Human Participants Protection Guidebook

Stephens College
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IRB - **Human Participants Protection Guidebook**

INTRODUCTION

All research involving human participants must be reviewed by the Institutional Review Board - Human Participants Protection Committee (IRB). During the review process various guidelines are used in reviewing the research proposal to ensure that it is in compliance with federal and state regulations, and in accordance with Stephens College's institutional assurance compliance filed with the Office for Protection from Research Risks (OPRR).

Submission of a proposal to the IRB -Human Participants Protection Committee and subsequent approval of the project means that the IRB - Human Participants Protection Committee has found the proposal to conform to scientific, ethical and legal standards for research involving human participants.

All survey forms that entail research activities that may involve little or no risk to participants must be submitted to the IRB. All research projects must be submitted to the IRB for review.

Research which is exempt from coverage by the regulations are activities in which the only involvement of human participants will be in one or more of the following categories (Public Health Service Grant Application [PHS 398, Rev. 9/91], pp. 25-26):

1. Research conducted in established or commonly accepted education settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2b) of this section, if: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the

personally identifiable information will be maintained throughout the research and thereafter.

4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or participant to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level, and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

POLICY

A. Stephens College has established the Institutional Review Board (IRB) -Human Participants Protection Committee to be responsible for the institution's review of all research projects involving human participants conducted by the College's faculty, staff and students or done under the sponsorship or auspices of the institution. The IRB - Human Participants Protection Committee has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving human participants.

B. The primary responsibility for protecting the rights and welfare of human participants rests with each individual who initiates, directs, or engages in research. It is the responsibility of the College to reasonably ensure that the human participants, in research conducted under its auspices, are adequately protected. Faculty is responsible to ensure that their students are made aware of these requirements.

C. Approval by the IRB - Human Participants Protection Committee must be obtained before the activity starts and the project must be reviewed annually for as long as it is

active. More frequent monitoring may be required if the Committee determines the research to be of greater risk to the participants.

D. This institution is guided by the ethical principles regarding all research involving human participants set forth in the report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Participants of Research (the "Belmont Report"). Copies of the "Belmont Report" may be requested from the Office of Sponsored Programs (OSP). [45CFR46, Final Regulations for Amending Basic HHS Policy for the Protection of Human Research Participants, 3/8/83]. Copies of 45CFR46 are available from the Office of Sponsored Programs. The following basic ethical principles to be applied when reviewing research are:

1. **Respect for persons.** This guideline refers to providing information about a research project to a prospective participant via informed consent and ensures voluntary participation in a study.

2. **Beneficence.** This guideline requires a favorable risk/benefit assessment. The benefits of a study must outweigh the risks to the participant.

3. **Justice.** This guideline addresses the moral requirement for an equitable participant selection in research, e.g., male vs. female, prisoner vs. free.

DEFINITIONS

The IRB/College has adopted the definitions included in the Federal regulations to guide researchers and others in the determination if human participants are involved in a research project.

A. **HUMAN PARTICIPANT:** "A living individual about whom an investigator (whether professional or student) conducting research obtains (I) data through intervention or interaction with the individual, or (2) identifiable private information.

B. **INTERACTION:** includes communication or interpersonal contact between investigator and participant.

C. **INTERVENTION:** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulation of the participant or the participant's environment that are performed for research purposes.

D. MINIMAL RISK: "The risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of

routine physical or psychological examination or tests."

E. **PRIVATE INFORMATION:** includes (i) information about behavior which occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and (ii) information which has been provided for specific purposes by an individual and which (s)he reasonably expects will not be made public (e.g., medical or employment record). If the identity of the participant is or may be readily determined by the investigator or associated with the private information gathered, this constitutes research with human participants.

F. **RESEARCH:** "A systematic investigation designed to develop or contribute to generalizable knowledge." Some "demonstration" and "service" programs may include research activities.

COMMITTEE STRUCTURE, MEMBERSHIP, AND RESPONSIBILITIES

A. The IRB - Human Participants Protection Committee is charged with certain responsibilities and authority in accordance with institutional policy and Federal regulations. These are listed below.

1. Determine whether a given activity should be considered human participants research.

2. Review and approve, require modifications in (to secure approval), or disapprove research activities which involve human participants.

3. The IRB - Human Participants Protection Committee shall approve research based on the Committee's determinations that the following requirements are satisfied:

a. Risks to participants are minimized:

1) By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and

2) Whenever appropriate by using procedures already being performed on the participants for diagnostic or treatment purposes.

b. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the committee shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research.) The Committee shall not consider long- range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

c. Selection of participants is equitable. In making this assessment, the Committee shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which participants will be recruited. In research that is proposed to seek answers that concern all persons, then a cross section including everyone is to be selected. For example: If a study is examining factors affecting the treatment of cardiac arrest, then the data must be collected on men and women, and all ethnicities. It is not allowed to select only males and then generalize to the rest of the population.

d. Require that information given to participants as part of informed consent is in accordance with institutional policy and may require that information, in addition to that specifically required by Federal regulations be given to the participant when, in the Committee's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.

e. Require documentation of informed consent or waive documentation in accordance with institutional policies in compliance with federal regulations as a minimum.

f. Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of the participant.

g. Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

4. Conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year, and shall have authority to observe or have a third party observe the consent process and research.

5. Determine which projects need verification from sources other than the research investigators that no material changes have occurred since the previous IRB - Human Participants Protection Committee review.

6. Report to appropriate institutional officials and, when appropriate, the Institutional Review Board (IRB) any serious or continuing noncompliance by investigators with the requirements and determinations of the Committee.

7. Suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement about the Committee's action and shall be reported promptly to the investigator, institutional officials and appropriate federal officials, if required.

B. In compliance with Department of Health and Human Services (DHHS) regulations, the Committee is comprised of people from diverse backgrounds and with professional competence necessary to review specific research activities. A variety of professions are represented including at least one member whose primary expertise is in a nonscientific area and at least one member who is not otherwise affiliated with the institution personally or through an immediate family member.

PRINCIPAL INVESTIGATOR / RESEARCH INVESTIGATOR RESPONSIBILITIES

It is the responsibility of the principal investigator to inform the appropriate department chairperson in writing prior to submitting a research project involving human participants to the IRB - Human Participants Protection Committee. Research proposals are to be submitted in accordance with Stephens College procedures and to comply with applicable institutional policies and federal and state regulations.

The principal investigator is responsible for obtaining informed consent from the participant, maintaining a signed copy of the consent (in both private research records and college records) and providing the participant with a signed copy. All categories II and III require signed consent forms. The principal investigator is responsible for maintaining all participant data relevant to the study.

The principal investigator must notify the IRB - Human Participants Protection Committee directly, of any modifications to the proposal, deviations from the proposal or adverse events associated with the research. Any new information which becomes available and which could potentially alter the risk benefit ratio must be reported to the IRB -Human Participants Protection Committee. The principal investigator should notify the **IRB - Human Participants Protection Committee when a proposal becomes inactive or is withdrawn. The principal investigator must provide the IRB - Human Participants Protection Committee, at least annually, with information requested during the continuing review process.**

Other responsibilities of the principal investigator/research investigator include:

A. Make a preliminary determination of human participant involvement recognizing that the authority for the final determination of whether or not a proposed research activity involves human participants rests with the IRB -Human Participants Protection Committee.

B. Inform all students and employees that might engage in human participants research of their obligations as described herein.

