IRB Number: _____
(IRB Use Only)

Institutional Review Board
1000 ASU Drive #210
Lanier Hall 114
Lorman, MS 39096-7500
Tel: 601-877-3964 Fax: 601-877-2327
E-mail: IRB@alcorn.edu

Application for Review of Research Involving Human Subjects

Federal regulations and the Alcorn State University policy require that all research involving humans as subjects to be reviewed and approved by the ASU Institutional Review Board (IRB). Any faculty, staff, student, or other persons wishing to conduct research involving humans as subjects of research at or through ASU must receive written approval from the IRB before beginning the research.

All forms must be completed, signed by the RPI, and submitted by FAX, Email, or single-sided hard copy.

Research Training): ☐ **Yes** ☐ **No** **If Yes, please attach a copy of verification.**

1. RESPONSIBLE PRINCIPAL INVESTIGATOR (RPI) The individual who has lead responsibility for conducting the research. The RPI may be a ASU employee or external individual. Whenever the responsible principal investigator is not a ASU faculty or staff member, the research must be supervised by a non-visiting ASU faculty or staff member, who will be designated as the Responsible Research Supervisor (RRS).

Last Name:	First Name:		Academic Degree(s):
Dept. or Unit:	Office Address:		Mail Stop:
Street Address:	City:	State:	Zip Code:
Phone:	Fax:	E-mail:	
ASU Status: ☐ Faculty ☐ Academic professional/Staff ☐ Student			

1A. Responsible Research Supervisor (RRS) A member of the ASU faculty or staff (i.e., an employee of ASU) who has supervisory responsibility for the protection of the subjects and the conduct of the human subjects research described in the research protocol submitted for review under the ASU policy and procedures for human research protection. ASU students and graduate assistants cannot serve as RRS.

Last Name:	First Name:		Academic Degree(s):
Dept. or Unit:	Office Address:		Mail Stop:
Phone:	Fax:	E-mail:	
ASU Status: ☐ Faculty ☐ Academic professional/Staff ☐ Other _____			

1B. List all other ASU Co-Researchers

_____

_____

_____

_____

2. PROJECT TITLE

2A. Project Type: ☐ Master's project/thesis ☐ Faculty research ☐ Sponsored research
☐ Student research ☐ Doctorate research/thesis ☐ Other: please specify _____

2B. Joint Project ☐ Yes ☐ No

Name of Lead Investigator/Organization:				
Name of Partner Institution/Organization:				
Partner Investigator Last Name:	First Name:		Academic Degree(s):	
Dept. or Unit:	Office Address:			Mail Stop:
Street Address:	City:	State:		Zip Code:
Phone:	Fax:	E-mail:		

3. FUNDING Indicate whether this research is funded by, or application has been made for, a grant, contract, or gift.

3A. STATUS ☐ Research is **not funded** and is **not pending** a funding decision (Proceed to Part 4).

☐ Research is **funded** (funding decision has been made).

☐ Funding decision is **pending**. Funding proposal submission date:

3B. SOURCE(S) If the research is funded or pending a funding decision, mark and name all sources:

	Type of Funding—Mark all that apply	**Name of Source**
☐	**ASU Department, College, or Campus** (includes research board and campus fellowship training grants)	
☐	**Federal** (from federal agencies, offices, departments, centers)	
☐	**Commercial Sponsorship** (from corporations, partnerships, proprietorships)	
☐	**State of Mississippi Department or Agency** (from any state office or entity)	
☐	**Gift or Foundation** (public or private foundations, not-for-profit corporations, private gifts)	
☐	**Local Government Agencies** (Cities, counties, municipalities)	
☐	**Mark if funding is passable through State sources**	
☐	**Mark if funding is passable through Federal sources**	

→ Mark here if the funding is through a Training Grant: ☐

3C. PROPOSAL Attach a complete copy of the funding proposal or contract. ☐ Attached

Sponsor-assigned grant number, if known: _____

Title of funding proposal or contract, if different from project title in part 2:

4. SUMMARIZE THE RESEARCH. In **LAY LANGUAGE**, summarize the objectives and significance of the research.

All boxes are expandable so please use as much detail as possible.

