Education of Investigators, IRB Members and other Relevant Personnel with Regards to Human Subjects Research

The IRB Chair, Human Protection Administrator and Signatory Official, and IRB personnel will familiarize themselves with 45 CFR, Subtitle A, Part 46 and the Belmont Report.

For the purposes of the Department of Health and Human Services Federal Wide Assurance of Protection for Human Subjects, the following groups or individuals are designated:

IRB – The Institutional Review Board

The IRB shall have at least five members who constitute the Research Ethics Committee at Lehigh Carbon Community College. The members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

- The members of the IRB for Lehigh Carbon Community College are:

  Marco Anglesio, Chair
  Dr. Andrea Friedman
  Erik Csikos
  Fae Schrack
  Dr. Hazel Carrera

Human Protections Administrator

Also known as the Human Subjects Administrator or the Human Subjects Contact Person – cannot be IRB Chairperson.

Name: Dr. Andrea Friedman
Title: Associate Professor of Sociology
Email: afriedman@lccc.edu
Phone: 610-769-1338

The Human Protections Administrator has completed Human Subjects Assurance Training

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Signatory Official

The Official Legally Authorized to Represent the Institution – cannot be IRB Chairperson or IRB member.

Acting officially and in an authorized capacity on behalf of this institution, the signatory official assures protections for human subjects.

Name: Larissa Verta
Title: Vice President for Academic Services and Student Development
Email: lverta@lccc.edu
Phone: 610-799-1877

Ethical and Procedural Guidelines

Human Subjects Research at the College is guided by the ethical principals laid out in The Belmont Report and procedures described in 45 CFR, Subtitle A, Part 46.

Procedures for Review of Proposals for Human Subjects Research

The types of research requiring review are outlined in the directions for Submission of Human Subjects Research for Approval by the Institutional Review Board at Lehigh Carbon Community College.

Exempt Research

It is expected that most research performed at the college will be exempt from review. This determination will be made by the IRB Chair after reviewing IRB Form 1 as submitted by the researcher. This determination will generally be made within 2 weeks of submission of the research for approval.

Types of research that do not require review include (see 45 CFR, Subtitle A, Part 46.101b for a more complete listing):

a. 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.
b. 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; or
    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.
    iii. the human subjects are minors.
c. 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. All decisions to exempt a proposed research project from review go, in writing, to the Vice President.

Expedited Review

It is expected that almost all research at Lehigh Carbon Community College that is not exempt from review will qualify for expedited review. Expedited review is used for research that presents no more than a minimal risk (*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) to human subjects and involve only procedures that fall into the following categories (a more detailed list is given in 45 CFR, Subtitle A, Part 46.110):

a. Collection of data from voice, video, digital or image recordings made for research purposes;
b. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.). Some research involving surveys or interviews of children must be submitted for full review. See IRB Form 2, Part B, 4 b for guidelines).
c. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Expedited reviews will be performed by the chair of the IRB and at least one other member of the IRB, at the discretion of the chair. An expedited review is usually accomplished within two weeks of application. All expedited reviews go to the Vice President for a final signature.

Full IRB Review

Full IRB review is necessary when the research involves any of the following:

a. Prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively impaired adults as subjects;
b. The subjects are under the age of 18 and the research does not meet the guidelines for expedited review (see IRB Form 2, Part B, 4 b).
c. The collection or recording of behavior which, if known outside of the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing to the subject;
d. The collection of information regarding sensitive aspects of the subject's behavior such as drug or alcohol use, illegal conduct, or sexual behavior;
e. Research that does not fall into any of the categories defined as exempt in 45 CFR, Subtitle A, Part 46.110.

Full IRB reviews will be performed by all members of the IRB. A full review is usually accomplished within three weeks of application.

If the research is approved, written verification of the approval will be sent to the researcher and to the Vice President for Academic Services and Student Development. The Vice President for Academic Services and Student Development will keep this approval on file for at least three years. Any other outcome of the review process will also be given in writing to the researcher.

