Policies and Procedures Institutional Review Board (IRB)

Southeastern Louisiana University

Revised Fall 2006

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Policies and Procedures
Southeastern Louisiana University
Institutional Review Board (IRB)

University faculty, staff and students add to knowledge through efforts in scholarly activities and research. This scholarship and research is necessary to improve the well-being of individuals, organizations, and society. At Southeastern Louisiana University, the Institutional Review Board (IRB) exists to assess and evaluate the ethical, safety, and legal ramifications of research projects. The review process in turn gives protection to the researcher. These policies and procedures exist to guide the researcher in the ethical and legal responsibilities set forth by federal and state governmental statutes and the university. These policies are subject to change as federal policies change.

Southeastern is guided by the ethical principles set forth in the Belmont Report (ohsr.od.nih.gov/guidelines/belmont.html) and follows federal regulations based on the Federal Policy for the Protection of Human Subjects (45 CFR 46: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) Southeastern has a Federalwide Assurance (FWA) for the protection of human subjects, a contract with the federal government, assuring that Southeastern will review all human subjects research conducted by any person affiliated with the university. Further information on a FWA, the rights of human subjects, and IRB responsibilities is available from the Office for Human Research Protection (www.hhs.gov/ohrp).

Research involving the use of human participants requires IRB approval. Examples of research which does not require IRB approval include: research using data such as economic indicators or data collected from plants; research using only laboratory equipment; and research involving only publicly available data (such as court cases available through Westlaw). Research involving hazardous, toxic or radioactive substances does not require IRB approval, however it does need approval from the Office of Safety and Hazardous Materials Management to insure that handling and disposal is in compliance with federal safety and environmental regulations as specified by OSHA and EPA. Research involving animals must receive IACUC approval, instead of IRB approval. It is the responsibility of the IRB to review all proposed research to ensure the following:

1. The benefits of the proposed research outweigh the potential risks of participation.
2. The requirements of informed consent of human participants are fully met.
3. The rights, welfare, confidentiality, and dignity of participants are maintained as fully as possible.
4. All necessary letters, licenses, and permits have been obtained.
5. Appropriate university personnel have reviewed all safety or liability concerns.
6. Adequate provisions for continuing review have been established.

If IRB approval is not obtained and the research is conducted, one or more of the following penalties may apply.

1. Federal funds may not be spent for research involving humans.
2. A federal agency can require termination of research support for any project where the university fails to comply with federal policies.
3. The state Office of Risk Management might decline to provide a legal defense to a principal investigator who failed to follow proper policies and procedures as outlined by the IRB.

Committee Membership

The IRB shall be composed of two representatives from each of the academic colleges (a representative from the Library may work with a single representative from a small college), a non-academic representative, a community member and the Chair of the IRB. At least one member of the committee should have experience in research involving children. It is recommended that a principal or a teacher from a local school serve as the community member.

Service on the IRB requires at a minimum a three year commitment. Service on this committee requires training and experience, and one of the best ways to obtain this experience is to attend committee meetings, where proposals are discussed and reviewed. Therefore, new members are urged to attend as many of the meetings as possible during their first year. It is the responsibility of the members from each college to ensure that at least one member is present at each meeting.

Researcher Responsibilities

The Principal Investigator, referred to hereafter as the PI, is responsible for providing all materials necessary for proper review to the IRB. Students working on a thesis or dissertation research are the PI, not their faculty advisor. University forms and materials necessary are identified for the PI at the appropriate point in this guide and are available on the IRB website. The forms will change as needed to meet federal guidelines. The PI is responsible for:

1. Completing training on the rights of human research participants. Proof of training completion must be provided with each IRB protocol. More information on available training can be found on the IRB website (www.selu.edu/irb).
2. Completing the appropriate IRB form, obtaining the required signatures, and submitting the form to either the College IRB representative or the Chair of the IRB. Forms may be submitted electronically and the review initiated, however, IRB approval will not be given until a hard copy with the appropriate signature(s) is submitted.
3. Retaining signed Consent/Assent Forms, all appropriate licenses, letters of permission to use facilities, etc., necessary to the project for a period of three years following completion of research.
4. Documenting and reporting to the IRB, via the department head, all instances of injury or harmful consequences to participants or research personnel that occurred as a result of participation in the research project.

