PROTECTION OF HUMAN SUBJECTS

Human Subjects Policy Statement

Lesley University is committed to the ethical principles for the protection of human subjects in research set forth in the *Belmont Report* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The University requires that all research and teaching activities involving human subjects be guided by these ethical principles. In summary, these principles are:

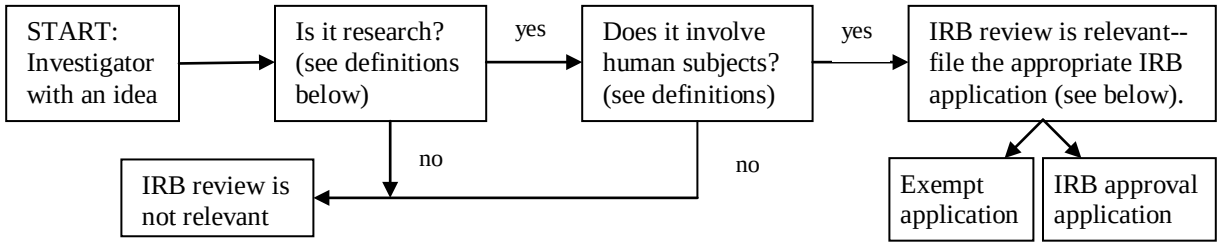
- Respect for persons. This principle requires researchers to obtain informed consent from all human subjects participating in their research. The consent process includes giving subjects full and comprehensible information about the research and providing a clear assurance that participation is strictly voluntary.
- Beneficence. The essence of this principle is concern for the wellbeing of subjects. It requires that the risk of harm to subjects be minimized to fullest extent possible. It further requires a risk/benefit analysis in favor of the research, such that the sum of benefits to the subject, as well as the importance of the knowledge to be gained, clearly justifies the remaining risk of harm to human subjects.
- Justice. Justice requires that the risks and benefits of research should be fairly and equitably distributed among subjects, with particular concern against the exploitation of subjects whose personal characteristics place them in vulnerable or dependent positions, i.e., children, prisoners, patients, impoverished persons, the cognitively impaired.

Human Subjects Research Internal Review Board (IRB)

The University, through the Provost's Office, maintains an Internal Review Board for Human Subjects Research (hereafter the IRB). The IRB shall determine whether an activity constitutes human subject research and whether the research is subject to full Board review or may be exempted from review.

Am I Doing Research With Human Subjects?

The flowchart below highlights the essential questions that must be asked to determine if your project is subject to IRB review under these policies and procedures.



Definitions

Research is defined under federal regulation as any *systematic* investigation designed to develop or contribute to *generalizable* knowledge. The scope of this definition is broad, encompassing

both faculty and student projects, as well as projects not intended to generate results for publication. However, most teaching and classroom activities, as well as most ad-hoc, anecdotal, or otherwise nonsystematic projects, do not qualify as research under this definition and are not subject to these policies and procedures.

A human subject is defined under federal regulation as any living individual about whom an investigator conducting research obtains either (1) information through *intervention* or *interaction* with the individual, or (2) identifiable *private information*.

Intervention includes any manipulation of the subject or the subject's environment performed for research purposes.

Interaction includes any and all communication or interpersonal contact between investigator and subject.

Private information includes any individually identifiable information about a human subject that the individual can reasonably expect will not be made public.

If a project is systematic in its approach to data collection, aims to collect generalizable knowledge that will be applied to other populations, and includes a specific intervention or interaction, then it is considered to be formal research and must adhere to guidelines for Human Subjects in Research.

Not all research that involves data from human subjects involves intervention or interaction. Projects that involve the examination of pre-existing data and do not involve actual *intervention* or *interaction*, and do not identify private information about subjects, may not qualify as human subject research. Examples include research that analyzes pre-existing test scores, samples of art works, recordings of language use, where identifying information about subjects is made unavailable to the researchers – although identity coding may be permissible provided that private information cannot be identified.

Educational Activities that are not Human Subjects Research

Not all data gathering activities by university faculty and students represent human subjects research, even when interactions and interventions are involved. Some activities are designed to teach research techniques or data analysis, and do not have generalizable, systematic research as its intent. All participants should understand and are clearly informed that these activities are instructional exercises and are not actual research. Examples that *may not constitute human subjects research* include: demonstrating professional practice; engaging in classroom inquiry; demonstrating already established curriculum, pedagogies and intervention methodologies; training of assessment tools and methods; guiding future procedures for data collection under human subjects research situations; collecting information about historical individuals that are no longer living; observing individuals without interaction or identity determination; studying identifiable public figures (without interaction or the collection of private information); as well as internships and practica.

