

LEHIGH UNIVERSITY

*Policy on the Protection of
Human Subjects in Research*

Research Integrity
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Contents

Definitions	1
Belmont Report.....	2
Human Subjects Research Principal Investigator	2
Unaffiliated Investigators	
Process for Making Submissions for IRB Review.....	2
Institutional Research	3
Class-Related and Student-Conducted Research	3
Types of Review	4
A. Exempt Review	4
B. Expedited Review	6
C. Full Committee Review.....	7
Researcher Certification.....	7
Special Considerations.....	7
A. HIPAA: The Privacy Rule.....	7
B. Children as Subjects in Research	8
C. Research Involving Fetuses, Pregnant Women, or Human In Vitro Fertilization	9
D. Research Involving Cognitively Impaired Persons.....	9
E. Research Involving Prisoners	9
F. Policy on Informing Those Tested About HIV Serostatus	10
G. Use of Lotteries, Raffles, and/or Drawings in Research	10
Informed Consent	11
A. General Requirements for Informed Consent.....	11
B. Documentation of Informed Consent	12
C. Waiver of Signed Informed Consent.....	13
Process for Submitting a Research Project for Review	13
Continuing Review Procedures	14
Modifications/Amendments.....	14
Termination	14
Reporting Unanticipated Problems	14
Reporting and Management of Concerns.....	16
IRB Membership	16
Recordkeeping	17
A. Investigators	17
B. IRB.....	17

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 (widely applicable) 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 (e.g. 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.

BELMONT REPORT

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 approves a waiver of documentation of informed consent, 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. Federal regulations require that IRBs give special considerations to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally or cognitively impaired persons, or economically or educationally disadvantaged persons. The IRB will ensure that subjects are selected fairly within a specific project and among all University research so that no unjust patterns emerge.

HUMAN SUBJECTS RESEARCH PRINCIPAL INVESTIGATOR

Under University policy, the principal investigator (PI) 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 Integrity. At any stage of the review process, the application may be referred to the initiating principal investigator for clarification or for alteration and resubmission.

UNAFFILIATED INVESTIGATORS

Researchers engaged in Lehigh University-initiated or centered research who are not employees of the university and not agents of an outside entity that can provide IRB review must sign an Individual Investigator Agreement to assure that they understand their obligations as human research personnel.

PROCESS FOR MAKING SUBMISSIONS FOR IRB REVIEW

New, renewal (continuing review) and/or modification/amendment applications for IRB review must be submitted electronically through IRBNet.org. All review comments, requests for additional information and decision letters will be issued electronically via IRBNet. The university has adopted the use of IRBNet for human subjects protocols to streamline and standardize protocol submission and review processes. To get started, go to IRBNet.org and click on “New User Registration” in the upper right hand corner. After the registration process is complete, the investigator will log in at IRBNet.org to get started. The IRB policy and application forms can be downloaded from the site, completed and then uploaded for submission, signature and review.

Tutorials for using IRBNet are available on the Office of Research Integrity’s website: <http://research.cc.lehigh.edu/irb>. Assistance is also available by calling 610-758-3021.

Continuing Review and re-approval of research is required at least annually as long as a project continues to involve human subjects. A research project no longer involves human subjects once investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, including using, studying, or analyzing identifiable private information. When research activity is ongoing, it is the responsibility of the principal investigator to submit the *Continuing Review Form* through IRBNet at least four weeks prior to expiration of IRB approval.

Changes to the research protocol are required to be approved by the IRB prior to implementation. Proposed changes must be submitted by the PI with an Amendment/Modification form through IRBNet.

Approval of a proposed investigation is granted for a period of no longer than one year.

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.

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 the quality of 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. The following types of class-related and student-conducted research activities **require** IRB review:

1. All doctoral dissertations and master's theses involving human subjects.
2. All undergraduate or graduate student-generated human subjects research projects if the students undertake a systematic investigation, produce a design or protocol for the research, sample a population, report findings, etc., such as independent study projects, honors papers, or theses.

B. The following types of class-related and student-conducted research are overseen by individual academic departments and **do not require** IRB review:

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 for the sole purpose 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.
 3. The informal collection of information by students from respondents, for example, informally interviewing friends or relatives for purposes of class discussion or assignments.
- C. Instructor-led class projects designed to teach research procedures and design, and involving human subjects who are not also students in the class, **may require** IRB review. This includes projects for which the instructor provides a research design and protocol, or assignments when the class designs and generates the research project.
1. Class projects that meet **ALL** of the criteria below **may** be eligible for a waiver of IRB review:
 - (a) No publication and/or presentation of the results of the project activities outside Lehigh University;
 - (b) Project activities are no more than minimal risk to participants (see definition of “minimal risk” on Page 1 of this policy);
 - (c) No participants under age 18 or members of vulnerable populations (e.g. prisoners, persons lacking the capacity to provide informed consent);
 - (d) Project does not involve deception of participants;
 - (e) Project does not involve activities in which participants could reasonably feel physically or psychologically threatened (e.g. use of weapons, verbal threats, striking an intimidating pose); and
 - (f) Project does not involve collection of information about the participants’ own: sexual history; medical history; mental health history; religious orientation and views; substance use and abuse; war experiences; criminal history; racial, ethnic biases/views.