5. Informing the IRB of any changes in the research protocol.
6. Providing adequate debriefing to human participants when deception is used.
7. Submitting a renewal/continuation (IRB 101-C) application annually for research extending more than one year, including changes in the originally submitted protocol.
8. Directly supervising and training all research personnel.

Types of Review and Procedures for Each Type

Grant Review

In some cases granting agencies will request human subjects assurance, however, the IRB can not provide approval at that time. For example, part of the grant is development of the instruments, but, the IRB can not approve an application unless all instruments to be used are included. In cases such as this, the PI should complete IRB Form 200 and submit the form to the Chair of the IRB. This form asks for minimal basic information, but will allow the Chair to determine what if any areas of the proposal will cause serious concern for the IRB. The Chair of the IRB will then send a memo to the PI indicating what forms and other documentation will need to be submitted, and also any areas of concern. This will allow the PI to obtain some level of IRB review, expedite the application process when formal approval is requested, and indicate any areas the PI may want to consult with the IRB while developing the research protocol.

Exempt Review of Human Participant Research

Research which falls under Exempt review is exempt from full committee review, and only requires review by a College IRB representative. For this type of research, the PI should complete an Exempt Form and forward the form to their college IRB representative (the names of representatives can be found on the IRB web page, www.selu.edu/irb). The college representative will review the form and contact the PI if there are any questions or concerns. Once any questions or concerns have been addressed, the college representative will approve the application and forward the form to the Chair of the IRB, who will then review the application and provide final approval. Data may **NOT** be collected until the PI has received notification from the Chair of the IRB that the application has been approved. If the PI is uncertain whether the research falls under Exempt review, the college IRB representative or the Chair of the IRB should be contacted. The following types of research are exempt:

1. Research done within the university setting involving effective teaching techniques (except when a researcher's current students are participants).
2. Research involving only the use of educational tests (cognitive, diagnostic, aptitude, achievement) if the data are recorded so that participants cannot be identified in any way, and none of the investigator's current students are participants.
3. Research involving only observation of public behavior, surveys, or interviews, unless the participant's responses or conduct (if they became public) may place the participant in risk of civil or criminal liability or be damaging to the participant's financial standing or employability, or if the responses deal with sensitive aspects of personal behavior (e.g., illegal conduct, drug use, sexual behavior, or alcohol use).

4. Research involving only surveys or interviews of elected or appointed officials or candidates for public office, regardless of the type of behavior.

Expedited Review of Human Participant Research

Research which falls under Expedited review will be reviewed by the Chair of the IRB and two other IRB representatives. For this type of research, the PI should complete a Form 101-H, and forward the form to the Chair of the IRB. The PI does not need to determine whether the research requires Expedited review or Full review, the Chair of the IRB will contact the PI if Full review is required. If there are questions or concerns about the application, the Chair of the IRB will contact the PI for clarification. If one of the reviewers requests a Full review, such a review will be necessary. Once the application has been approved by the Chair of the IRB and two other representatives, the PI will be notified that the application has been approved. Data may **NOT** be collected until the PI has received notification from the Chair of the IRB that the application has been approved. The following types of research fall under Expedited review:

1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.
2. Collection of data from voice, video, digital, or image recordings made for research purposes.
3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, or quality assurance methodologies.

Full Review of Human Participant Research

Research which requires Full review will be reviewed by all members of the IRB. For this type of review, the PI should complete a Form 101-H and submit the application to the Chair of the IRB. The IRB meets the second Wednesday of each month to review all Full review applications. Applications must be received the preceding Thursday to be eligible for review at that particular meeting. The PI is strongly encouraged to attend the meeting at which the application will be discussed, in order to answer questions, address concerns, and lead to a more timely approval of the application. If the PI does not attend the meeting, approval may take up to two months. Once the PI has addressed the questions and concerns of the IRB, a vote will be taken. In order for an application to be approved, a majority of the IRB present must vote in favor of the application. If a quorum (5 voting members) is not present, a vote may not take place. An application may be approved contingent on the PI modifying parts of the proposal, or providing further documentation. It is then the responsibility of the PI to provide the further documentation, or proof of modifications that are required. The Chair of the IRB will not provide final approval of the application until all documentation is provided. Data may **NOT** be collected until the PI has received notification from the Chair of the IRB that the application has been approved.

