Human Participants Protection Guidebook

Stephens College
1200 East Broadway Avenue
Columbia, Missouri 65215
(573) 876-7227

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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 that 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.

Review 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. All human research conducted at, by, or under the auspices of this institution, whether funded or not and whether conducted by administrators, faculty, staff, or students, must be reviewed and approved before the research begins. 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 College's responsibility to ensure that the human participants, in research conducted under its auspices, are adequately protected. Faculty are 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 (Belmont Report). The following basic ethical principles to be applied when reviewing research are:

1. **Respect for persons.** Refers to providing information about a specific research project

to a prospective participant via informed consent, ensuring voluntary participation in that 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 Stephens College IRB Committee/ 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. **Risk:** any harm or discomfort (physical, psychological, social or legal) that is anticipated in the research.

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, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
We would not consider it to be research, when evaluation, using instruments designed to test on-going success of programs (e.g. alumni surveys) or employing routine classroom activities that involve informal surveying.

Purpose of IRB Committee

- Protect the rights and welfare of human subjects who participate in research conducted by faculty, staff, and students of Stephens College. The Stephens College IRB follows the basic ethical principles of respect for persons, beneficence, and justice as set forth in the Belmont Report. These principles are codified in 45 Code of Federal Regulations Part 46, subparts A-D - Protection of Human Subjects.
- Independently assess and evaluate the risks and benefits of proposed research, and ensure that risks to human subjects are kept to an absolute minimum and are justified by potential benefits of the research.
- Ensure the confidentiality of information obtained from research subjects to the extent allowed by law.
- Ensure that, where appropriate, an Informed Consent or Informed Consent and Health Information Use and Disclosure Authorization are obtained from each research subject.
- Facilitate high quality research at Stephens College.
- Create a cooperative process, encouraging dialogue with researchers.
- Comply with applicable state and federal privacy laws.

Responsibilities of IRB Committee

The Stephens College IRB operates under the principles of The Belmont Report. The Belmont Report exists because of the unfortunate history of unethical research conducted on human subjects. It clearly explains the three principles that are the main tools that all IRB members should use to evaluate the ethics of specific research proposals.

- Respect for Persons is the first principle that mandates that subjects voluntarily consent to participate in research, that they are thoroughly informed about the research and what is required and that their privacy and confidentiality are protected.
- Beneficence is the second principle that mandates the risks of research are justified by potential benefits to the individual or society and that those risks are minimized.
- Justice is the third and final principle that mandates the equitable distribution of risks and benefits among those who may benefit from the research, meaning that one subset of a population should not take on all the burden of risk and reap all of the rewards; risks and rewards should be applicable and available to all subsets of a community.

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 Committee when a **proposal becomes inactive** or is **withdrawn. The principal investigator *must* provide the IRB Committee, at least annually, with information requested during the continuing review process.**

1. To inform subjects of all risks and benefits of research;
2. To provide subjects with information necessary to decide whether they will participate in a study, and to obtain and document voluntary consent, provided that the IRB may waive the requirement of documentation;
3. To inform subjects of conditions which may affect risks, benefits, or willingness to continue in a study.

General Responsibilities

1. To learn, acknowledge, and accept the responsibilities for protecting the welfare and rights of human subjects as set forth in the Federal wide Assurance (FWA00008602) established between Stephens College and the DHHS, and to comply with all provisions of the Assurance;
2. To submit all protocols involving research with human subjects to the IRB for determination of status (Exempt from Review, Expedited Review, or Full Review);
3. To be informed concerning all federal, state, local, and Stephens College regulations that pertain to their study; and to comply with them.

Responsibilities during the Application Process

1. To provide clear and accurate information in the IRB application, and to clarify the questions raised by the IRB;
2. To modify research protocols when the IRB requests modification.

Responsibilities during the Research Process

1. **To begin subject recruitment only after notification that a protocol has been approved by the IRB;**
2. To report to the IRB promptly any injuries or other unanticipated problems involving risks to subjects or to others;
3. To monitor research, and to inform the IRB of findings that may affect risks and benefits to subjects;
4. To inform the IRB of developments in the literature that may affect risks and benefits to subjects;
5. To inform the IRB of significant changes in research procedures;
6. To submit research reports to the IRB as requested;
7. To allow IRB observation of research procedures;
8. To retain signed informed consent forms for at least three (3) years past completion of the research activity.

Researcher Non-compliance - what happens if a PI does **NOT comply with IRB protocol?**

- All investigators working with human subjects have a responsibility to comply with the regulations specified in federal law and college policy designed to protect the rights and welfare of those research subjects. The most common lapses in investigator compliance are related to a misunderstanding of the application and reporting requirements, failure to submit necessary documents to the Institutional Review Board, and forgetting to submit an application to conduct research involving humans before the study commences. Most of these cases can be resolved by the IRB without jeopardizing the welfare of the subjects.