Outcomes of the Review Process

For proposals reviewed by the IRB, three outcomes are possible:

Approved:

A protocol which has been approved by the IRB requires no further action from the investigator prior to initiating the study. If the study should extend beyond 12 months, the investigator should send a letter to the IRB chair, informing her/him of the current status of the project, any changes in the protocol, and whether any adverse events have occurred.

Revise and Resubmit:

A protocol that has been deferred by the IRB usually requires that additional information be submitted to the IRB prior to approval. A revised application should be submitted to the IRB clarifying the issues involved or providing the requested documentation. The IRB will review the revised application at its next meeting.

Denial:

A protocol that has been denied approval by the IRB cannot be initiated by the investigator. The reasons for the denial are provided in writing. The investigator will be given the opportunity to respond either in writing or in person at the next meeting of the IRB.

If the research is approved, written verification of the approval will also be sent to the Vice President for Academic Services and Student Development and to the researcher. The approval will be kept on file for at least three years. Any other outcome of the review process will also be given in writing to the researcher.

Procedures for Continuing Oversight of Ongoing Research

If the research goes on for more than one year, approval by the IRB must be obtained at least annually, though high-risk procedures may require more frequent review. The re-approval may be obtained through expedited review if no significant changes have been made to the protocol, at the discretion of the chair of the IRB.

General Issues:

Anyone who plans to do research that involves human subjects should first review the procedures and guidelines as laid out in this document.

Procedures followed by the IRB are outlined in the Lehigh Carbon Community College IRB Procedures for Approval of Human Subjects Research.

For the context of this document "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 CFR, Subtitle A, Part 46.102d.

Types of research that require review include:

a. Both funded and un-funded research;
b. Pilot studies;
c. Class projects that involve human subjects.
d. Independent research performed by faculty, students, or staff.

All research involving human subjects must be reviewed annually at the minimum. Some research may require more than annual review.

If research requires IRB approval, two copies of IRB Form 2 should be submitted to the IRB Chair.

Types of research that do not require review include: (see 45 CFR, Subtitle A, Part 46.101b for a more complete listing):

a. 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.
b. 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; or
    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; or
    iii. the human subjects are minors.
c. 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.

If your research does not require IRB approval, submit IRB Form 1 to the IRB Chair.

If it is not clear if review is necessary, the proposed research should be discussed with the IRB Chair.

Guidelines for Human Research at Lehigh Carbon Community College

1. Research on Human subjects shall follow the Code of Federal Regulations 45 CFR, Subtitle A, Part 46, Protection of Human Subjects as most recently amended, and should be guided by the principles laid out in The Belmont Report. For non-invasive experiments special attention should be placed on the sections in 45 CFR, Subtitle A, Part 46 on minimization of risk to the subjects and informed consent procedures. These regulations do not pertain to activities relating to students within the context of an academic course. Activities by students enrolled in a course which involve subjects outside the course may, however, be subject to review if funded by the U.S. Government or if requested by the Vice President for Academic Services and Student Development of Lehigh Carbon Community College.
2. Subjects should not normally be placed in emotionally stressful situations. If such stress is deemed essential to the experiment, adequate provision must be made for rapid termination of the experiment at the subject's request. The informed consent form to be signed by all subjects shall explicitly describe how the subject may withdraw from the experiment at any time and for any reason without penalty. A copy of the form must be given to the subject. In all experiments a mechanism shall be provided by which the subject may anonymously comment on their experience in the experiment if they so desire. (At least two contacts must be given; the Vice President for Academic Services and Student Development's office or the IRB would be appropriate avenues.)
3. Subjects' participation must be voluntary; their participation and performance should not be linked to participation in a college course either directly or by implication. (For example, the faculty member performing the research might be a reader on a thesis committee or in some other way cause the student to believe it would be to their advantage to participate in the experiment.)
4. The experimenter should maintain privacy of the subjects' records. In most cases data should be coded and the subjects' names or SS numbers removed from the records and destroyed. Subjects' names or other identifiers should not be published in any report of work performed for either internal or external publication without the express, written permission of the subject. There should be no file of identifying names or numbers that would permit the association of responses or results with subjects which is maintained beyond the duration of the experiment.

