**KENTUCKY STATE UNIVERSITY**

**APPLICATION FOR EXPEDITED REVIEW**

**POLICIES AND PROCEDURES**

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Federal regulations make provisions for certain categories of research to be reviewed through an expedited procedure if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period covered by the original approval. Reviews are done on an ongoing basis, meaning that the review is accomplished independently of the IRB meeting schedule.

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## Guidelines for Expedited Review

In accordance with 45 CFR § 46.110, HHS has established guidelines regarding the applicability of expedited review and categories of research that are eligible for expedited review. These guidelines are posted on the [HHS website](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) and are as follows:

### Applicability

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
2. The categories in this list apply regardless of the age of subjects, except as noted.
3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review procedure may not be used for classified research involving human subjects.
5. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.
6. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

### Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electro-encephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

## Procedures

Researchers seeking expedited review will submit an application package to the Office of Sponsored Programs (OSP). In turn, OSP staff will conduct a preliminary screening of the application package, and once the screening has been completed and any issues with the screening have been addressed, OSP staff will consult with the IRB Chair to determine who will be responsible for the expedited review. The expedited review may be carried out by the IRB Chair, an IRB member designated by the Chair, or the HRPP specialist serving as an alternate IRB member. Consultants may assist the IRB Chair and other IRB members in making decisions in expedited review, but expedited review cannot be performed solely by persons who are not voting members of the IRB.

Expedited reviewers only approve research that meets the federal criteria for approval. Also, expedited reviewers ensure that the study’s informed consent process and documentation meet the requirements as specified in 45 CFR § 46.116 and 21 CFR § 50.25. Expedited reviewers exercise all the authority of the IRB in completing their review, except that the reviewers may not disapprove research. A research activity may be disapproved only after full Board review. Expedited reviewers should take into account any protective measures included in the research design as part of the process of determining if the proposed research involves no more than minimal risk. However, some social and behavioral studies involve more than minimal risk, even though they include such protective measures.

## Outcomes of Review

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

APPROVED. IRB approval indicates that the IRB reviewer(s) concluded the research and consent forms meet the federal criteria for approval. An approval determination verifies the IRB agrees with the assessment of the protocol and/or specific findings as described by the researcher in the application. OSP staff process the determination, and the research is provided with an approval letter and, when applicable and practicable, stamped informed consent/assent documents.

REVISIONS and/or ADDITIONAL INFORMATION REQUIRED. The IRB reviewer(s) withhold approval pending submission of revisions and/or additional information. OSP staff return the protocol to the researcher to address concerns and questions provided by the reviewer(s). The researcher responds and re-submits the application to the OSP within 90 days of receiving the requested revisions. OSP staff assign the response to the primary expedited reviewer who made the initial determination for further review and a new determination. Barring extenuating circumstances, if a researcher does not respond to requested revisions in the 90-day time period, the application is withdrawn, and a new protocol submission is required.

FULL REVIEW REQUIRED. The primary expedited reviewer may determine the protocol requires full review by the IRB at a convened meeting.

The primary expedited reviewer may also determine that the project is eligible for exemption or the activities do not fall under the purview of the IRB. If the protocol is determined to be eligible for exemption, the researcher will withdraw their application and submit a new application for determination of exempt status.

## Approval Periods

OSP staff will include in the approval letter the beginning and end date of approval. The date the primary expedited reviewer approves the study is the date the approval period starts. The approval period will last no more than one year. In some cases, the expedited reviewer may require continuing review of the project more frequently than once per year. In these cases, the reviewer must write a justification for this requirement and provide the explanation to OSP staff.

**KENTUCKY STATE UNIVERSITY**

**APPLICATION FOR EXPEDITED REVIEW**

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 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 \_x\_\_\_\_

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.

11. Research activities that qualify for an expedited review must fall with one of the nine categories listed under [45 CFR § 46.110](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html%2346.110) (also listed on pages 1 -3 of this application package). Please identify the number of the category that applies to the proposed research and provide any additional explanation that may needed.

10. Please provide the following about the proposed research. Please provide complete information.

1. Objectives (list the objectives of the research activities)

1. 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).
2. 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.). See attached enrollment flyer
3. Research Procedures (describe the procedures that will be used).
4. 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).
5. Potential Risks (describe any potential risks the study poses to subjects, whether seen or unforeseen, including physical, social, psychological, legal, or other risks).
6. 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).
7. 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:**

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**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:**

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**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.