- Occasionally, an investigator will either avoid or ignore the IRB. Such cases present a serious challenge to the IRB and to the college. *Regardless of investigator intent,* unapproved research involving human subjects places those subjects at unacceptable risk, **and places the College at risk for federal sanctions.**

- It is the responsibility of the IRB and its staff to facilitate researcher compliance with regulations and policies governing human subject research. However, failure to cooperate with the IRB in fulfilling application and reporting requirements, and failing to respond to requests for information and documentation constitutes non-compliance. If an investigator fails to supply the IRB with requested information or documents after a third request from the IRB, the VPAA will be informed of this non-compliance. The VPAA will notify the investigator's academic Dean of this non-compliance, and instruct the investigator to cease further research involving humans until they comply with all IRB requirements. Depending on the nature of the research and the level of risk to subjects, the VPAA will have the option of confiscating all data collected prior to approval of the research by the IRB.

Privacy/Confidentiality

Privacy refers to a person's interest in controlling the access of others to himself or herself. Confidentiality refers to the way in which personal information is handled by a second party who controls access to that information by others. Anonymity refers to the separation of personal identifiers from any information about an individual. The procedures for protecting confidentiality, anonymity, and the limitations to confidentiality and anonymity must be discussed in the informed consent document.

Basic elements for maintaining confidentiality:

1. The instruments for procuring data should be carefully constructed to ensure that only personal information that is essential to the study is acquired.

2. Any information that reveals the identity of human subjects should be stored in files accessible only to the researcher and authorized personnel.

3. Information about the identity of the subject should be changed into coded form as soon as possible. (Social Security numbers, even the last four digits are not adequate protection.)

4. Publication of the data must carefully safeguard the identity of the subjects and care must be taken to protect the identity of institutions in the research protocol.

5. Information that might link the subjects to the research must be disposed of in a timely fashion and in a way that safeguards the privacy of the subjects.

6. Special care must be taken with information that asks subjects about sensitive or illegal activities (such information could be obtained by a government subpoena) and subjects need to know the limits of protecting their confidentiality.

IRBs must decide to what extent privacy, confidentiality, and anonymity apply to each project to protect participants adequately. An essential concern of the IRB is how any proposed invasion of privacy could harm an individual. The investigator can regulate the degree of risk that occurs in a project by varying one of these three variables:

1. Do not collect any sensitive personal data: Complete respect for privacy, low risk.
2. Increase the safeguards in maintaining sensitive data: Respect for confidentiality, mild risk.
3. Do not collect information that could link data to subject: Provide complete anonymity, mild risk.

Varying the level of each of these factors in accordance with the level of risk will allow investigators to collect the needed data. It is important to remember that limitations to confidentiality and anonymity must be addressed in the informed consent document.

Selection of Subjects

- The burdens of research should be distributed equally among the persons who will benefit from it; therefore, overinclusion or under inclusion of any class of subjects must be justified;

- Convenience alone does not justify using a particular class of subjects; the nature of the research should require or justify the use of a particular class of subjects;

- As a matter of social justice, there should be an order in the selection of classes of subjects: adults before children, competent individuals before incompetent individuals, and noninstitutionalized persons before institutionalized persons; in brief the least vulnerable classes of subjects should always be selected;

- Participation in research is voluntary; therefore, researchers are discouraged from using subjects who may have restricted freedom to refuse to participate (e.g., researchers' students, employees, or patients); and

- In order to ensure voluntary participation, subjects should be recruited through general announcements or advertisements rather than through personal solicitation.

Incentives for Participation

Frequently, subjects receive remuneration for participating in research, e.g., money, free medical care, or course credit. Modest incentives or reimbursements for expenses incurred by subjects are appropriate.

However, if incentives are so strong that prospective subjects do not think that they can refuse them, then the incentives become essentially coercive (i.e., “undue”. Undue inducements are troublesome because:
(1) offers that are too attractive may blind prospective subjects to the risks of a study or impair their ability to exercise proper judgment, and
(2) they may prompt subjects to lie or conceal information that, if known, would prevent them from enrolling or continuing as participants in research projects.

IRB standards for judging whether incentives constitute undue influence must vary according to research procedures and subject populations, but the following questions form the general basis for determining whether incentives are appropriate:

1. Are all research conditions in keeping with standards for voluntary and informed consent?

2. Are the incentives offered reasonable, based on the complexities and inconveniences of the study and the particular subject population?

Informed Consent

Informed consent is an integral component of research insuring that participants are aware of and understand fully the consequences of participation. Informed consent is the process by which participants are provided the information necessary to make a decision about participation. Current Federal regulations (45 CFR 46.116) describe **eight basic elements of informed consent** that are necessary to provide an individual with adequate information for making such a decision:

1. A clear statement that the project involves research. The informed consent explains the **purpose**s of the research, as well as the expected **duration** of the participant's participation. The informed consent must include a description of the procedures to be followed and identification of any procedures that are experimental. Descriptions must be **clear and detailed** enough for the participants to understand their involvement.