5. Data Collection (mark all that apply)

☐ From existing data, documents, or records that are **publicly available**.

☐ From existing data, documents, or records that are **confidential**. Access to the documents or records is restricted and can occur by permission only.

☐ From existing biological, diagnostic, or pathological specimens that are **confidential**. Access to the specimens is restricted and can occur by permission only.

☐ By directly or indirectly **interacting with subjects individually or in groups**.

☐ From the **observation of public behavior**.

☐ Other (please explain) _____

5A. TYPE OF RESEARCH (mark all that apply)
(Data collected from schools, institutions, organizations, etc., research must have written approval, on letterhead, from those organizations.)

A. ☐ Research conducted in a school setting that focuses on the following normal educational practices:

- ☐ Instructional strategies, techniques, or curricula for regular education
- ☐ Instructional strategies, techniques, or curricula for special education
- ☐ Classroom management methods for regular education
- ☐ Classroom management methods for special education

B. ☐ Research that involves the use of educational tests (diagnostic, aptitude, achievement), surveys, interviews, and/or observation of public behavior.

C. ☐ Research that involves the collection or study of existing data, documents, pathological specimens, and/or diagnostic specimens.

D. ☐ Research that involves the collection of biological samples by finger stick, heel stick, ear stick, or venipuncture.

E. ☐ Research that involves the collection of data by non-invasive means using one or more of the following procedures:

- ☐ voice, video, digital, or image recordings
- ☐ weighing or testing sensory acuity
- ☐ moderate exercise
- ☐ muscular strength testing
- ☐ physical sensors applied to the surface of the body or at a distance, and the procedure does not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
- ☐ flexibility testing
- ☐ magnetic resonance imaging (MRI)
- ☐ electrocardiography (ECG)
- ☐ electroencephalography (EEG)
- ☐ finger nail or hair clipping
- ☐ mouth or skin swab

F. ☐ Research that is conducted by or subject to the approval of a department or agency head and is designed to study, evaluate, or otherwise examine a public benefit or service program, its procedures for obtaining benefits of services, possible changes in or alternatives to the program or its procedures, or possible changes in methods or levels of payments for benefits or services provided.

G. ☐ Taste and food quality evaluation and consumer acceptance studies in which wholesale foods without additives are consumed, and the food consumed contains food ingredients at or below the level known to be safe and for a use known to be safe.

5B. ANTICIPATED NUMBERS How many subjects, including controls, will you study in order to get the data that you need? If you plan to study disproportionate numbers of a given sex, race, or minority group, provide scientific rationale in 11. Please list and describe each performance cite separately.

Performance Site		**Total**
1.		
2.		
3.		
TOTALS		

List anticipated numbers for additional performance sites on an attachment and mark here: ☐

5C. AGE RANGE Mark all that apply. Researchers planning to include children in research projects involving *more than minimal risk* must provide written documentation of the benefits that are likely to accrue to a child participating in the project. This should include information gathered on adults, if it exists, or an explanation about why it does not exist.

☐ 0–7 years ☐ 8–17 years ☐ 18–64 years ☐ 65+ years

→ ☐ If applicable, written documentation of benefits for including children in ***more than minimal risk*** research is attached.

