UNIVERSITY OF CENTRAL ARKANSAS™ | RESEARCH COMPLIANCE

IRB EXPEDITED REVIEW

Research activities that (1) present no more than minimal risk* to human research participants, and (2) involve only procedures listed in one or more of the following categories may be reviewed by the Institutional Review Board through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. 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 research participants.

> **Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]*

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

The expedited review procedure may not be used where identification of the participants is possible directly, or through identifiers linked to them **and** their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, or reputation.

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

The standard requirements for informed consent (or its waiver, alteration, or exception) apply.

Categories one (a) through seven (b) pertain to both initial and continuing IRB review.

RESEARCH CATEGORIES REVIEWED THROUGH AN EXPEDITED PROCEDURE

(Use categories 1 – 7 to complete question number one (1) on the second page of the application form)

(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.
(b) Research on medical devices for which (1) an investigational device exemption application (21CFR Part 812) is not required; or (2) 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, non-pregnant adults who weigh at least 110 pounds (not to exceed 550 ml in an 8 week period and collected not more frequently than 2 times per week; or
(b) from other adults, 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, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collected not more frequently than 2 times per week.

(3) Prospective collection of biological specimens (hair and nail clippings, excreta and external secretions, deciduous teeth, uncannulated saliva) for research purposes by noninvasive means.

(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 participant's privacy,
(b) weighing or testing sensory acuity,
(c) magnetic resonance imaging,
(d) electrocardiography, electroencephalography, 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 non-research 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 research participants. [45CFR46.101 (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 research participants [45CFR46.101(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;
  (ii) all participants have completed all research-related interventions; and
  (iii) the research remains active only for long-term follow-up of participants; or
(b) where no participants have been enrolled and no additional risks have been identified;
(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.

Date Received in Office: _____ IRB #: _____

UCA IRB
APPLICATION FOR EXPEDITED

For any questions regarding this form, please contact the Research Compliance Officer at 501-852-7460.

Submit one (1) *.pdf file of a complete application (including signature pages and attachments) to researchcompliance @uca.edu. DO NOT submit hard copies of applications or attachments.

Date:

Principal Investigator Name(s):

Email: Phone:

If Student(s), Research Advisor's Name:

Email: Phone:

UCA Address (of Research Advisor, if a student): Building: Room #:

Department: College:

Project Title:

Anticipated dates of project: Beginning: Ending:

FUNDING: Anticipated source of funds, if any, including UCA Research Funds. (If this project will be funded under a grant to another investigator, please give the title of the grant, name of agency or institution, and the investigator's name.)

Proposal has been (will be) submitted for funding (date):

Will proposed research be conducted with investigator(s) from other agency/institution(s)? ☐ Yes ☐ No

If YES, complete and attach the **Study Personnel Form**

Is proposed research being conducted to meet course or degree requirements at another university? ☐ Yes ☐ No

If YES, has the research been reviewed by that university's IRB? ☐ Yes ☐ No

If YES, what were the results?
(attach approval letter)

Required Training/Education in protections for human research subjects: (Complete for each investigator.)

Name: Name:

CITI Certificates are: ☐ attached ☐ on file CITI Certificates are: ☐ attached ☐ on file

Name: Name:

CITI Certificates are: ☐ attached ☐ on file CITI Certificates are: ☐ attached ☐ on file

RESEARCH PARTICIPANT INFORMATION:

1. State the Category (1-7) of Expedited Research from **pages 1 and 2:** #

2. Total number of Participants and Controls: # of Males: # of Females:

3. Categories of Participants and Controls
   - ☐ Adults (18 years and over)
   - ☐ Adolescents (13-17 years of age)
   - ☐ Mid-Childhood (6-12 years of age)
   - ☐ Preschool (3-5 years of age)
   - ☐ Infants (0-2 years of age)
   - ☐ Pregnant Women
   - ☐ Other (specify):
   - ☐ Using existing data, no subjects recruited

   Institutional Affiliation of Participants
   - ☐ None
   - ☐ Schools/College/University
   - ☐ Prisons
   - ☐ Hospitals/Clinics
   - ☐ Other (specify):

4. Mentally Competent **Adult** (able to give consent) ☐ Mentally Incompetent **Adult** (unable to give consent) ☐

5. Demographic Information (check all applicable items):
   - ☐ Names
   - ☐ Social Security #s
   - ☐ Addresses
   - ☐ Phone #s
   - ☐ Age/Date of Birth
   - ☐ Sex
   - ☐ Race/Ethnicity
   - ☐ Marital Status
   - ☐ Income
   - ☐ Job Title
   - ☐ Names of Employers
   - ☐ Types of Employers
   - ☐ Other (specify): _____

6. Briefly explain how the demographic information will be used.

7. How will the participants be chosen? (If using existing records, attach a copy of the permission.)

8. How will the participants be recruited and contacted?

9. Will the participants receive any inducement or remuneration (e.g., $$, gift certificates, class credit) or token gifts (e.g., candy, stickers) to participate in the research? ☐ Yes ☐ No

(**if YES**, describe)

10. What is the **time** requirement for the participants?

11. Will participants be charged for any research related procedures? ☐ Yes ☐ No

(if YES, explain)

12. Describe any potential short and long term benefits from this research to the participants and/or society. (If there are none, state none.)