2. A description of any reasonably **anticipated risks or discomforts** the participant may experience.

3. A description of **any benefits** to the participant or to others that may reasonably result from participation in the study.

4. Disclosure of any appropriate **alternative procedures or treatments**, if they exist, that may benefit the participant.

5. A statement describing the extent to which **confidentiality** of identifying data will be maintained.

6. In the case of research **involving more than minimal risk**, an explanation as to whether any compensation is involved, and whether medical treatment is available if injury is sustained.

7. **Identification** of whom to contact to answer pertinent questions, to explain participants' rights, or to contact in the event of an emergency.

8. A statement that participation is **voluntary:** Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. The participant may discontinue participation at any time without penalty or loss of benefits.

Each of these elements serves a specific function in the process of informing participants of their involvement in the research project. However, informed consent is more than a form it is an **ongoing process** (Porter, 1995; OPRR, 1993; & Grunder, 1986)**.** It is crucial to consider the participant's specific involvement in a project and a participant's abilities to assure proper informed consent. Often involvement in a research project may occur over the course of several weeks or months. In these instances, it is important to review informed consent issues from time to time in order to reaffirm the participant's understanding. The need for renegotiating informed consent will vary from study to study. As with many aspects of IRB review, this issue must be considered on a case-by-case basis. The IRB will make a final determination as to the extent to which an investigator will need to reaffirm consent. This could range from reminding the participants of what will be expected at each session to a formal review of the informed consent document. Regardless of the determination by the IRB, the **investigator bears the responsibility** for assuring that participants have a full understanding of the nature of their involvement in the research throughout the project.

Deception

Many research questions cannot be adequately addressed when full informed consent is required. In many cases, incomplete disclosure or deception is necessary to obtain essential information. This presents a “Catch 22” in the informed consent process. The first solution should be to attempt to design a study, which can answer the research question without any form of deception. The IRB will expect an explanation as to the necessity of deception in any project. When it is not possible to answer the research question without deception, the IRB will assess the risks to participants and make a decision as to what is necessary to protect them. With any research utilizing deception, a thorough debriefing procedure is necessary. The **debriefing** allows the investigator to explain tactfully what happened and why deception was necessary. At times deception may generate ill feelings among research subjects. It is the responsibility of the investigator to address the ill will. The investigator should attempt to restore subjects to the pre-testing state of feeling and mind that was disrupted by deceptive methodology.

Placebo, Randomizing, and Blind Clinical Trials

A related issue is that of placebo, randomized, and blind clinical trials. When these types of designs are used, it is impossible to inform the participants concerning which treatment they will receive. The informed consent document should define single and double blind procedures in a way participants can understand. They should be informed of all the possibilities that may occur if they agree to participate.

Language Used in Consent Forms

Many special circumstances can arise when developing an adequate informed consent procedure. One of the most important factors to consider is the language of the document. While investigators have complete control over the language contained in the document, they have limited control over the prospective participants' comprehension levels. It is crucial that investigators consider the possible variation in comprehension levels of subjects in their sample and write informed consent documents that reflect the subjects' reading abilities. While this is a difficult task to accomplish, there are several rules of thumb to follow:

1. Avoid technical jargon; rephrase in lay terms.

2. Do not include any language that implies that subjects may waive any rights based on their participation in the research.

3. Do attempt to write documents at a sixth grade level.

Research with Vulnerable Populations

Special Population Issues

A special issue in consent arises when participants are unable to give consent for themselves, as with children or cognitively impaired individuals. In such cases, consent is generally given by "proxy." However, **this proxy consent is not the same as true consent,** and thus raises other ethical questions. In the event proxy consent is obtained, the subject should be given veto power whenever feasible. Such is often the case with **children** involved in research activities. While they are unable to give legal consent, they may still be able to grasp at least basic aspects of the research project. When this is the case, **assent of the subject is necessary**. While there is no clear rule regarding the age, at which children can adequately give assent to participate, the rule of thumb is that assent should be obtained from children seven years and older. In general, if the participants have the cognitive ability to understand what they will be asked to do in a project, they should be asked if they would like to participate. Again, this issue must be assessed on a case-by-case basis, and the IRB will make a final determination as to whether both assent from participants and consent from guardians are necessary.

This discussion is taken directly from (OPRR 1993). Investigators, who are interested in research with the special classes of subjects discussed here, should refer to (OPRR) for more information or contact IRB staff.

Certain groups of persons are **especially vulnerable research subjects.** They include:

- children and minors;
- pregnant women and fetuses;
- prisoners;
- persons with cognitive or emotional impairments;
- economically or educationally disadvantaged persons;
- members of minority groups;
- elderly persons; and
- persons who are in a subordinate relationship to researchers (e.g. students, employees, or patients).

