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| **Name of Reviewer:** |  | **Date** |  |
| **Research/Project Title:** | Click here to enter text.  |
| **Principal Investigator:** |  |

1. **Research Determination**

*Complete the checklist below to determine if a protocol is Research. All protocols must include provisions to ensure that the safety, rights, and welfare of participants are appropriately protected as applicable.*

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| **Check “Yes” or “No” for each of the following:** | **YES** | **NO** |
| 1. Is the protocol a systematic investigation (the gathering and analysis of information), including research development, testing, and evaluation
 |[ ] [ ]
| 1. Will the protocol contribute to/develop generalizable knowledge (e.g. to generate conclusions or research findings that can be applied to other groups or settings **AND** yield same or similar results)?
 |[ ] [ ]
| 1. Does the protocol involve human subjects (living individual)?

 A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains(1) data through intervention or interaction with the individual**,** or (2) identifiable private information.”(45 CFR 46.102(f) (1)(2))  |[ ] [ ]
| *If* ***all answers*** *to questions 1-3 are marked* ***“YES”, continue.****If any answer to**questions 1-3 is marked* ***“No”, STOP,*** *the protocol is* ***NOT research.******Complete Sections D and F to complete approval process as Non-Research*** |
| 1. **Exception to Research Determination**
 |  |  |
| 1. Is the protocol a **scholarly AND journalistic activity** collecting information on a specific individual (e.g. oral history, journalism, biography, literary criticism, etc.)?
 |[ ] [ ]
| 1. Is the protocol a public health surveillance activity, conducted, supported, requested, ordered, required, or authorized **by a public health authority**?
 |[ ] [ ]
| 1. Is the protocol a collection and analysis of information, biospecimens, or records by or **for a criminal justice agency**?
 | [ ]  |[ ]
| 1. Is the protocol an authorized operational activity **in support of intelligence, homeland security, defense, or other national security missions**?
 |[ ] [ ]
| *If any answer to questions 4-7 are marked* ***“YES”, STOP,*** *the protocol is an* ***EXCEPTION to research*** *(NOT research).* ***Complete Sections D and F to complete approval process as Non-Research*** *If all answers to 4-7 are marked* ***“No”, continue*** *to determine if research is exempt.* |

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| 1. **Exempt Research Determination**
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| *If any of the**answers to questions 1-8 are marked* ***“YES”,*** *this indicates that the research is an* ***EXEMPTION*** *to research and does not have to follow the federal regulations.* *Select only* ***ONE*** *of questions 1-8 if research is determined to be* ***exempt.******Complete Sections D and F to complete approval process as Non-Research****If all answers to questions 1-8 are marked* ***“NO”,*** *the research is either expedited or full board review.* ***Complete sections D, E and F*** |
|  | **YES** | **NO** |
| 1. Is the research, conducted in **established or commonly accepted educational settings**, that specifically involves **normal educational practices** that are not likely to adversely impact students? (e.g. regular/special education, instructional techniques, curricula, or classroom management methods)
 |[ ] [ ]
| 1. Does the research only include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior **AND** if **at least one** of the following criteria is met:

[ ]  The information obtained is recorded that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;[ ]  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[ ]  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 to make the determination required by 45 CFR 46.111(a)(7). |[ ] [ ]
| 1. Does the research involve **benign behavioral interventions** (brief in duration, harmless, painless, not physically invasive) & the collection of information from an adult subject **through verbal or written responses** (including data entry) or **audiovisual recording** AND if **at least one** of the following criteria is met:

[ ]  The information obtained is recorded that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;[ ]  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[ ]  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 to make the determination required by 45 CFR 46.111(a)(7). |[ ] [ ]
|  | **YES** | **NO** |
| 1. Is the research “secondary research” for which consent is not required? Secondary research is research that uses identifiable private information or identifiable biospecimens, AND if **at least one** of the following criteria is met:

[ ]  The identifiable private information or identifiable biospecimens are **publicly available**;[ ]  Information is **recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained**, the investigator **does not contact** the subjects, and the investigator **will not re-identify** subjects (for example, retro-active chart review);[ ]  The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is **regulated under HIPAA;**[ ]  The research is **conducted by, or on behalf of,** **a Federal department or agency** using government-generated or government-collected information  |[ ] [ ]
| 1. Is the research a project or demonstration that is **conducted or supported by a Federal department or agency**, or otherwise subject to the approval of department or agency, and that are designed to **study, evaluate, improve, or otherwise examine public benefit or service programs**
 |[ ] [ ]
| 1. Is the research a taste and food quality evaluation or consumer acceptance study?
 |[ ] [ ]
| 1. Is the research for storage or maintenance for secondary research for which broad consent is required?
 |[ ] [ ]
| 1. Is the research secondary research for which broad consent is required (see HIPAA)? Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if **all of the following** criteria are met:

[ ]  Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens [ ]  Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the Common Rule;[ ]  An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent. |[ ] [ ]

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| 1. **Vulnerable Subjects**
 | **YES** | **NO** |  |

|  |  |
| --- | --- |
| 1. Does the protocol involve pregnant women, fetuses, or neonates?
 |[ ] [ ]   |
| 1. Does the protocol involve children (under the age of majority)?
 |[ ] [ ]   |
| 1. Does this protocol involve prisoners?
 |[ ] [ ]   |
| *If any answer to questions 1-2 is marked* ***“YES”****, please consult the IRB Chair or IRB Legal Counsel.* |  |

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| 1. **Determination of IRB Review (non-exempt)**
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| *If protocol is determined to be research, but is not an exception or exempt:* |  |

Does the research pose more than minimal risk to human subjects or involve vulnerable subjects?

***Minimal risk*** *means that the probability and magnitude of harm or discomfort anticipated is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*.

***Vulnerable subjects*** *include* *children, prisoners, persons who are decisionally or psychologically impaired, and persons who are economically or educationally disadvantaged.*

**Recommendation to IRB Chair**

[ ]  FULL BOARD Review

[ ]  EXPEDITED Review

* No more than minimal risk to vulnerable subjects
* No more than minimal risk to non-vulnerable subjects AND meets expedited category
1. **Approval Recommendation:**

|  |  |
| --- | --- |
| [ ] Approve and Full Release as **non-research**[ ] Approve and Full Release as **Exempt** research[ ] Approve and Full Release as **Expedited** review | [ ] Approve as **non-research with Modification**[ ] Approve as **Exempt** research with **Modification**[ ] Approve as **Expedited** review with **Modifications**  |
| **Modifications Required for Approval:** |
| Click here to enter text. |