver of Signed Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds: 1) the only record linking the subject to the research would be the consent form and the principal risk would be the potential harm resulting from a breach of confidentiality, and 2) the research poses no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

In the case of mailed questionnaires, the investigator must provide a written explanation of the study and inform subjects of their rights. This information can be provided in a cover letter which the subject can retain. In the case of telephone surveys, the investigator must provide a verbal explanation of the study and inform subjects of their rights. These explanations must be submitted to the committee for approval.

PROCEDURES FOR SUBMITTING A RESEARCH PROJECT FOR REVIEW

1. All protocols should be sent to the Executive Secretary of the IRB, Office of Research and Sponsored Programs. All the required information must be submitted, including the appropriate number of copies. Proposal review will not begin until all the required materials have been received.

2. Investigators should submit all information well in advance of the anticipated start date of data collection and, in the case of sponsored research, in advance of submission of the proposal to the agency, if required. It is recommended that protocols are submitted six weeks in advance of the anticipated start date of data collection. ***Proposals which must be reviewed by the full committee must be received no later than two weeks prior to the next scheduled meeting.*** Generally, the committee meets on the second Tuesday of every month. It is best to confirm the date of the next meeting.

3. Investigators should request the type of review most appropriate for their study. All protocols are first reviewed by the Office of Research and Sponsored Programs. If there is any change in the type of review, additional copies of the material may be requested prior to the review process.

4. The following information should be submitted:

	Number of Copies Required		
Form	Expedited Review	Limited Review	Full Review
a. Human Subjects Questionnaire	2	4	14
b. Informed Consent and/or other Explanation of Study to Subjects or Parents/Guardians	2	4	14
c. Instruments (surveys, tests, etc.)	2	4	14
d. Progress Report (if renewal)	2	4	14
e. Full Proposal (dissertation, sponsor application, etc.)	1	1	1
f. Certificate of completion of on-line tutorial (see pg. 7)	1	1	1

The Human Subjects Questionnaire, the Progress Report Form, and a sample Informed Consent Form can be found in the Appendices.

5. The committee's actions, comments and recommendations will be sent to the investigator. If a proposal is disapproved, the principal investigator may request to attend the next committee meeting. The IRB meets on the second Tuesday of each month.

6. Any changes made in a protocol or consent form must be promptly reported to the Executive Secretary of the IRB.

7. All adverse reactions and unexpected side effects must be reported immediately, in writing, to the Executive Secretary of the IRB.

8. Interim reports should be submitted if requested by the IRB, and continuing review is mandatory.

CONTINUING REVIEW PROCEDURES

Sixty days before the anniversary of the last approval date the following should be submitted, in the same number of copies as required for a new proposal:

1. Progress Report (Appendix C).

2. Consent form(s) and/or other written explanation of study to subjects or parents/guardians, with any changes highlighted.

3. Instruments, with any proposed changes noted (even though these should have been reported and approved).

Any changes to the approved protocol, including the consent form and any instruments, may require submission of a new Human Subjects Questionnaire. Significant changes to a protocol may affect the category of IRB review (expedited, limited, full). Please reconsider the review categories.

TERMINATION

When a project is completed, withdrawn, or past the phase of involving human subjects, please inform the Executive Secretary of the IRB in writing.

MISCONDUCT/FRAUD

Any complaint about research procedures and allegations of improper conduct involving research procedures should be reported to the IRB Chair. The chairperson will promptly share all such complaints and allegations with all members of the IRB. If the chair or any board member finds this to be serious or in any way suspicious of fraud, it shall be reported immediately to the Vice Provost for Research.

IRB MEMBERSHIP

The IRB comprises thirteen standing members. Nine representatives are drawn from the University faculty, one from the University graduate student body and four from the community. Each is appointed for a three-year renewable term. Associate members drawn from faculty, staff, students, and the community who have agreed to serve are selected on an as-needed basis to review those projects and activities that fall within their areas of expertise and/or interest. Although the make-up of the IRB will change, there must always be a person not associated with the University on the committee and present at a convened meeting. In addition, there will be at least one member whose primary concern is in scientific areas and one member whose primary interests are in nonscientific areas. The IRB will not be composed entirely of men, or entirely of women, or entirely of members of one profession.

There are also alternate voting members of the committee for special circumstances such as when alternate members are needed to insure a quorum, when a protocol requires the expertise of an individual such as when reviewing protocols on student health or protocols involving prisoners. The IRB Administrator is also a voting member of the committee. This allows the IRB Administrator to approve minor changes to protocols after committee review and to vote if the committee should lose the quorum during a meeting.

