Procedure and Form for Submitting an IRB Application

Researchers Checklist:

Please be sure the following items are provided to the IRB Committee on Human Research

- ◯ Application form (starts on next page)
- ◯ Abstract: A narrative of 250 words maximum that clearly describes the purpose of this study, subject selection, and the strategies used to protect the subjects and general approach to data analysis.
- ◯ Procedures: A detailed description of the methods and procedures of the study. Include copies of relevant surveys, questionnaires, recording documents, observation criteria, etc.
- ◯ Risks/Benefits Analysis: A description of the potential risks, including adverse effects, and benefits to the subjects. Include strategies employed to reduce the risks or a justification for continuing despite known risks.
- ◯ Confidentiality Statement: Describe the steps you will take to protect the privacy of subjects and to maintain confidentiality of identifiable information. Explain how your procedures accomplish this objective; such as means of data storage, data location and duration, description of persons with access to the data, and method of destroying the data when completed.
- ◯ Disclosure Statement and Consent Form: Include a copy of the statement provided to the subjects about the investigation. Is any of this information deceptive? Informed Consent is the requirement that human subjects, or their legally authorized representatives, both understand the nature and purposes of the research and freely give their consent to be participants in the study.
- ◯ Letters of collaboration (if applicable)
- ◯ Data collection instrument (if applicable)
- ◯ Human subjects section of grant/thesis proposal or outline of thesis proposal (if applicable)

SEND THE APPLICATION WITH ORIGINAL SIGNATURES TO:

Dr. Trish Parsons, Associate Vice President for Academic Affairs, xxxxxxxxxxxxxxxx

Dr. Mary Amanda Haskins, Associate Professor, mhaskins@stephens.edu

Exempt or Expedited proposals must be submitted at least two weeks prior to the desired research start date. Full committee review proposals must be submitted two weeks prior to the next scheduled IRB meeting to ensure consideration at that meeting; you are required to attend that IRB meeting. You will be notified in writing of the Committee's decision.

Stephens College
Committee on Human Research
Application for Research Involving Human Subjects

Name of Principal Investigator: _____

Faculty Status: Full time ◯ Part time ◯ Tenure track ◯ Non-tenure track ◯

E-Mail Address _____ **Tel. No** _____

Campus Address _____

Name(s) of Co-Investigator(s): _____

_____

_____

Project Title: _____

_____

_____

Academic Program _____ **Duration Month/Year** _____

Grant Funded ◯ **Funding Source** _____

Note: CR 46.101

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted education settings, involving normal education practices, such as

(i) Research on regular and special education instructional strategies, or

(ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

The following examples are for research projects that are not under the purview of the Stephens College IRB. This is neither an exclusive nor an exhaustive list:

- Using the "self "as the subject
- Library research
- Interviews of political figures or experts in a specific field where they are not the subjects of the research
- Oral histories except when using minors, institutionalized mentally ill or mentally challenged
- Public documents
- Academic Program Review

Identify the category under which you suggest this research project falls. Information to assist you to determine your suggested category can be found on the IRB website: www.stephens.edu/assets/Docs/About-Stephens/HumanParticipantsProtectionGuidebook.pdf

The Committee on Human Research reserves the right to make the final determination as to which category is most appropriate.

◯ **Full Committee Review** (Research that does not qualify for exempt or expedited review must be considered by the Full committee)

a. ◯ Research in which more than minimal risks are involved.

b. ◯ Research that involves information about the subject that is sensitive or could cause embarrassment (e.g. sexual behavior) if linkages can be made to the subject's name.

c. ◯ Research that involves information about illegal behavior such as drug taking or underage drinking.

d. ◯ Research that involves children, pregnant women or prisoners.

e. ◯ Research that involves deception in which the subject cannot be told in advance the purpose of the study and therefore, informed consent is compromised.

f. ◯ Research that involves use of information that is not publicly available, such as student records or medical charts, and contains identifiers.

◯ **Expedited Review** (check all possible categories including those found in Appendix B, which pertain largely to physical aspects of the human body.)

a. ◯ Voice recordings made for research purposes such as investigations of speech defects.

b. ◯ Moderate exercise by healthy volunteers.

c. ◯ The study of existing data, documents, records, pathological specimens, or diagnostic specimens that are rendered anonymous.

d. ◯ Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

e. ◯ Research involving the continuation of a previously approved research protocol for an additional period of time that involves no changes in the protocol.

f. ◯ Other categories from Appendix B. Please specify:

In addition to the above, please briefly describe further the reason(s) for expedited status rather than full committee review. Your notation is simply a suggestion to the committee.

Exempt from Full Committee Review (check all possible categories)

a. ◯ Research falls into number _____of the six categories defined by federal regulation as exempt from review. (See below for description of the categories).

b. ◯ Research is low risk for subjects and the investigator assures confidentiality and informed consent.

c. ◯ Research does not involve pregnant women, children, or prisoners when they are specifically chosen as the subject population. (These topics would require a full committee review process.)

In addition to the above, please briefly describe further the reason(s) for exempt status. Your notation is simply a suggestion to the committee.

These conditions are neither exclusive nor exhaustive but represent the most common types of research at Stephens College that fall into the categories of full committee review, expedited review and exempt from full committee review. Carefully review the full lists of criteria found below.

SIGNATURES The undersigned acknowledge that:

- This application is an accurate and complete description of the proposed research.
- The researcher is competent to conduct the proposed research.
- The research will be conducted in compliance with the recommendations of and only after approval has been received from the Institutional Review Board (IRB).
- The lead researcher (in the case of undergraduate student research, the faculty sponsor is considered the lead researcher) is responsible for all aspects of this research, including: reporting any serious adverse events or problems to the IRB, requesting prior IRB approval for modifications, and requesting continuing review and approval. The PI acknowledges responsibility to obtain sufficient resources for this research.
- If the above conditions are not met, approval of this research could be suspended or terminated.

A. Principal Investigator

_____	_____	_____
Date	Printed Name	Signature

B. Faculty Sponsor (for Student) : The IRB must be notified in writing of any change in faculty sponsorship during an active protocol

_____	_____	_____
Date	Printed Name	Signature

END OF APPLICATION FORM