In general, when an IRB is considering research with **especially vulnerable subjects**, the IRB can approve research that is of minimal risk or will benefit subjects directly. If the research involves more than minimal risk and does not benefit the subject directly, the study may be subject to approval by the Secretary of Health and Human Services.

Children and minors are defined as persons who have not attained the legal age for consent to treatment or procedures involved in the research. In the State of Missouri, the age of consent is 18. When children or minors are research subjects, researchers must obtain both the **permission** of the parents (i.e., parental informed consent) and the **assent** of the child (i.e., the child's affirmative agreement to participate). Mere failure to object is not assent. The IRB has the authority to waive the requirement of assent. Special DHHS regulations applying to children may be found in 45 CFR 46, Subpart D.

Pregnancy encompasses the period from the confirmation of implantation until the expulsion or extraction of the **fetus**. A fetus is the product of conception from the time of conception until a determination is made, following expulsion or extraction, that it is viable. Viable as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. Nonviable refers to a fetus ex utero, which is living but not viable. Dead fetus means a fetus ex utero that exhibits neither heartbeat, spontaneous respiration, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord. In vitro fertilization means any fertilization of the human ova that occurs outside the body of a human female. Special DHHS regulations applying to pregnant women and fetuses may be found in 45 CFR 46, Subpart B. No research may be conducted with pregnant women or fetuses unless the following conditions have been met:

- appropriate studies on animals and non-pregnant individuals have been conducted;
- the risk to the fetus is minimal, except where the activity is to meet the health needs of the mother or particular fetus, and the activity involves the least possible risk;
- individuals engaged in research will have no part in (a) decisions as to the timing, method, and procedures used to terminate the pregnancy, and (b) determining the viability of the fetus at the termination of the pregnancy;
- when the pregnancy is terminated, no changes in standard procedure will be introduced for the purpose of research if the changes cause greater than minimal risk to the mother or the fetus;
- no monetary or other inducements may be offered to terminate a pregnancy for the purpose of research.

Prisoners are persons involuntarily confined or detained in a penal institution. The term encompasses individuals sentenced to such institutions under a criminal or civil statute, individuals detained in other facilities by virtue of statutes of commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Special DHHS regulations applying to prisoners may be found in 45 CFR 46, Subpart C. No research may be conducted with prisoners unless the following conditions have been met:

- the research examines (a) the possible causes, effects, and processes of incarceration and criminal behavior; provided that the research poses no more than minimal risk or inconvenience to the subjects; (b) prisons as institutional structures or prisoners as incarcerated persons; (c) conditions particularly affecting prisoners as a class; or (d) practices (both innovative and accepted) having the intent and reasonable probability of improving the health and wellbeing of the subjects;
- the possible advantages of participation must not be of such a magnitude that they impair the subjects' ability to weigh the risks against the benefits of participation;
- the risks must be commensurate with risks that would be accepted by non-prisoner volunteers;
- subject selection must be fair to all prisoners;
- there is adequate assurance that participation will not affect the prisoner's chance of parole, and the prisoner is informed of this fact in advance of participation.

Persons with cognitive or emotional impairments are those persons having a psychiatric or developmental disorder that affects cognitive or emotional functions to the extent that the capacity for judgment and reason is significantly diminished. Other persons, including those under the influence of or dependent on alcohol or drugs, those affected by degenerative brain diseases, those who are terminally ill, and those who have severe physically disabling handicaps, may be compromised in their

ability to make decisions in their best interests. Persons with cognitive or emotional impairments may not be able to give legally valid informed consent. However, researchers have a responsibility to persons with cognitive impairments (1) to inform subjects with impairments about the procedures, risks, and benefits of the research to the extent that the subject can understand, and (2) to obtain affirmative assent in so far as the subject is able to do so.

Selection of subjects is a particularly important issue as it relates to persons with cognitive or emotional impairments. Research involving persons whose autonomy is compromised by disability or restraints on personal freedom should bear some direct relationship to their condition or circumstances. *Persons who are institutionalized* should not be chosen as subjects simply because it is convenient to the researcher. Nevertheless, persons do not become incompetent the moment they enter a mental institution, and their right and considered judgment to participate in research should be respected.

Economically or educationally disadvantaged persons are those persons placed at special risk by socioeconomic and educational background. Economically disadvantaged persons include those persons who struggle to provide necessities for themselves and their families or communities. Therefore, the use of financial incentives for research participation is a special issue with economically disadvantaged persons. Medical care, remedial education, and financial remuneration are common incentives in research.

To a person who is economically disadvantaged, seemingly nominal inducements may be **powerfully coercive.** Incentives cannot be so strong that they take away a person's voluntary choice to participate in research. Educationally disadvantaged persons may have educational deficits, learning disabilities, or cultural backgrounds that limit communication with a researcher. It is the responsibility of the researcher to ensure that a subject is fully informed. This includes **presenting material at an appropriate level, in an appropriate language, and via an appropriate medium (e.g., verbal or visual).**

Members of racial and ethnic minority groups are vulnerable research subjects in two respects: *overrepresentation and underrepresentation*. On the one hand, members of minority groups should not be over-included in research out of mere convenience or availability. No group of persons should be asked to bear the risks of research when many groups will share the benefits of that research.

