**KENTUCKY STATE UNIVERSITY**

**DETERMINATION OF EXEMPT STATUS**

**POLICIES AND PROCEDURES**

**POLICIES REGARDING EXEMPT STATUS**

According to [45 CFR § 46.104](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.104), as of 2024, research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one of eight categories. The five most common exempt categories are as follows:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves 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 instruction strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, 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 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; (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; or (iii) 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).
3. (i) Research involving 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 and at least one of the following criteria is met: (A) The information obtained 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; (B) 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; or (C) 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).

(ii) 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) 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.

1. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for a nonrelated primary or initial activity, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) 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; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or (iv) 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, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The full list of exempt categories can be found in 45 CFR § 46.104. Although research in exempt categories do not need to be review and approved by the full IRB, the *Belmont* *Report* principles of respect for persons, beneficence and justice still apply.

Research in categories 1-6 is not exempt if it involves prisoners. All research involving prisoners requires obtaining a certification from OHRP and must be reviewed by the convened IRB. Research that involves children and falls into categories 1 - 6 may be found to be exempt by the IRB. However, the exemption category 2, pertaining to survey or interview procedures or observations of public behavior, does not apply to research involving children, except for research involving public behavior when the researcher does not participate in the activities being observed.

Researchers seeking a determination of exempt status will complete an application for exemption and submit to the OSP. OSP staff members designated as alternate IRB members are the primary reviewers tasked with making exemption determinations. OSP staff may assign submissions to the IRB Chair or another IRB member to assist with or conduct the exemption review as needed or if specific expertise is required. OSP staff members who have a conflict of interest related to a specific application will assign the application to another reviewer.

Following review, the reviewer will make one of the following recommendations, and OSP will notify the researchers of the IRB reviewer’s decision by email:

APPROVED. Approval indicates that the reviewer(s) concluded the research protocols meet the federal criteria for exempt status. OSP staff process the determination, and the researcher is provided with an approval letter and, if applicable and practicable, stamped informed consent/assent documents.

REVISIONS and/or ADDITIONAL INFORMATION REQUIRED. The reviewer(s) withhold approval pending submission of revisions or additional information. OSP provides the request for revisions to the researcher, and the researcher responds and re-submits the application within 90 days of receiving the requested revisions.

EXPEDITED or FULL REVIEW REQUIRED. The reviewer(s) may determine the protocol requires expedited or full review by the IRB.

When the IRB has certified a project as exempt, the IRB does not require continuation or annual administrative reviews. The exemption approval can be in effect for up to three years. After three years, if the research is still ongoing, researchers are required to submit a new application for determination of exempt status.

**APPLICATION PROCEDURES**

The researcher preliminarily determines whether a research project is eligible for exemption based on the categories referenced above. If the research falls into one of the categories, the researcher completes the Exemption Application. If the research is being conducted to fulfill academic requirements, the researcher’s faculty advisor overseeing the project must sign the application.

If the research is supported by an extramural funding agency or program, please include a copy of the proposal narrative or contract. If the research includes a survey, interview, focus group, or assessment, the survey instrument, interview guide, focus group questions, or assessment scale must be submitted with the application. Please also include a copy of any informed consent documents that will be used. Please note that for most surveys, interviews, and focus groups, it is best practice to include a consent preamble. If the research is subject to the Health Insurance and Portability Act (HIPAA) regulations, the HIPAA Authorization OR waiver must be submitted with the application.

After the application is completed and signed, the application should be sent to staff in the Office of Sponsored Programs (OSP) as an email attachment, along with any supporting documentation that may be required.

**KENTUCKY STATE UNIVERSITY**

**EXEMPTION APPLICATION**

1.Researcher’s Contact Information

Name:

Campus Address:

Telephone Number:

Email Address:

Fax Number:

Faculty Advisor Supervising Research (if applicable):

2. Researcher’s Identification Information

Employee/Student ID Number:

Degree and Rank:

College/School/Department/Unit:

3. Title of Research Project (if funded, use the same title used on the grant application/contract):

4.Check all items that apply to your research project.