For class-related projects meeting ALL the criteria in C.1.(a- f) above, the instructor must submit a completed Request for Waiver of IRB Review for Class Projects form (available at <https://research.cc.lehigh.edu/irb>) to inors@lehigh.edu.

2. If the class-related project proposed does not meet ALL the criteria outlined for waiver of IRB review, then IRB review is required following the process for submitting a regular IRB application.

TYPES OF REVIEW

There are three categories of review: exempt, expedited and full committee review.

A. Exempt Review

Under certain circumstances, human subjects research activities may be granted exempt status. Exemption means that all the research activities fall under one or more of the exemption categories defined by the federal regulations. The significance of exempt status is that the research activity is not subject to continuing IRB oversight. Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report and in disciplinary codes of professional conduct. Depending on the circumstances, investigators performing exempt studies may need to obtain informed consent, protect confidentiality, minimize risk, and address problems and complaints. 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.

Exempt status may only be granted by the IRB. Investigators must request exempt review by submitting

an application to the IRB. Please note that once exempt status is granted, investigators are required to submit amendments to the IRB before making changes to the research activity. Significant changes can affect the eligibility of the research to continue to qualify for exempt status.

The following types of research may fall into the exempt 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 exempt 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.

In other words, the only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Otherwise, all the requirements of the human subjects regulations apply.

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. Expedited Review

The expedited 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. Research eligible for expedited review is reviewed by a subcommittee of the IRB. Expedited review of continuing reviews where the protocol is unchanged from the previous year or minimal risk amendments/modifications may be conducted by a single designated reviewer. 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. The IRB will be notified of all research activities that have been approved by expedited review.

The following types of research may qualify for expedited review:

1. Clinical studies of drugs when an IND is not required, or; clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weight >110 pounds where the amount drawn is <500 ml/8 week period and collection occurs at most 2 times/week, or; collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (at most 50 ml or 3 ml/kg/8 week period), and the frequency with which it will be collected (at most 2 times/week.)
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
5. Research involving materials (data, documents, records, or specimens) that have been, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(Note: some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior or research employing survey,

interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects, or; Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or any other relevant source, or; Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, and expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)
9. Continuing review of research, not included under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified.

C. Full Committee Review

Any research not covered under the exempt or expedited 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 investigator 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 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 submitting the study package through IRBNet.

The tutorial is found at: <http://phrp.nihtraining.com/users/login.php>

Remember to print the completion certificate and submit a scanned copy as part of your IRB application. You may also use the "print screen" function and paste the 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. Upload the document into your application package by using the "Add new document" button, designating the Document Type as "Other", and attaching the file.

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 Set³, (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.

B. Children as Subjects in Research

When children are involved as subjects in research, the range of activities that may be approved by exempt 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 Exempt Review above) may not receive exempt 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

1 PHI includes the following 18 individual identifiers: names; geographic subdivisions smaller 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.

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.

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.

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

Special regulatory requirements govern the participation of pregnant women in research. Research involving women who are or may become pregnant receives special attention from IRBs because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. Further, in the case of a pregnant woman, IRBs must determine when the informed consent of the father to the research is required. Special attention is justified because of the involvement of a third party (the fetus) who may be affected but cannot give consent and because of the need to prevent harm or injury to future members of society.

Research involving the human fetus raises special concerns for IRB reviewers. The fetus has a unique and inextricable relationship to the mother. It cannot consent to be a research subject. These circumstances have aroused lengthy public debate on the ethics of fetal research, and led to special federal regulations that guide IRB deliberations about fetal research. The fetus may also be an indirect subject of research when women who may be pregnant participate.

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

D. Research Involving Cognitively Impaired Persons

Cognitively impaired persons are defined as having either a disorder (e.g. psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g. dementia) or a developmental disorder (e.g. intellectual disability) that affects cognitive or emotional functions to the extent that capacity for

judgement and reasoning is significantly diminished. Others, including persons under the influence of or dependence on drugs or alcohol, those suffering from degenerative disease affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interested.

Additional protection and limitations are placed on research involving cognitively impaired persons. Please contact the IRB for additional information.

E. Research Involving Prisoners

The federal regulations governing research with human subjects recognize that the very fact of incarceration may make it difficult or impossible for prisoners to give voluntary, informed consent. Prisoners are defined as individuals involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g. for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution.