5D. Research Will Focus on Specific Subject Groups
Eligibility for participation in this research will be restricted based on the following criteria:

☐ Gender or sex ☐ Race/Ethnicity ☐ Religion
☐ Socioeconomic status ☐ Sexual orientation ☐ Age
☐ English as a first language ☐ Other (please describe) _____

5E. Adults (persons 18 years of age and older)

☐ ASU students ☐ Adults in the community (not ASU students)
☐ Pregnant women ☐ Adults in treatment ☐ ASU faculty and staff
☐ Adults having legal representatives (guardians)
☐ Adults with limited civil freedom (prisoners, parolees, probationers)
☐ Adults with psychological, cognitive, neurological, or intellectual impairment
☐ Adults with a life-threatening illness
☐ Adults with known history of trauma or victimization
☐ Elected or appointed public officials or candidates for public office

5F. Minors (children and adolescents under 18 years of age)

☐ ASU students ☐ Non-ASU minors ☐ Juvenile detainees

☐ Minors with known history of trauma or victimization

☐ Minors with known physical or psychological conditions

5G. Financial Interests: Indicate below if any investigators or any members of their immediate families have any relationships, commitments, or activities with the sponsor of this research that might present or appear to present a conflict of interest with regard to the outcome of the research. (If a financial conflict of interest exists, please submit the ASU approved conflict management plan. If you have questions about conflict of interest contact the Office of the Vice Chancellor for Academic Affairs and Provost at 217.206.6614.)

☐ Ownership, equity or stock options Has been disclosed to the ASU campus **OR** ☐ has not been disclosed to the ASU campus

☐ Personal compensation such as royalties, consulting fees etc. has been disclosed to the ASU campus **OR** ☐ has not been disclosed to the ASU campus

☐ Intellectual property such as patents, trademarks, copyright, licensing, etc. has been disclosed to the ASU campus **OR** ☐ has not been disclosed to the ASU campus

☐ Other conflict of interest: Has been disclosed to the ASU campus **OR** ☐ has not been disclosed to the ASU campus

☐ No conflicts exist

6. RECRUITMENT

6A-1 RECRUITING PROCEDURES SPECIFICALLY describe the systematic procedures for finding and recruiting subjects or requesting pre-existing data or materials. 1) State whether any of the researchers are associated with the subjects (*e.g.,* subjects are students, employees, patients). 2) Name any specific agencies or institutions that will provide access to subjects or subject data. 3) Who will contact the prospective subjects? 4) Who gives approval if subjects are chosen from records? 5) Describe solicitation through the use of advertising (*e.g.,* posters, flyers, announcements, newspaper, radio, television, Internet), face-to-face interaction, direct mail or phone contact, classrooms, subject pools, health care registries, patient referrals, and institutional "gatekeepers," as applicable.

6 A-2 Attach final copies of recruiting materials including the final copy of printed advertisements and the final version of any audio/taped advertisements and mark here: Attached ☐ Not applicable ☐

6 A-3 Attach written approval from agency, organization, or facility giving permission to conduct research at their location. Approval must include reference to a full understanding of the nature of the research and degree of their participation.

☐ Attached ☐ Not applicable ☐ Institutional Research

6B. WITHHELD INFORMATION Do you propose to withhold information from subjects prior to or during their participation?
☐ Yes ☐ No

If yes, describe what will be withheld, justify the withholding (address risks, provide rationale), describe the debriefing plan, and attach a labeled copy of a written debriefing form, to be provided to subjects. ☐ Debriefing attached

7. RESEARCH PROCEDURES:

7A. Subjects will be asked to: (Mark all that apply)

☐ complete an online survey or questionnaire

☐ complete a paper survey or questionnaire

☐ complete a face-to-face interview ☐ with ☐ without audiotaping/videotaping

☐ complete a telephone interview

☐ perform research tasks such as viewing pictures or listening to a presentation

☐ provide biological samples (e.g., hair or nail clippings, saliva, etc.)

☐ other (please explain) _____

☐ does not apply -- data will be collected from existing records or documents only.

☐ does not apply -- data will be collected through behavioral observation only.

7B. Data will include: (Mark all that apply)

☐ private information about each subject (i.e., age; income; health status; psychological, educational, or physical test scores; grades; biological specimens; audio, video, or photographic records; etc.).

☐ the subject's personal opinions, beliefs, perceptions, views, values, experiences, and/or behaviors.

☐ the subject's professional opinions or expertise.