On the other hand, members of minority groups should not be excluded from research out of mere convenience or availability. For generalizability of research findings, investigators must include the widest possible range of population groups. Therefore, *investigators must provide a "clear compelling rationale for their exclusion or under representation" of minority group members from research.*

Elderly subjects are persons over the **age of 65**. Advancing age may place them at increased physical, cognitive, or financial risks. However, there is no specific age at which persons become high-risk subjects and thereby ineligible for research. Researchers have the responsibility to determine the level of risk that research poses on an individual basis and to minimize risks accordingly. The use of age *per se* to define the ability to consent and therefore to participate in research is not valid, and the inclusion of older persons in the research enterprise is important.

When older persons are cognitively impaired or institutionalized, the same protections apply to them that apply to persons with cognitive or emotional impairments and to children. They should not be used as subjects merely because they provide a convenient sample, but research involving elderly

institutionalized persons should bear some direct relationship to their condition or circumstances. Furthermore, they should be informed and given the opportunity to assent to research; to the extent they are able, even if a guardian must provide informed consent for them to be subjects.

Persons who are in a subordinate relationship to researchers may experience a loss of autonomy because of that relationship. Students, employees, and patients may fear a loss of grades, work benefits, or maximal health care when they are asked to be research subjects. This means that they are subject to **undue coercion**, even if researchers do not intend to be coercive.

Therefore, proposed research using any subjects who are in direct subordinate relationships to investigators is scrutinized by the IRB. The researcher is obligated to inform the subject clearly that the subject's participation is voluntary, that the subject **may withdraw from participation at any time**, and that course grades, employment, or health care will not be affected by the subject's choice to participate or not to participate.

Off-Campus Research

Frequently, faculty and graduate students may conduct their research at sites other than the Columbia, Missouri Stephens College campus. As always, researchers have a primary responsibility to protect human subjects from undue research risks. In research away from the college campus, researchers incur **additional obligations** including **obtaining the permission of institutions to conduct the research** in their locations and with subjects for whom they have some responsibility.

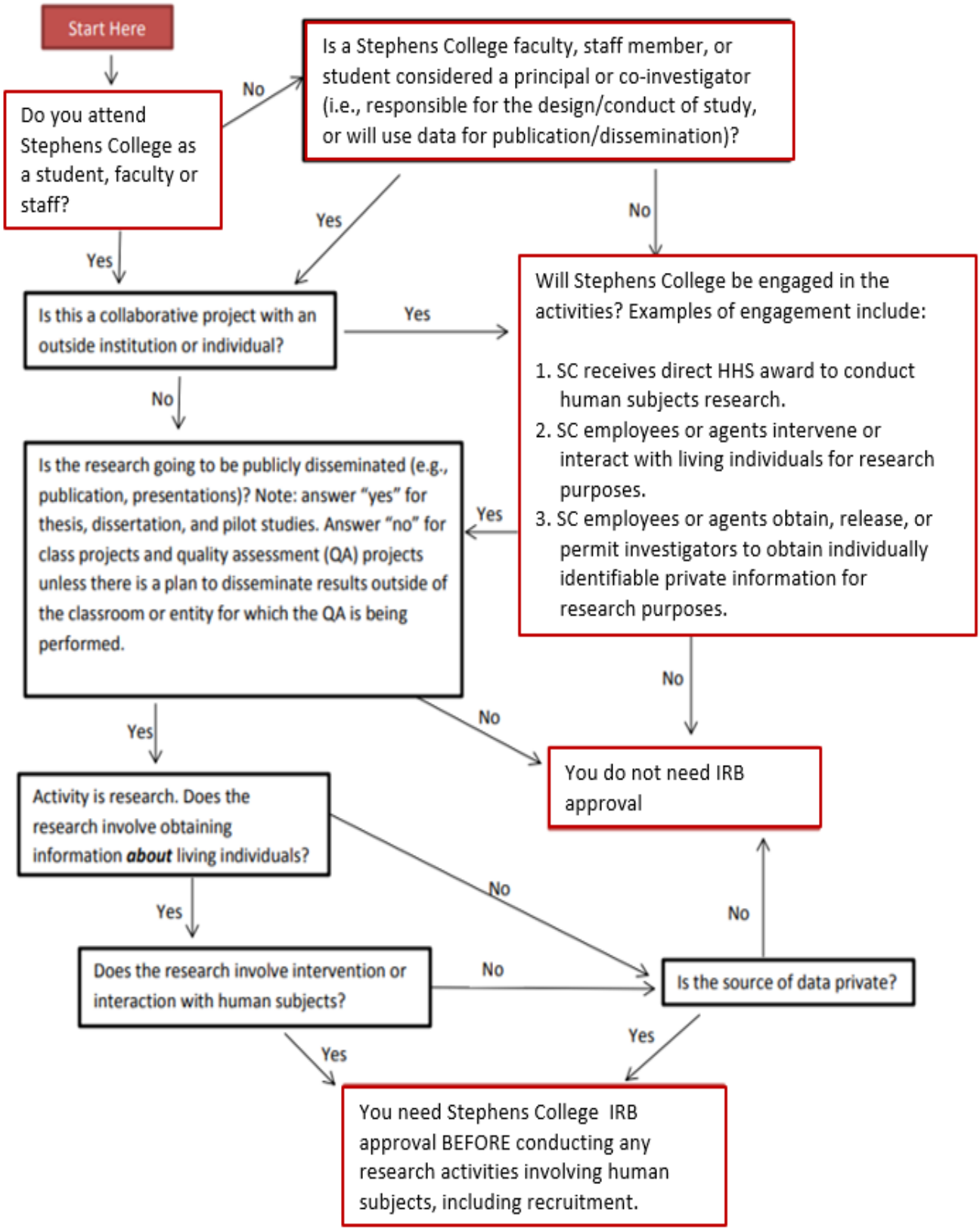
The Stephens College IRB requires that researchers provide documentation from the off-campus institution that the researcher **has been given permission** to conduct research at locations administered by the institution. The type of permission depends on the location and the nature of the research.