If it is necessary to retain the name of the respondent, then there must be some other assurance of protection of privacy. The proposal should identify a specific date by which all relevant identifying information will be destroyed and the College informed of this action in writing. Privacy considerations include work in which the subject is only measured or photographed and work in which subjects only respond to a questionnaire (but see questionnaires sent by mail, below.)

The College IRB does not grant approval for experiments performed at other institutions although the IRB will make suggestions after reading a proposal. Responsibility for protection of subjects at other institutions must be borne by the other institution.

As a general matter, the IRB does not deal with questionnaires sent through the mail as the College is not responsible for the content of the mails. (Anyone has the right to send a student a questionnaire in the mail.) The IRB does, however, deal with cases in which human subjects are interviewed at the College and cases in which funding for the project is provided by U.S. Government or its agencies, (i.e., approval is required as part of the application process).

If individuals outside the College propose to perform experiments or administer questionnaires other than by mail, they must request permission from the Vice President for Academic Services and Student Development's office. The Vice President for Academic Services and Student Development then forwards the proposal including all protocols, informed consent forms, questionnaires and other documentation to the IRB for review. The IRB sends the results of its review to the Vice President for Academic Services and Student Development for use in his or her decision to grant permission for the study.

Currently, the NIH training for IRB costs approximately $39.99. The Office of Vice President of Academic Services and Student Development will reimburse any LCCC affiliated faculty/staff for completing this training. Any other IRB training which is conducted within 2 years can also be submitted in place of the NIH human subject research training certificate for IRB. Please consult with IRB Chair at manglesio@lccc.edu for specific information pertaining to this requirement. The link to this training is provided in forms 1 and 2 below.

IRB Form 1

Checklist for Human Subjects Research That Is Exempt From IRB Review

Before performing Human Subjects Research at Lehigh Carbon Community College you must read and understand Lehigh Carbon Community's Guidelines for Human Subjects Research.

In addition to this form, kindly provide a brief description of the research and how the data will be collected. Where applicable, a copy of the letter of informed consent along with a copy of any survey or interview instrument to be used should also be included.

Name of Principal Investigator: _____

Title of Principal Investigator: _____

Title of Research Project: _____

Signature of Principal Investigator: _____

Date: _____

If this is a student research project, then it requires a faculty or staff sponsor. The sponsor is required to complete the National Institutes of Health (NIH) training on human subjects. Following is the link to access the NIH training on human subjects:
https://phrp.nihtraining.com/#!/login

An application will be considered incomplete if the certificate of completion of NIH training on human subjects is not attached to it.

Name of Sponsor: _____

Title of Sponsor: _____

Signature of Sponsor: _____

Date: _____

IRB Form 1

Use the following checklist to ensure that your research is exempt from IRB review:

__ 1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

___2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

___ 3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

___ 4. The research does not involve subjects under the age of 18, **except** as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B. Category B 2 studies that include minors should be submitted for expedited or full review (see IRB Form 2, Part B, 4 b, for guidelines).

___ 5. The research does not involve deception.

___ 6. The procedures of this research are generally **free of foreseeable risk** to the subject.

___ 7. The research does not require a waiver from informed consent procedures.

Part B (at least one item should apply). Put a check mark near all items that apply to your research.

__ 1. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on 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, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). [NB: All survey/interview/ observational research in which elected or appointed public officials or candidates for public office serve as subjects is exempt, whether or not data collection is anonymous.]

__ 3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

___4. Research (including demonstration projects) conducted by or subject to the approval of federal department or agency heads, and designed to study, evaluate, or otherwise examine (i) public benefit or service programs (e.g., social security, welfare, etc.); (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.

___5. Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives, or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the U.S. Department of Agriculture.

IRB Form 2

Application for Review of Human Subjects Research at Lehigh Carbon Community College

Before performing Human Subjects Research at Lehigh Carbon Community College you must read and understand Lehigh Carbon Community College's Guidelines for Human Subjects Research.

Please submit 2 copies of the following to the IRB Chair.

- A copy of this document with the information about the principal investigator and research project filled out and the check lists completed.
- A brief description of your research project.
- A description of the aspects of the research involving Human Subjects.
- A copy of any consent forms. These forms must have an expiration date of no more than one year from the beginning of the project.
- The National Institutes of Health (NIH) certificate of completion of human research participants training should be attached with the IRB application. Following is the link to complete the training: https://phrp.nihtraining.com/#!/login

If the project goes on for more than one year, a new application must be submitted.

Name of Principal Investigator: _____

Title of Principal Investigator: _____

Title of Research Project: _____

Duration of Research Project: _____

Signature of Principal Investigator: _____

Date: _____

If this is a student research project, then it requires a faculty or staff sponsor.

Name of Sponsor: _____

Title of Sponsor: _____

Signature of Sponsor: _____

Date: _____

Complete the following checklists to determine if you believe your research should qualify for expedited review:

This research does qualify for expedited review: _____

This research does **not** qualify for expedited review: _____

Expedited Review

Part A (all items must apply) Put a check mark near all items that apply to your research.

__ 1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

___2. The research does not involve children as subjects or, if it does involve children as subjects, the research can be dealt with via expedited review as specified in Part B 4 b below.

__3. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

__ 4. The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

__ 5. The procedures of this research present **no more than minimal risk** to the subject. ("Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Part B (at least one item should apply). Put a check mark near all items that apply to your research.

__ 1. Research involving *existing identifiable data*, *documents*, *records, or biological specimens* (including pathological or diagnostic specimens), where these materials, in their entirety, *have been collected prior to the research* for a *purpose other than the proposed research*. [NB: These sources are not publicly available and, although confidentiality will be strictly maintained, information will *not be recorded anonymously* (e.g., use will be made of audio- or videotapes, names will be recorded, even if they are not directly associated with the data).]

__ 2. Collection of data through use of the following procedures: a) *non-invasive procedures* routinely employed in clinical practice and not involving exposure to electromagnetic exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.); b) *physical sensors* that are applied either to the surface of the body or at a distance and *do not involve input of significant amounts of energy* into the subject or an invasion of the subject's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography,

sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects.

__ 3. Collection of *data from voice, video, or image recordings* made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

__ 4. Research on *individual* or *group characteristics* or *behavior* (including but not limited to research involving *perception*, *cognition*, *surveys*, *interviews,* and *focus groups*) as follows:

a) Involving adults, where (i) the research *does not involve stress to subjects*, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability. or reputation;
b) *Involving children*, where (i) the research involves *neither stress* to subjects *nor sensitive information* about themselves or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

__ 5. Research involving the *use of educational tests* (cognitive, diagnostic, aptitude, achievement), *survey procedures*, *interview procedures,* or *observation of public behavior*. [NB: Although confidentiality will be strictly maintained, *information will not be recorded anonymously* (e.g., use will be made of audio- or videotapes, names will be recorded, even if they are not directly associated with the data).]

__ 6. Research that involves deception. [NB: Deception must be scientifically justified and de-briefing procedures must be outlined in detail.]

__ 7. Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.

__ 8. Research *previously approved by the IRB* as follows: (a) 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 (b) where the research remains *active* only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; (d) where no subjects have been enrolled and no additional risks have been identified.

Full Committee Review

If ANY of these apply. Put a check mark near all items that apply to your research.

__ 1. The research involves *prisoners*, *fetuses*, *pregnant women*, the *seriously ill,* or *mentally* or *cognitively compromised adults* as subjects.

__ 2. The research involves the *collection or recording of behavior which, if known 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.*

__ 3. The research involves the *collection of information regarding sensitive aspects* of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

__ 4. The procedures of the research involve **more than minimal risk to the subject** (where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

__ 5. Any research which does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

__6. The research involves *children under the age of 18* as subjects.

Resources:

Swarthmore College, Institutional Research websites

Bloomsburg University, Institutional Research websites

Capella University, Institutional Research websites

Code of Federal Regulations, TITLE 45, PUBLIC WELFARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46, PROTECTION OF HUMAN SUBJECTS retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Belmont Report retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

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