IRB EXPEDITED CERTIFICATION REQUEST
PROCEDURES AND APPLICATION

Expedited Research:

The Code of Federal Regulations (Title 45 Part 46) identifies several different categories of research that poses minimal risk that qualify for expedited review. To qualify for an expedited review, research must fall into nine (9) federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous, and that involves no more than minimal risk to subjects.

Expedited review as defined by federal regulations allows the IRB chairperson OR one or more experienced reviewers designated by the chairperson from among members of the IRB to evaluate and approve specific types of research. Reviewers conducting an expedited review may exercise all of the authority of the IRB except that they may not disapprove a study. When a subcommittee cannot approve the research under expedited review, the study is referred to the full committee for review.

Applicability of Expedited Review:

A. 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.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. 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.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB (i.e., expedited or full committee review).

F. Categories one (1) through seven (7) in the application (Question 12) below pertain to both initial and continuing IRB review.
**Expedited Research Procedures:**

1. The researcher preliminarily determines the applicability of expedited review based on the level of risk.

2. If the research appears to meet the criteria for an Expedited review, the researcher completes the Expedited Certification Application.

3. The Expedited Certification Application must be reviewed and approved by the researcher’s Department Chairperson or subsequent administrative supervisor (e.g., Dean). If the research is being conducted to fulfill academic requirements, the researcher’s faculty advisor overseeing the project must sign the Application.

4. If the research being submitted to OR is supported by extramural or internal funding agency or program, a copy of the grant or contract proposal must also be submitted with the Application.

5. If the research includes a survey, interview, or assessment, then the survey instrument, interview guide, or assessment scale must be submitted with the Application.

6. The KSU IRB will notify the researcher upon review of the materials whether (1) Expedited Certification is Approved; (2) Additional Information is required from the researcher before a determination can be made; or (3) Expedited Certification is not approved because the research does not qualify.

7. The KSU IRB will notify the researcher if another type of application is required.
EXPEDITED CERTIFICATION 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 I.D. Number ____________________________________________
   Degree and Rank _________________________________________________________
   College/Department/Unit ________________________________________________

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

4. State the anticipated number and age range of the human subjects in your study.
   Number of subjects _____       Age Range of subjects _____

5. Check (v) all items that apply to your research project.
   □ Academic Degree/Required Research
   □ Consent & Assent (if applicable) Authorization
   □ Consent Preamble Used
   □ Waiver of Informed Consent
   □ Waiver of Requirement for Documentation of Informed Consent

6. Check (v) all items that apply to your research project if the research is being submitted to, supported by, or conducted in cooperation with an external or internal funding source.
   □ Not Applicable
   □ DHHS (Dept of Health and Human Services)
   □ NIH (National Institutes of Health)
   □ CDC (Center for Disease Control)
   □ HRSA (Health Resources and Services Administration )
   □ SAMHSA (Substance Abuse and Mental Health Services Administration)
   □ NSF (National Science Foundation)
   □ DOE (Dept of Education)
7. Specify the external or internal funding source(s) and/or cooperating organization(s):

8. Check (✓) the appropriate response:
   - Grant/contract application attached
   - Not Applicable

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

10. State 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):

11. All individuals who engage in externally-funded research activities shall comply with University requirements concerning Research Financial Disclosure and Research Conflict of Interest standards.

12. Research activities that qualify for an Expedited review pursuant to 45 CFR 46.110 and 21 CFR 56.110 must meet one of the categories below. Check (✓) the appropriate category(ies) that apply to your research.

   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:
   - hair and nail clippings in a nondisfiguring manner;
   - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   - permanent teeth if routine patient care indicates a need for extraction;
   - excreta and external secretions (including sweat);
   - 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;
   - placenta removed at delivery;
   - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   - 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;
   - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   - 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:
   - 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;
   - weighing or testing sensory acuity;
   - magnetic resonance imaging;
   - electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   - 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 regulation for the protection of human subjects, 45 CFR 46.101(b)(4). 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, 45 CFR 46.101(b)(2) and (b)(3). 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; (b) 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.

Note: In Kentucky a “child” is anyone under the age of 18 unless the court has entered an order of emancipation. This definition meets the federal definition for a “child” as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted” (45 CFR 46.402(a). If research is conducted outside of Kentucky, the researcher shall also comply with the applicable state law regarding the definition.
EXPEEDITED CERTIFICATION RESEARCH DESCRIPTION

1. Background. (Provide information about the proposed research activities.)

2. Objectives. (List the objectives of the research activities.)

3. 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.)
4. Subject Recruitment. (Describe the process of identifying and recruiting subjects for the research activities. Attach a copy of any recruitment material, such as flyers, advertisements, cover letters, etc.)

5. Research Procedures. (Describe the procedures that will be used.)

6. 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 survey instruments, interview guide, assessment tools, and data collection form for existing data.)
7. Potential Risks. (Describe any potential risks that the study poses to subjects, whether seen or unforeseen, including physical, social, psychological, legal, or other risks.)

8. Research Materials, Records, and Privacy Issues. (Identify the sources of material 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.)

9. 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 Assurances:

I understand Kentucky State University’s policies concerning human subjects research. I agree to the following conditions in support of my research activities:

1. I agree to comply with all 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;
3. I agree to obtain approval from the KSU IRB prior to amending or modifying the research protocol, including any changes to the approved consent/assent form and procedures;
4. I agree to notify the University in writing as appropriate of the development of any financial interest or conflict of interest that has not already been disclosed;
5. I agree that I and all research staff listed on the application have received the mandatory human subjects protections education training.
6. I attest that the research activities and only involvement of human subjects will be in a category that qualifies for an exemption.

Researcher’s Signature ___________________________ Date __________________

Researcher’s Printed Name: __________________________

Department Chair or Next Level Administrator’s Assurances:

This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of these activities. I attest to the competency of the researcher(s) to conduct the research and support these activities. I will provide continued guidance as appropriate.

Signature: ___________________________ Date __________________

Printed Name: __________________________
*Faculty Advisor’s Assurances:

This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of these activities. I attest to the competency of the researcher(s) to conduct the research and support these activities. I will provide continued guidance as appropriate.

Signature: ___________________________ Date: ________________

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 assurance in addition to the Department Chair.