C. Prepare a proposal according to institutional requirements giving a description of the proposed research as detailed in "Project Category I" (see pp. 20-21, 26) through "Informed Consent." In the proposal, research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research participants and

insure that pertinent laws and regulations are observed. Research investigators shall include samples of proposed informed consent forms with the proposal.

D. Submit proposal to the Institutional Review Board Committee.

E. Submit material described in "Miscellaneous Research Activities - Review Requirements" as necessary.

F. May not initiate any research activity involving human participants until the IRB-Human Participants Protection Committee has completed review and approval of proposal. Research investigators shall be responsible for complying with all IRB – Human Participants Protection Committee decisions, conditions and requirements.

G. Are responsible for obtaining informed consent in accordance with provisions of "Informed Consent" as required by the IRB - Human Participants Protection Committee.

H. Are responsible for retention of the signed consent documents. These documents shall be retained for at least three years after termination of the last IRB - Human Participants Protection Committee approval period.

I. Are responsible for complying with the continuing review procedures, as often as in the manner prescribed by the IRB - Human Participants Protection Committee but no less than once per year.

J. Are responsible for reporting promptly in writing to the IRB, any injuries to human participants. Research investigators are responsible for reporting promptly to the IRB any unanticipated problems that involve risks to the human research participants or others.

K. Are required to report changes in research in accordance with provision of **"Miscellaneous Research Activities -Review Requirements, Reporting Changes in the Research."**

L. Researchers who are aware of any serious or continuing noncompliance with the requirements of this assurance or the determination of the IRB - Human Participants Protection Committee should communicate the alleged noncompliance with the principal investigator or researcher in question. Ethical standards of various disciplines and professional societies may offer guidelines and principles for appropriate conduct in this regard. Should this effort for direct communication fail to bring about compliance with institutional policies or should the concerned party judge the direct communication as inappropriate in a given instance, the concerned party should notify the IRB with all deliberate speed.

M. Shall be responsible for notifying the Food and Drug Administration (FDA) and the IRB whenever it is anticipated that an investigational new

drug or device exemption will be required.

COMMITTEE ADMINISTATION

The administrative office of the Institutional Review Board -Human Participants Protection Committee is in the School of Organizational Leadership and Strategic Communication. Any questions about human research proposals should be directed to Orlando Smith, Chair, Institutional Review Board, 573-442-2211 x4456.

INFORMATION REQUIRED FOR REVIEW

Procedural Information

1. Discussion/Preliminary Screening. If the prospective researcher has any questions about the project and the review process or has not recently submitted a proposal to the Committee for review, the investigator should contact the Chair of the Institutional Review Board, Orlando Smith

2. The authority for the final determination of whether or not a proposed research activity involves human participants rests with the IRB - Human Participants Protection Committee, **not the individual research investigator.**

3. Once it has been determined that an activity includes human participants research, it will be reviewed under one of three categories. Categories I and II are eligible for "expedited review" by only the Committee Chair or one or more Committee members designated by the Chair. Category III requires "full review" by the full committee at one of the monthly meetings or other designated dates during the academic year. Each researcher makes the initial determination regarding the appropriate category of review, although the Committee Chair may require review under another category. The researcher may request a higher category review level.

4. The research investigator submits to the Chair of the Institutional Review Board written information required for review depending on the project category, as described in the Project Categories. The materials (forms) initiating review are available on the Stephens College webpage. Students conducting research projects must have the forms reviewed and signed by a faculty advisor.

USE OF STUDENTS AS RESEARCH PARTICIPANTS

Students **may not be required** to participate in any research project as a participant as a course requirement or required by faculty member to serve as a participant for pilot testing research

instruments. Courses that involve a research requirement must make clear that participation in research as a participant is one of several options to fulfill the research requirement. A written explanation of all research alternatives is required. The informed consent for projects proposing to recruit student participants must make clear the voluntary nature of their participation. Ex. In some situations, a PI may ask for student participation in a research activity. If extra-credit is given to the students who participate, then those students who choose not to participate must be given alternative ways to earn the extra credit with the same amount of effort as those participating in the research. Questions regarding this policy should be referred to the Institutional Review Board committee.

ROLE OF THE INSTITUTIONAL REVIEW BOARD- HUMAN PARTICIPANTS PROTECTION COMMITTEE

The functions of the Institutional Review Board - Human Participants Protection Committee are as follows:

1. To safeguard the rights and welfare of individuals who participate as participants in research activities.

2. To determine the adequacy of proposed research procedures related to protecting the rights and welfare of participants and approve those sections of applications or proposals pertaining to involvement of human participants in research activities that are in conformity with the Public Health Service regulations.

3. To monitor compliance with Public Health Service regulations regarding human participants.

The Institutional Review Board (IRB) - Human Participants Protection Committee is charged with reviewing all research involving human participants at Stephens College The review process is guided by federal and state regulations and is conducted in accordance with the Assurance of Compliance with the Department of Health and Human Services (HHS) Regulations for Protection of Human Research Participants. Review of research proposals is based on both ethical considerations and scientific merit in maintaining protection from minimizing research risks to the participants. A fundamental responsibility of the IRB - Human Participants Committee is to protect human participants from risks associated with research activities.

The IRB - Human Participants Protection Committee has the authority to approve, require modifications or disapprove research projects involving human participants. The IRB - Human Participants Protection Committee has the authority to suspend .or terminate research activities that do not meet with IRB - Human Participants Protection Committee requirements or that have been associated with unexpected serious harm to participants.

COMMITTEE MEETINGS

Stephens College IRB - Human Participants Protection Committee meet "as needed" during the academic year.

Sample A

APPLICATION TO
STEPHENS COLLEGE INSTITUTIONAL REVIEW BOARD - HUMAN PARTICIPANTS PROTECTION COMMITTEE

1. Name:
   Dept/Scho
   ol: Phone
   No:

   Mailing Address:

2. Project period: From _____ To _____
   Mo. Yr. Mo. Yr.

3. Funding Source(s):

4. Site of Work:

5a. Title of project:

5b. Brief description of its general purpose:

6. Give details of the procedures that relate to the participants' participation, including at a minimum the following information (use additional page(s) if necessary):

   a. How were the participants selected and recruited? (You are required to append copies of letters, ads or transcripts of verbal announcements.)

   b. What compensation is offered, if any? (Be very specific.)

c. Number and salient characteristics of participant, i.e., age range, sex, institutional affiliation, other pertinent characterization(s).

d. If a cooperating institution (school, hospital, prison, etc.) is involved, has written permission been obtained? (Append letter.)

e. Number of times observations will be made?

f. (1) What do the participants do, or (2) what is done to them, in the study? (Append a copy of questionnaires or test instruments, or description of procedure to be conducted on the participant.)

g. Is it clear to the participants that their participation is fully voluntary?

h. Is it clear to the participants that they may withdraw at any time?

1. Is it clear to the participants that they may refuse to answer any specific question that may be asked them?

J. Cite your experience with this type of research.

7. How do you intend to obtain the participants' informed consent? If in writing, attach a copy of the consent form. If not in writing, include a written summary of what is to be said to the participant(s), and justify the reason that oral, rather than written, consent is being used. Also, explain how you will ascertain that the participants understand what they are agreeing to.

8. In your view, what benefits may result from the study that would justify asking the participants to participate?

9a. Do you see any chance that participants might be harmed in any way? Do you deceive them in any way? Are there any physical risks? Psychological? (Might a participant feel demeaned or embarrassed or worried or upset?) Social? (Possible loss of status, privacy, reputation?)

9b. How do you ensure confidentiality of information collected? [Consider 9a and 9b from the point of view of the participant.)