IRB Approval for Off-Campus Research
When the off-campus institution has an Institutional Review Board, the Stephens College IRB expects the researcher to provide an approval letter from the off-campus IRB stating its permission for research to be conducted at that location. Examples of institutions with IRBs include another comprehensive university, a teaching hospital, or a state mental health institution.

A Letter of Permission
When the off-campus institution does not have an IRB, the Stephens College IRB requires a letter of permission from an official of the institution, on institutional letterhead. Examples of institutions without IRBs include public and private elementary schools, small colleges, and health care clinics.

Do I Need Stephens College IRB Approval
Decision Tree Diagram

(Adapted from Virginia Tech)



Researchers Checklist:

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

- ◯ Application (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:

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

Classifications of Research Review

Code of Federal Regulations 45 CFR 12/13/01

I. **Research Requiring Full Committee Review:** The conditions listed on the cover sheet and application are not exclusive nor exhaustive but are offered as examples of the most common types of research at Stephens College that require full committee approval. Additional criteria identified in the Code of Federal Regulations 45 Part 46 "Protection of Human Subjects" (effective 12/13/01) may require the IRB Chair to designate a particular protocol as needing full committee review.

II. **Expedited Research**: Additional research that qualifies as expedited is listed below.

1. Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice (including 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 subject or an invasion of the subject's privacy; also including such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, hermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography; but not including exposure to electromagnetic radiation outside the visible range [for example, x-rays and microwaves])
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often that two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routing prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

III. **Exempt Research:** These six categories have been defined by federal regulation as exempt from full committee review.

1. Research conducted in established or commonly accepted educational settings, involving normal educational 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.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless:
   i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
   ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (Should the linkages be removed by authorized person other than the researcher, the protocol would still be considered exempt)
3. Research involving the use of educational tests, surveys or interview procedures which is not exempt under Section 2, and in which respondents will be elected or appointed public officials or candidates for public office.
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 subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of the department or agency heads, and which are designed to study evaluate, or otherwise examine:
   i. public benefit or service programs;
   ii. procedures for obtaining benefits or services under those programs;
   iii. possible changes in or alternatives to those programs or procedures; or
   iv. 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, if:
   i. wholesome foods without additives are consumed, or
   ii. a food is consumed that contains a food ingredient 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.

Child Assent Requirements and Models for Assent

Age	Requirement
0-6	— None required.
7-13	1) Provide a script showing exactly what you will tell the child about the study.
	2) Show your procedure for recording a "yes" or "no" response. (See **Model I** below.)
14-17	1) Provide a written form explaining the study for the child to read and sign.
	2) Get assent in writing on the form. (See **Model II** below.)

I. **Oral Assent Script with Record of Child's (Aged 7-13) Response**

I would like to ask you to help me with a project that I am doing at Stephens College. If you agree, you would (*answer some questions about your math class and work some puzzles.*) It will take about (*15 minutes*).

What questions do you have about what you will do for me?

Will you do this?

Name: _____ Date: _____

Response: ❑ YES ❑ NO

II. **Guide for Writing an Assent Form for Use with Class Projects Involving Children (Aged 14-17**)*

Dear (*Participant*):

I would like to invite you to help me with a project that I am doing at Stephens College.

The purpose of this project is to help me learn more about (*research topic*). No one will see your answers except my instructor and me, and I won't use your name in any reports.

If you take part in my research, you will (*fill out a survey on how much you like math and then do some number puzzles*). It will take you about _____ (*minutes/hours*) to finish.