The following types of research require Full review:

1. Research involving minors.
2. Research involving prisoners.
3. Research in which the participant's responses or conduct (if they became public) may place the participant in risk of civil or criminal liability or be damaging to the participant's financial standing or employability.
4. Research in which the participant's responses deal with sensitive aspects of personal behavior (for example, illegal conduct, drug use, sexual behavior, or alcohol use).
5. Research which includes the collection of physical and/or biological specimens.
6. Research in which participants are students in the PI's class.

Research Lasting More Than One Year

Approval is given for one calendar year from the date the approval is given. If data collection lasts more than one year and the protocol has not changed, Form 101-C must be completed and submitted to the Chair of the IRB. Data may **NOT** be collected once a year has expired until notification of continued approval has been received from the Chair of the IRB. If there have been changes in the research protocol, the PI should contact the Chair of the IRB to determine if the changes are significant enough to warrant a new approval process. Continuation of research which required initial Full Review will also require Full Review.

Research Guidelines for Research Involving Human Participants

1. Experiments involving any intrusive procedures (e.g., administration of drugs, venipuncture, or any skin penetrating procedures) must be supervised by a licensed physician, nurse practitioner, or registered nurse as the case merits. The person performing the procedure must be educationally and legally qualified to carry it out.

2. Experiments involving any procedure which may alter a person's self-image or mental state must be supervised by a qualified behavioral scientist (e.g., a psychiatrist, psychiatric nurse specialist, psychiatric social worker, certified counselor, or a licensed psychologist).

3. Whenever possible, research should capitalize on procedures already being performed on the participants for diagnostic, educational, or treatment purposes.

4. The research should be based on a thorough knowledge of the problem under study and so designed that the anticipated results will justify its performance.

5. Whenever risk is unavoidable, the nature of the risk must be reasonable in relation to the anticipated benefits and the importance of the knowledge that may reasonably be expected to result.

6. The research should describe fully the recruitment procedures, including the methods used to encourage participation.

7. Selection of participants and the division into “control” and “test” groups must be in accordance with accepted scientific procedures.

8. If participants are offered non-monetary compensation of any kind, individuals in the same class or group of potential participants who choose not to participate must be offered another comparable alternative to being research participants in order to receive the same compensation.

9. A copy of the Informed Consent/Assent Form must be on file with the IRB before any research is begun except when a survey is conducted, in which case the cover letter should state that completion of the survey implies consent.

10. In the event that research is to be conducted at a facility other than on the Southeastern Louisiana University campus, a written letter of approval must be filed with the IRB by an individual responsible for the alternate research facility.

11. The research procedure must make appropriate provision for monitoring the data collected to ensure that all IRB requirements for that study are scrupulously met.

12. Adequate provisions must be made to ensure that the privacy of participants and the confidentiality of all data are reasonably preserved.

13. Where some or all of the participants are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards must be included to protect the rights and welfare of these participants.

14. Participants must be allowed to discontinue participation in a study at any time they choose, without penalty.

15. In the event that research participants are minors or interdicts, two types of consent must be obtained. The parents or guardian must provide a written Informed Consent to allow the participants to participate, and the participant must provide a written Informed Assent expressing his/her willingness to participate. The two forms must not be attached to one another in order to protect the participant from possible coercion.

16. The PI is the ultimate and essential protector of the participant's rights and safety. As such, he/she has a prime obligation to be personally certain that each participant is adequately informed and freely consents to participate. The PI must personally ensure that every reasonable precaution is taken to reduce to a minimum any risk or discomfort to the participant. Complete compliance with all applicable required procedures as set forth herein provides evidence that the PI is protecting the subject's rights and safety; however, formal compliance cannot take the place of ethical practice.

17. The PI is directly responsible for the training and proper conduct of any research assistant involved in the project and for immediate supervision of all research conducted by such assistants.