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

F. 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.

G. Use of Lotteries, Raffles, and/or Drawings in Research

The Commonwealth of Pennsylvania considers all forms of gambling to be illegal unless specifically accepted by law. Lotteries or raffles used in the context of providing incentives to research participants may be permitted under some circumstances. The IRB will determine, on a case-by-case basis, whether lotteries or raffles may be used to recruit research participants.

Subject compensation should be equitable across all participants who are experiencing the same level of risk and/or inconvenience. In the case of lotteries or raffles, all participants may have an equal chance of receiving an incentive, but the resulting compensation for research participation is arbitrarily different. Researchers should explore all other options for distributing incentives equitably among research participants before proposing the use of lotteries or raffles. The IRB will always give preference to incentive structures providing small incentives to all participants over those providing one or several larger incentives to fewer than all participants. There is also concern than most people overvalue their likelihood of winning, and therefore, offering a large prize may present undue influence or coercion, undermining the process of informed consent. For these reasons, the use of lotteries and raffles in research is discouraged.

In order for the IRB to consider the use of lotteries or raffles the following must be addressed:

1. The study is no more than minimal risk.
2. Incentive amounts and proposed method and timing of disbursement cannot be coercive or present undue influence. Incentive values should not be so high as to unduly induce subjects to participate in or stay enrolled in the study when they would have otherwise withdrawn. The dollar value of incentives must be low (i.e. no more than \$50).
3. Compensation must be appropriate to the study population and commensurate to the level of effort and amount of time spend on the research tasks. For example, it is not appropriate to

provide a chance of receiving a \$1,000 bookstore credit to an undergraduate student in return for completing a 10 minute survey.

4. Cash cannot be distributed.
5. The study protocol, the informed consent, and all advertisements/recruitment materials must clearly define the incentives, the timing of distribution, the process for selecting recipients, and the definitive odds for receiving an incentive (e.g. “There will be 100 participants recruited for this study. There will be 20 thank you gifts randomly distributed. Each individual has a one-in-five chance of being randomly selected to receive a thank you gift.”).
6. Eligibility for receipt of an incentive must not be contingent upon completing the study. This means that the entire recruitment pool, not just those who enroll and/or complete the study, must be eligible for the incentives.
7. Recipients cannot be selected by drawings, and there can be no discussion of “having your name entered into a drawing” in the informed consent or advertisements. Recipients must be selected on a truly random basis.
8. The process for distributing incentives must not compromise the privacy of participants or the confidentiality of their data.

Additionally, researchers approved by the IRB to use raffles or lotteries in research are responsible for securing all other required institutional approvals, including, but not limited to, the Office of the Controller.

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 study package should be the **final** version of the form. If any revisions are made to the informed consent form after approval, the IRB must approve the consent form prior to implementation. A **copy of the amended/modified form must be submitted as an Amendment/Modification for 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>

Informed consent must include the following basic elements:

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.
9. 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 be 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.

PROCESS FOR SUBMITTING A RESEARCH PROJECT FOR REVIEW

1. All protocols/study packages should be submitted through IRBNet at IRBNet.org. All the required information must be submitted. Proposal review will not begin until all the required materials have been received. Please click this [link](#) for a tutorial for using IRBNet to submit human subjects applications to the IRB.
2. Investigators should submit the study package 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 four 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, the change will be noted in the study package on IRBNet.

4. The following information should be submitted:
 - a. Human Subjects Application
 - b. Informed Consent and/or other explanation of study to subjects and/or parents/guardians
 - c. Instruments (surveys, tests, etc.)
 - d. Full Proposal (dissertation, sponsor application, etc.)
 - e. Certificate of completion of on-line tutorial.
 - f. Subject recruitment material (e.g. flyers, emails, letters, etc.)
 - g. *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.*
5. The committee's actions, comments and recommendations will be posted in IRBNet and an e-mail will be sent to the investigator. If a proposal is disapproved, the researcher/principal investigator may request to attend the next committee meeting. The IRB meets on the second Tuesday of each month.

CONTINUING REVIEW PROCEDURES

Sixty days before the anniversary of the last approval date you must submit a Continuing Review package via IRBNet. Please click this [link](#) for a tutorial for using IRBNet to submit Continuing Review applications to the IRB.

Generally, you will to upload the following items in IRBNet as part of your Continuing Review package:

1. Continuing Review Form
2. If proposing modifications during continuing review, provide complete details in the response to question 4 on the Continuing Review Form, include all revised consent forms, measures, instruments, etc. with any proposed changes noted.
Note: If the modifications to the research involve 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.

MODIFICATION/AMENDMENT PROCEDURES

Any changes to the approved protocol, including the consent form and any instruments, require submission of a Modification/Amendment package via IRBNet. Please click this [link](#) for a tutorial for using IRBNet to submit Modification/Amendment applications to the IRB.