You are free to quit this research at any time and I won't be upset with you. If you have any questions or concerns, please ask me now or call me at (*telephone number*). Thank you for your help.

Sincerely,

(*Your name*)

I agree to help with this research project. ❑ YES ❑ NO

Name: _____ Date: _____

Template for Parental Permission [delete text in red and insert other information where appropriate]

Stephens College
Parental Permission Form for Child's Research Participation

Study Title:

Principal Investigator:

Student Researcher: [if applicable]

Your child is being asked to take part in a research study. This form has important information about the reason for doing this study, what we will ask your child to do, and the way we would like to use information about your child if you choose to allow your child to be in the study.

Why are you doing this study?

Your child is being asked to participate in a research study about ….

The purpose of the study is …

What will my child be asked to do if my child is in this study?

Your child will be asked to [explain what participants will be asked to do]. [Explain if you will be asking any personal or sensitive questions.] Participation should take about [insert expected amount of time].

[If you will be tape recording subjects, include the following]

We would like to video record [or audio tape] your child as he/she performs [study task(s) that will be recorded], to make sure that we remember accurately all the information. The researchers will keep these tapes in [explain where you will keep them] and they will only be used by [explain who will have access to the tapes]. We will only video record [or audio tape] your child if you and your child give us permission.

[If subjects may participate without being taped, include "I agree …" and "I do not agree…" options at the end of this form. If audio/video recording are not optional, then state "Audio/Video recording is required for participation in this study. If you or your child do not wish to be recorded, it is not possible for your child to be in this study."]

[NOTE: if the parent is also a participant in the study, include a section describing what research tasks the parent will be asked to do OR create a separate consent form addressing the parent as a participant]

What are the possible risks or discomforts to my child?

Explain any foreseeable risks to subjects here.

Examples:

To the best of our knowledge, the things your child would be doing in this study have no more risk of harm than the risks of everyday life.

OR

Your child's participation in this study does not involve any physical or emotional risk to your child beyond that of everyday life.

OR

Your child's participation in this study may involve the following risks… [describe any reasonably foreseeable risks to psyche, reputation, employability, insurability, social status, criminal or civil liability that may occur as a result of participation]

Examples of risk explanations:

•Your child may get tired during the tasks. Your child can rest/take a break at any time.

•Your child may feel emotional or upset when answering some of the questions. Your child can tell the interviewer at any time if he/she wants to take a break or stop the interview.

•Your child may be uncomfortable with some of the questions and topics we will ask. If your child is uncomfortable, they are free to not answer or skip to the next question.

As with all research, there is a chance that confidentiality of the information we collect about your child could be breached – we will take steps to minimize this risk, as discussed in more detail below in this form.

What are the possible benefits for my child or others?

Your child is not likely to have any direct benefit from being in this research study. This study is designed to learn more about [insert purpose/topic of study]. The study results may be used to help other people in the future.

OR

Taking part in this research study may not benefit your child personally, but we may learn new things that will help others.

OR

The possible benefits to your child from this study include…

[Do NOT include information on payment/reimbursement in the description of benefits – that information belongs in a separate Financial Information section.]

How will you protect the information you collect about my child, and how will that information be shared?

Results of this study may be used in publications and presentations. [Explain measures to protect data confidentiality/personal privacy here. If disclosure of faces or voices is necessary to understanding the research and so identifying information may be used in reports/presentations, explain this and provide "I agree" "I do not agree" options at the end of the consent form.]

[If you will be sharing data with other researchers and/or archiving data, explain here and state whether identifiers will be included.]

If we think that your child intends to harm him/herself or others, we will notify the appropriate people/agencies with this information.

Mandated Reporter language – in studies in which researchers are probing for or likely to elicit information about child abuse or neglect, the following statement should be added (choose one):

If we learn about current or ongoing child abuse or neglect, we will report this information to the appropriate authorities.

OR

An exception to our promise of confidentiality is that we will report evidence of child abuse or neglect.

OR

We will not ask about child abuse or neglect, but if your child tells us about child abuse or neglect we will report that information to the appropriate authorities.

Financial Information

Participation in this study will involve no cost to you or your child. Your child will not be paid for participating in this study.

OR

[If subjects will be paid, explain the amount and terms of payment/reimbursement. If payments will be prorated if a subject withdraws from the study, state the terms]

What are my child's rights as a research participant?

Participation in this study is voluntary. Your child may withdraw from this study at any time -- you and your child will not be penalized in any way or lose any sort of benefits for deciding to stop participation. [Include this if research is being done in a school setting: If you and your child decide not to be in this study, this will not affect the relationship you and your child have with your child's school in any way. Your child's grades will not be affected if you choose not to let your child be in this study.]

If your child decides to withdraw from this study, the researchers will ask if the information already collected from your child can be used [or in the alternative, state that the information already collected will not be used.]

Who can I contact if I have questions or concerns about this research study?

