

**Full Human Subjects Protocol Form**

Research activities that pose greater than minimal risk, involve deception or vulnerable populations, or plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal) require full IRB review.

Principal investigators will follow the [Full 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 Full Human Subjects Protocol form, along with the associated documents. This form must contain all required digital or wet ink signatures.

Protocols for full IRB review must be submitted 10 days prior to the regularly scheduled IRB meeting.

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

Refer to the [Full 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

**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 [ ]  Disapproved

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