

**Expedited Human Subjects Protocol Form**

The federal regulations provide for certain types of research involving no more than minimal risk to be reviewed by means other than the full IRB. Under an expedited review procedure, the review will be carried out by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB.

Principal investigators will follow the [Expedited Human Subjects Protocol Guidelines](https://www.cscc.edu/employee/our-college/irb/irb-forms.shtml) and submit to the IRB administrator (irb@cscc.edu) this completed Expedited Human Subjects Protocol Form, along with the associated documents. This form must contain all required digital or wet ink signatures.

**Additional Documents to be included with this completed form:**

Refer to the [Expedited Human Subjects Protocol Guidelines](https://www.cscc.edu/employee/our-college/irb/irb-forms.shtml) for detailed descriptions of the items listed below

* Protocol narrative
* Consent documents, including minor assent and parental consent documents if applicable
* All surveys, interview or focus group questions, and other testing instruments or data collection tools; including informational letters or scripts
* Recruitment materials
* Evidence of completion of the Social/Behavioral Research Investigator course within the past two years via [CITI](https://about.citiprogram.org/en/homepage/) (Collaborative Institutional Training Initiative); any PI/Co-PI/Sub Investigator must be trained in human subjects protection; the training is free to Columbus State employees
* Multi-site and collaborative research – contact the IRB administrator about the possibility of a reliance agreement with the IRB of an external institution
* For those completing doctoral dissertation research - IRB approval letter from the external institution
* Letters of support from outside institutions or entities that are allowing recruitment, research, or record access at their sites (if applicable)
* Grant proposal (if applicable)

 **Date:** Click or tap to enter a date. **Log # (IRB use):** Click or tap here to enter text.

**Title of Research Project:** Click or tap here to enter text.

**Projected Dates of Research:**Start Date: Click or tap to enter a date. End Date: Click or tap to enter a date.

**Principal Investigator and Research Team:**

Principal Investigator/Project Director: Click or tap here to enter text.CSCC Department or Other Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

Doctoral or Other Academic Advisor (if applicable): Click or tap here to enter text.

Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

Those who have a significant role in the research project (participate in the design, conduct, and reporting of the research):

Co-Principal Investigator/Project Director: Click or tap here to enter text.

CSCC Department or Other Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

Co-Principal Investigator/Project Director: Click or tap here to enter text.

CSCC Department or Other Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

Those who assist in the research project (recruit participants and collect study data):

Sub Investigator: Click or tap here to enter text.

CSCC Department or Other Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

Sub Investigator: Click or tap here to enter text.

CSCC Department or Other Institution: Click or tap here to enter text.
Email: Click or tap here to enter text.

External evaluators for externally grant funded research projects:

External Evaluator: Click or tap here to enter text.

Organization: Click or tap here to enter text.
Email: Click or tap here to enter text.

External Evaluator: Click or tap here to enter text.

Organization: Click or tap here to enter text.
Email: Click or tap here to enter text.

**Collaborators** (list any other organizations/agencies involved in the research project):

Click or tap here to enter text.

**Project Funding Source** (select all that apply)**:**

[ ]  External Grant (provide sponsor name): Click or tap here to enter text.

 Date proposal submitted: Click or tap to enter a date.

[ ]  Columbus State Grant (provide title of grant): Click or tap here to enter text.

 Date proposal submitted: Click or tap to enter a date.

[ ]  Non-funded Research

[ ]  Other (please specify): Click or tap here to enter text.

*If grant funded, provide a copy of the grant proposal to the IRB either with this application or as soon as it is available.*

**Project Information** (provide a response for A-G)**:**

1. This research project involves Columbus State Community College **students**

 [ ]  Yes [ ]  No

This research project involves Columbus State Community College **employees**

 [ ]  Yes [ ]  No

1. Human Subjects from the following populations will be involved in this research project:

[ ]  Adults unable to consent/Cognitively impaired

[ ]  Minors (specify exact age range): Click or tap here to enter text.

[ ]  Prisoners or other detained individuals

[ ]  None of the above

1. Total number of research subjects to be studied: Click or tap here to enter text.
2. Procedures Involved (select all that apply):

[ ]  One-on-one interviews

[ ]  Focus groups

[ ]  Questionnaires/surveys

[ ]  Analysis of secondary data (educational records, government or private sector datasets, etc.)

[ ]  Ethnographic observation

[ ]  Physiological measurements (e.g., EEG, EKG, MRI)

[ ]  Biospecimen collection (saliva samples, blood draws, hair samples, etc.)

[ ]  Mobile applications/data collection devices (e.g., Fitbits, etc.)

[ ]  Behavioral decision making tasks (e.g., puzzles, interactive games, etc.)

[ ]  Physical activities such as walking and other forms of exercise

[ ]  Other procedures (list types of procedures if not covered above): Click or tap here to enter text.

1. Request Waiver of Written Consent (justification required): [ ]  Yes [ ]  No
2. Request General Waiver of Informed Consent (justification required): [ ]  Yes [ ]  No
3. Request Alteration of Consent (justification required): [ ]  Yes [ ]  No

**Expedited Category** (select one):

Review the nine categories listed below and indicate the category that applies to your research.

[ ]  1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

1. Research on drugs for which an investigational new drug application is not required.
2. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

[ ]  2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
2. From other adults and minors, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

[ ]  3. Prospective collection of biological specimens for research purposes by noninvasive means.

[ ]  4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

[ ]  5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

[ ]  6. Collection of data from voice, video, digital, or image recordings made for research purposes.

[ ]  7. Research on individual or group characteristics or behavior (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 regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

[ ]  8. Continuing review of research previously approved by the convened IRB as follows:

1. 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
2. where no subjects have been enrolled and no additional risks have been identified; or
3. where the remaining research activities are limited to data analysis.

[ ]  9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Principal Investigator and Research Team Signatures:**

My signature indicates that I will respect and protect the rights and welfare of individuals enrolled in this research project. I will also carry out my responsibilities as outlined in Federalwide Assurance of Protection for Human Subjects, for which Columbus State is registered with OHRP/DHHS, and as detailed in the Columbus State IRB Standard Operating Procedures. I will be guided by the principles contained in the Belmont Report and The Code of Federal Regulations governing research with human subjects (45 CFR 46). I understand that any future changes to the research project will be submitted to the IRB, via Request for Modification, for review and approval prior to implementation. I also understand that any unanticipated problems or noncompliance must be reported to the IRB. *Digital or wet ink signatures are required for submission.*

Principal Investigator/Project Director Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signatures of all other research team members listed above (advisor, co-PI, sub investigator, external evaluator):**

Research Team Member Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Member Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Member Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Member Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Member Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Team Member Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Dean/Director Signature:**
My signature indicates that this project has been reviewed by the appropriate departmental parties, who have judged that 1) there is a scholarly and a scientific justification for the protocol, that the study is feasible, and that the proposed methods are scientifically valid, 2) that the department has made the space and time commitment necessary to carry out the project, 3) that the financial implications of the research have been considered and deemed acceptable to the department and 4) that all ethical principles have been appropriately addressed. *Digital or wet ink signature is required for submission.*

Dean/Director Typed Name: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FOR IRB USE ONLY
IRB Determination**

[ ]  Approved [ ]  Modification Required [ ]  Referred for Full IRB Review

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_