7C. The data collected will be: (Mark only one)

☐ coded for research purposes but the research data include codes or demographic identifiers that would permit **the researcher** to identify individuals either directly or indirectly, through links to individual subjects. In other words, the subject could be identified either directly or indirectly through demographic data or a master code list linking names and research code numbers.

☐ recorded in a way that does not allow the subject to be identified, either directly or indirectly by anyone (including the researcher), through coding, demographic information, or other identifiers linked to the subject cases.

7D. Data will be: (Mark only one)

☐ Anonymous. The researcher will not know who gave what answers. No identifying information will be collected. No links between subject names and research code numbers exist.

☐ Confidential. Research coding will allow the researcher to match subject identifiers with the data; however, the researcher will store the data securely and will not disclose any individually identifiable information collected.

☐ Confidential, unless the subject provides explicit written permission, on the consent form, indicating that his or her identifying information can be included in the research.

☐ Not confidential. Potential participants will be informed, on the consent form, that confidentiality will not be maintained.

7E. Using LAYPERSON'S LANGUAGE, specifically describe what the participants (treatment groups and controls) will do and where the research activities will take place. Give approximate dates and durations for specific activities, including the total number of treatments, visits, or meetings required and the total time commitment. (for schools-based research where class time is used, describe in detail the activities planned for nonparticipants and explain where (*e.g.,* in a classroom, in a private area) both participants and nonparticipants will be located during the research activities. Include a concise description of procedures, locations, time commitments, and alternate activities on the relevant consent and assent forms.)

☐ Attach final copies (survey, consents, protocols, power points, transcripts of oral presentations, etc.)

8. INFORMED CONSENT: University policy requires the execution of a comprehensive, written document that is signed by the subject (or the subject's authorized representative) as the principal method for obtaining consent from subjects. The language in the document must be understandable to the subject or the subject's legally authorized representative. (Attach informed consent and checklist)

Children must *assent* (or, voluntarily agree) to participation and a parent must separately consent on behalf of their child (*i.e.,* two different forms are generally required). Children under age 8 may assent either orally or passively, depending on their level of maturity. Children 8–17 years old should sign a written form unless the ASU IRB approves a different process.

8A. TYPE OF CONSENT Mark all that apply and attach one copy of each relevant form, letter, or script on university letterhead. Include translations, if consent will be obtained in a foreign language. Use headings, headers, or footers to uniquely identify each document and associate it with the subject group for which it will be used.

☐ **Informed consent (assent) with an online document.**

☐ **Written informed consent (assent) with a document signed by**

☐ adult subjects ☐ parent(s) or legal guardian(s) ☐ adolescents aged 8–17 years

☐ **Waiver or alteration of informed consent (attach request for waiver form.)**

☐ adult subjects ☐ parent(s) or legal guardian(s) ☐ adolescents aged 8–17 years

☐ **Waiver of documentation (signature) of informed consent (attach request for waiver form.)**

☐ adult subjects ☐ parent(s) or legal guardian(s) ☐ adolescents aged 8–17 years

8B. USE OF PROXY Will others (*e.g.,* next of kin, legal guardians, powers of attorney) act on behalf of adult subjects in giving consent to participate in this research? ☐ Yes ☐ No If yes, describe

8C. USE OF PROXY OUTSIDE Mississippi If a proxy is used in research conducted outside Mississippi and/or the United States, provide justification (e.g., statement of an attorney or copy of applicable law) that the proxy is authorized under the laws of the jurisdiction in which the research will be conducted to consent to the procedures involved in this protocol.

8D. CONSENT PROCESS Describe when and where voluntary consent will be obtained, how often, by whom, and from whom. If cognitively impaired subjects (including children under age 8) will be involved, explain how the subject's understanding will be assessed and how often; include the questions that will be asked or actions that will be taken to assess understanding.

Describe any waiting period between informing the prospective subject and obtaining the consent. Describe steps taken to minimize the possibility of coercion or undue influence. Indicate the language used by those obtaining consent. Indicate the language understood by the prospective subject or the legally authorized representative.