Informed Consent/Assent

Informed consent should provide information about the nature of the study, be comprehensible to the intended sample, and indicate that participation is voluntary. The consent should be tailored to the comprehension level of the participants, for example if children are the participants, the consent should be in clear, simple language. In some cases, testing of the informed consent may be warranted. In most cases survey research does not require signed informed consent, however all elements of a consent form should be included. The PI must assure that each consent and assent is given freely without duress, coercion, or threats (even by implication), without promise of unrealistic results, and without excessive material reward for participation. Pressures to comply may be implicit in the clinical situation, but everything feasible must be done to reduce such pressures. Sample copies of an informed consent, informed assent, and survey cover letter can be found in Appendix A. An informed consent/assent form needs to contain the following:

1. The purpose of the investigation and a general statement as to its nature and relation to other knowledge.
2. The use of the results obtained.
3. If video or audio tapes are made, how long they will be stored and for what specific purposes they will be used. The participant's portion of the tape can be erased at his/her request.
4. Information on the procedures to be used, including any invasive techniques, restriction of normal activities, long-term follow-up examinations, or the possibility of being assigned to the “control” group.
5. Any known risks, inconvenience, or side-effects that may be anticipated and all measures that will be taken to minimize them.
6. Precautions to prevent injury and whom to contact for further information.
7. Any benefits that may accrue to the participant as a result of participation.
8. How confidentiality of the data will be maintained.
9. Who to contact for further information and how they may be contacted.
10. A statement that the Chair of the IRB may be contacted regarding rights as a research participant, as well as the Chair’s contact information.
11. A statement on voluntary participation, including:
    1. Participation is voluntary
    2. Participant is free to withdraw at any time
    3. Refusal to participate will involve no penalty
    4. Participant has been given the opportunity to ask questions and has received satisfactory answers.
12. IRB approval date
13. IRB Expiration date (one year after approval)

Policies on Classroom Activities

Classroom activities which may involve human participants for the purpose of "research" should be approved by the IRB before implementation. However, if students are to design and implement surveys, questionnaires, or interviews, approval is not required for each individual student. The faculty member should complete the appropriate form for the entire class, providing general topics and procedures. The instructor is responsible for ensuring that students are aware of the ethical issues involved in research. Failure to acquire full approval from the IRB before implementation for any classroom activity which involves humans as "participants" means that the instructor is not acting "in good faith" with university policy and is not, therefore, guaranteed the protection of the university.

Policies on E-mail Surveys

When a survey is conducted via e-mail, the PI knows who submits all responses, which can create confidentiality challenges. The IRB encourages a PI to use a web-based survey instead, with notification via e-mail. E-mail surveys are allowed, however the PI may be requested to provide additional information regarding methods of maintaining confidentiality.

Definitions

The definitions below are based on the 45 CFR 46.

Research - A systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

Human Subject - A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or the researcher obtains identifiable private information. Private information includes behavior in which the individual reasonably expects that the behavior has not been observed or recorded or information provided for a specific purpose and the individual can reasonably expect it will not be made public.

Minimal Risk - The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. Minimal risk is affected by the context of the research, including characteristics of the subjects.

Appendix A

Consent Form, Assent Form, and Survey Cover Letter Samples

(Must be on department letterhead)

Consent Form for Study Involving Only Minimal Risk

(Complete title of research project)

Introduction I, _____, have been asked to participate in this study. _____, who is conducting this research to (**state why research is being done)** e.g. fulfill the requirements for a masters thesis in _____(**subject**) at Southeastern Louisiana University, has explained the study to me.

Purpose of the Study The purpose is to learn more about _____.

Description of Procedures This study will be performed at _____. I will be asked to (**state specific procedures**) e.g. complete a set of questionnaires and tests, which will take about two hours to complete. I have been given an opportunity to examine these _____. Approximately _____ participants will be in this study.

Risks and Discomforts There are no known or expected risks from participating in this study, except for mild frustration sometimes associated with performance of the _____ test.

Benefits I understand that this study is not expected to be of direct benefit to me, but the knowledge gained may be of benefit to others.

Contact Persons For more information about this research, I can contact X at xxx-xxxx or his/her supervisor, Dr. Y, at yyy-yyyy.

For information regarding my rights as a research participant, I may contact the Chair of the Institutional Review Board at 549-2077.

Confidentiality I understand that any information obtained as a result of my participation in this research will be kept as confidential as legally possible. In any publications that result from this research, neither my name nor any information from which I might be identified will be published without my consent.

Voluntary Participation Participation in this study is voluntary. I understand that I may withdraw from this study at any time. Refusal to participate or withdrawal will involve no penalty or loss of benefits for me. I have been given the opportunity to ask question about the research, and I have received answers concerning areas I did not understand. Upon signing this form, I will receive a copy.

