| **Protocol Director:**       | **Protocol ID:**  |
| --- | --- |
| **Exemption Permitted** – if the only involvement of human participants will be in one or more of the following categories: *Complete only Category section(s) that apply.* |
|  **Category 1** |
| Research conducted in established or commonly accepted educational settings involving 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 | No [ ]  | Yes [ ]   |  **Category 1** **[ ]** OK if both “yes” |
| The research is on:**[ ]**  regular and special education instructional strategies, *Or* **[ ]**  the effectiveness of or the comparison among instructional  techniques, curricula, or classroom management methods  | No [ ]  | Yes [ ]   |
|  **Category 2** – Adult Population |
| The research involves the use of one or more of the following**[ ]**  Educational tests (cognitive, diagnostic, aptitude, achievement)**[ ]**  Survey procedures**[ ]**  Interview procedure**[ ]**  Observation of public behavior of adults (including visual or auditory recording) |  No **[ ]**  | Yes **[ ]**   |  **Category 2 [ ]** OK if both “yes”If VA, assign VA Privacy Officer/Info Security Officer & SU IRB reviewer for limited reviews |
| **[ ]**  Information obtained is recorded in such a manner that participants CANNOT be identified, directly or through identifiers linked to the participants*Or***[ ]**  Any disclosure of the participants’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability, or be damaging to their financial standing, employability, reputation*Or***[ ]**  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 an IRB conducts a limited IRB review:* IRB member approval required
* Privacy and Confidentiality section must be complete and sufficient
* Privacy and Confidentiality section must be consistent with Research Information Sheet
 |  No **[ ]**  | Yes **[ ]**   |
|  **Category 2** – Children Population |
| The research involves the use of either or both of the following**[ ]**  Educational tests (cognitive, diagnostic, aptitude, achievement)**[ ]**  Observation of public behavior of children where the investigator(s) will NOT  participate in the activities being observed (including visual or auditory recording) |  No **[ ]**  | Yes **[ ]**   |  **Category 2 [ ]** OK if both “yes”If VA, assign VA Privacy Officer/Info Security Officer & SU IRB reviewer for limited reviews |
| **[ ]**  Information obtained is recorded in such a manner that participants  CANNOT be identified, directly or through identifiers linked to the participants*Or***[ ]**  Any disclosure of the participants’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation*Or***[ ]**  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 an IRB conducts a limited IRB review:* IRB member approval required
* Privacy and Confidentiality section must be complete and sufficient
* Privacy and Confidentiality section must be consistent with Research Information Sheet
 |  No **[ ]**  | Yes **[ ]**   |
|  **Category 3** |
| The research involves 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  |  No **[ ]**  | Yes **[ ]**  |  **Category 3 [ ]** OK if all “yes”If VA, assign VA Privacy Officer/Info Security Officer & SU IRB reviewer for limited reviews |
| **[ ]**  Information obtained is recorded in such a manner that participants  CANNOT be identified, directly or through identifiers linked to the participants*Or***[ ]**  Any disclosure of the participants’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation*Or***[ ]**  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 an IRB conducts a limited IRB review:* IRB member approval required
* Privacy and Confidentiality section must be complete and sufficient
* Privacy and Confidentiality section must be consistent with Research Information Sheet
 |  No **[ ]**  | Yes **[ ]**  |
| **[ ]**  The research does NOT involve deception *Or***[ ]**  The subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research  |  No **[ ]**  | Yes **[ ]**  |
|  **Category 4** |
| Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens |  No **[ ]**  | Yes **[ ]**   |  **Category 4 [ ]** OK if both “yes” |
| **[ ]**  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  ***(WHEN APPLICABLE, SEND COMMENT CODE - EXEMPT 4ii)****Or***[ ]**  The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities |  No **[ ]**  | Yes **[ ]**   |
|  **Category 5** |
| The project is a research or demonstration project |  No **[ ]**  | Yes [ ]   |  **Category 5 [ ]** OK if all “yes” |
| The project is conducted by or subject to the approval of Department or Agency heads |  No **[ ]**  | Yes [ ]   |
| The project is designed to study, evaluate, or otherwise examine one or more of the following: **[ ]**  Public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act) programs; **[ ]**  Procedures for obtaining benefits or services under those programs; **[ ]**  Possible changes in or alternatives to those programs or procedures; **[ ]**  Possible changes in methods or levels of payment for benefits or services under those programs |  No **[ ]**  | Yes [ ]   |
|  **Category 6** |
| The research involves a taste and food quality evaluation and consumer acceptance studies  |  No **[ ]**  | Yes **[ ]**   |  **Category 6 [ ]** OK if all “yes” |
| The research involves one of the following: **[ ]**  Wholesome foods without additives will be consumed**[ ]**  A food will be consumed that contains a food ingredient when the food ingredient is at or below the level to be safe OR the food ingredient is for a use found to be safe |  No **[ ]**  | Yes **[ ]**   |
| A food will be consumed that contains an agricultural chemical or environmental contaminant and one of the following is true: **[ ]**  The agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration  **[ ]**  The agricultural chemical or environmental contaminant is at or below the level  approved by the Environmental Protection Agency **[ ]**  The agricultural chemical or environmental contaminant is at or below the level  approved by the Food Safety and Inspection Service of the U.S. Department of  Agriculture |  No **[ ]**  | Yes **[ ]**   |
| **Other Determinations – *Complete this section*** |
| The project does NOT involve significant physical invasions or intrusions upon the privacy of participants  | No [ ]  Yes [ ]   |
| The project meets the organizations ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, maintenance of confidentiality, and protections for vulnerable populations) | No [ ]  Yes [ ]   |

***----------------------------------------------------------------------------------------------------------------------------***

**[ ]  This protocol DOES meet the criteria for Exemption**

Check if:

[ ]  Protocol involves interactions with participants ***and reviewer determined a consent process is required***

(to disclose basic information)

**Comments:**

Signature & date: