Date Received in Office: _____ IRB #: _____

UCA IRB
APPLICATION FOR FULL

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:

Building: Room #:

Department: College:

***Note: If additional investigators are assisting in the research project, complete the **Study Personnel Form** and submit with application.*

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

2. 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):

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

4. 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): _____

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

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

7. How will the participants be recruited and contacted?

8. 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)

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

10. Will participants be charged for any research related procedures? ☐ Yes ☐ No
(if YES, explain)

11. 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 subjects,

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 SUBJECTS

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.

Will your research include any of the following?

(a) Possible invasion of privacy of subject or subject's family, including use of personal information or records ☐ Yes ☐ No

(b) The administration of physical stimuli other than auditory and visual stimuli associated with normal situations and levels ☐ Yes ☐ No

(c) Manipulation of psychological and/or social variables, e.g., sensory deprivation, social isolation, psychological stresses, etc., or deprivation of physical or psychological requirements such as nutrition or sleep ☐ Yes ☐ No

(d) Any probing for information which an individual might consider to be personal or sensitive (sexual or illegal activities, alcohol or drug use) ☐ Yes ☐ No

(e) The presentation to the subjects of any materials which they might find to be offensive, threatening, or degrading ☐ Yes ☐ No

(f) The requirement of physical exertion beyond normal situations ☐ Yes ☐ No

If any of the above items are checked YES, indicate, as appropriate:

(1) What precautions or procedures have been taken to minimize the additional risks?

(2) What arrangements have been made for the care of a subject(s) in the event of psychological/emotional distress, an accident, or complication related to the research?

NOTE: Add this statement to the consent form if more than minimal risk of physical harm:

In the case of an emergency, a participant may be seen by Student Health Services or a local or regional medical facility. All expenses associated with care will be the responsibility of the participant and his/her insurance (if the research is **NOT** conducted at UCA or the participants are not UCA-affiliates, leave out the option of using Student Health Services).

2. CONFIDENTIALITY OF DATA

Will any data be made a part of any 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**