However, if such data are to be employed as part of a doctoral dissertation or a master's thesis, then IRB review should be sought. When the results of the activities described above may be subject to later publication or public presentation at professional conferences, and when there is any possibility of individually identifiable information being made public, then IRB review should be sought.

Obviously, an education activity that involves the use of experimental drugs, agents, devices, or medical procedures, even when they are a part of a course curriculum, always represent human subjects research, and therefore necessitate IRB review and approval.

If Students Conduct Research as part of a Class Assignment

Given that courses are first approved by the faculty and the appropriate Curriculum Committee, research done by a student as part of an approved class assignment does not fall under these policies (with exception of master's thesis and doctoral dissertation). This includes the gathering of original data on human subjects. In such cases, however, the instructor of the course will be the principle investigator and will be responsible for seeking informed consent of subjects, for informing students of proper procedures regarding the conduct of such research, and for monitoring the work done by students. Thus, it remains very important that both faculty and students understand the regulations and procedures regarding the conduct of human subjects research. Faculty are encouraged to include relevant information on their course syllabi along with instruction where appropriate. Any university course that addresses appropriate methodologies for Human Subjects research should be aware of this entire policy and guide university students in understanding it fully. Faculty who are supervising Independent Study Projects should contact the IRB if there are any concerns that a student research project might qualify for review by the Committee.

Human Subjects Research Procedures

Faculty who propose to conduct, direct, or supervise research involving human subjects shall evaluate the undertaking and ensure that it is consistent with the policies and procedures of Lesley University. The principal investigator has primary responsibility for protecting human subjects from harm by participation in the research. All others involved in conducting the study share this responsibility. When students engage in research, the faculty member supervising that research serves as the Principal Investigator for purposes of Federal and State statues and regulations – including research undertaken by doctoral and master's students.

The IRB shall determine whether an activity constitutes human subjects research and whether the research is exempt from formal review. Researchers shall submit applications for approval of research proposals involving human subjects to the IRB, using the forms provided by the IRB. Application review is ongoing during the calendar year and may take up to 6 weeks.

The IRB gives approval only for the specific research plan contained in the application presented to it, and for a specific period of time not to exceed one year. <u>This period begins on the date of the IRB action, not the date the researcher begins to collect data</u>. No part of the plan relevant to human subjects shall be changed, nor shall subjects be used beyond the specified time, without further approval of the IRB.

All key personnel on non-exempt research projects involving human subjects must complete an approved Human Subjects Educational Training before beginning work on the project. The federal government defines key personnel as all individuals responsible for the design and conduct of the study. See http://ohsr.od.nih.gov and select computer-based training, then select IRB Members. This site is available to all interested parties. The last page of the training module will provide a certificate verifying completion. This should be saved electronically with the investigator's name in the title and emailed to irb@lesley.edu.

All non-exempt research projects must maintain active IRB approval throughout both the data collection and analysis phases of the research. If the project continues **beyond one year**, a "Project Renewal Application" and any supporting materials must be submitted to the Committee for review prior to the expiration date. Project renewals and approval of minor changes to projects are eligible for expedited review.

A *Project Renewal Application* may take the form of an email or a letter delivered by USPS. It should include the following information: IRB project number, PI name and current contact information, date, title of the project, length of renewal (up to one year), and a statement that no changes to the original proposal have been made and that no adverse effects of the project have been observed. Where an amendment to the original application is sought, a *Project Amendment Application* should include the same information and describe in detail the proposed changes from the original application (e.g., change in the number of subjects, the duration of the intervention, the number of interactions with subject).

Investigators shall immediately suspend an inquiry if they observe an adverse change in the health or behavior of a subject that may be attributable to the research. They shall promptly report the circumstances to the IRB. They shall not resume the use of human subjects without the approval of the IRB.

It is University policy that these policies and procedures apply to all research involving human subjects conducted by faculty or students regardless of the source of funding or whether the research is funded. In the case of conflict between the stipulations of the funding agency, University policy, DHHS regulations, or other state or federal statutes or regulations, the more restrictive regulations shall prevail.

Exempt Research

Some research studies that meet the definition of research may still be classified as exempt from full IRB review. It is important to keep in mind, however, that exempt status only exempts a project from full IRB review; adherence to all other requirements for the protection of human subjects -- including university policy, state and federal statutes and regulations, or conditions stipulated in your grant -- is still required for exempt research. The decision to categorize a study as exempt can ONLY be made by the IRB. The investigator cannot make this determination. The IRB will retain records of studies classified as exempt.

