APPENDIX B — PROTOCOL FORM

IRB Review Protocol Number (Year - Control Number)_____

HUMAN SUBJECTS REVIEW
UNIVERSITY OF ARKANSAS AT MONTICELLO

PROTOCOL FORM

The University Institutional Review Board is responsible for recommending policies and monitoring 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 prior to the implementation of the human subject protocol. Violation of procedures and approved protocols can result in the loss of funding by the sponsoring agency or the University of Arkansas at Monticello and may be interpreted as scientific misconduct. (Faculty Handbook, p. 64).

Supply the information requested in items 1-14 as appropriate. Type entries in the spaces provided using additional pages as needed. In accordance with school/division policy, submit the original and one (1) copy of this completed protocol form and all attached materials to the Human Subjects Committee or the Institutional Review Board, as appropriate.

1. **T**itle 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 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 ☐ Class Project ☐ Independent Study ☐ Honors Project

5. Is the project receiving extramural funding?

☐ NO ☐ YES

If yes, specify the source of funding

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

7. Estimated number of participants. Complete all that apply.

☐ Children under 14 ☐ Children 14-17 ☐ UAM students (18 yrs. 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: purpose of the research; identification of researchers and their institutional affiliation; expected duration of the subject's/respondent's participation; how confidentiality will be ensured; that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits.

☐ 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. Will participants in the research be exposed to more than minimal risk? 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. Other than the contribution of new knowledge, describe the countervailing benefits of this research.

☐ NO ☐ YES Describe any such risks or discomforts associated with the study and precautions that will be taken to minimize them.

12. Check all of the following that apply to the proposed research and supply the information requested 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?

☐ H. Research involving participants in institutions (prisoners, mentally disabled, etc.). Specify agencies or institutions involved. Attach letters of approval.

☐ I. Research approved by an IRB at another institution. Specify agencies or institutions involved. Attach letters of approval.

☐ J. Research that must be approved by another institution or agency. Specify agencies or institutions involved. Attach letters of approval.

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_____