Generally, you will to upload the following items in IRBNet as part of your Modification/Amendment package:

1. Modification/Amendment Form
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).
4. *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.*

NOTE: Significant changes to a protocol may affect the category of IRB review, so please reconsider the review categories.

TERMINATION

When a project is completed, withdrawn, or past the phase of involving human subjects, please notify the IRB in writing at inors@lehigh.edu. Research projects are considered to no longer involve human subjects and can be closed with the IRB once investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects; including using, studying, or analyzing identifiable private information.

REPORTING UNANTICIPATED PROBLEMS

Federal regulations require institutions engaged in human subjects research to have written procedures for ensuring prompt reporting to the IRB of “unanticipated problems involving risks to subjects or others”. Unanticipated problems are any information that is (1) unanticipated and (2) related or possibly related to participation in research, and (3) indicates that subjects or others are at increased risk of harm. Investigators are required to report the following items to the IRB within five business days of learning the information:

1. Any information that meets all of the following criteria:
 - a. Unanticipated or unexpected, in terms of nature, severity, or frequency, given the research procedures that are described in the protocol-related documents (e.g. the IRB-approved research protocol and informed consent document) and the characteristics of the subject population.
 - b. Related or possibly related to participation in the research (there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
 - c. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
2. Information that indicates a new or increased risk, or a safety issue. For example:
 - a. New information (e.g. an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
 - b. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
 - c. Protocol violation that harmed subjects or others and indicates that subjects or others might be at increased risk of harm.
 - d. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
 - e. Any changes significantly affecting the conduct of the research.
3. Non-compliance with federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such noncompliance.
4. Audit, inspection, or inquiry by a federal agency.
5. Written reports of external/sponsor study monitors to the investigator; data safety monitoring board reports; or written reports of sponsors to investigators.
6. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. Breach of confidentiality.
8. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to the subject.
9. Incarceration of a subject in a study not approved by the IRB to involve prisoners.
10. Complaint of a subject that cannot be resolved by the research team.
11. Premature suspension or termination of the research by the sponsor, investigator, this institution, or another institution.

When reviewing an Unanticipated Problem report, the IRB assess the information to determine:

1. Whether the reported event is an unanticipated problem involving risks to subjects or others.
2. Whether the event could be categorized as noncompliance, in addition to or instead of an unanticipated problem.
3. What action is appropriate in response to the report.
4. Whether suspension or termination of approval is warranted.
5. Whether further reporting to university officials, federal agencies, and department heads is required.

The types of action the IRB may take include:

1. Requesting the investigator to make modifications to the protocol.
2. Requiring more frequent review of the protocol (e.g. more often than the minimal annual review).
3. Requesting the investigator to modify the consent process or consent documents.
4. Requiring the investigator to provide additional information to current and/or past participants or re-consenting to participation.
5. Requiring additional training of the investigator and/or study staff.
6. Reconsideration of IRB approval.
7. Implementation of monitoring of the research.
8. Implementation of monitoring of the consent process.
9. Recommendation to the Institutional Official to suspend the privileges of an investigator or study team member to conduct human subjects research.
10. Suspension of the research.
11. Termination of the research.

The IRB generally reviews adverse events that are (a) unexpected (b) serious (c) probably related to the study treatment or intervention and (d) occurred in a subject or at a site under the IRB's purview. "Serious" means the occurrence of the event suggests that the research places the subjects or others at greater risk of harm than was previously known or recognized. Generally, events that meet the definition of "serious" either result in or require intervention to prevent events such as, but not limited to, death, life-threatening reactions, significant disability (either physical or psychological), inpatient hospitalization, congenital anomaly/birth defect, or other significant medical incident that, based upon appropriate medical judgment, may jeopardize the subject and require medical or surgical intervention to prevent one of the previously listed outcomes. "Unexpected" means the event is not anticipated given the subject population being studied and the specificity, severity or frequency of the adverse event is not consistent with the protocol or consent documents. "Probably related" means the adverse event is more likely than not to be caused by the research procedures.

If the event is determined to be serious, unexpected, and probably related, the IRB also determines the potential effect of the event on the risks, benefits, and alternatives for subjects as well as whether any additional action is needed, as described above.

REPORTING AND MANAGEMENT OF CONCERNS

Questions, concerns, complaints, allegations of undue influence, allegations or findings of noncompliance, misconduct, fraud, or improper conduct involving research procedures may be reported orally or in writing. Concerns may be reported to the IRB Chair, Deans, Department Chairs, the Institutional Official, the office of Research Integrity, Internal Audit, or General Counsel. Reports may also be submitted anonymously and confidentially through the [Lehigh University Ethics and Compliance Hotline](#). The IRB Chair 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 is comprised of representatives drawn from the University faculty, the University graduate student body, and from the local community. Each is appointed for a three-year renewable term. 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, or 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).