Examples of research likely to be conducted at Lesley University that may be considered exempt include:

- Research that clearly presents no risk of harm to subjects.

- Research conducted in established or commonly accepted educational settings, involving normal educational practices (e.g., observing two approaches to mathematics instruction).
- Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior where the information obtained is recorded in such a manner that human subjects cannot be individually identified.
- Research involving preexisting data/records/information already in the public domain.

To request exempt status, complete and submit the appropriate application to the IRB at irb@lesley.edu. The application form should indicate that an exemption is sought and that you believe your project satisfies the exemption criteria as defined on the form.

Expedited Review

Researchers may request an expedited review only for certain categories of research activities that (1) present no more than minimal risk to subjects, AND (2) involve only procedures authorized for expedited review by the federal government. Under an expedited review procedure, the chairpersons of the Committee, may approve a proposal qualifying for expedited review and inform the full Committee of the result at the next scheduled meeting.

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

Procedures likely to be conducted at Lesley University that are candidates for expedited review include most survey research, interviews, focus groups, research involving data or records previously collected for non-research purposes (i.e., clinical or educational records), as well as most behavioral and cognitive research.

To request expedited review, complete and submit the appropriate application to the IRB at irb@lesley.edu. Indicate on the form that you are requesting expedited review only if you believe your project satisfies the criteria as explained above.

Board Review

All research projects involving human subjects that do not qualify for exempt status or expedited review, must undergo board review consisting of one of the chairpersons and two committee members. Investigators shall complete and submit the application to the IRB at irb@lesley.edu.

Informed Consent

Copies of all written consent forms to be used in the project must accompany the IRB Application Form. University policy requires researchers to obtain the written informed consent of all human subjects who participate in any research that poses a risk of harm to subjects, regardless of degree of risk involved or the exempt or funding status of the project. In addition, the University requires written parental/guardian consent for all research involving children or those unable to provide informed consent.

Consent forms may be designed by the researcher, in keeping with the objectives of the research and data collection. The written consent form is simply a record of the agreement between investigator and subject concerning the content and terms of the project. In brief:

- The form must include a brief, clear statement of exactly what is involved so that there can be no question later as to whether the individual or parent/guardian was properly informed.
- The consent form should not be deceptive in any way. There may be legitimate reasons for withholding information from subjects until the debriefing sessions, but the consent form itself must neither deceive nor mislead subjects.
- The form itself should be written in the second person ("You will be asked to complete the following tests….") so that it accurately reflects the exchange between investigator and subject.
- The consent form should be written in a manner that will be fully understood by the subject.
- Department letterhead may be used with permission, but in that case the "consent form" heading should be clear and separate.
- The written consent form should clearly indicate that the subject is free to withdraw from the study at any time and without penalty.
- The form should not include any language suggesting that the subjects waive their rights by signing—the right, for instance, to sue.
- The form should assure the subject that all appropriate steps will be taken to preserve privacy, confidentiality and anonymity. The researcher should assure the subject that the subject's name or other identifiers will never be revealed. In those unusual instances where permission is sought to identify a subject in a research report (or any subsequent publication), then the IRB will seek to determine whether a sufficient reason is given for doing so, and that the subject has been fully informed of that risk.
- In instances where subjects are asked in interviews, for example, to reveal personal experiences and states of mind, the form should make clear that if the subject should reveal something which Federal or State laws require the researcher to report, then the researcher will be obliged to do so, even where such reports appear to violate confidentiality – applicable Federal and State laws take precedence.
- *Consent forms must include contact information for the Lesley University IRB chairpersons*.

Researchers should be advised that the IRB has found that the most common reason for the delay in approval of applications has been the lack of clarity of consent forms and lack of adequate measures to protect privacy, anonymity and confidentiality.

For further guidance on how to prepare letters of informed consent, see Guidelines for Informed Consent Forms.

Children as Subjects of Research

Whenever research involves the use of children, Lesley University requires that researchers shall obtain an oral assent to participate from the child, as well as written permission from the child's parent or guardian.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research in the state where the research will be conducted. *Assent* means a child's affirmative agreement to participate in the research. Mere failure to object shall not be construed

as assent. *Permission* means the informed and voluntary agreement of the parent(s) or guardian to the participation of their child in the research. Failure to object shall not be construed as permission.

