

IRB EXEMPTION REVIEW

Research activities in which the only involvement of human subject research participants will be in one or more of the following categories is exempt from further IRB review. Exemption applies to research that is of minimal risk and with adults **except:**

Category A (below) - which also applies to children and

Category B (below) – which applies to children in two circumstances: 1) when the research involves the use of standardized educational tests and 2) when the research involves observation of public behavior when the investigator(s) <u>do not</u> participate in the activities being observed. (Survey and interview procedures do not apply to children.)

Final determination as to whether a research project is exempt from further review rests with the IRB. If the project is determined to be exempt by the IRB, the principal investigator is still required to submit any project modifications to the IRB as modification could change the status to non-exempt research.

RESEARCH CATEGORIES EXEMPT FROM FURTHER IRB REVIEW

A. Research conducted in established or commonly accepted educational settings, involving normal education instruction practices, such as

1) research on regular and special education instruction strategies; or

2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless**:

1) information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to them; **and**

2) any disclosure of the research participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the their financial standing, employability, or reputation.

C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (B) of this section, **if**:

1) the research participants are elected or appointed officials or candidates for public office; or

2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, **if**:

1) these sources are publicly available; or

2) the information is recorded by the investigator in such a manner that participants *cannot* be identified, directly or through identifiers linked to the participants.

IRB #: _____

Room #:

UCA IRB APPLICATION FOR EXEMPTION

The IRB retains final judgment as to whether a research study is exempt from further IRB review. Note: Exempt status does not necessarily mean that the investigator is exempt from informed consent procedures. For any questions regarding this form or Exempt status, 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:

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

Email:

Phone:

College:

Phone:

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

Department:

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.)

Building:

RESEARCH CATEGORIES OF EXEMPTION FROM FURTHER IRB REVIEW

Research activities in which the only involvement of human research participants will be in one or more of the following categories, are usually exempt from further IRB review: (*Check all that apply to your research study.*)

- A. Research conducted in established or commonly accepted educational settings, involving normal education instruction practices, such as
- (1) research on regular and special education instruction strategies, or
- (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.
- (1) information obtained will be recorded in such a manner that research participants can be identified, directly or through identifiers linked to the participants;
- (2) any disclosure of the research participants' responses outside the research could reasonably place the them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
- C. Research involving the use of educational tests (as above), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph B.(2) of this section, **if**:
- (1) the research participants are elected or appointed officials or candidates for public office; or
- (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, **if**:
- (1) the sources are publicly available, or
- (2) the information will be recorded by the investigator in such a manner that participants *cannot* be identified, directly or through identifiers linked to the participants.
- *Note:* If you have checked B(1) <u>and</u> B(2), your research is not exempt from IRB review. You must apply for Expedited or Full IRB review.

ANSWER EACH QUESTION (1 – 9): (If you are using existing data, some questions may not apply: use N/A.)

1. Briefly, what is the purpose of your research (what do you want to learn from the project)?

2. What will be required of the research participant(s)?

- 3. From where will you recruit the participant(s)?
- 4. Total number of Participants and Controls:
- 5. Categories of Participants and Controls Adults 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

6. Mentally Competent Adult (able to give consent)

Mentally Incompetent Adult (unable to give consent)

Note: Some categories of research participants are considered more vulnerable than others and are not eligible for participation in Exempt research.

7. 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): _____

Note: Some types of demographic information are considered personal identifiers and may increase the level of risk of the research to the participants.

Please explain how any of the above demographic information will be used.

Describe the steps to be taken to protect the privacy and/or confidentiality of participants' responses or to maintain anonymity of the research records. (If privacy/confidentiality will not be maintained, state this.)

Note: If personal identifiers will be retained and used, you must explain this in the informed consent agreement and tell participants how you will use their identifiers.

8. How will you inform participants about the research project and procedures? Check one:

Informed Consent Cover Letter	Informed Consent Agreement	Not Applicable

9. Where will the research be conducted (where will you interact with participants or obtain existing data)?

Note: If not at UCA, in some circumstances you may need a signed permission letter. If so, attach a copy of the letter.

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.

Research Advisor Signature, if Student PI

****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

PI Signature

Co-Investigator Signature

Co-Investigator Signature

Date

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

Date

Date

Date

Date