I willingly consent to my participation in this study.

_____ _____

Signature of Participant Date

_____ _____

Signature of Investigator or Investigator's Representative Date

Approval Date: Expiration Date:

(Must be on department letterhead)

Parental Consent Form for Study Involving Only Minimal Risk

(Complete title of research project)

Introduction I, _____, have been asked to allow my child, _____, to participate in this study. _____, who is conducting this research to (**state why research is being done)** e.g. fulfill the requirements for a masters thesis in _____(**subject**) at Southeastern Louisiana University, has explained the study to me.

Purpose of the Study The purpose is to learn more about _____.

Description of Procedures This study will be performed at _____. My child will be asked to (**state specific procedures**) e.g. complete a set of questionnaires and tests, which will take about two hours to complete. I have been given an opportunity to examine these _____. Approximately _____ participants will be in this study.

Risks and Discomforts There are no known or expected risks from participating in this study, except for mild frustration sometimes associated with performance of the _____ test.

Benefits I understand that this study is not expected to be of direct benefit to me, but the knowledge gained may be of benefit to others.

Contact Persons For more information about this research, I can contact X at xxx-xxxx or his/her supervisor, Dr. Y, at yyy-yyyy.

For information regarding my child's rights as a research participant, I may contact the Chair of the Institutional Review Board at (985) 549-2077.

Confidentiality I understand that any information obtained as a result of my child's participation in this research will be kept as confidential as legally possible. In any publications that result from this research, neither my name nor any information from which I might be identified will be published without my consent.

Voluntary Participation Participation in this study is voluntary. I understand that I may withdraw my child from this study at any time. Refusal to participate or withdrawal will involve no penalty or loss of benefits for me or my child. I have been given the opportunity to ask question about the research, and I have received answers concerning areas I did not understand. Upon signing this form, I will receive a copy.

I willingly consent to my child's participation in this study.

_____ _____

Signature of Parent or Guardian Date

_____ _____

Signature of Investigator or Investigator's Representative Date

Approval Date: Expiration Date:

(Must be on department letterhead)

Assent Form for Study Involving Only Minimal Risk

(Complete title of research project)

Introduction I, _____, have been asked to be in this research study, which has been explained to me by _____.

Purpose of the Study I have been told the purpose of this study is to learn more about _____.

Description of Procedures This study will be performed at _____. I will be (**state specific procedures**) e.g. given several lists of written questions to answer. It will take about two hours for me to answer the questions. I do not have to answer all of the questions.

Discomforts some of the questions will be difficult and I may not enjoy trying to answer them.

Benefits I understand that this study is not expected to help me, but what they learn from the study may help other people.

Confidentiality I have been promised that anything they learn about me n this study will be kept as secret as possible.

Voluntary Participation I have been told that I do not have to do this. No one will be mad at me if I refuse to do this or if I decide to quit. I have been allowed to ask questions about the research, and all of my questions were answered. I will receive a copy of this form after I sign it.

I willingly agree to be in this study.

_____ _____

Signature of Participant Date

_____ _____

Signature of Investigator or Investigator's Representative Date

Note: The assent form may need to be modified. It must be at the level of the participants for whom you are obtaining assent. For example, if you are using 5 year olds as participants, they must be able to fully understand the assent form.

(Must be on department letterhead)

Survey Cover Letter

Information similar to the following should be included as part of a survey cover letter.

This survey is designed to _____.

Taking the survey will take approximately XX minutes of your time. Completion and return of this survey indicates voluntary consent to participate in this study. For information regarding my rights as a research participant, I may contact the Chair of the Institutional Review Board at (985)549-2077.

This survey contains an identification number. This is done for research purposes and to avoid sending you needless reminders about completing the survey. The information you provide will be completely confidential, the coding list will be destroyed after the data is collected. The information gained from this survey will only be reported as group data, at no time will your name be identified with any response. If you have any questions regarding this survey, please contact X at (xxx)xxx-xxxx or his/her supervisor, Dr. Y, at (yyy)yyy-yyyy.

Appendix B

IRB Forms

Application for Exempt Review (IRB-500)

You must receive approval from the IRB prior to beginning the research described below.