The Committee shall be responsible for determining that adequate provisions are made for soliciting the assent of the children if, in the judgment of the Committee, the children are capable of providing assent. The Committee shall take into account the ages, maturity, and psychological state of the children involved in the research under a particular protocol, or for each child as the Committee deems appropriate, to determine whether the children are capable of assenting. The Committee may waive the assent requirement if the Committee determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted (e.g., research involving infants).

Student Research

The University's policies and procedures on human subjects shall apply to all research at Lesley University, whether conducted by faculty or students. All student research shall be supervised by a faculty advisor. It is the responsibility of all faculty to review these policies and procedures, to share this information with students, and to ensure that the rights of human subjects are protected. Policies specific to student research include:

- The faculty advisor shall be the principle investigator. A student cannot be the principle investigator. This also applies to doctoral research and master's thesis research.
- The faculty advisor shall assure that all students are aware of the policies for the protection of human subjects, and that all research protects human subjects to the fullest.
- All students seeking to participate in research involving human subjects must first complete the mandatory educational training module and submit documentation of this to the faculty.
- The IRB shall serve as a consultant and resource to faculty in interpretation of these procedures and policies as they relate to student research and projects.

Institutional Review Board

The Committee for Human Subjects Research functions as the Institutional Review Board (IRB) and its membership is such as to satisfy requirements of the Department of Health and Human Services (HHS). The IRB has at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by Lesley University. At least one member of the Committee is a non-scientist, and one member is a person not affiliated with Lesley University.

A quorum consists of a simple majority of the Committee's membership, including at least one member whose primary concerns are in non-scientific areas. Actions requiring a vote are taken at convened meetings. Decisions are made by a majority of those present.

Proposals to be reviewed are submitted to the Committee via email on the application form prescribed by the IRB. The IRB actions are communicated in writing to the principal investigator. Copies are retained in the Committee's files.

At the initial review, the Committee determines whether review is required at intervals more frequent than yearly. Investigators are instructed to report promptly to the Committee

chairperson any unanticipated problems involving any risks to subjects. It is the chairperson's responsibility to ensure that such reports are communicated to the full Committee.

The membership and functioning of the Committee are reviewed annually by the Provost, or designee. Members are appointed, or re-appointed each year. The ordinary term of service is three years.

Application for Review of Human Subjects Research

A unified form for human subjects research appears in the Faculty Handbook. The form allows for a single submission of an application for exempt, expedited, or full review by the IRB. Instructions are provided on the form. At the present time, the application form is available as an electronic document (MSWord) from the Provost's web page. Applicants are asked to download the form, enter the requisite information, save the document with a file name that includes an identifier, like the applicants name, and send the completed application to irb@lesley.edu as an email attachment (include letters of informed consent). Many applications have arrived with the file name "IRB app" resulting in delays and the increased likelihood that applications will not be properly identified and filed.

Note: Do not begin your research (including contacting potential research subjects) until you are notified that your application has been approved by the IRB, which will take at least four weeks. If you have questions, consult the Human Subjects Research Policy on the Lesley web site at http://www.lesley.edu/provost/institutional-review-board/. If you have further questions, contact an IRB representative, the Chairs of the Committee.

Informed Consent letters used in the study should be submitted along with the application. Interview protocols, questionnaires, observation protocols, and other materials that might be of assistance to the Committee in making its determination should be attached as well. Any studies that involve the use of pharmaceuticals or medical devices or procedures should immediately contact the Committee – additional approvals as required by Federal regulations may be necessary.

The following pages provide (1) a further guide to determining whether a proposed project may qualify for exempt status and (2) a lengthy guide to preparing letters of informed consent.

Worksheet for consideration of Exempt Research

Does the study meet the following criteria?

YES	NO	Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular of special educational instructional strategies, or the relative effectiveness of instructional techniques, curricula, or classroom management techniques. *45CFR46.101(b)(1)*
YES	NO	Research involving the collection or study of *existing data*, documents, records. *Existing Data: means that all the data, documents or records are in existence prior to IRB Review.* And, these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects. *45CFR46.101(b)(4)*
YES	NO	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, and information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects, nor place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation. *45CFR46.101(b)(2)*

If you answered yes to at least one item above, the protocol **will potentially qualify** for exempt approval.

However, Does this study involve?

YES	NO	Interactions, surveys or interviews involving minors?
YES	NO	Pregnant women or prisoners?
YES	NO	Any procedures that may cause a subject either physical or psychological discomfort or are perceived as harassment above and beyond what the person would experience in daily life?
YES	NO	Deception?

