APPLICATION FOR HUMAN SUBJECTS RESEARCH PROJECTS

For IRB OFFICE Use Only:
Project Identification Number: Unit _____ Year_____ ID#_____
(e.g. CG, DO) (e.g. 2013) (e.g., 001, 002)

APPLICATION FOR HUMAN SUBJECTS RESEARCH PROJECTS
CCM Institutional Review Board

Project Director or Investigator: Phone:
Department:

Institution:

Project or Grant Title:

Project Status: ☐ New Project ☐ Revision to Previously Approved Project
☐ Periodic Review of Continuing Project

Project Start and End Dates to **Where will work be done:**

Project Type (Check the one that applies.)

☐ Faculty research
☐ Student research (under faculty direction)
☐ Student class project (under faculty direction)
If class project, list class/course no.

☐ Federal grant application
List source:
☐ Nonfederal grant application
List source:
☐ Thesis or dissertation
☐ Other, specify:

Does your project involve participants or individuals from any of these special/vulnerable populations? (Check all that apply.)

☐ Children under 18 years of age
☐ Individuals with intellectual disabilities
☐ Prisoners
☐ Economically disadvantaged
☐ Elderly
☐ Individuals with physical disabilities

Subjects Research Project/Study Checklist (Check as appropriate.)

	YES	NO	
1.	◯	◯	Does this project or study involve collection of data that identifies individuals (e.g., cohort databases include SSN# data on individuals, surveys, or interviews identifiable by name or student number etc.)?
2.	◯	◯	Will data identifiable by individual be shared with anyone (such as in a performance report for a funding source, conference presentations, published articles and reports, etc.)?
3.	◯	◯	Are the participants being offered one or more of the incentives to participate (such as money, extra credit for the class, etc.)? List the incentive(s) here:
4.	◯	◯	Is participation in this project or study voluntary for the individuals participating in the program or study?
5.	◯	◯	Will participants be fully informed about the benefits and any risks?
6.	◯	◯	Will participants be videotaped during the project or study?
7.	◯	◯	Will participants' privacy and personal information be protected? Briefly explain how privacy and information will be protected:
8.	◯	◯	Will participants be debriefed following completion of the project or study?
9.	◯	◯	Will participants, prior to the project, indicate informed consent to participate by completing and signing a written form? Sample is included? YES ◯ NO ◯
10.	◯	◯	Does the funding source have any potential for financial or professional benefit from the outcome for this study or project? If yes, please explain
11.	◯	◯	Are data sources clearly identified (such as interviews, survey, existing project data such as services received, reports, grades, existing school records, focus group, etc.)?

Check all that apply and estimate total number of individual participants in each relevant category about whom you will be collecting data on for your project or grant:

- ☐ College Students
- ☐ General Public
- ☐ Faculty
- ☐ Children and Youth under 18
- ☐ Staff
- ☐ Other (specify category and number)

Comments (optional):

I. Abstract Describing Project and Purpose: Briefly describe (a) the project or study and (b) what human participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used , design and program activities. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests, or other instruments are to be used, include a brief description and one copy of the instruments. **Note to Grant Projects Directors:** In the case of educational or training grants, data collected about the participants served, assessment testing, pre- and posttesting and other aspects of project evaluation plans are critical.

II. Methodology: Specify who the project participants or research subjects will be. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant or subject. Describe procedures to which individuals will be subjected. Use additional pages if necessary.

III. Voluntary Participation: Specify the steps that will be taken to insure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.

IV. Confidentiality of Data and Privacy Protection: Describe the methods to be used to safeguard the privacy of your participants and ensure the confidentiality of data obtained, including plans for publication, disposition and destruction of data, including that of computer, print, videotape, and audio materials.

V. Informed Consent: Attach a copy of all consent forms to be signed by the participants and /or any statements to be read to or provided to the participant.

To attach a file, go to Comment on Reader Tool Bar. Select ANNOTATIONS and click on the PAPER CLIP icon. Browse to locate your attachment and select OK.

VI. Risks to Participants: a) Describe any potential risks to participating individuals- physical, psychological, social, legal, or other; b) include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc.; and c) in research that proposes substantial risk to human participants, list emergency backup procedures that are in place such as medical or counseling interventions.

VII. Benefits: (a) Describe the benefits and/or any compensation that the participating individuals can expect and (b) describe the gains in knowledge that may result from the project or research study.

VII. Human Subjects Research Protection Exemption Categories: Federal law 45 CFR 46.10l(b) identifies the six (6) EXEMPT categories listed below using the language found in the legislation. *Check all that apply to your project or study and explain why your proposed project or study falls into the category.*

NOTE: The exemptions at 45 CFR 46.10 I (b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The exemption at 45 CFR 46.1 0 I (b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Special Note to Grant Project Directors:

In most cases, your grant projects are not what we traditionally think of as research studies. Nevertheless, the participant data, pre- and posttests of student learning, and other information you generate, compile, analyze, and report on in carrying out project activities and project evaluation are now considered Human Subjects Research by federal funding agencies. As you review the exemption categories listed below, think about the data you are collecting and reporting for the participants you serve and other data you will be using for project evaluation purposes.

☐ (1.) 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.

Please provide an explanation as to how your research falls into this category:

☐ (2.) 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; AND (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.

Please provide an explanation as to how your research falls into this category:

☐ (3.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Please provide an explanation as to how your research falls into this category_:

☐ (4.) 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.
Please provide an explanation as to how your research falls into this category:

☐ (5.) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: a) public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) possible changes in methods or levels or payment for benefits or services under those programs.
Please provide an explanation as to how your research falls into this category:

☐ (6.) Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods without additives are consumed orb) if a good is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspective Service of the U.S. Department of Agriculture.
Please provide an explanation as to how your research falls into this category:

Attachments: Attach all that apply to your proposal. (Check the ones you've included with proposal.)

- ☐ Informed Consent Form(s): first page(s) on letterhead
- ☐ External support proposal or award letter
- ☐ Letters of approval from cooperating entities
- ☐ Research methods (research design, data source, sampling strategy, etc)
- ☐ Questionnaires, surveys, or other data-gathering forms
- ☐ Letters, flyers, questionnaires, etc., that will be distributed to the study subjects
- ☐ Copy of thesis/dissertation, approved proposal, or prospectus
- ☐ If the research is part of a research proposal submitted for federal, state, or external funding, submit a copy of the FULL proposal

The information should be in sufficient detail to allow the IRB to determine if the study can be classified as EXEMPT under Federal Regulations 45 CFR 46.101(b).

Certification and Signatures

In making this application, I certify that:

1) I have successfully completed the IRB Required Tutorial.
2) I have read and understand the protocol and method of obtaining informed consent, as outlined by the CCM IRB Reference Document, and will follow them during the period covered by this research projects.
3) I intend to comply with the letter and spirit of CCM IRB Policies.
4) I agree to comply with federal, state, and local laws regarding the protection of human participants in research.
5) I will submit any future changes to the research project to the IRB for review and approval prior to implementation, as these may alter the exempt status of the project.
6) I agree that any new findings that develop during the course of this study that may affect the risks and benefits to participants will be promptly reported to the IRB in writing.
7) I agree that any adverse events that occur in the course of this study will be promptly reported to the IRB in writing.
8) I agree and understand that records of the participants will be kept for at least three (3) years after the completion of the research.
9) I may begin research when the IRB gives notice of its approval.

Signature of Principal Investigator: _____ Date :

Printed Name:

Co-Investigator (Name):

Approval by Faculty Sponsor (e.g., dissertation, thesis, special project). I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the supervision of human participants, and the maintenance of informed consent documentation as required by the IRB.

Signature of the Faculty Sponsor: _____ Date:

Printed Name:

Approval by the College or District (Department Chair, Dean, Vice President, Vice Chancellor, or Other Primary Administrator). I confirm the accuracy of the information stated in this application. I am familiar with and 1 approve of the procedures that involve human participants.

Signature of Department Chair, Dean, Vice President, Vice Chancellor or Other Primary Administrator:

_____ **Date:**

Printed Name:

SUBMIT

For IRB OFFICE Use Only:

This application has been reviewed by the CCM IRB as:

☐ Approved, Categories:

☐ Approved, Subject to Restrictions:

☐ Tabled (insufficient information for IRB to make a final decision)

☐ Disapproved:

Authorizing Signature:_____ Date:

Printed Name: