Lehigh Carbon COMMUNITY COLLEGE

Lehigh Carbon Community College
Institution Review Board

Record and Review of Research Protocol

Researcher: _____
(Last) (First) (Middle Initial)

Email: _____

Student ID: _____

Research Advisor/
Co Investigator: _____

Email: _____

Academic Level

☐ 1. Undergraduate Project
☐ 2. Other: _____

Affiliation

☐ 1. LCCC Student
☐ 2. LCCC Faculty
☐ 3. LCCC Administration/Staff
☐ 4. Affiliation other than LCCC: _____

Forms Check List

☐ 1. Training Certificate*

*Check with your research advisor for training requirements
*Training certificate cannot be older than three years

There is a training program that everyone must go through as part of this process. At this link, you will find five training modules: https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html
After completion of the five modules, submit pdf copies of the certificate of completion with this paperwork.

☐ 2. Consent Forms or Invitations
☐ 3. Instrument(s)
☐ 4. Internal and/or External Research Approval Letter
☐ 5. Other: _____

This section is to be completed by the LCCC IRB Committee

Archive Number: _____

Research Category: Select an item

Final Approval Date: _____

Project Information

Working title of study:

Concise problem, problem of practice, or purpose statement (one paragraph):

Research purpose; include key literature citations and information:

External Research

If the research will involve other organizations, it is necessary to obtain permission from these organizations prior to collecting data. Some organizations have Institutional Review Boards (IRBs), and it may be necessary to obtain formal approvals from these IRBs. In other cases, a document from an appropriate organizational executive specifically approving the research would be sufficient. The researcher is responsible for determining what type of approval is required and obtaining the approval.

In cases where approval from Lehigh Carbon Community College's IRB is required as a precondition to obtaining approval from another organization, the IRB's approval will be provisional, requiring the additional step of obtaining research approval documents from other organizations before receiving full approval from Lehigh Carbon Community College's IRB.

	YES	NO
Does this research involve other organizations?	☐	☐

If the research involves other organizations, please answer these questions.

	YES	NO
Do these organizations require approval by their IRBs?	☐	☐
Has IRB approval been obtained? If **YES**, please attach the approval to this submission	☐	☐
Have other permission documents been obtained? If **YES**, please attach the approvals to this submission.	☐	☐

Other relevant information or comments:

Internal Research

If the research will involve collecting quantitative (including survey) and/or qualitative data from Lehigh Carbon Community College, its students, or employees, it is necessary to obtain permission from the College. The appropriate LCCC IRB Committee will render consideration of permission for the research via the IRB Research Request process. The approval email (document) must be attached to this protocol submission.

	YES	NO
Does this research involve collecting Lehigh Carbon Community College data?	☐	☐

*If **YES**, please attach the approval email to this submission.*

Population Information

Population to be studied: Gender _____ Age _____ Race/ethnicity _____

What is the anticipated sample size?

How will participants be recruited?

What inclusion criteria will be used to identify the sample's participants?

What criteria will be used to exclude participants from the sample?

How will participants be selected?

What are the procedures the participants will undergo in the proposed research project including the physical location and duration of participation?

Describe where the research instruments are derived; if self-created, explain the vetting process, pilot, panel of experts, etc., if using a validated tool, explain its origin, authors, and attach acquired permissions (email or letter).

Attach a copy of all research instruments, e.g., surveys, questionnaires, interview questions.

Confidentiality and Security

Select **YES** to certify that:

	YES	N/A
Procedures have been taken to ensure that individuals cannot be identified via names, digital identifiers (e.g., email address, IP address), images or detailed demographic information.	☐	☐
Code to name association data/information is securely and separately stored. (Participants are given codes and the codes are securely stored separately from their answers.)	☐	☐
All data is maintained in encrypted and/or password protected digital/electronic files. Records retention/encryption instructions process.	☐	☐
Individually identifiable information will be securely maintained for three years past the completion of the research, and then destroyed rendering the data unusable and unrecoverable.	☐	☐

Describe the procedures you are taking to maintain anonymity, confidentiality, or information security.

Research Protocol

Does this research involve?

