Oakwood University

Institutional Review Board

EXEMPT FROM REVIEW FORM

Research projects that involve human participants must be reviewed and approved by Oakwood University IRB Office prior to beginning research. Complete this form if you believe that your project qualifies for an exemption under the federal regulations at 45CFR46.104. If the IRB Office determines that your study is not exempt, you will be notified so that a General Application can be submitted. IRB review and approval of exempt research requires up to 2 weeks and research cannot be initiated until IRB approval is granted.

LIMITATIONS TO EXEMPT CATEGORIES (Exempt categories are found beginning on page 2).

1. *Exemption 2 is <u>not</u> applicable to research involving interventions.*
2. *Exemption 3 applies to behavioral interventions only. It is not applicable to biomedical research. Additionally, it applies only to research with adults; it is not applicable to research with children (less than 18 years of age).*
3. *Research involving prisoners cannot be exempt.*
4. *Research involving use of personal records such as health care information, drug and alcohol treatment records, psychiatric treatment records, educational records, and other records protected by the Federal Privacy Act and other federal and state laws cannot be exempt, unless as stated in the Exemption categories.*
5. *Research that qualifies for exemption must be minimal risk. (Minimal risk means where the probability of any magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine or psychological examination or tests.)*

A. Basic Project Information DATE:

B. Project Title

C. Principal Investigator: **Email:**

School:

Department:

CO-PI(s) or students: **Email:**

Undergraduate Student Research Yes No (Please attach faculty approved protocol.)

Graduate Student Research Yes No (Please attach faculty approved protocol.)

D. LIST OF EXEMPT CATEGORIES (As listed in Code of Federal Regulations, Title 45, Part 46.104)
Review the 8 categories of Exemptions listed below, before completing this form, to determine if your research is Exempt. Then proceed and mark the category(ies) that applies to your research.

_____Exemption #1: Educational Research Conducted in Educational Settings (*This exemption requires approval of the proposed research by the University***.)**

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, This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods such as:
(Check one)

(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.

(iii)___Quality assurance and other administrative studies and initiatives.

_____Exemption #2: Research Involving Educational Tests, Surveys, Interviews, or Observations

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude and achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i). the information obtained, is recorded in such a manner that information cannot be linked to subjects;

(ii). 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;

(iii). If 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, an IRB conducts a limited IRB review to make the determination as required by §46.111(a)(7).

Exemption 2 is not applicable to research involving interventions.

(Check all that apply)

_____Educational tests (cognitive, diagnostic, aptitude, achievement, etcetera)

_____Survey

_____Interview

_____Observation of Public Behavior

_____Exemption #3: Research involving benign behavioral interventions with adults

Exemption 3 applies to research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings, and:

(i) The information cannot be linked to subjects, or

(ii) Information disclosure would not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) Identifiable information recorded with limited IRB review for adequate privacy and confidentiality §46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless 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.

Exemption 3 applies to behavioral interventions only. It is not applicable to biomedical research. Additionally, it applies only to research with adults; it is not applicable to research with children.

Check all that apply:

____ collection of information from an adult subject through verbal or written responses (including data entry), or

____ collection of information from an adult subject through audiovisual recording.

_____Exemption #4: Secondary research use of identifiable private information or identifiable biospecimens.

The private information and biospecimens no longer have to be in existence prior to the start of the research. A research study that proposes to analyze samples or information that will be collected for clinical purposes in the future could qualify for this exemption if it meets at least one of the applicability provisions.is met:

(i) When the identifiable private information or identifiable biospecimens are publicly available;

(ii) When the information is recorded by the investigator in a no identifiable manner.

(iii)When the investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or "public health." Note that HIPAA does not apply to bio specimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from bio specimens).

(iv)When the secondary research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for non-research purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption.

Check all that apply:

___ The identifiable private information or identifiable biospecimens are publicly available.

___ 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.

___The research involves only information collection and analysis involving the investigator's use of identifiable health information.

___ the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities.

_____Exemption #5: Research that is designed to study, evaluate, improve, or otherwise examine public benefit or public service programs

Exemption 5 applies to research that is designed to study, evaluate, improve, or otherwise examine public benefit or public service programs, if the research is conducted by a federal department or agency. This has been expanded to include research that is also supported by a federal department or agency (for example, through a grant of funding). Also, the federal entity conducting or sponsoring the research must publish a publicly available list of the projects that are covered by this exemption before the research begins.

Check all that apply

___Internal studies by Federal employees,

___Studies under contracts or consulting arrangements, cooperative agreements, or grants.

_____**Exemption #6: Taste and food quality evaluation and consumer acceptance studies:**

(i) If wholesome foods without additives are consumed, or

(ii) If 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.

Check all that apply:

___ wholesome foods without additives are consumed.

___ a food is consumed that contains a food ingredient at or below the level and for a use found to be safe.

___a food is consumed that contains agricultural chemical or environmental contaminant at or below the level found to be safe,

_____**Exemption #7: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research**.

Secondary research refers to research with materials originally obtained for non-research purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

The use of exemption 7 requires the IRB to conduct a <u>limited review of specific requirements</u> that pertain to the use of the exemption. The IRB is not asked to conduct a standard IRB review using all the criteria.

Check all that apply:

_____storage and maintenance of identifiable private information used for secondary research.

_____ storage and maintenance of identifiable biospecimens used for secondary research.

_____**Exemption #8: Secondary research for which broad consent is required:**

Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i). Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii). Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii). An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv). The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Check all that apply:

_____ secondary research involving use of identifiable private information.

_____ secondary research involving use of identifiable biospecimens.

E. Investigator's Assurance

As Principal Investigator, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human participants, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for human participant's research. I hereby assure the following:

- The information provided in this application is accurate to the best of my knowledge
- Adequate provisions are available to carry out this research and ensure participants' safety.
- All named individuals on this project have read and understand the procedures outlined in the application.

- All experiments and procedures involving human participants will be performed under my supervision or that of another qualified professional listed on this protocol as Co-Principal Investigator. I understand that, should I use the project described in this application as a basis for a proposal for research funding (either intramural or extramural), it is my responsibility to ensure that the description of human research used in the funding proposal(s) is/are identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to ensure these are identical. I and all the co-investigators and research personnel agree to comply with all applicable requirements for the protection of human participants in research including, but not limited to, the following:
- Making no changes to the approved protocol without first having submitted those changes for review and approval by the Institutional Review Board; and
- Promptly providing the IRB with any information requested relative to the project; and;
- Promptly reporting the premature completion of a study;
- Promptly and completely complying with an IRB decision to suspend or withdraw its approval for project; and
- Obtaining continuing review approval prior to the expiration of approval. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and study activity muse cease until current IRB approval is obtained.
- I understand that the report of an unanticipated problem may require me to inform participants

I assume responsibility for ensuring the competence, integrity and ethical conduct of any student researcher(s). I certify that any student researcher(s) is/are fully competent to accomplish the goals and techniques stated in this application and supporting documents, and that all researchers (faculty and student) have current IRB certifications.

As PI, I have read and understand the Exempt Research Application.

_____ _____

Principal Investigator Date