

**IRB DISPOSITION -** WORKSHEET: Exemption

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| **Research Title:**  |       |
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| **Researcher(s):** |
| 1. |       |
| 2. |       |
| 3. |       |
| 4. |       |
| 5. |       |
| 6. |       |
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| **Reviewer:** |       |

**Approval Criteria**

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| **EXCLUSIONS FROM EXEMPTIONS**(Check if “Yes”- If any are checked, the research does not qualify for exempt.) |
|[ ]  This research involves products regulated by the Food and Drug Administration (FDA). |
|[ ]  The research involves interactions with vulnerable populations such as prisoners, pregnant women, children under the age of 18, fetuses. |
|[ ]  The study involves the use of in vitro fertilization. |
|[ ]  The research involves deception.  |
|[ ]  The research involves survey or interview procedures with children (participants under the age of 18 years). |
|[ ]  The research involves observation of public behavior when the researcher(s) participates in the activities being observed.  |
|[ ]  Data collected includes protected health or medical information when there is a direct or indirect link that would identify the participant. |
|[ ]  The research explores sensitive aspects of the participant’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. |

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| **The study falls within one or more of the following categories: (One or more categories must be checked)** |
|[ ]  Research which does not utilize human subjects. |
|[ ]  Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, from publicly available sources or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects such as in content or secondary data analyses. |
|[ ]  Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular or special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
|[ ]  Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), anonymous survey or interview procedures, or observation of public behavior and, the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or throughidentifiers linked to the subjects, and any disclosure of the human subjects’ response outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. |
|[ ]  Taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which a food 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 Inspection Service of the U.S. Department of Agriculture. |
|[ ]  Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior and the subjects are elected or appointed public officials or candidates for public office. |
|[ ]  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: (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. |

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| **Approval criteria (Check the appropriate answer)** |
|[ ]  Researchers have completed human subject protection training.  |
|[ ]  The research presents no more than Minimal Risk to subjects. |
|[ ]  Has obtained Site Permission Letter (An approval letter from an institution where research will be conducted). |
|[ ]  The study is appropriate for the subjects being studied.  |
|[ ]  Participants recruitment procedure appropriate. |
|[ ]  Risks to participants are reasonable in relation to anticipated benefits and the importance of the expected knowledge.  |
|[ ]  Participants selection procedure is fair and appropriate for the study. |
|[ ]  Informed consent will be obtained from each participant or their legal representative, documented according to federal regulations. |
|[ ]  Adequate safeguards are in place to ensure participant safety during data collection. |
|[ ]  Participants' right to privacy and confidentiality is protected.  |

**(Check the appropriate answer)**

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| **Yes** | **No** | **N/A** | **Criteria**  |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:** are consistent with sound research design. |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:**do not unnecessarily expose subjects to risk (pregnant women excluded from exercise). |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:**when appropriate, are already being performed for diagnostic or treatment purposes. |
|[ ] [ ] [ ]  Risks to subjects are reasonable in relation to anticipated benefits. |
|[ ] [ ] [ ]  Selection of subjects is equitable, and subjects will be selected from the least vulnerable population possible given the nature of the planned research. |
|[ ] [ ] [ ]  **Risk/benefit ratio of exposure to** deception is acceptable. |
|[ ] [ ] [ ]  **Risk/benefit ratio of exposure to** coercion is acceptable. |
|[ ] [ ] [ ]  Plan for desensitization and/or dehoaxing is acceptable. |
|[ ] [ ] [ ]  Subjects are protected from coercion related to researcher-subject relationship. |
|[ ] [ ] [ ]  Procedures for maintenance of subjects’ data are acceptable for the planned design. |
|[ ] [ ] [ ]  All subjects have equitable access to research findings. |

**(Check the appropriate answer)**

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| **Yes** | **No** | **N/A** | **Required elements of INFORMED CONSENT:** |
|[ ] [ ] [ ]  Statement that the study involves research. |
|[ ] [ ] [ ]  Name of primary researcher. |
|[ ] [ ] [ ]  Title of research or general topic of research. |
|[ ] [ ] [ ]  Explanation of the purposes of the research. |
|[ ] [ ] [ ]  Expected duration of the subject’s participation. |
|[ ] [ ] [ ]  Description of the procedures to be followed. |
|[ ] [ ] [ ]  Identification of any experimental procedures to be used. |
|[ ] [ ] [ ]  Description of possible risks and/or discomforts. |
|[ ] [ ] [ ]  Description of realistic benefits to the subject or others. |
|[ ] [ ] [ ]  Disclosure of appropriate alternate procedures and/or treatments, if any, that might be advantageous to subjects. |
|[ ] [ ] [ ]  Extent to which confidentiality or anonymity will be maintained. |
|[ ] [ ] [ ]  Statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. |
|[ ] [ ] [ ]  Statement that subject may withdraw participation and when and how subject can do |
|[ ] [ ] [ ]  Contact person for questions about research and subject’s rights. |

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| **Overall Comments and Recommendations**  |
| ***Please provide your written feedback and recommendations for improvement on each section of the protocol.*** |
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| **Disposition: Check the appropriate disposition**  |
|[ ]  Full Approval (no changes required)  |
|[ ]  Approval with recommendation: Proceed with Suggestions (minor improvements recommended)  |
|[ ]  Approval with Conditions: (There are severe and many concerns)  |
|[ ]  Disapproval (major revisions required) |
|[ ]  Approval ID (Administrator use only):  |
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