	YES	NO
Prisoners, probationers, pregnant women (if there is a medical procedure or special risk relating to pregnancy), fetuses, the seriously ill or mentally or cognitively compromised adults, or minors (under 18 years) as participants	☐	☐
The collection of information regarding sensitive aspects of the participants behavior (e.g., drug, or alcohol use, illegal conduct, sexual behavior)	☐	☐
The collection or recording of behavior which, if known outside the research, could place the participants at risk of criminal or civil liability or could be damaging to the participant's financial standing, employability, insurability, or reputation	☐	☐
Procedures to be employed that present more than minimal risk[1] to participants	☐	☐
Deception – include a debriefing script.	☐	☐
Possible or perceived coercion (e.g., a concern in power relationships such as teacher/student, employer/employee, senior/subordinate)	☐	☐
Benefits or compensation to participants (beyond the general benefits of the knowledge to be gained or small gifts/lottery prizes). Cannot offer extra credit without offering an alternative assignment.	☐	☐
A conflict of interest/grant funded research (e.g., the researcher's material or other interests may bias collection, interpretation, or use of data)	☐	☐

If you answered "**NO"** to all of the questions, please proceed to the next page.

If you answered "**YES"** to any of the questions, provide evidence that you have taken the training module(s) that relate to this risk and discuss what you learned about reducing the risk or mitigating bias from the training in the textbox below and/or by attaching the evidence to this document.

[1] 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 everyday life or during the performance of routine physical or psychological examinations or tests

Consent Forms

	YES	NO
Is a consent form included with this study? If **YES**, attach a copy.	☐	☐
Are child assent forms included with this study? If **YES**, attach a copy.	☐	☐
Is implied consent being used? If **YES**, attach a copy of the invitation.	☐	☐

Minors must provide an affirmative consent to participate by signing a simplified form, unless the researcher can provide evidence that the minors are not capable of assenting because of age, maturity, psychological state, or other factors.

Please refer to the informed consent outline and checklist and the assent outline, which can be found in the Human Subjects Review Committee section of the Lehigh Carbon Community College website.

Implied consent – For some exempt or expedited research, it is not necessary to have a signed consent form. For example, a relatively short survey of competent adults which is anonymous and deals with noncontroversial topics could use a less formal means of providing information. In such cases, the person's voluntary participation indicates implied consent. Typically, the invitation to participate would be less legal in tone than a consent form but would provide information about the researcher, study purpose, voluntary participation, nature/duration of participation, and anonymity/confidentiality.

How is consent being obtained?

Obligations of Researcher

Any substantive changes made to the research protocol must be reported to and reviewed by your college's IRB representative(s) prior to implementation of such change. Any complications, adverse reactions, or changes in the original estimates of risks must be reported at once to the HRSC chairperson before continuing the project.

Select **YES** to certify that:

	YES
Research data, including signed consent form documents, will be retained for a minimum of three years past the completion of the research in accordance with federal regulations	☐
The researcher will submit document and form revisions and updates, as appropriate. If anything changes in protocol, you MUST notify the IRB committee.	☐
The researcher will submit a renewal petition if the data collection has not been completed within one year of the most recent IRB approval*	☐

* **Note**: IRB approval expires after one year, requiring renewal of the IRB Protocol

The researcher's signature below certifies that the Researcher has (a) read and understands the obligations as a researcher, (b) research approval expires one year after the final approval date shown on page 1, and (c) that the information contained in and submitted with this IRB protocol is accurate and complete.

Researcher:

Print name: _____

Signature: _____ Date: _____

Obligations of the Research Advisor

The research advisor has two major obligations. First, the research advisor must ensure the researcher completes all relevant training courses. Second, the research advisor must ensure the researcher submits all document and form revisions and updates, as appropriate for the research.

The research advisor's signature below certifies that the advisor has (a) read and understands the obligations as an advisor and (b) that the information contained in and submitted with this IRB protocol is accurate and complete.

Research Advisor:

Print name: _____

Signature: _____ Date: _____

*Research advisor's CITI certificate expiration date: _____

PROTOCOL REVIEW

This section is to be completed by the HSR Committee.

Researcher: _____

Date Submitted: _____

The protocol and attachments were reviewed:

The proposed research is approved as:

☐ Exempt ☐ Expedited ☐ Full Committee

☐ Provisional (see External Research section) Provisional Date: _____

The proposed research was approved pending the following changes:

☐ See attached letter

☐ Resubmit changes to the IRB chairperson

The proposed research was disapproved:

☐ See attached letter for more information.

IRB Chair
or Representative _____
Printed Name

_____ _____
Signature Date

IRB Chair
or Representative _____
Printed Name

_____ _____
Signature Date

References