RECORDKEEPING

A. Investigators

The following records must be maintained by the investigator in a secure location for not less than three years from the date of official notification to the IRB of project termination:

1. Copies of all signed informed consents.

2. Copies of the raw data (surveys, questionnaires, transcripts, etc.)

B. IRB

The following records must be maintained by the IRB for three years:

1. Copies of all research proposals reviewed; scientific evaluations, if any, that accompanied the proposal; approved sample consent documents; progress reports and renewals submitted by investigators; and reports of injuries to subjects.

2. Minutes of IRB meetings which should be in sufficient detail to show attendance at the meeting; actions taken; the vote on these actions including the number voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a summary of the discussion.

3. Copies of all correspondence between the IRB and the investigators.

4. A list of the IRB members detailing their name, earned degree, representative capacity, indications of experience sufficient to describe each member's chief anticipated contribution to the IRB, and any employment or other relationship between the member and Lehigh University (e.g. full-time employee).

LEHIGH UNIVERSITY
HUMAN SUBJECTS QUESTIONNAIRE

Submitted By (Proposer): _____ Department: _____

Mailing Address: _____ Phone No.: _____

_____ E-mail: _____

Title of Proposal: _____

Principal Investigator (Faculty Investigator/Supervisor/Advisor): _____

New Proposal _____ Start & End Dates: _____ to _____

TYPE OF PROJECT

Master's Thesis _____
Dissertation _____
Other Graduate Student Project _____
Undergraduate Senior Thesis _____
Undergraduate Course Project _____ Course #: _____
Other UG Student Project _____ Please Explain: _____
Non-Sponsored Research _____
Sponsored Research _____ Please List Sponsor: _____

REVIEW CATEGORY

Expedited Review _____
Limited Review _____
Full Committee Review _____

CHECKLIST OF ITEMS TO ENCLOSE

Form	Number of Copies Required		
	Expedited	Limited	Full
a. Human Subjects Questionnaire	2	4	15
b. Informed Consent and/or other Explanation of Study to Subjects or Parents/Guardians	2	4	15
c. Instruments (surveys, tests, etc.)	2	4	15
d. Progress Report (if renewal)	2	4	15
e. Full Proposal (dissertation, sponsor application, etc.) ***Double-sided copy***	1	1	1
f. Certificate of completion of on-line tutorial	1	1	1

SIGNATURES

Proposer's signature: _____ Date: _____

For student **or non-faculty** projects:

This is to certify that I am the Principal Investigator for this study; I have examined the procedures involved in this study, and I take overall responsibility for the conduct of this research.

Principal Investigator's signature: _____ Date: _____

Principal Investigator's name: _____ E-mail: _____
Print or Type

Dept/Center Approval (if required): _____ Name: _____
Signature Print or Type

Please return to: Office of Research and Sponsored Programs
526 Brodhead Avenue (610-758-3021)

LEHIGH UNIVERSITY
HUMAN SUBJECTS QUESTIONNAIRE

1. Summarize the purpose of the proposed research, making clear the research question(s) and hypothesis(es). Avoid the use of technical terms or discipline specific language. Your explanation must be concise and clear to those unfamiliar with your field. Describe all study procedures. Limit this section to one page.

2. Describe the research design. Specify how the data will be used to answer the proposed research question(s). Provide the name of each of the measures that will be used (attach a copy of each), provide information on the reliability and validity of each measure (references or results from prior use of the measure). State the details of the statistical or qualitative analysis that will be used to analyze these data.

3. CHARACTERISTICS OF SUBJECTS

Sex: M _____ F _____ Both _____ Special Ethnic Group: Yes __ No __

Number of Subjects: ____

Age Group: _____ Handicapped: Yes ___ No ___

Institutionalized: Yes ____ No ____ General State of Health: _____
Other (Explain):

4. If subjects are either (A) children, (B) mentally incompetent, or (C) legally restricted (i.e., institutionalized), please explain necessity for using this particular group. **[Studies using these populations always involve some risk, Question #11 must be answered]**

5. How will the subjects be sampled, recruited or otherwise enlisted as subjects in this study?

   If subjects are recruited from a school, an institution (group home, church, adult day care, etc.), a university, or a similar situation where you are collecting data within the confines of the group/institution, ***documentation must be provided confirming that permission has been obtained*** from the school administration, a person with authority within the group/institution (professor of a class from another institution that is being recruited), or the director of the program (group home, adult day care, etc.).

6. Describe the manner in which informed consent will be obtained for each appropriate category.

   A. Adult Subjects (Includes persons 18 years of age and over). Subject consent required.

   B. Institutionalized Subjects: Subject consent form and consent of appropriate, responsible institutional staff person required.

   C. Parents/Guardians consent for Child Subjects (Includes all persons under 18). Written permission is required of both parents or the child's guardian for each child under the age of 18 who will be the subject of research. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; or (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child. Please provide a justification if you will only be asking for the signature of one parent. *Note: Protocols for research being conducted in elementary, middle or high schools must be accompanied by a letter of approval from the principal or superintendent of the school.*

7. If subjects are 14-17, will their written assent be obtained? Yes ____ No ____.
If no, why not? If yes, how? (*Please see requirements regarding <u>assent</u> under "Children as Subjects in Research" in the Lehigh University Policy.*)

8. If subjects are 14 and younger, will you obtain their assent? Yes ____ No ____.
If no, why not? If yes, how?

9. What precautions will be taken to insure the privacy and confidentiality or anonymity of the subjects?
(Please include the reporting of data.)

10. What specific procedures will be taken to safeguard the data in your possession?

11. Are audio or visual images of the subjects going to be recorded? Yes ____ No ____.
If yes, the following questions should be addressed:

    a. What type of recordings will be made (audio or visual)?

    b. How will the recordings be utilized in your study or analysis?

    c. What specific procedures will be taken to protect the recordings?

    d. Do you envision any other uses for the recordings, such as illustrations in publications or as a training tool?

    e. Will the recordings eventually be destroyed? When? How?

12. Since there are always some risks in any study, even if minimal, describe in detail the possible physical, psychological, social, legal, economic or other risks to the subjects, either immediate or long range. Estimate the seriousness and extent of the risks.

13. Describe the procedures that will be used to reduce the risk. How effective do you feel they will be?

14. Assess the benefits of this research to:
(A) The subjects

(B) Society at large

(C) Do you feel that the benefits significantly outweigh the risks involved?
Yes ___ No ____

EXPLAIN

INFORMED CONSENT

The attached informed consent form is meant merely as a guide. Appropriate deletions should be made and blanks should be filled with wording that fits your particular research project.

Particular consideration should be given to the possibility of physical risk to your research subjects. Should any physical risk exist, current regulations require that the informed consent form indicate whether medical treatment and/or compensation are available, and of what they consist. If no physical risk exists, this statement need not be made a part of the informed consent form.

A disclosure of any appropriate alternative procedure that might be advantageous for the subject should also be included if appropriate.

Full discussion of the elements of an informed consent can be found on page 9 of the "Human Subjects Policy." In the case of subjects under the age of 18, also refer to the section on "Assent" on page 8.

The informed consent form submitted with the Human Subjects Questionnaire should be the **final** version of the form. If any revisions are made to the informed consent form after approval, **a copy of the revised form must be submitted for expedited review and approval.**

For additional information on the informed consent process, see the informed consent tips offered by the Office of Human Research Protections:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm

SAMPLE INFORMED CONSENT FORM

This form is to request your agreement (request your permission for your child) to participate as a subject in the research project (investigation, experiment, study) on (entitled) _____ conducted by _____ (under the supervision of) _____.

The purpose of the study is to....(explain research questions and purpose in lay terms and language)

The procedures which will be used in this study are.... (explain tasks and procedures)

Your (your child's) participation in the study will involve (duration of subject's participation including number of visits)....

The possible risks associated with the study are (describe physical, psychological, social, economic or other risks or discomforts, if any, such as threat to dignity, invasion of privacy, inconvenience, as well as the likelihood of the risks)....

You (your child) may not receive any direct benefits from participating in this study, but participation may help to increase knowledge that may benefit others in the future. (If the subject may derive direct benefits, use the following statement): The possible benefits to you (your child) from participation in this study are....

Any data or answers to questions will remain confidential with regard to my (child's) identity.

Any information collected through this research project that personally identifies you will not be voluntarily released or disclosed without your separate consent, except as specifically required by law.

Your decision whether or not to participate is voluntary. You are free to withdraw (your child) from this study at any time without jeopardizing your relationship with Lehigh University. (If study involves a questionnaire or survey, explain that subject may skip any questions he/she is not comfortable answering.)

If you have any questions about this study and what is expected (required) of you in this study, you may call… (investigator's name and telephone number).

You may report problems that may result from your participation or direct questions in regard to your rights as a subject in this study to the Office of Research and Sponsored Programs, Lehigh University, (610)758-3021. All reports or correspondence will be kept confidential.

To confirm that you have read and understand the foregoing information, that you have received answers to any questions you asked, and to consent to participate in the study, please sign below.

