

**Exempt Human Subjects Protocol Form**

Research activities that pose no more than minimal risk in which the only involvement of human subjects will be in one or more of the categories listed below are exempt from full board review, but still require review by the IRB chair and/or a designee of the chair.

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

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

* Research project abstract – include summary of objectives and significance of the research, participants and recruitment procedures, study site, data collection and storage procedures, confidentiality, disposition of the data, research subject compensation or reward, potential risks and benefits to research subjects
* Informational letter or script and consent documents appropriate to the activity – include what the research involves, what the research subject will be expected to do, how the project will affect the research subject, compensation or reward, contact information of the principal investigator
* All surveys, interview or focus group questions, and other testing instruments
* Recruitment materials (if applicable)
* 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)
* For those completing doctoral dissertation research - IRB approval letter from the external institution

 **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.*

**Exempt Category** (select at least one category):
Review the six categories of exemption listed below and indicate the category or categories that apply to your research. The IRB reviewers, not the investigator, shall make the final determination as to whether a research project is or is not exempt.

**Research Involving Minors:** Exemption categories 1, 4, 5 and 6 may be applied to research involving minors if the conditions of the exemption are met. Category 2(a) and (b) only may apply to minors involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Category 2(c) may not be applied to research involving minors. In addition, the IRB shall determine that adequate provisions are made for soliciting the assent of the minors, when in the judgment of the IRB, the minors are capable of providing assent and that adequate provisions are made for soliciting the permission of each minor's parents or guardian.

**Research Involving Pregnant Women, Fetuses, or Neonates:** Each of these exemptions may be applied to research involving pregnant women, fetuses, or neonates if the conditions of the exemption are met.

**Research Involving Prisoners:** Each of these exemption categories do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

[ ]  1. Research, conducted in established or commonly accepted educational settings that involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

[ ]  2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review.

[ ]  3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review.
[**Note:** (1) To be eligible for this exemption, the research cannot involve deception; (2) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.]

[ ]  4. Research involving the collection or study of existing data sets, documents, records, or specimens, but only if these sources are publicly available **or** if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects. Alternatively, the research is exempt when information collection and analysis involves the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E; **or**, (d) research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501.

[ ]  5. Research and demonstration projects conducted by a federal department or agency designed to study or evaluate public programs, procedures for obtaining benefits or services under those programs, possible changes or alternatives to those programs, or possible changes in methods or levels of payment for benefits under those programs.

[ ]  6. Taste and food quality and evaluation and consumer acceptance studies, as long as safe, normal foods are being consumed, and federal guidelines regarding acceptable levels of agricultural chemical or environmental contaminants are adhered to.

**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). *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 Chair or Designee**

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

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