**Study Proposal Application**

**Catawba College Institutional Review Board: *Exempt Review Application***

**Section I: Research Study Overview**

1. **Name of Principal Investigator(s) (must be a faculty member):**
	1. **Names of any other investigators on this study proposal, including student investigators:**

**2. Date of submission:**

**3. Time span for the study:**

**4. The study is essentially a student project: Yes**[ ]  **No**[ ]

 **If Yes, the course for which the study will be submitted:**

 **If Yes, the name(s) of Student Investigator(s):**

**5. Funding source(s) for the study (if none, so indicate):**

**6. Title of study proposal:**

**Section II: Exempt Research Categories**

**Exempt reviews are conducted by at least one reviewer. To qualify for review at the exempt level, the research must not be greater than minimal risk\* and must fall into one or more of the exempt categories described below.**

**\*Minimal risk is defined by federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of healthy persons.**

1. Does your study include activities that would put individuals at more risk than their normal daily life (e.g., extreme physical exertion, asking details about traumatic experiences, identifying aspects of individuals that could create vulnerability in a specific situation)?

**Yes**[ ]  **No**[ ]

1. The research may not involve individuals who are cognitively impaired, prisoners, and sometimes children (under 18 years of age). Does your research focus on any of these classifications?

**Yes**[ ]  **No**[ ]

1. Will the research involve recording participant responses in the form of voice, video, digital or image recordings other than for one or more of the following?

● transcription of interviews/focus groups

● observation of public behavior

● recordings occurring as a part of normal educational practices

**Yes**[ ]  **No**[ ]

**The following categories of human subject research activities may be exempt from the requirement of the Federal Policy for the Protection of Human Subjects (45 CFR 46). Review the categories below and check the applicable statements under the category/ies that apply/ies to your research.**

2.1. ☐ **Exempt Category 1: Involving Instructional Research in Educational Settings**

☐ The research will be conducted in an established or commonly accepted educational setting;

**AND**

☐ The research involves 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 educational techniques, curricula, or classroom management methods.

2.2 ☐ **Exempt Category 2: Survey/Interviews; Standardized Education Tests; Observation of**

 **Public Behavior**

☐ The research does NOT involve children as subjects, when the research procedures include

interviews, surveys, or observations of public behavior with investigator participation in the observed activities; **AND**

☐ The research only includes interactions involving educational tests (cognitive, diagnostic,

aptitude, achievement), survey procedures, interview procedures, and/or observations of public behavior (including visual or auditory recording) if at least ONE of the following criteria is met:

☐ The information obtained is recorded by the investigator in such a manner that the

identity of the human subjects cannot readily be ascertained, directly, through identifiers linked to the subjects or indirectly through indirect identifiers (e.g., multiple demographics, etc.); **OR**

☐ 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.

 2.3. ☐ **Exempt Category 3: Public Officials; Surveys/Instruments, Education Tests, Observation of**

 **Public Behavior**

 ☐ The research is NOT exempt under Category 2 above; **AND**

 ☐ The research will involve the use of educational tests (cognitive, diagnostic, aptitude,

achievement), survey procedures, interview procedures and/or observations of public behavior; **AND**

☐ Research participants are elected or appointed public officials or candidates for public office,

**OR** federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

2.4. ☐ **Exempt Category 4: Existing Data; Records Review; Biospecimens**

☐ The research involves the collection or study of existing data, documents, records or

biospecimens; **AND**

☐ All materials used to conduct the research exist at the time of the IRB submission and no on-

going or prospective collection of material or data will occur; **AND**

☐ The identifiable private information or identifiable biospecimens are publicly

available; **OR**

☐ Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **AND**

 ☐ The research is **NOT VA** research and involves the review of existing medical records. **NO**

identifiers will be recorded for research purposes except for those described in a limited data set as defined by HIPAA. A limited data set includes “Elements of Dates” and “Geographic Codes” less specific than street address and are allowable in a HIPAA defined “Limited Data Set” with a “Data Use Agreement.” No codes derived from part of those elements will be recorded for research purposes, **OR** if protected health information (PHI) is reviewed, a waiver of HIPAA authorization to review PHI is requested and justified.

 2.5. ☐ **Exempt Category 5: Public Service Programs and Demonstration Projects**

☐ The project is a research or demonstration project; **AND**

☐ The project is conducted by or subject to the approval of department or agency heads.

(Department or agency head means the head of any federal department or agency and any other officer or employee of any department or agency to which authority has been delegated.); **AND**

 ☐ The project is designed to study, evaluate, or otherwise examine (i) public benefit or service

programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs; **AND**

☐ The program(s) under study deliver a public benefit (e.g., financial or medical benefit as

provided under the Social Security Act) or service (e.g., social, supportive, or nutritional services as provided under the Older Americans Act); **AND**

 ☐ The project is conducted pursuant to specific federal state authority; **AND**

☐ The project has no statutory requirements for IRB review; **AND**

☐ The project does not involve significant physical invasion or intrusions upon the privacy

interests of research participants; **AND**

☐ The project has an authorization or concurrence from the funding agency (Please upload a

copy of the authorization or concurrence if applicable).

2.6. ☐ **Exempt Category 6: Taste Testing and Food Quality Evaluation**

☐ The research involves taste and food quality evaluation or is a consumer acceptance study;

**AND**

☐ Wholesome foods without additives are consumed; OR a food is consumed that contains a

food ingredient at or below the level and for a use found safe, OR a food is consumed that contains an 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 Inspection Service of the U.S. Department of Agriculture.

**Section III: Study Description**

1. **Purpose of the study, stated clearly.**
2. **Include a brief summary of salient background information, what research issue is being addressed, the research purpose/hypothesis. Background literature with citations is required.**
3. **Describe the qualifications of the researchers to conduct this study.**
4. **Describe the study methodology, including data collection, management, analysis, storage, and elimination.**
5. **Describe *why* the use of human subjects is *necessary* for this study.**
6. *Example answer: Humans are needed to study this topic as the topic concerns humans because…*
7. **Describe the *benefits* to be gained by individuals and society.**
8. **Reference(s) for your intended procedures (including existing literature on this topic):**

**Section IV: Informed Consent Issues**

1. **Describe the method for obtaining INFORMED CONSENT:**
2. **Answer the following questions regarding Informed Consent**

**Participants are informed of their right to withdraw during the study** Yes[ ]  No[ ]

**Participants are informed of any consequences of declining or withdrawing from the study**  Yes[ ]  No[ ]

 **Participants are informed of the pertinent attendant risks** Yes[ ]  No[ ]

**Participant are informed about whom to contact for questions about the study and/or their rights.**

Yes[ ]  No[ ]

**The study requires disclosure of personal information** Yes[ ]  No[ ]

 **The study ensures data are kept confidential and secure?** Yes[ ]  No[ ]

 **A copy of "Informed Consent" Form is attached** Yes[ ]  No[ ]

 **All data collection tools are attached as appendices** Yes[ ]  No[ ]

**PI Signature(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**