_____ _____

Date Subject's Signature

To confirm your consent to the participation of your child, a minor, as a subject in the study described, please sign below. *(Use this statement if it applies to your study.)*

_____ _____

Date Signature of minor subject's parent or guardian

I, the undersigned, have defined and fully explained the study to the above subject. *(Use this statement only if the subject may need assistance in reading or understanding the consent form.)*

_____ _____

Date Investigator's Signature

I was present when the study was explained to the subject(s) in detail and to my best knowledge and belief it was understood. *(Use this statement IF it applies to your study.)*

_____ _____

Date Witness

NOTE: WHEN A CONSENT DOCUMENT IS USED, A COPY MUST BE PROVIDED TO THE SUBJECT SO THEY WILL HAVE A RECORD OF THEIR AGREEMENT TO PARTICIPATE.

LEHIGH UNIVERSITY
HUMAN SUBJECTS PROGRESS REPORT

Submitted By (Proposer): _____ Department: _____

Mailing Address: _____ Phone No.: _____

_____ E-Mail: _____

Title of Proposal: _____

Principal Investigator (Faculty Investigator/Supervisor/Advisor):_____

Renewal: _____ Revision: _____ Start & End Dates: _____ to _____

TYPE OF PROJECT **REVIEW CATEGORY**

Master's Thesis	_____	Expedited Review	_____
Dissertation	_____	Limited Review	_____
Other Graduate Student Project	_____	Full Committee Review	_____
Undergraduate Senior Thesis	_____		
Undergraduate Course Project	_____	Course #:_____	
Other UG Student Project	_____	Please Explain:_____	
Non-Sponsored Research	_____		
Sponsored Research	_____	Please List Sponsor:_____	

CHECKLIST OF ITEMS TO ENCLOSE

Please Note: Proposal review will not begin until all the required materials have been received. To facilitate the review process, please submit the following, as appropriate to the project:

Form	Number of Copies Required		
	Expedited	Limited	Full
a. Progress Report	2	4	15
b. Informed Consent and/or other Explanation of Study to Subjects or Parents/Guardians	2	4	15
c. Instruments (surveys, tests, etc.)	2	4	15

SIGNATURES

Proposer's signature: _____ Date: _____

For student **or non-faculty** projects:

This is to certify that I am the Principal Investigator for this study; I have examined the procedures involved in this study, and I take overall responsibility for the conduct of this research.

Principal Investigator's signature: _____ Date: _____

Principal Investigator's name: _____ E-mail: _____
Print or Type

Dept/Center Approval (if required): _____ Name:_____
Signature Print or Type

Please return to: Office of Research and Sponsored Programs
526 Brodhead Avenue (610-758-3021)

1. Please describe the status of the research in regard to collecting, analyzing, and publishing the data. Your response should address the following questions: Are you still recruiting subjects? Are you still collecting data? If your data collection is complete, are you in the analysis stage? If you are in the analysis stage, have the data been stripped of identifiers and does a link exist/no longer exists between the data and the subjects? How are you going to protect the confidentiality of the data while you are doing the analysis?

   How many subjects did you plan on recruiting? _____

   How many subjects have enrolled/participated in your study? _____

   How many more subjects do you intend to enroll/invite to participate in your study? ____

2. Have any risks to the subjects in your research project been found that you did not foresee? Yes __ No __ If yes, describe the nature of these risks and how the risk is being minimized.

3. Have there been any adverse effects to the subjects or complaints due to your research project? Any complaints must be reported to the Office of Research and Sponsored Programs. Yes __ No __ If yes, describe.

4. Have you altered your investigative procedure in any way that has not been previously reported to the committee? Have you changed any forms or questionnaires previously approved? Yes __ No __ If yes, describe the change and attach any revisions.

5. Have you obtained an informed consent form from each subject?
   Yes __ No __ If no, why not?

6. Has any breach of security of records or project files occurred? Yes __ No ___If yes, describe the nature and extent of the measures taken to correct the deficiency.

7. Have you received any complaint regarding any part of your procedure or its results from a subject that has not been previously reported to the committee?
   Yes ___ No __ If yes, describe the nature and extent of any measures taken.

8. Have any subjects withdrawn from the study? Yes __ No ___ If yes, please describe the situation under which the subject withdrew and give the reason, if known.

Changes, Revisions to Approved Procedures

If this progress report is being submitted to request approval for a change to your original protocol, please summarize the changes including pertinent information such as characteristics of the subjects, recruitment, procedures for obtaining informed consent, procedures for maintaining confidentiality/anonymity of the subjects, and risks and benefits. Any revised forms, questionnaires or instruments should be attached.