Applicant's signature	Faculty Advisor's Signature (For student applications)	Date

INSTRUCTIONS FOR THE COMPLETION OF THE "APPLICATION TO IRB- HUMAN PARTICIPANTS PROTECTION COMMIYFEE"

The form "Application to Stephens College Institutional Review Board- Human Participants Protection Committee" was designed to be self-explanatory. Occasionally there are questions; therefore, the following is offered as a guide to assist you in completing the application thoroughly.

The applicant should answer all questions thoroughly and provide attachments as appropriate. If any question does not apply to your research project, mark it N/A (not applicable). The application was designed to serve as a checklist for the researcher, ensuring the research plan includes all necessary elements. If you do not answer questions that are pertinent to your proposed research, or if you do not attach a copy of the research instrumentation, procedures, etc., your application will be returned to you or held for receipt of all necessary documentation. If you have any questions about what should be included in your application packet, please call Orlando Smith of the IRB at 573-876-7207 x4456.

I. **Name, department, etc.:** Who are you? What department/school (or division or laboratory, etc. if doing work with another institution) do you work with? At what phone number can you be reached? Where do you receive your campus mail (give your P.O. Box)?

2. **Project period:** Give approximate time period of participant involvement. This is important if your project is a long-term one; the IRB- Human Participants Protection Committee must review ongoing projects every twelve months. Our interest here is in the period of participant involvement, not in your subsequent data analysis.

3. **Funding source(s):** If your project is supported, totally or partially, by external funding, the IRB- Human Participants Protection Committee wants to know. (We keep track of sponsored human participant research.) If you are self-funded, enter "N/A." If the proposal has not been funded, but has been submitted, enter the proposed funding source.

4. **Site of work:** Where are you going to involve the participants? On campus? At a local high school? All over the state? (Interested in participants' location, not in the place of data analysis.)

5a. **Title of project:** List title of project.

5b. **Brief description of its general purpose:** List brief synopsis of your project.

6a. **How were participants selected and recruited?:** Where did you get your participant population? Passers-by-at-large? Random selection from the telephone book? The Psychology pool? Inmates at the nearest penitentiary? Residents of a nursing home? How did you select your population? Was it through an advertisement in the paper, letter, announcement, etc.?

6b. **What compensation is offered?:** If participants are to receive a stipend, grade points, or any other compensation for participating, what is it? If there is no compensation, enter **"N/A."**

6c. **Number and salient characteristics of participants:** How many participants do you plan to involve? Do you plan on distributing 50 or 1,000 survey forms? What is the number of participants you intend to involve? Also, characterize them--females, ages 8 to 80, or males, 18-22, or what? Are your participants all 8th grade students, or members of a specific church, or holders of a Missouri hunting or fishing license? Give any specifics that categorizes your participant population.

6d. **If a cooperating institution is involved, has written permission been obtained?** APPEND LETTER(S). Researchers must have written permission from the head of an organization or member of the administration with sufficient rank to grant such permission. If research involves an entity with its own IRB, then the researcher must earn that entities IRB approval before research is begun.

6e. **Number of times observations will be made?** Are you asking the participants to complete one instrument once? Are you asking them to report their diet three times a week for six weeks, and take blood samples weekly for the six weeks? How much of the students' time will you take up--half an hour? Six hours?

6f. **What do the participants do, or what is done to them, in the study?** APPEND COPY OF QUESTIONNAIRE(S), TEST INSTRUMENT(S) OR DESCRIPTION OF PROCEDURES TO BE CONDUCTED ON THE PARTICIPANTS. If you are involved in thesis, dissertation, or sponsored research, attach a copy of your research procedure. If not, give a clear, concise description of what you intend to do to or with the participants. The IRB - Human Participants Protection Committee is not only interested in what type of analysis you intend to carry out on the data but is also interested in what you are going to measure and how.

6g. **Is it clear to participants that their participation is completely voluntary?** Does your informed consent form or statement make this clear to the participants? Is it written in language they can understand?

6h. Is it clear to the participants that they may withdrawn at any time? See 6g.

6i. Is it clear to the participants that they may refuse to answer any specific question that may be asked them? See 6g.

6j. Cite your experience with this type of research: The IRB- Human Participants Protection Committee's interest here is mainly in projects where there is an element of risk for the participants--physical, emotional, through potential breach of confidentiality, etc. In such cases when the researcher does not have adequate experience, the IRB - Human Participants Protection Committee will work to ensure the participants' safety by having someone with adequate experience monitor the project.

7. How do you intend to obtain the participants' informed consent? **If** in writing, attach a copy of the consent form. **If** not in writing, include a written summary of what is to be said to the participants, and justify the reason that oral rather than written consent is being used. Also, explain how you will ascertain that the participants understand what they are agreeing to. The Stephens College IRB - Human Participants Protection Committee may allow consent to be obtained other than through the full consent form, provided: (1) there is no risk, or risk to the participants minimal, (2) the written consent procedure would not be normally used outside the research context, and (3) the consent document would be the only link between the participant and the research data.

The decision as to whether an informed consent document is required is reserved to the IRB - Human Participants Protection Committee. However, the IRB - Human Participants Protection Committee does specifically require the following list to be made available to the participant.

a. inform them that they are being asked to participate in a research project (the word "research" will be used);
b. the title of the project is stated;
c. state who is conducting the research and under whose auspices;
d. explain what they are being asked to do or what will be done to them;
e. tell them how much of their time will be involved in the study;
f. explain that participation is fully voluntary, the participant may quit at any time, and the participant may refuse to answer a question(s);
g. define method of ensuring participants' confidentiality;
h. provide name of person who would furnish participants with additional information about the research project; and
i. offer to answer any questions the participants might have about the study.

8. In your view, what benefits may result from the study that would justify asking the participants to participate? What expected value is there to the study that gives the researcher the right to ask the participants to participate?

9. Do you see any chance that participants might be harmed in any way? Do you deceive them in any way? Are there any physical risks? Psychological? (Might a

participant feel demeaned or embarrassed or worried or upset?) Social? (Possible loss of status, privacy, reputation?) This is part of the application that is concerned with the cost/benefit ratio of the proposed research, and calls for an honest evaluation by the researcher of these considerations from the point of view of the participant.

10. How do you ensure confidentiality of information collected? See 9a.

The applicant signs the application in the lower left corner. If the applicant is a student, the faculty advisor must also sign in the indicated place. This faculty advisor signature indicates that the advisor has reviewed the proposed research and approves of it as being methodologically and ethically sound, taking full responsibility for the conduct of the research, if approved.

Sample B

STEPHENS COLLEGE INSTITUTIONAL REVIEW BOARD - HUMAN PARTICIPANTS PROTECTION COMMITTEE

APPLICATION FOR APPROVAL OF INVESTIGATIONS INVOLVING HUMAN PARTICIPANTS

PLEASE TYPE:

1. Principal Investigator's Name: _____
(Student, Faculty, Staff--Circle one.)

Co-Investigator: _____
(Student, Faculty, Staff--Circle one.)

Department: _____ Phone: _____ Box #_____

2. **If** you are a student, provide the following:

Faculty Sponsor: _____ Department: _____ Phone: _____

Is this your class research project/assignment, thesis or dissertation research?
Yes No

3. Title of project:

4. Has this project previously been considered by the IRB? Yes ____ No ____

If yes, give approximate date of review._____

5. Is a proposal for external support being submitted? Yes No

If yes, you must submit one complete copy of that proposal as soon as it is available and complete the following:

a. Is notification of Human Participant approval required? Yes No

b. Is this a renewal application? Yes No

c. Sponsor's Name: _____

d. Project Period: From: _____ To: _____

In an application letter to the Institutional Review Board- Human Participants Protection Committee or on a separate sheet, please provide the following information.