If you answer yes to any of these four items, the protocol **will not qualify** for exempt approval. *45CFR46.101(h)*

Please answer the following questions to the best of your ability.

YES	NO	Is the probability of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?
YES	NO	Is the magnitude of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life, or during the performance of routine physical or psychological examinations or tests?

If you answer yes to either question above the study **will not qualify** for exempt approval. *45CFR46.102(i)*

Guide to the Preparation of Letters of Informed Consent

1. Title: Descriptive title.

2. Principal Investigator: Include name of Principal Investigator and other researchers as appropriate with their contact information and institutional or program affiliations. This includes the faculty principal investigators supervising research carried out by students (including doctoral and masters).

3. Sponsor: If the study is funded, include the sponsor's name.

4. Description and Purpose: (Required in all consent forms). May be one or more sections; modify heading(s) as appropriate.

This part of the consent form must include:

- A statement that potential subjects are being asked to volunteer for a research study;
- An explanation of why the subject is being asked to volunteer;
- A clear explanation of the purpose of the research;
- The expected duration of the subject's total participation;
- The approximate number of subjects to be enrolled in the study at Lesley University and elsewhere. (This information is only required when the number of subjects is material to the person's decision to participate; e.g., small sample size might compromise anonymity.)

5. Procedures: (Required in all consent forms)

a) A description and explanation of the procedures that will be performed on the subject, e.g., filling out questionnaires, being interviewed, being audio or videotaped, engaging in role-playing or performing computerized experiments.

b) A full explanation of all responsibilities and expectations of the subject. Be sure to communicate the following:

- All of the different people with whom the subject will interact.
- Where the research will be done.
- When the research will be done.
- How often the procedures will be performed.
- How much of the subject's time will be involved in each session and the number of sessions.

6. Risks: (Required in all consent forms)

a) A description of any possible discomforts or **risks** that may exist. Explain how **anonymity** will be assured if that is a potential problem. Explain what will happen to data collected, including any video or audio recordings, once the study is completed.

This section should include a statement that the research may not provide any benefit to the subject. Any benefits to the subject or others that can be expected should be described in a way that is not coercive, enticing, or self-serving. Benefit to society is appropriate. Do not refer to financial compensation in this section.

The following is acceptable wording for this section:

Participation in research is voluntary. You have the right to refuse to be in this study. If you decide to be in the study and change your mind, you have the right drop out at any time. You may skip questions. Whatever you decide, you will not lose any benefits to which you are otherwise entitled.

b) If your study does involve any risk of physical harm to subjects, the following statement shall be included on the consent form:

If you are injured during the course of the study and as a direct result of this study, you should contact the investigator at the number or e-mail address provided. Although compensation is not available, Lesley University will assist you in obtaining medical treatment, including first aid, emergency treatment, and follow-up care as needed. Your insurance carrier should be billed for the cost of such treatment. If your insurance carrier denies coverage, Lesley University is under no obligation to pay for the treatment but may do so at its discretion. By providing financial or other assistance, neither Lesley University nor the researchers are stating that they are legally responsible for the injury.

7. Confidentiality, Privacy and Anonymity: (Required in all consent forms)

The following is acceptable wording for this statement, but this wording can be modified as appropriate:

You have the right to remain anonymous. If you elect to remain anonymous, we will keep your records private and confidential ***to the extent allowed by law****. We will use numerical identifiers rather than your name on study records. Your name and other facts that might identify you will not appear when we present this study or publish its results.*

If for some reason you do not wish to remain anonymous, you may specifically authorize the use of material that would identify you as a subject in the experiment.

The consent form should end with statements similar to the following:

We will give you a copy of this consent form to keep.

Both the investigator and the subject should keep a copy of the signed form.

8. Signatures and names: (Required in all consent forms)

a) **Investigator's Signature**:

_____	_____	_____
Date	Investigator's Signature	Print Name

b) **Subject's Signature**:
I am 18 years of age or older. The nature and purpose of this research have been satisfactorily explained to me and I agree to become a participant in the study as described above. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise during the course of the research.

_____	_____	_____
Date	Subject's Signature	Print Name

If needed:

_____	_____
Date	Signature Parent/Guardian or Legally Authorized Representative	Print Name

(This line is required only if the subject is not able to consent for herself or himself).

c) We suggest that you add this paragraph at the bottom of the form:
There is a Standing Committee for Human Subjects in Research at Lesley University to which complaints or problems concerning any research project may, and should, be reported if they arise. Contact the Committee Chairperson at irb@lesley.edu.