

UNIVERSITY OF ARKANSAS INSTITUTIONAL REVIEW BOARD
PROTOCOL FORM

The University Institutional Review Board recommends policies and monitors their implementation, on the use of human beings as subjects for physical, mental, and social experimentation, in and out of class. . . . Protocols for the use of human subjects in research and in class experiments, whether funded internally or externally, must be approved by the (IRB) or in accordance with IRB policies and procedures prior to the implementation of the human subject protocol. . . . Violation of procedures and approved protocols can result in the loss of funding from the sponsoring agency or the University of Arkansas and may be interpreted as scientific misconduct. (see Faculty Handbook)

Supply the information requested in items 1-14 as appropriate. **Type** entries in the spaces provided using additional pages as needed. In accordance with college/departmental policy, submit the original **and** one copy of this completed protocol form and all attached materials to the appropriate Human Subjects Committee. In the absence of an IRB-authorized Human Subjects Committee, submit the original **and** one copy of this completed protocol form and all attached materials to the IRB, Attn: Compliance Officer, OZAR 118, 575-3845.

1. Title of Project _____

2. (Students **must** have a faculty member supervise the research. The faculty member must sign this form and all researchers and the faculty advisor should provide a campus phone number.)

	Name	Department	Email Address	Campus Phone
Principal Researcher	_____	_____	_____	_____
Co-Researcher	_____	_____	_____	_____
Co-Researcher	_____	_____	_____	_____
Co-Researcher	_____	_____	_____	_____
Faculty Advisor	_____	_____	_____	_____

3. Researcher(s) status. Check all that apply.

- Faculty
 Staff
 Graduate Student(s)
 Undergraduate Student(s)

4. Project type

- Faculty Research
 Thesis / Dissertation
 Class Project
 Independent Study /
 Staff Research
 M.A.T. Research
 Honors Project
Educ. Spec. Project

5. Is the project receiving extramural funding?

- No
 Yes. Specify the source of funds _____

6. Brief description of the purpose of proposed research and all procedures involving people. Be specific. Use additional pages if needed. (**Do not** send thesis or dissertation proposals. Proposals for extramural funding must be submitted in full.)

Purpose of research:

Procedures involving people:

7. Estimated number of participants (complete all that apply)

_____ Children under 14 _____ Children 14-17 _____ UA students
(18yrs and older) _____ Adult non-students

8. Anticipated dates for contact with participants:

First Contact _____ Last Contact _____

9. Informed Consent procedures: The following information must be included in any procedure: identification of researcher, institutional affiliation and contact information; identification of Compliance Officer and contact information; purpose of the research, expected duration of the subject's participation; description of procedures; risks and/or benefits; how confidentiality will be ensured; that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. See *Policies and Procedures Governing Research with Human Subjects*, section 5.0 Requirements for Consent.

- Signed informed consent will be obtained. **Attach copy of form.**
- Modified informed consent will be obtained. **Attach copy of form.**
- Other method (e.g., implied consent). **Please explain on attached sheet.**
- Not applicable to this project. **Please explain on attached sheet.**

10. Confidentiality of Data: All data collected that can be associated with a subject/respondent must remain confidential. Describe the methods to be used to ensure the confidentiality of data obtained.

11. Risks and/or Benefits:

Risks: Will participants in the research be exposed to more than minimal risk? Yes No Minimal risk is defined as risks of harm not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Describe any such risks or discomforts associated with the study and precautions that will be taken to minimize them.

Benefits: Other than the contribution of new knowledge, describe the benefits of this research.

12. Check all of the following that apply to the proposed research. Supply the requested information below or on attached sheets:
- A. Deception of or withholding information from participants. Justify the use of deception or the withholding of information. Describe the debriefing procedure: how and when will the subject be informed of the deception and/or the information withheld?
 - B. Medical clearance necessary prior to participation. Describe the procedures and note the safety precautions to be taken.
 - C. Samples (blood, tissue, etc.) from participants. Describe the procedures and note the safety precautions to be taken.
 - D. Administration of substances (foods, drugs, etc.) to participants. Describe the procedures and note the safety precautions to be taken.
 - E. Physical exercise or conditioning for subjects. Describe the procedures and note the safety precautions to be taken.
 - F. Research involving children. How will informed consent from parents or legally authorized representatives as well as from subjects be obtained?
 - G. Research involving pregnant women or fetuses. How will informed consent be obtained from both parents of the fetus?
 - H. Research involving participants in institutions (cognitive impairments, prisoners, etc.). Specify agencies or institutions involved. Attach letters of approval. Letters must be on letterhead with original signature; electronic transmission is acceptable.
 - I. Research approved by an IRB at another institution. Specify agencies or institutions involved. Attach letters of approval. Letters must be on letterhead with original signature; electronic transmission is acceptable.
 - J. Research that must be approved by another institution or agency. Specify agencies or institutions involved. Attach letters of approval. Letters must be on letterhead with original signature; electronic transmission is acceptable.

13. Checklist for Attachments

The following are attached:

- Consent form (if applicable) or
- Letter to participants, written instructions, and/or script of oral protocols indicating clearly the information in item #9.
- Letter(s) of approval from cooperating institution(s) and/or other IRB approvals (if applicable)
- Data collection instruments

14. Signatures

I/we agree to provide the proper surveillance of this project to insure that the rights and welfare of the human subjects/respondents are protected. I/we will report any adverse reactions to the committee. Additions to or changes in research procedures after the project has been approved will be submitted to the committee for review. I/we agree to request renewal of approval for any project when subject/respondent contact continues more than one year.

Principal Researcher _____ Date _____

Co-Researcher _____ Date _____

Co-Researcher _____ Date _____

Co-Researcher _____ Date _____

Faculty Advisor _____ Date _____

PROTOCOL APPROVAL FORM

(To be returned to IRB Program Manager with copy of completed protocol form and attachments)

Human Subjects Committee Use Only (In absence of IRB-authorized Human Subjects Committee, send protocol to IRB.)

Recommended Review Status

Human Subjects Committee can approve as exempt because this research fits in the following category of research as described in section 9.02 of the IRB policies and procedures (**Cite reasons for exempt status.**):

Printed Name and
Signature of the HSC Chair _____ Date _____

 Expedited Review by a designated member of the IRB because this research fits in the following category of research as described in section 9.03 of the IRB policies and procedures (**Cite reasons for expedited status.**):

Printed Name and
Signature of the HSC Chair _____ Date _____

 Requires Full Review by the IRB because this research fits in the following category of research as described in section 9.04 of the IRB policies and procedures (**Cite reasons for full status.**):

Printed Name and
Signature of the HSC Chair _____ Date _____

IRB/RSSP Use Only

Project Number _____ Received RSSP _____

Sent to: _____ Date: _____

Final Status

Approved as **Exempt** under section 9.02 of the IRB Policies and Procedures (**Cite reasons for exemption.**):

Approved as **Expedited** under Section 9.03 of the IRB Policies and Procedures because (**Cite reasons for expedited status.**)

Printed Name and
Signature: _____ Date _____
IRB (for the Committee)

Approved by **Full** review under Section 9.04 of the IRB as meeting requirements of the IRB Policies and Procedures.

Printed Name and
Signature: _____ Date _____
IRB Chairperson