Title of Proposal: _____

Principal Investigator(s) (PI): _____

Department: _____ E-mail:_____

Phone:_____ Box Number:_____

Date Research Begins:_____ Expected Date of Completion:_____
(Must be after Approval Received)

	Yes	No
1. The research only involves effective teaching techniques done within the university setting	❒	❒
2. The research involves only the use of educational tests and the participants cannot be identified and they are not currently in a course I teach.	❒	❒
3. The research involves only the observation of public behavior, surveys, or interviews.	❒	❒
If Yes to 3	❒	❒
3-a. Responses will place the participant at risk of civil or criminal liability.		
3-b. Responses will damage the participant's financial standing or employability.	❒	❒
3-c. The responses deal with sensitive aspects of personal behavior (e.g, illegal conduct, drug use, sexual behavior, or alcohol use).	❒	❒
4. The research involves only surveys or interviews of elected or appointed officials or candidates for public office.	❒	❒

If you answered "YES" to questions 3-a, 3-b, or 3-c, this research is not eligible for Exempt Review. Also, if you answered "NO" to questions 1, 2, 3, and 4, this research is not eligible for Exempt Review.

5. Explain the procedures involved in the research:

6. Explain any known risks to human participants:

7. Explain how records will be kept:

A cover letter addressed to respondents, or an introductory statement for telephone surveys, must accompany any survey or questionnaire. The cover letter **must** be on your departmental letterhead and **must** include the following:

- a statement that the project is research being conducted in partial fulfillment of the requirements for a course, master's thesis, dissertation, etc.
- purpose of study
- a statement regarding the anonymity or confidentiality of participants' responses (if confidentiality is not ensured, explain how written permission will be obtained).
- if audiotaping or videotaping, a statement that participant is being audiotaped or videotaped (explain how tapes will be stored or disposed of during and after the study)
- a statement that participants do not have to answer every question
- a statement that class standing or grades (or status on an athletic team, if applicable) will not be affected by refusal to participate or by withdrawal from the study
- a statement that participation is voluntary

Attached are:

_____ Questionnaire/survey to be used
_____ Telephone text (including introductory remarks as in a cover letter — see above)
_____ Cover letter
_____ Permission from external institution, on their letterhead (if applicable)

I assure Southeastern Louisiana University that I will comply with all requirements to ensure the protection of human participants and that the statements made above are correct. I will permit the University to conduct reviews as may be required for the implementation of this assurance.

_____ _____
Signature of Principal Investigator Signature of College IRB Representative

_____
Signature of Department Head

FOR PROJECTS PROPOSED BY STUDENTS

This research involving human participants, if approved, will be conducted under my immediate supervision.

_____ _____
Name of Faculty Sponsor Signature of Faculty Sponsor

For Office Use Only Date Received:_____IRB Number_____

Southeastern Louisiana University
Continuation of Research (IRB 101C)

Title of Proposal: _____
(As submitted on the original protocol)

IRB Number: _____

Principal Investigator(s) (PI): _____

Department: _____ E-mail:_____

Phone:_____ Box Number:_____

Please provide the following information on a separate page(s):

1. The number of subjects for whom you have collected data.
2. A summary of any unanticipated problems and available information regarding adverse events.
3. A summary of any withdrawal of subjects from the research since the last IRB review.
4. A summary of any complaints about the research since the last IRB review.
5. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last IRB review.
6. Any other relevant information, especially information about risks associated with the research.
7. Please submit a copy of the informed consent document (statement) you are currently using and any newly proposed consent documents.

Date original protocol filed:_____

Please be advised that if any changes have been made in this protocol, you must contact the Chair of the IRB to determine if a new protocol needs to be filed. If no changes have been made, sign the statement below, date it, and return it to the Chair of the IRB. You may not collect further data until you have received notification that this form has been received and filed.

I, _____, hereby affirm that the protocol I

submitted to the IRB on _____ is the one I am following. No changes have been made.

Signature: _____ Date: _____

Signature of IRB Chair: _____ Date:_____

Southeastern Louisiana University
Grant Review (IRB 300)

Title of Proposal: _____

Principal Investigator(s) (PI): _____

Department: _____ E-mail:_____

Phone:_____ Box Number:_____

Who are the potential participants for the research? (Check all that apply)
❒ Adults ❒ Minors ❒ Prisoners ❒ Mentally Retarded ❒ Animals

Please briefly describe anticipated procedures.