I. PROPOSED RESEARCH PROTECT

A. Provide a brief summary of the proposed research. Include major hypotheses and research design.

B. Describe the sources(s) of participants and the selection criteria. Specifically, how did you obtain potential participants, and how will you contact them?

C. Informed Consent: Describe the consent process and attach all consent documents. Elements of informed consent are:

1. A clear statement that "the study involves research"
2. All the research purposes are clearly stated
3. The expected procedures to be followed
4. The duration of involvement by the participant
5. When procedure(s) are experimental
6. Reasonably foreseeable discomfort and risks
7. If more than minimal risk, "In case of injury or severe adverse, reaction..."
   a. Is medical care available? By whom? Where?
   b. Is compensation available? How?
   c. Whom should the participant contact?
8. Reasonably expected benefits to participant and others
9. The alternatives to the research's diagnostic method or treatment
10. How confidentiality or anonymity are maintained
11. Who will answer questions about the research itself?
12. Who will answer questions about the participant's rights?

D. Procedures: Provide a step-by-step description of each procedure, including

the frequency, duration, and location of each procedure.

E. How will confidentiality of the data be maintained?

Additions or changes in procedures involving human participants, as well as any problems connected with the use of human participants once the project has begun, must be brought to the attention of the IRB- Human Participants Protection Committee.

II. SIGNATURES

A. I certify that to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project.

_____

Principal Investigator Date
(Student, Faculty, Staff---Circle one.)

_____

Principal Investigator Date
(Student, Faculty, Staff---Circle one.)

B. Approval of Faculty Sponsor (required for all students):

I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research, the supervision of human participants, and maintenance of informed consent documentation as required by the IRB - Human Participants Protection Committee.

_____

Faculty Sponsor Date

C. Approval by Departmental Committee/Chair

I confirm the accuracy of the information stated in this application. I am familiar with, and approve of the procedures that involve human participants.

Departmental Committee/Chair Date

(This form is for IRB -Human Participants Protection Committee use only.)

IRB Determination:

Exempt from Review ( ) Expedited Review ( ) Full IRB Review ( )

( ) Disapproval

( ) Approval

a. approval, participant to minor changes
b. approval in general but requiring major alterations, clarifications or assurances
c. restricted approval

Comments:

Institutional Review Board- Human Participants Protection Committee Chair /Date

Institutional Review Board- Human Participants Protection Committee Administrator /Date

If you have questions regarding review procedures or completion of this application, contact the IRB Administrator, Institutional Review Board- Human Participants Protection Committee or Office of Sponsored Programs.

PROJECT CATEGORY I

A. Federal regulations allow certain research activities which involve little or no risk to participants to be exempt from formal committee review. Since institutional policy requires that Stephens College Institutional Review Board - human Participants Protection Committee be apprised of all human participants research being conducted under its auspices in the event any questions or problems arise and in order to assure that, regardless of risk, all research participants are afforded the same protections, an expedited review procedure is used for this type of research.

The initiation of the review process occurs within the departments of the undergraduate research projects.

B. Eligible Projects for Project Category I

Research activities in which the only involvement of human participants will be as described below may be considered in this category.

1. Research involving survey or interview procedures and observations (including observation by participants) of public behavior, except where any of the following conditions exist:

(i) responses/observations are recorded in such a manner that participants can be identified in any way. If any identification is possible (i.e., the retention of names or codebooks for follow-up or longitudinal studies), the project is NOT Category I;

(ii) if responses/observations became known outside the research and could place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability;

(iii) the research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug abuse, sexual behavior or the use of alcohol. Research involving survey or interview procedures is exempt from review when the respondents are elected or appointed public officials or candidates for public office.

2. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to participants.

3. Unless specifically required by statute or by the Public Health Service (PHS), research and demonstration projects which are conducted by or participant to approval by the Department of Health and Human Services (DHHS) and are designed to study, evaluate or examine programs under the Social Security Act or other public benefit or service programs, procedures for obtaining benefits or services, possible changes in or alternatives to these programs or possible changes in methods or levels of payments for benefits or services under those programs.

C. The research investigator makes the initial decision on whether the research falls into one or more of the "exempt" categories. The Human Participants Research Review Form (cover sheet and Items 1-7) should be completed and submitted to the Institutional Review Board.

PROJECT CATEGORY II

Depending on the research activities involving human participants, two types of formal Committee review are possible--FULL or **EXPEDITED.** "Expedited Review" is the review and approval by the IRB -Human Participants Protection Committee Chair or one or more Committee members designated by the Chair.

A. Qualifying Criteria for **Expedited Review**

1. Research activities in which the <u>only</u> involvement of human participants will be in one or more of the categories listed below, providing the procedures are carried out through standard methods <u>and</u> no more than minimal risk is involved are Project Category II. (See **"Definitions"** for description of" minimal risk.")

2. <u>Only Involvement is in One or More of the Following Categories</u>

(a) Research conducted in established, or commonly accepted educational

settings, involving normal educational practices, such as (1) research on regular and special educational instructional strategies, or (ii) 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), if the information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

(c) Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth and permanent teeth, if patient care indicates a need for extraction.

(d) Collection of excreta and external secretions including sweat, uncannulated saliva, and placenta removed at delivery, amniotic fluid at time of rupture of the membrane prior to or during labor.

(e) Recording of data from participants 18 years of age or older using non-invasive procedures routinely employed in clinical practice. Tills includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the participant or an invasion of the participant's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does <u>not include</u> exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(t) Collection of blood samples by venipuncture, in amounts not exceeding *450* milliliters in an eight-week period and no more often than two times per week, from participants 18 years of age or older and who are in good health and not pregnant.

(g) Collection of both supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(h) Voice recordings made for research purposes, such as investigations of speech defects.

(i) Moderate exercise by healthy volunteers.

(j) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(k) Research on individual or group behavior characteristics or individuals, such as studies of perception, cognition, game theory or test development, where the investigator does not manipulate participants' behavior and the research will not involve stress or deception of participant.

(1) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

3. **Expedited review for projects involving minors.** Research proposals involving minors but meeting the criteria described in **"Project Category I, B.2 and 3"** and **"Project Category II, A.2(a) and (b)"** may be reviewed under the expedited review category. Research involving the observation of public behavior of minors as participants, where the investigator(s) does not participate in the activities being observed, may be reviewed under expedited review, **"Project Category II."**

4. **Other Eligible Projects.** Specifically, the expedited review procedure may be used to review projects as described below:

(a) New Research activities which present no more than minimal risk and in which the only involvement of human participants will be in one or more of the 12 categories noted above.

(b) Minor changes in previously approved research.

(c) Annual Reviews of previously approved proposal which present no more than minimal risk and in which the only involvement will be in one or more of the 12 categories described above.

5. **Written Information Required.** The information requested on Human Participants Review Form (cover sheet and Items 1-10) should be completed and submitted to the Office of Sponsored Programs. A project which is eligible for expedited review is still participant to the review and informed consent criteria outlined in **"Informed Consent."**

B. **Executive Approval.** Review and approval by the Chair of the IRB, or a designee. This form of approval is considered a subcategory of Expedited Review and will be used for the following situations:

1. Upon receipt of specific proposal modifications or documentation requested by the full Committee as a condition of approval.