If the research involves pregnant women, fetuses, or neonates, indicate whether consent will be obtained from the pregnant woman, mother, father, or all. If the research involves children, indicate whether consent will be obtained from: Both parents and legal guardians unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or from one parent regardless of the status of the other parent.

9. RISKS

9A. DESCRIPTION Specifically describes all known risks to the subjects for the activities proposed and describes the steps that will be taken to minimize the risks. Include any risks to the subject's physical well-being, privacy, dignity, self-respect, psyche, emotions, reputation, employability, and criminal and legal status. Risks must be described on consent forms.

9B. RISK ASSESSMENTS

Determining risk related to research is not always an easy task. Risks can be physical, psychological, social, economic, legal, or unknown. The probability (likelihood) as well as the magnitude (i.e., severity, duration, and reversibility) of potential harm must be considered. When evaluating research risk, it is also important to focus on the immediate or reasonably foreseeable risks of the research, as separate from potential risks or benefits associated with the consequences of applying the knowledge that might be gained from the research. The potential benefits of a study do not alter the risk classification. The risk/benefit assessment only refers to the acceptability of the risk, not the level of the risk.

A commonly accepted definition of minimal risk is a level of risk no greater than that typically encountered in the daily lives of healthy individuals in the general population. Thus, the researcher should consider (a) the likelihood of potential harm; (b) the magnitude of potential harm; (c) whether the likelihood and magnitude of potential harm are greater than those encountered in the ordinary daily life of a healthy person; (d) what research procedures are in place to minimize the probability and/or magnitude of harm to subjects; and (e) the extent to which those research procedures are adequate to diminish the risk of harm. For example, a breach of confidentiality is a serious risk, but protections such as restricted access (locked files, stand-alone computers, password protections, and certificates of confidentiality) reduce the absolute risk significantly and may thereby make the overall risk to the subject minimal.

Please consider the immediate or reasonably foreseeable risks of the research rather than the risks associated with the long-term outcome or consequences of applying the knowledge gained from the research.

9C. RISK LEVEL: ☐ **No more than minimal risk**
(the probability and magnitude of harm or discomfort anticipated for participation in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

☐ **More than minimal risk**

9D. Data Monitoring Plan: Must describe the provisions for monitoring the data to ensure the safety of subjects (List who will periodically have access to the data, and monitor harms and benefits experienced by subjects? How often will monitoring occur? Where will the data be stored (locked cabinets, password protected files etc)? If appropriate, what criteria will be used to stop the research based on monitoring of the results?)

10. BENEFITS Describe the expected benefits of the research to the subjects.

11. BENEFITS Describe the expected benefits of the research to society.

If additional risk/benefit information is attached, mark here: ☐

12. INVESTIGATOR ASSURANCES: The signature of the responsible principle investigator is required (scanned or faxed signatures are acceptable). Other investigators are also responsible for these assurances and are encouraged to sign.

I certify that the information provided in this application, and in all attachments, is complete and correct.

I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of this study, and the ethical performance of this project.

I agree to comply with all ASU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

I certify that

- The project will be performed by qualified personnel according to the ASU IRB-approved protocol.
- The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
- No change will be made to the human subjects protocol or consent form(s) until proposed changes approved by the ASU IRB.
- Legally effective informed consent or assent will be obtained from human subjects as required.
- Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the ASU IRB Office (601.877.3964) and to my Departmental Dean.
- Student and guest investigators on this project are knowledgeable about the regulations and policies governing this research, including any confidentiality and safety requirements.
- I agree to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.
- If I will be unavailable, as when on sabbatical or other leave, including vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence. I will advise the ASU IRB by letter of such arrangements.

I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

Responsible Principal Investigator	Date	Investigator	Date
Investigator	Date	Investigator	Date
Responsible Research Supervisor (if RPI is a student, or otherwise applicable)	Date		