If you or your child have any questions, you may contact the researchers at [add your contact information, including name, telephone number, and email address].

If you have any questions about your child's rights as a participant in this research, you can contact the following office at the Stephens College:

Parental Permission for Child's Participation in Research

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I give permission for my child to participate in the research study described above and will receive a copy of this Parental Permission form after I sign it.

Optional Study Elements

[This section should include other explicit consents for optional elements of the research procedures, such as audiotaping, videotaping, storing photographs for future use, or using the subjects' actual name in research publications.]

Initial one of the following to indicate your choice:
_____ (initial) I agree to…
_____ (initial) I do not agree to…

Examples:

Consent to Quote from Interview

I may wish to quote from the interview with your child either in the presentations or articles resulting from this work. [If a pseudonym will be used, include this statement: A pseudonym (fake name) will be used in order to protect your child's identity.]

Initial one of the following to indicate your choice:

_____ (initial) I agree to…

_____ (initial) I do not agree to…

Consent to Audio-Record Interview

Initial one of the following to indicate your choice:
_____ (initial) I agree to…
_____ (initial) I do not agree to…

_____ _____

Parent/Legal Guardian's Name (printed) and Signature Date

_____ _____

Name of Person Obtaining Parental Permission Date

For studies taking place in a school, this paragraph generally should be included (if you are unsure whether to include this paragraph for your study, please contact the SBS IRB for guidance):

Parents, please be aware that under the Protection of Pupils Rights Act (20 U.S.C. Section 1232(c)(1)(A)), you have the right to review a copy of the questions asked of or materials that will be used with students. If you would like to do so, you should contact [Principal Investigator] to obtain a copy of the questions or materials.

Research in Schools or Childcare Facilities

1. School District(s) and School(s) Name(s) & location(s)

2. Does the School District/Facility have its own IRB or Research review policies?

◯ Yes – Include documentation of approval

◯ No - Include documentation of approval of superintendent or principal (email is acceptable)

3. Indicate the subject(s) of the research (about whom or from whom will you collect data?)

◯ Students. Include parental consent form, student assent forms, and/or procedures, and where applicable signed release for students' records. (can combine this with consent form below the signature block)

◯ Teachers. Include teacher's consent form (if collecting data from them) or information letter.

◯ Administrative personnel. Include consent form (if collecting data from them) or information letter.

4. If students are the subjects, explain what role the teacher(s) play in the project:

HUMAN SUBJECTS RESEARCH INCIDENT REPORT FORM

PLEASE NOTE: A SEPARATE FORM SHOULD BE COMPLETED FOR EACH INCIDENT OR EACH SUBJECT

PRINCIPAL INVESTIGATOR:	**ADVISOR (IF PI IS STUDENT):**
PROJECT TITLE:	**REVIEW CATEGORY:** ◯ Exempt ◯ Expedited ◯ Full Board
IF THIS INCIDENT INVOLVED A SUBJECT, NOTE AGE: **SEX:** ◯ **M** ◯ **F** ◯ **NOT APPLICABLE**	
◯ **INITIAL REPORT** ◯ **FOLLOW-UP REPORT**	**INCIDENT OCCURRED AT:** ◯ **UM OR AFFILIATED SITE** ◯ **NON-ASSOCIATED SITE**

INCIDENT ONSET: / /	**INCIDENT TERMINATION:** / /	**INCIDENT CONTINUING?** ◯ **YES** ◯ **NO**

DESCRIPTION OF INCIDENT:	**SEVERITY OF INCIDENT:** ◯ **MILD** ◯ **MODERATE** ◯ **SEVERE** ◯ **SERIOUS** ◯ **LIFE-THREATENING** ◯ **DEATH**

ACTION TAKEN AND RESULT:

INCIDENT RELATED TO RESEARCH? ◯ **YES** ◯ **NO** ◯ **UNDETERMINED**	**CAUSE OF INCIDENT** (if not related to research)**:** ◯ **UNDETERMINED**
HAS SAME INCIDENT OCCURRED PREVIOUSLY? ◯ **YES** ◯ **NO**	**IF YES, HOW OFTEN?**

SHOULD CONSENT FORM BE REVISED TO INFORM SUBJECTS OF INCIDENT? ◯ **YES ~** attach revised consent form for review by committee ◯ **NO ~ EXPLAIN:**

SHOULD ENROLLED SUBJECTS BE INFORMED OF INCIDENT? ◯ **YES** ◯ **NO**	**HAVE THEY BEEN INFORMED?** ◯ **YES** ◯ **NO**

IRB - Amending a Protocol

What do I need to do to amend a previously approved protocol?

All amendments to the previously approved protocol must be sent through the official IRB email and approved by the IRB committee prior to any changes being implemented.

When submitting an amendment, please include

1) a document with the original plan and the amended plan, and

2) a statement on why the amendment is needed to strengthen the research and/or protect the interests of your human subjects.

The IRB Committee will send you notification of approval for the changes to the protocol.