Research Involving Human Subjects

The University of West Alabama Research Oversight Committee is responsible for reviewing all research projects involving human subjects. All research involving human subjects conducted by faculty and/or staff must be approved by the Research Oversight Committee before human subjects can be involved. The University of West Alabama also recognizes students as legitimate research participants. The following principles will be followed when using students as research participants:

1. Informed Consent will be required to ensure the minimal amount of coercion or undue influence (sample attached).
2. The students will be assured that participate is voluntary, that non-participation will not involve penalties, that participation can be terminated at any time, and individual results will remain confidential.

Research Involving Human Subjects Review Process

The Chair of the Research Oversight Committee must receive the following information before the review process begins:

1. Research Proposal including a brief review of relevant literature, the theoretical purpose of the research, any potential risks that might be involved, and potential benefits for individual participants and/or society in general
2. Informed Consent Form to be Used
3. Appropriate Attachments (survey instruments, examples, etc.)

In order to approve research, the Research Oversight Committee shall determine that all of the following requirements are satisfied:

1. Risks to the participants are minimal;
2. Risks to the participants are reasonable in relation to the anticipated benefits, if any, to the participants, and the importance of the knowledge that may reasonably be expected to result;
3. Selection of the participants is equitable and participants have not been coerced to participate;
4. Informed consent shall be obtained from each participant;
5. Provisions have been made to protect the privacy of the participants and the confidentiality of data;

Approximate Time Required for Review Process:
Expedited Review--2 weeks
Full Review--30 days

* The review process may take longer if all required information is not submitted to the Research Oversight Committee.

Research Involving Human Subjects Expedited Review Process

The Research Oversight Committee may review certain kinds of research involving human subjects using an Expedited Review Process. The Department of Health and Human Services has established a list of categories of research that may be reviewed using an Expedited Review Process in §46.110 as follows:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an

investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluation the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. 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, human factors evaluation, or quality assurance methodologies.
8. Continuing review of research previously approved by the IRB as follows:
    (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    (b) where no subjects have been enrolled and no additional risks have been identified; or
    (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The Research Oversight Committee may utilize the Expedited Review Process if the research fits one or more of the previous categories and (a) the research is found to involve no more than minimal risk and/or (b) minor changes are being made to previously approved research during the period for which the approval was authorized.

The Expedited Review Process allows the Research Oversight Committee (ROC) chairperson and two other members of the ROC to review the research and allows them all authorities of the ROC except that they cannot disapprove the research. Only the entire ROC can disapprove research. If the research is approved through the Expedited Review Process, all members of the ROC will be notified.

Any proposed research not covered by the conditions of the Expedited Review Process will be referred to the Research Oversight Committee for full review.

Review

In the event that any questions arise concerning the interpretation or implementation of this policy, such questions should be referred to the senior administrator in the area (i.e., Provost,

Vice President for Financial Affairs, etc.) for final decision in accordance with all applicable University policies.

Notification

Faculty or staff preparing grants which will involve the University as set forth above should file a "Notification of Grant Proposal Development" form developed by the Office of Sponsored Programs.

INFORMED CONSENT

Project Name _____

The University of West Alabama

You are invited to participate in a study (state what is being studied). We hope to learn (what the study is designed to investigate). You were selected to participate because (state why the participant was selected).

Explanation of Study: (Describe procedures to be followed, including purposes, how long the procedures will take, and the frequency of the procedures. Describe any discomforts and/or inconveniences to be expected from the study. Estimate the total time required of the participant for the study. Describe any risks associated with the study and any precautions taken to reduce risks. Describe the benefits expected from the study but if benefits are described include the following statement: "We cannot promise you will receive any or all of these benefits.")

Confidentiality of Study: Any data that can be identified with you will remain confidential and will be disclosed only with your permission.

Compensation: (Describe the amount or nature of compensation the participant will receive. If medical treatment is available in case of physical injuries, state the extent of the treatment that will be provided. If extra credit is involved, state the amount of extra credit.)

Voluntary Participation: Your decision to participate or not to participate will not prejudice your relations with The University of West Alabama. If you decide to participate, you may withdraw your consent and discontinue participation at any time.

Questions Regarding Study: If you have any questions regarding this study now or at any time during your participation, you may contact (state who is responsible for answering questions and give his/her address and telephone number).

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

Date Time	Subject's Signature
Witness	Investigator's Signature