Southeastern Louisiana University

IRB Application for Projects Using Human Subjects

Title of Proposal: _____

Principal Investigator(s) (PI): _____

Department: _____ E-mail:_____

Phone:_____ Box Number:_____

Date Research Begins:_____ *(Must be after Approval Received)*

Expected Date of Completion:_____

Please mark the appropriate classification:

❒ Southeastern Student ❒ Southeastern Faculty ❒ Southeastern Staff

❒ Student From Another Institution ❒ Faculty From Another Institution

Human participants will be involved in the proposed research as:

❒ Adults ❒ Prisoners

❒ Minors ❒ Mentally Retarded

❒ Other (Specify) _____

For Office Use Only	Grant Proposal Number_____
Date Received:_____	IRB Number_____

1. Please summarize your research procedures. Include what instructions will be given to the participants, the experimental manipulation (if any), how participants are assigned to groups, and what participants will be expected to do. **(Limit your response to 250 words)**

2. Please answer each of the following items.	Yes	No
a. The participants are volunteers.	❒	❒
b. All participants will consent by signature.	❒	❒
c. Participants have the freedom to withdraw at any time.	❒	❒
d. The data collected will be used only for purpose(s) approved by the participants.	❒	❒
e. The participants will be informed beforehand as to the nature of the activity.	❒	❒
h. All questions concerning the proposed research will be answered to the participant's satisfaction.	❒	❒

For each "No" answer to any of the above, the PI must provide an explanation. If more space is needed for statements a-h than is provided, please attach additional sheets of paper.

3. Please answer each of the following items.	Yes	No
a. Individual performances/responses will be disclosed to persons other than those involved in the research or authorized by the participants.	❒	❒
b. Data collected is related to illegal activities.	❒	❒

For each "Yes" answer to any of the above, the PI must provide an explanation. If more space is needed for statements a-c than is provided, please attach additional sheets of paper.

4. Will anyone, including the researcher, be able to identify a participant's response with the participant at any time? If yes, please explain what steps will be taken to ensure the participant's confidentiality.

5. If minors or interdicts are to participate in this experiment, explain how valid consent will be obtained from parents or guardians and how valid assent will be obtained from participants.

6. Does this research entail stress or possible psychological, social, legal, or physical harm to participants? Please explain. What steps have been taken to minimize these risks? Have provisions been made to ensure that appropriate facilities and professional attention necessary for the health and safety of participants are available and will be utilized?

7. University policy requires that any risk associated with participation be outweighed by potential benefits to participants and to humankind in general.

   a. Identify any benefits to participants resulting from participation in this research.

   b. Identify any benefits to humans in general resulting from the research.

8. Please describe your participants. Include all of the following:

   a. Number of participants _____

   b. Age range of participants _____

   c. How potential participants will be identified (if identified from an external source provide proof of permission to use source) _____

   _____

   _____

   d. How participants will be recruited (include a description of any incentives or compensation used)

   _____

   _____

   _____

9. Please describe your procedures in detail.
   a. How data will be collected

   b. How data will be stored

   c. When and how data will be destroyed

   d. How confidentiality will be maintained

   e. How informed consent will be obtained

   f. If deception (e.g., masking procedures, providing false information) is necessary, justify and describe debriefing procedures to be used

   g. If minors or other vulnerable participants are involved, outline procedures to be used in obtaining their individual agreement to participate, in addition to the consent of the parent or guardian.

10. Attach a copy of all cover letters, instruments, informed consent forms, handouts, verbal or phone scripts

I assure Southeastern Louisiana University that I will comply with all requirements to ensure the protection of human participants and that the statements made above are correct. I will permit the University to conduct reviews as may be required for the implementation of this assurance.

Signature of Principal Investigator: _____ _____
Signature Date

FOR PROJECTS PROPOSED BY STUDENTS

This research involving human participants, if approved, will be conducted under my immediate supervision.

_____ _____ _____
Name of Faculty Sponsor Signature of Faculty Sponsor Date

Signature of Department Head: _____ _____
Signature Date

For IRB Use Only:

The proposed research received:

_____Full Review
_____Expedited Review
_____Exempt

Committee Action:

_____ Full Approval
_____ Denied Approval

Comments or Conditions:

Signature of IRB Chair: _____ _____
Signature Date