Research Participants:

Society (Science / Scholarship):

13. Study site: Where will the research be conducted? If not at UCA, has permission been granted? (Attach a copy of permission or collaboration letter.)

RESEARCH PROJECT DESCRIPTION:

Use *LAY TERMS and/or PROVIDE DEFINITIONS* of technical terminology. [Use extra pages as necessary.]

1. Briefly describe the background or justification for your research.

2. Describe your research focus (the purpose or questions to be answered).

3. Describe the research design including the use of a control group and any intervention or treatment to be administered to the participants, whether performed by the researchers or others.

4. Describe your data collection procedures in detail.
   What will the participants (and controls) be doing to create the data (e.g., filling out a survey, performing a task, etc.)? If the participants will need training, explain in detail. (Attach copies of any instruments, tests, surveys, interview guides, etc., and descriptions of any research data collection equipment.)

RISKS AND CONFIDENTIALITY:

1. RISKS TO RESEARCH PARTICIPANTS

Will the participants be placed *<u>*at risk of harm*</u> as a consequence of participating in this research? ☐ Yes ☐ No

*Definition of <u>*at risk of harm*</u>– to be placed in a position with greater potential for physical, mental, social, legal or financial harm than would be expected for that individual in his or her normal occupation or daily activities.
If you are not sure of the answer to the above question, please contact the Research Compliance Officer for guidance. If the answer is YES to the above question, then this research needs to be reviewed by the full IRB.

2. CONFIDENTIALITY OF DATA

Will any data be part of a permanent record that can be identified with the participants? ☐ Yes ☐ No
(if yes, explain)

What steps will be taken to ensure the confidentiality of the data? (How will the participant's privacy be protected?)

Where will the data be stored for the three (3) year minimum? Specify the precise location, preferably in a locked file cabinet with limited access by others, and on the UCA campus.

INFORMED CONSENT PROCEDURES: (See the consent/cover letter/permission/assent templates.)

1. What type of informed consent will be used? (Check one or more as appropriate to your project.)

☐ Informed consent agreement, parent permission, assent (signatures obtained).

☐ Informed consent cover letter (no signature obtained). **One of the criteria below must be met and checked off.**

- ☐ The research presents no more than minimal risk of harm and involves no procedures for which a signature is normally required outside of the research.
- ☐ The only record linking the subject and the research would be the consent and the principal risk would be potential harm from a breach of confidentiality.

☐ Waiver from informed consent process. **All four criteria must be met. Describe this need in your project description.**

- ☐ The research involves no more than minimal risk to participants.
- ☐ The waiver will not adversely affect the rights and welfare of participants.
- ☐ The research could not practicably be carried out without the waiver.
- ☐ Whenever appropriate, participants will be given additional pertinent information after participation.

☐ Oral consent. (Attach a copy of the script for informed consent and the short written form that will be signed by the participant and a witness.)

2. Describe clearly (step-by-step) how informed consent/permission/assent will be obtained from or presented to participants, parents, and/or legal guardians.

3. Are you purposely withholding some information from participants or using deception in the research? ☐ Yes ☐ No **(if YES, provide the following information)**

Describe the withheld information or the deception:

Justify the reason:

Describe the post-research debriefing of the participant, including when and where participants will be debriefed: (Attach a copy of the debriefing statement that will be given to participants.)

ATTACHMENTS:

- ☐ questionnaire, survey, list of potential interview questions, etc. to be used with research participants
- ☐ consent agreement, cover letter, telephone introductory script
- ☐ permission to use existing data and/or permission from external institution (if applicable)
- ☐ other _____

PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT:

I understand the University of Central Arkansas' policies concerning research involving human subject research participants and I agree:

1) to comply with all IRB policies, decisions, conditions, and requirements;
2) to accept responsibility for the scientific and ethical conduct of this research study;
3) to obtain prior approval from the IRB before amending or altering the research protocol or implementing changes in the approved consent/assent form as it could change the exempt status of this research study;
4) to report to the IRB in accord with IRB policy any adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5) to notify the Research Compliance Office and Sponsored Programs if external funding is received during the research study and comply with any additional regulatory requirements;
6) each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting this study.

_____ _____

PI Signature **Date**

_____ _____

Co-Investigator Signature **Date**

_____ _____

Research Advisor Signature, if Student PI **Date**

****DEPARTMENT CHAIR'S ASSURANCE STATEMENT**:

This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study: to the competency of the investigator(s) to conduct the project and the time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate.

_____ _____

Signature of Department Chair **Date**

****If the Principal Investigator is also the Chair of the department, the College Dean or Associate Dean should sign the Assurance Statement.**

_____ _____

Signature of Department Review Committee Chair **Date**