2. When an updated assurance form is needed by a granting agency, provided there are no changes in proposal (i.e., resubmissions) and not more than 12 months have elapsed since the last Committee review and approval of the proposal.

PROJECT CATEGORY III

A. This category includes research which has the potential for causing physical, social, economic or psychological injury to participants, violating their legal rights or which requires special protections for participants. Examples of such research include:

- o Research involving psychological or physiological intervention
- o Research involving deception
- o Interviews or surveys on sensitive topics (e.g., sexual behavior, alcohol or drug use, illegal behavior)
- o Research on special populations (e.g., minors, prisoners, and mentally incompetent or institutionalized)
- o Research which might put participants at risk

The outcome of full review by the IRB - Human Participants Protection Committee is not necessarily a determination that participants are "at risk." For all research, documentation of legally effective informed consent will be required. Research on minors or participants incompetent to give consent will require written permission by a parent or legal guardian and usually, the assent of the participant. Research involving deception (i.e., the presentation of false information or the omission of information necessary for valid informed consent) will only be approved if it meets certain conditions (e.g., thorough debriefing).

Additional protections are required for projects that involve children as participants in research. Different review criteria will be applied when (1) research involves greater than minimal risk but presents the prospect of direct benefit to the individual participant

or (2) research involves greater than minimal risk and no prospect of direct benefit to child but likely to yield generalizable knowledge about the participant's disorder or condition. See also **"Informed Consent, Minors as Research Participants."** THOSE PLANNING RESEARCH INVOLVING GREATER THAN MINIMAL RISK TO CHILDREN AS PARTICIPANTS ARE STRONGLY URGED TO REVIEW THE FEDERAL REQUIREMENT FOR "ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED AS PARTICIPANTS IN RESEARCH" PRIOR TO SUBMISSION OF A PROPOSAL. COPIES ARE AVAILABLE FROM THE OFFICE OF SPONSORED PROGRAMS.

B. Written Information Required. A research investigator must provide a typewritten proposal for review by the Committee. The proposal constitutes a statement of the researcher's responsibilities toward the human participants involved in the research, detailing the procedures, risks, benefits, etc., of the project. The information requested on the application form, cover sheet and items 1-18, constitutes the proposal following the Committee meeting; the investigator will receive a memorandum noting the Committee's action.

PROJECT CATEGORIES:

All research involving human participants must be reviewed and approved prior to initiating the research. The method of review (expedited or full review) depends on the category of research appropriate for the project. Below are listed the three project categories, along with examples of the types of projects included in each category. If you have questions regarding the appropriate category for your project, contact Orlando Smith for assistance.

Project Category I (Expedited Review)

- Anonymous mail or telephone surveys on innocuous topics
- Anonymous, non-interactive nonparticipating observation of public behavior
- Secondary analysis of existing data

Provide cover sheet and information requested in items 1-7.

Project Category II (Expedited Review)

- Research on educational curriculum or teaching methods involving normal educational practices
- Research involving the use of educational tests if information taken from these sources is recorded in such a manner that participant's cannot be identified
- Research on individual or group behavior of normal adults where there is no psychological intervention, physiological intervention or deception
- Interviews and interactive surveys

Provide cover sheet and information requested in items 1-11.

Project Category III (Full Review)

- Research which might put participants at risk
- Research involving psychological or physiological intervention
- Non-curricular, interactive research iri schools
- Research involving deception
- Interview or surveys on sensitive topics
- Research on special populations (e.g., minors, prisoners, and the mentally incompetent)

Provide cover sheet and information requested in items 1-17 and any additional forms required.

SUBMIT TO:	Orlando Smith Chair of the IRB. Box 2015 Telephone: 573-876-7207 x4456

HUMAN PARTICIPANTS RESEARCH REVIEW FORM

Sample C

A. Principal Investigator(s) _____ Dept.. _____ Phone #: _____

B. Title of Project: _____

C. Location of Study

D. Duration of Study _____ Average Time Participant is Involved

E. Sources of Funding for Proposed Study (check as appropriate):

_ Department _ Federal Agency _ Other

F. If the principal investigator is a student, list name, department and local telephone of faculty supervisor. Please note that *the faculty supervisor must indicate knowledge and approval of this proposal by signing this form.*
Faculty Supervisor Name: _____
Location, Address, and Telephone #: _____

O. Check appropriate category of research project:

Category I	_Category II	_Category III
(Expedited Review)	(Expedited Review)	Full Review)

H. The Principal Investigator (P.I.) must sign this form. (If the P.I. is a student, his/her faculty supervisor must also sign this form.)

I certify that: a) the information provided for this project is accurate; b) no other procedures will be used in this project; and c) any modifications in this project will be

submitted for approval prior to use.

_____

Signature of Investigator *Date*

Undergraduate Students: _____

I certify that student investigator(s) named are competent to conduct these activities and have received training in the ethical-behavior aspects of experimental research with human participants.

In addition, as faculty supervisor, I will monitor the activities of the students assisting me, to the extent appropriate to their experience and training.

_____

Faculty Supervisor *Date*

ITEMS 1-7 **ARE REQUIRED FOR ALL PROJECTS**

1. **BRIEF PROJECT DESCRIPTION:** In a few words, describe the objectives, methods and procedures of the project. The emphasis should be on the human participant involvement in the project. Discussion of theoretical or statistical aspects of the project should be avoided. If a questionnaire and/or testing instrument is to be used, describe how it will be administered. If interviews are to be conducted, describe the nature of the interview and how responses will be recorded. (This summary will be used to describe your project in the official record of Stephens College IRB -Human Participants Protection Committee.)

CHARACTERISTICS OF HUMAN PARTICIPANTS INVOLVED IN PROJECT:

2. Number and relevant characteristics of participants (e.g., policemen, students, random sample, etc.)

3. Please specify compensation, if any, to be received by participants for their participation (e.g.. academic credit, money, etc.)

4. Relationships of participant(s) to investigator (e.g., students, advisees, etc.). if no relationship prior to project, so state.

5. How will participant(s) be chosen for participation (e.g., random sample, course, participant pool, etc.)?

6. Explain the information which will be given to the participant that participation in the project is done with "informed consent." (See "Guidelines for the Development of an Informed Consent Form," a copy of the informed consent form, explanatory cover letter summary to be read to each participant, etc., must be attached).

7. Attach copies of all questionnaires testing instruments or interview proposals; include any cover letters or instructions to participants.

ITEMS 8-11 ARE REQUIRED FOR CATEGORIES II AND III ONLY

8. What personal identifying indicators, if any, will be kept on participants (e.g., name, social security numbers, etc.)? What specific steps will be taken to guard anonymity of participants and/or confidentiality of their responses? Specify procedures for storage and ultimate disposal of personal information.

9. If the participants are to be drawn from an institution or organization (e.g., hospital, social service agency, prison, school, etc.) which has the responsibility for the participants, then documentation of permission from the institution must be submitted to IRB - Human Participants Protection Committee before final approval can be given.

10. If this project is being reviewed by any other human participants review group (e.g., hospital institutional review board), a copy of the approval of that institution should be attached or a statement of the status of the review should be noted below.

11. Will the participants come into contact with any mechanical, electrical or other equipment? If yes, explain.

ITEMS 12-18 ARE CATEGORY III ONLY

ON ADDITIONAL SHEET(S) OF PAPER, PROVIDE THE FOLLOWING INFORMATION:

12. In addition to the brief description provided in Item 1, describe in greater detail the research procedures proposed, i.e., physiological, psychological intervention, the means used to administer the intervention, the behavior expected of the participant(s) and the behavior of the investigator during the intervention.

13. Information for risk/benefit analysis:

    a. Description of the benefits to the human participants, if any, and the benefits to human or scientific knowledge;

    b. Description of the risks and/or discomforts, if any, to the participants. Such deleterious efforts may be physical, psychological or social. Some research involves neither risks nor discomforts but rather violations of normal expectations. Such violations, if any, should be specified;

    c. Description of the safeguards to be taken to minimize potential risk, effects or violations.

14. Identify anticipated and possible psychological, physiological or social consequences of this procedure for the participant(s). (Note the consequences may be different from the risks to the participant during the research project.)

15. If **DECEPTION** is to be used in this project, explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigators.

16. Describe in detail the plans for debriefing participants.

17. Some research procedures may require certain investigator competence and training. If these qualifications to conduct the research are not explicitly obvious to the IRB - Human Participants Protection Committee, details of the investigator's competence and qualifications, by training and experience to conduct, should be indicated.

18. Research procedures involving the investigation of new drugs, biomedical devices or other special interventions require additional information. Please consult the Office of Sponsored Programs for details.

STEPHENS COLLEGE
INSTITUTIONAL REVIEW BOARD -
HUMAN PARTICIPANTS PROTECTION COMMITTEE

IRB Process

Stephens College is committed to excellence in teaching, research, and public service. The College is committed to the conduct of these activities with the highest possible ethical standards. The Institutional Review Board - Human Participants Protection Committee of Stephens College is responsible for reviewing all research and training projects proposed by faculty, staff, and students that involve humans as participants.

IRB Process

I. The principal investigator (faculty, staff, or student) prepares the IRB- Human Participants Protection Committee application according to the IRB - Human Participants Protection Committee guidelines.

2. The complete application packet is submitted to the Chair of the IRB. Meetings will be established as needed.

3. The application is logged in.

4. The application is reviewed by an appropriate IRB - Human Participants Protection Committee Reviewer based on the IRB guidelines.

5. A **Technical Review** is conducted by the Chair of the IRB to determine that the IRB – Human Participants Protection Committee application is complete and contains the following:

   a. Completed IRB -Human Participants Protection Committee application form;

b. Informed consent documentation (if informed consent is not required, verification of a request to waive informed consent is necessary);

c. A copy of the actual survey instrument, questionnaire or data record form to be used in the project;

d. Signatures of the principal investigator, faculty sponsor (if student project), and chair of IRB and/or IRB -Human Participants Protection Committee.

Incomplete application packets will be returned to the principal investigator, with a memo stating deficiencies. Once corrected, these applications should be resubmitted for review.

6. Complete IRB - Human Participants Protection Committee applications will receive an **Initial Evaluation** by the assigned IRB - Human Participants Protection Committee reviewer to determine content and impact of the project on human participants. Applications which receive positive review from the IRB - Human Participants Protection Committee Reviewer will be allocated to one of the following categories:

   a. Exempt from Review

   b. Expedited Review- minimal risk to human participants

   c. Full Board Review Recommended- Possible risk to human participants or a sensitive topic area is being researched;

   d. Full Board Review Required - Human participants at risk. Complete IRB – Human Participants Protection Committee review is mandatory.

7. The IRB - Human Participants Protection Committee Reviewer will recommend one of the following:

   a. Exempt from Review -The IRB - Human Participants Protection Committee Coordinator verifies exemption.

   b. Expedited Review

   c. Full Board Review Recommended or Required

8. Disposition of the IRB - Human Participants Protection Committee application is forwarded to the applicant by the IRB Coordinator within two weeks following the IRB - Human Participants Protection Committee meeting.

Special Considerations

I. All student-initiated research projects (with the exception of opinion research) which are conducted outside of the classroom require IRB -Human Participants Protection Committee review.

2. All Training Programs, regardless of source of funding, with a research component require IRB- Human Participants Protection Committee review.

3. All dissertations, theses, and projects in which human participants are utilized and in which data plans to be/will be used in publications require IRB -Human Participants Protection Committee review.

For further information regarding the IRB- Human Participants Protection Committee, please contact Orlando Smith, School of Organizational Leadership and Strategic Communication at 573-876-7207 x4456.

TO: Faculty, Staff and Administrators

FROM: Chair, Institutional Review Board

DATE: August 1, 2012

PARTICIPANT: IRB Guidelines for Student Based Survey Research Projects

If you are designing survey research projects for your students to conduct as part of a course requirement and these research projects use human participants, IRB - Human Participants Protection Committee approval must be sought prior to initiation of the project. In an effort to clarify which types of survey projects require IRB - Human Participants Protection Committee approval, we are attaching a copy of the **"Guidelines for Classroom Projects Based on Survey Research With Human Participants."** The deadline for receipt by IRB of surveys for IRB review is seven (7) working days prior to the scheduled meeting. Requests after that time may not be reviewed in time for students to conduct projects before the end of the semester. As you can see in the attached document, if you direct your students to conduct opinion survey research, IRB - Human Participants Protection Committee approval is not necessary. We hope that you will use these parameters as a guide when creating assignments for your students that require the use of human participants.

If you are working toward earning a degree and your research or survey involves Stephens College's students, faculty, staff and/or administrators or if you plan to utilize data in any form from Stephens College, you must seek approval from the IRB - Human Participants Protection Committee.

If you have any questions regarding these guidelines or the IRB - Human Participants Protection Committee process, please contact Orlando Smith, Chair, IRB.

Thank you.

Enclosures

IRB - Human Participants Protection Committee Members

GUIDELINES FOR CLASSROOM PROJECTS BASED ON SURVEY RESEARCH WITH HUMAN PARTICIPANTS

The Institutional Review Board (IRB) - Human Participants Protection Committee recognizes that many projects conducted to fulfill course requirements involve research with human participants. Such research occasionally entails certain risks to the participants involved. As students vary in expertise regarding research procedures designed to protect the rights of human participants, the IRB - Human Participants Protection Committee has developed the following guidelines regarding classroom based research projects. These guidelines are intended to provide clarification and simplify the process for obtaining IRB - Human Participants Protection Committee approval.

Conditions Under Which IRB -Human Participants Committee Approval is Required for Survey Research

I. Any interview that asks randomly selected interviewees specific questions that identify his/her own views and/or behaviors and experiences requires IRB - Human Participants Committee approval;

2. Any project that systematically selects participants from a specific group and asks questions regarding their opinion, behavior or experiences, i.e., gifted children, alcoholics, homosexuals, etc., requires IRB - Human Participants Protection Committee approval;

3. Any project that proposes to investigate opinions, behaviors, and/or experiences regarding the following sensitive topic areas requires IRB - Human Participants Protection Committee approval:

a. Sexual Orientation
b. AIDS or HIV
c. Incest
d. Rape or Date Rape
e. Sexual Molestation
f. Substance Use and/or Abuse, including alcohol, marijuana, steroids, cocaine, crack, heroin, or any prescription or non-prescription or use oflegal or illegal drugs.
g. Eating Disorders or Behaviors
h. Contraception, Pregnancy or Abortion
1. Questions dealing with any aspect of the participant's mental health, i.e., suicide, depression, compulsive behaviors such as gambling, smoking, eating, etc.
J. Use of participants under the age of 18 years old
k. Religious Orientation and/or Views
1. Veteran and/or Wartime Experiences

Conditions Under Which LRB- Human Subjects Protection Committee Approval is Not Required for Survey Research

Students wanting to collect data from human participants as part of the requirements **for a specific class** may conduct **opinion research** that is not specific to the behaviors and/or experiences of the interviewees, as long as informants are not identifiable by name or description.

