

LEHIGH UNIVERSITY

*Policy on the Protection of
Human Subjects in Research*

Research Integrity
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HUMAN SUBJECTS POLICY

All human subjects research in which Lehigh University faculty, staff, students, and other agents are engaged 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. 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.

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 610-758-2871.

Continuing Review and re-approval of research protocols with an IRB expiration date 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.

Certain minimal risk, unfunded research protocols may be approved by the IRB without an expiration date. In these cases, the decision will be communicated to the PI during the approval process. Rather than requiring a Continuing Review submission, the Research Integrity office will contact the PI one year after initial and approval and then annually subsequently to determine if the project is still open and is still minimal risk and unfunded.

Proposed changes must be submitted by the PI with an Amendment/Modification form through IRBNet. Changes to the research protocol are required to be approved by the IRB prior to implementation. The IRB must be notified immediately if funding sources change.

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 activity meets the definition of human subjects research.

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.

Students that are engaged in activity that meets the definition of human subjects research are required to obtain IRB approval in advance of any research conduct. There IRB website offers comprehensive guidance for determining whether or not an activity meets the definition of “human subjects research” and is subject to IRB review. Please contact Research Integrity for help determining if a proposed activity is human subjects research and subject to IRB policy.

Whether or not subject to IRB policy, students are strongly encouraged to design research projects that present “minimal risk” to participants. As defined in the federal regulations and in this policy, “minimal risk” means that the participants will encounter no harms or discomforts greater than those that are a normal part of their daily lives. Faculty advisors and research program staff are asked to guide students in developing minimal risk projects. **If, in the opinion of the student or faculty advisor, an intended project might be greater than minimal risk, the student or faculty member is required to seek the advice of the Research Integrity office. This applies whether or not the proposed activity meets the definition of “human subjects research” and is subject to IRB policy.**

TYPES OF REVIEW

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

A. Exempt Review

The IRB policy on exempt review is available under “IRB Standard Operating Procedures and Policies”: <https://research.cc.lehigh.edu/irb>

B. Expedited Review

The IRB policy on expedited review is available under “IRB Standard Operating Procedures and Policies”: <https://research.cc.lehigh.edu/irb>

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 TRAINING

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
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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.

All personnel on NIH-supported projects that meet the definition of a "clinical trial" are also required to complete the Society of Behavioral Medicine's "Good Clinical Practice for Social and Behavioral Research eLearning Course". Training must be refreshed every three years. This training is designed for investigators involved in behavioral clinical trials. Lehigh University researchers involved in NIH-supported biomedical clinical trials must contact the Research Integrity office for assistance identifying suitable training.

The SBM eLearning course can be found at: <http://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course>

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

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.

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 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

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.

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 that 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 spent 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>

Please see the [IRB website](#) for all required and additional elements of informed consent.

All required elements are included in the informed consent templates provided by the IRB. The templates should be modified as appropriate for the study.

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.

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.

TERMINATION

When a project is completed, withdrawn, or past the phase of involving human subjects, please notify the IRB in writing at inirb@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 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.

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).