\_\_\_ Academic Degree Required Research

\_\_\_ HIPAA Authorization

\_\_\_ HIPAA Waiver of Authorization

\_\_\_ HIPAA De-Identification

\_\_\_ Waiver of Informed Consent

\_\_\_ Waiver of Requirement for Documentation of Informed Consent

\_\_\_ Consent & Assent (if applicable) Forms

\_\_\_ Consent Preamble

5.Specify the external or internal funding source(s) and/or cooperating organization(s):

6.Check appropriate response:

Grant proposal/contract attached \_\_\_\_\_ Not applicable \_\_\_\_\_

7. Specify the site(s) where the research will be conducted (attach any documentation, if available, approving such activities):

8. List all individuals who will be assisting in the research activities. Include Name, Rank/Degree, Employee/Student I.D. Number, Contact Information, and responsibility in the research activities.

1.

2.

3.

4.

5.

All individuals who engage in externally funded research activities are required to comply with university requirements concerning financial disclosure and conflict of interest.

9. Please review the policies and procedures on pages 1-3 and explain briefly why you believe this project is exempt.

10. Please provide the following about the proposed research:

1. Objectives (list the objectives of the research activities)
2. Study Population (describe the characteristics of the study population, including the anticipated number of subjects, age range, gender, ethnicity, and health status. Specify any inclusion and exclusion criteria).
3. Subject Recruitment (describe the process of identifying and recruiting subjects for research activities. Attach a copy of any recruitment materials, such as flyers, advertisements, cover letters, etc.).
4. Research Procedures (describe the procedures that will be used).
5. Data Collection (specify the data collection process that will be used and the data that will be collected from subjects. Attach all instruments to be used, such as surveys, interview guides, assessment tools, and the data collection form for existing data).
6. Potential Risks (describe any potential risks the study poses to subjects, whether seen or unforeseen, including physical, social, psychological, legal, or other risks).
7. Research Materials, Records, and Privacy Issues (identify the sources of materials that will be obtained from subjects, what information will be recorded, concerns relating to privacy of subjects, and explain why this information is needed to conduct the research activities).
8. Confidentiality (specify the procedures that will be used to safeguard and protect information gathered to maintain privacy and confidentiality. Explain the process that will be used to destroy the information upon conclusion of the study. If the information will be maintained, provide an explanation. Also discuss what safeguards will be used by the researcher if data will be shared with other entities (e.g., aggregate data, de-identification, etc.).

**RESEARCHER’S SIGNATURE**

I understand Kentucky State University’s policies and federal regulations regarding exempt research, and I agree to the following related to my research:

1. I agree to comply with KSU IRB policies, decisions, conditions, and requirements.
2. I agree to accept responsibility for the scientific and ethical conduct of the research activities that I engage in.
3. I agree to obtain approval from the KSU IRB prior to amending or modifying the research protocol, including any changes to the consent/assent forms and procedures.
4. I agree to notify the KSU IRB of any problems or events that occur in the course of the research that presents risk to human subjects.
5. I attest that the research activities and only involvement of human subjects will be in a category that qualifies for exemption.

**Researcher’s Signature: Date:**

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**Researcher’s Printed Name:**

**CHAIR, DEAN, OR SUPERVISOR’S SIGNATURE**

I have reviewed this research protocol; I am aware of the researcher’s plans and goals for this project, and I support the submission of this application for IRB review and approval.

**Signature: Date:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Supervisor’s Printed Name:**

**\*FACULTY ADVISOR’S SIGNATURE:**

I have reviewed this research protocol and support the submission of this application for IRB review and approval. As the applicant’s faculty advisor, I will provide continued guidance as appropriate.

**Signature: Date:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Advisor’s Printed Name:**

\*If the researcher is a student who is completing this project to meet academic requirements, the student’s faculty advisor who is responsible for supervising the research project must sign the application.