For example, IRB- Human Participants Protection Committee approval is **not required** for a student to survey people's opinions about topics such as the following:

a. opinions of political candidates or issues
b. opinions regarding American made vs. foreign made products
c. opinions concerning environmental issues or policies
d. opinions regarding the participant's favorite television show, preferred vacation spot, musical preference, etc.

The key factor shared by these examples is that they do not require participants to reveal anything about their personal experiences, behaviors, and/or identity. Therefore, the participants are not considered to be placed**at risk** by their participation. Thus, in these cases, IRB -Human Participants Protection Committee approval is not required.

If you have any questions regarding a project, please contact Orlando Smith, 876-7207 x4456.

GUIDELINES FOR WRITING INFORMED CONSENT

An informed consent form outlines the research study and expectations for potential participants. This document should be written in layperson terms and typed on Stephens College letterhead. If a technical term must be used, define it the first time it is used. Also, any abbreviation should be spelled out the first time it is used. The title of the research project must be on the informed consent. Each consent form should include the following elements:

Purpose - Include a statement that the study involves research, an explanation of the purposes of the research procedure and the expected duration of the participant's participation, a description of the procedures to be followed and identification of any procedures that are experimental.

Risks and Discomfort - Describe any reasonably foreseeable risks or discomforts--physical, psychological, social, legal or other associated with the procedure, and include information about their likelihood and seriousness.

Discuss the procedures for protecting against or minimizing any potential risks to the participant. Discuss the risks in relation to the anticipated benefits to the participants and to society.

Benefits - Describe any benefits to the participant or other benefits that may reasonably be expected from the research. If the participant is not likely to benefit personally from the experimental proposal note this in the statement of benefits. Discuss the risks in relation to the anticipated benefits to the participants and to society.

Alternative procedures - Include a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous.

Costs and Payments – It is assumed that there are no costs to participants enrolled in research

proposals. Any anticipated costs to the participant for tests/procedures performed specifically for the study, experimental procedures or use of equipment must be stated.

Any payments to be made to the participant (e.g., travel expenses, stipends) must also be stated, including when the payment will be made.

Confidential information - Provide a statement describing the extent, if any, to which confidentiality or records identifying the participants will be maintained, and note the possibility that the Food and Drug Administration or drug company supplying the experimental drug may inspect the records.

Compensation -For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs, and it so, what they consist of or where further information may be obtained.

Inquiries - Explain whom the participant should contact for answers to questions about the research or research-related injuries (usually the PI) and the research participant's rights (IRB-Human Participants Protection Committee chairperson).

Voluntary Participation - Include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits.

Required signatures - Each research participant or the surrogate decision-maker must sign an informed consent form prior to entering the research proposal unless a proposal was specifically exempted because of the nature of the study. Provide a statement of consent written in the first person, i.e., "I hereby consent," etc.

Signature lines for the following should be included on the informed consent form:

a) The participant or the participant's legally authorized representative.

b) The witness of both the oral presentation and execution of the written consent.

c) The investigator or the person obtaining the participant's consent form.

Each participant (or authorized representative) should be given a copy of the signed informed consent. Include such a statement on the informed consent form.

For further information, please contact Orlando Smith, Chair, IRB, 876-7207 x4456.

A. No investigator may include a human participant in research without first obtaining the legally effective informed consent of the participant or the participant's legally authorized representative.

B. Informed consent information should be prepared in accordance with the attached "Informed Consent and Human Participants Research" document and submitted with the research proposal for IRB - Human Participants Protection Committee review and approval.

C. **Minors as Research Participants.** If minors are involved in a research project, the consent of parent(s) or guardian is needed. If the child is at least 11 years of age, but below the age of majority, his/her "assent," or agreement to participate, should also be obtained.

D. **Documentation of Informed Consent.** Informed consent shall be documented by the use of a written consent form signed by the participant or his/her representative unless one or both of the following situations exist.

1. **Waiver of Requirement for Signed Consent Form.** The requirement for the investigator to obtain a signed consent form may be waived if:

   a. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

   Or

   b. The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. All participants, however, must be asked whether they want documentation linking them with the research. The participant's wishes will govern.

In cases where the signed informed consent requirement is waived, the investigator may be asked to provide the participants with a simple written statement (Lay Summary) about the research.

2. **Signed Consent Document Required.** If the research does not meet the criteria for waiving signed consent documentation (Category III) (i.e., more than minimal risk of harm, involves procedures for which written consent is normally required, potential harm resulting from a breach of confidentiality is not the principal risk), a written consent document must be signed. A copy of the consent form must be given to the person signing it **ALL CONSENT FORMS MUST BE APPROVED BY THE IRB- HUMAN PARTICIPANTS PROTECTION COMMITTEE PRIOR TO USE.**

   a. Types of Consent Documents. The consent form may be either of the following types of documents.

      (1) A written consent document that embodies the elements of informed consent noted in "Informed Consent and Human Participants Research" (seep. 44). This form may be read to the participant or his/her representative, but in any event, the investigator shall give either the participant or the representative

adequate opportunity to read it before it is signed, or

(2) A "short form" written consent document stating that the elements of informed consent have been presented orally to the participant or to the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRE - Human Participants Protection Committee must approve a written summary of the oral presentation. The person obtaining consent signs a copy of the summary. The witness shall sign both the short form and a copy of the summary; only the short form itself is to be signed by the participant or the representative. A copy of the summary shall be given to the participant or the representative, as part of the "short form" consent document.

Oral Informed Consent shall be documented as a script to be reviewed and approved by the IRB – Human Participants Protection Committee. For research in Category's I and II.

D. Development of informed Consent Forms. Detailed guidelines about the colleges policies and procedures regarding informed consent and human participant research and a sample comprehensive consent form are contained in the attached document "Informed Consent and Human Participant Research."

E. Providing Additional Elements of Informed Consent.

1. When required by the IRB - Human Participants Protection Committee, a research investigator shall provide one or more of the following additional elements of information to each participant:

a. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;

b. Anticipated circumstances under which the participant's participation may be terminated by the research investigator without regard to the participant's consent;

c. Any additional costs to the participant that may result from participation in the research;

d. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;

e. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and

f. The approximate number of participants involved in the study.

INFORMED CONSENT AND HUMAN PARTICIPANTS RESEARCH

Research investigators are responsible for obtaining informed consent from human participants (or their legally authorized representative). The consent information must be in language understandable to the participant or the participant's representative. Wording should not include conditional language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or release the research investigator, the sponsor, the institution or its agents from liability for negligence.

Avoid the person/tense used in the wording of the consent form. Statements interchanging "I," "you," and "one" can be very confusing to the reader.

An effort should be made to be precise. As in our sample, the entire copy may be produced on one side of paper.

A. BASIC ELEMENTS OF THE INFORMATION NECESSARY FOR "INFORMED CONSENT" INCLUDE:

1. Statement that the **study involves <u>research</u>,** an explanation of the purposes of the research, and the expected duration of the participant's participation. Use the word "research" to make this element clear.

2. An invitation to participate--worded perhaps as "You are invited to participate in a study of .... We hope to learn ...."

3. Why the participant was selected--if this is appropriate to the project.

4. A description of the procedures to be followed and identification of any procedures which are experimental.

5. A description of any reasonably foreseeable risks or discomforts.

6. If any benefits can be reasonably expected, they should be described.

7. A disclosure of any appropriate alternative procedures that might be advantageous for the individual.

8. Aspects of **confidentiality of information--if** data is in form of tape recordings, photographs, movies or videotapes, researcher should describe period of time they will be retained before destruction. Showing or playing of such data must be disclosed, including instructional purposes.

9. An explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of research-related injury to participant. This is usually the researcher or the faculty advisor.

10. An explanation of whom to contact concerning issues on human participants rights. This is

11. If participants are paid a fee or receive some service in lieu of financial compensation for participating, this should be described.

12. A statement that **participation is voluntary,** refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without penalty or loss of benefits. If the participant is receiving some form of course "credit" for his/her participation, the effect of withdrawal from the experiment on "credit received" should be explained.

13. For research involving **more than minimal risk,** an explanation as to whether any compensation and/or medical treatments are available if any injury occurs and, if so, what they consist of, or where further information may be obtained.

14. Concludes with statement of acceptance to participate in the research study including the signature (Category III) of the participant or responsible agent, unless nature of research is such that signed consent forms are unnecessary.

B. DOCUMENTATION OF INFORMED CONSENT

I. Research investigators shall be responsible for insuring that informed consent is documented by the use of a written consent form approved by the IRB -Human Participants Protection Committee and signed by the participant or the participant's legally authorized representative, unless this requirement is specifically waived by the IRB - Human Participants Protection Committee. A copy of the signed consent form is given to the person signing the form; the original signed consent form is retained by the research investigator.

2. The requirement for the investigator to obtain a signed consent form may be waived by the IRB - Human Participants Protection Committee if it finds that either:

   a. the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality.

   b. the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

3. When the IRB- Human Participants Protection Committee waives the documentation requirement, it may require the investigator to provide participants with a written statement about the research, generally including the relevant elements of informed consent. In all cases, a written statement describing the informed consent procedure shall be provided to the IRB – Human Participants Protection Committee.

PLEASE NOTE THAT THE FINAL FORM ADMINISTERED MUST BE APPROVED BY THE IRB- HUMAN PARTICIPANTS PROTECTION COMMITTEE BEFORE IT CAN BE LEGALLY ADMINISTERED; SAMPLE COPIES OF THE FORM MUST BY LAW BE RETAINED BY THE IRB- HUMAN PARTICIPANTS PROTECTION COMMITTEE.

Sample Participant's Consent Forms are attached. **NOTE:** Three samples are shown, a comprehensive

form, a cover letter format and oral consent- investigators should develop a consent form Appropriate to the type of participant and the nature of the proposed research. Please remember to write at the educational level of the intended participant population.

SAMPLE COVER LETTER FOR CATEGORY 1111 PROJECTS

(When signed consent form is not required or appropriate,
e.g., anonymous research involving minimal risk, nonsensitive data, etc.) Dear

(potential participant pool, e.g., student, teacher, manager):

Yon are invited to participate in a research study [state what is being studied]. We hope to learn (state what the research project is designed to discover or establish]. You are being asked to participate in this study because [state why person is appropriate participant].

If you decide to participate in the project [describe the procedures to be followed, e.g., please complete the attached survey and return it in the enclosed envelope]--[describe confidentiality conditions].

If you have any questions about this research, please call **[name of faculty advisor/investigator].** If you have questions concerning the rights of participants involved in research studies, please call the Institutional Review Board Chair at 876-7207 x4456.

Your voluntary completion of the survey constitutes consent to participate. Thank you for assisting us with this study.

Sincerely,

Name of faculty/student researchers and
College affiliation

e.g., **John Smith**
Joan Brown
Students in Biology 395

Obtaining Oral Consent: If oral consent is necessary due to limited literacy or language comprehension, the participant or his/her legal representative will be asked to sign a short form stating that the basic consent form elements have been orally presented. Both the short consent form and the oral presentation must be approved by the IRB - Human Participants Protection Committee. A witness must also be present for this presentation and must sign both the short form and a written summary of the oral presentation. The participant or his/her legal representative must be furnished with a copy of both signed documents.

Sample Oral Consent

HELLO--I am a **[describe who you are, include college affiliation,** e.g., **student in (Department) at Stephens College].** We are conducting research **[describe project and method of data collection,** e.g., **telephone survey, etc.).**

You are being contacted because [explain why you are calling, e.g., random survey, resident of Columbia, listed in yellow pages].

If you agree, I would like to ask you some questions about [describe nature of survey]. The survey should take [specify amount of time]. Your responses are [confidential] and will be grouped with other people who are called.

Do you have any questions about the research project? May I proceed with the interview?

Sample Participant Consent Form/Statement

Project Director or Principal Investigator: _____ Title of Project: _____

You are invited to participate in a research study of [state what is being studied]. We hope to learn [state what the study is designed to discover or establish]. You were selected as a possible participant in this study

because [state why the participant was selected].

If you decide to participate, we [or: Dr. _____and associates] will [describe the procedures to be followed, including their purposes, how long they will take, and their frequency]. [Describe the discomforts and inconveniences. An estimate of the total time required must be included]. [Describe the risks reasonably to be expected). [Describe any benefits reasonably to be expected. If benefits are mentioned, it is advisable to add:] We cannot and do not guarantee or promise that you will receive any benefits from this study.

[Describe appropriate alternative procedures that might be advantageous to the participant, if any. Any standard treatment that is being withheld must be disclosed.]

[A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.) If you give us your permission by signing this document, we plan to disclose [state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure.]

[If the participant will receive a fee for participating, or services in lieu of a fee, describe the amount or nature.] [If there is a possibility of additional costs to the participant because of participation, describe it.]

[For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs, and if so, what they consist of or where further information may be obtained.)

Your decision whether or not to participate will not prejudice your future relations with]. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

Before you complete and sign the form, please ask questions on any aspect of the study that is at all unclear to you. If you have any additional questions later, Dr._____(give a phone number or address) will be happy to answer them. If at any time you have questions concerning your rights as a research participant, you may call the Institutional Review Board at 573-442-2211 x4456.

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE, HAVING READ THE INFORMATION PROVIDED ABOVE.

I acknowledge that I have received a personal copy of this consent form.

Copy received: _____ Date: _____ Time: _____a.m./p.m.
(Initial)

_____
Signature

Relationship to participant
(This line should not appear on forms that will be given to participants consenting for themselves.)

_____
Signature of Witness

Signature of investigator

MISCELLANEOUS RESEARCH ACTIVITIES -REVIEW REQUIREMENTS

A. Annual Review. Continuing review of on-going research must be conducted at intervals appropriate to the degree of risk involved, but not less than once per year. It is the responsibility of the investigator to provide an annual update on the progress of the proposal to the Committee.

B. Reporting Changes in the Research

I. Research investigators are responsible for reporting promptly to the Office of Sponsored Programs proposed changes in a research activity.

2. Changes in research during the period for which the IRB - Human Participants Protection Committee approval has already been given shall not be initiated by research investigators without IRB - Human Participants Protection Committee review and approval, except where necessary to.eliminate apparent immediate hazards to the participant.

C. Research Conducted Outside the United States. Participants are required to notify the IRB of any research conducted outside of the U.S. and any cooperative research with other institutions.

D. Student Research. All student investigators must have a Stephens College faculty supervisor who is responsible for insuring that all provisions of the approval are complied with by the investigator. The faculty supervisor must sign the cover sheet certifying that the project is under his/her supervision.

Class projects using the same procedures may be reviewed as one proposal, at the direction of the instructor. If the same procedure is not used, each student or group of students must submit the required information.

F. Research Involving Equipment. Briefly describe how equipment will be used in research project involving human participants.