The JSU IRB

The Institutional Review Board exists because federal regulations require that federal departments and federal agencies scrutinize all human subject research conducted or sponsored by each department or agency. These regulations, found in 45 CFR 46 and the subsequent "Common Rule" and "Belmont Report" spell out the requirement that any institution receiving federal funding for human subject research have an Institutional Review Board for the Protection of Human Subjects in Research (IRB) that reviews all human subject research, despite its source of funding, conducted at, by, or under the auspices of that institution, in this country or abroad. Thus, the IRB exists to uphold at Jackson State University federal statutes designed for maximum protection of human subjects in research.

It is in the best interest of the moral and scholarly reputation of the University to maintain a regulating body that provides a check on the procedures of research projects involving human subjects. The IRB is not designed to be punitive or overly critical in its review of applications; rather, the basic intent of the IRB is to provide technical assistance to researchers in order to facilitate research that meets the highest standards of human subject protection. In this way, the IRB serves both regulatory and didactic functions.

IRB Membership

The JSU IRB is comprised of individuals knowledgeable in the area of human subject research. The membership is comprised of persons from the JSU faculty and Jackson community, appointed by the Vice President of Research Administration. The appointment process is consistent with that suggested in the Manual of the Office for Human Research Protections (OHRP), the federal agency responsible for overseeing IRB's nationwide. The appointees likewise meet federal requirements in terms of a balance between University and community and between various areas of human research specialty. A list of current IRB members is available on request from the IRB Assistant, Research Development Support and Federal Relations office, sixth floor Tower building.

IRB Staff

The IRB Chair oversees the general operations of the IRB. Under the Chair's direction is the IRB Assistant, who performs initial reviews and clerical duties associated with routing applications and directing correspondence. The IRB Assistant disseminates blank IRB applications, receives completed ones, acts as a recording secretary at IRB meetings, and provides information on meetings, deadlines, etc., at the request of the applicants.

Accessibility of the IRB

The JSU IRB is designated to provide technical assistance as needed to applicants and potential researchers. By calling the IRB Assistant or IRB Chair, most questions regarding the application and review process can be answered. The IRB Assistant, who is available in the Research Development Support and Federal Relations Office, sixth floor Tower building, can perform a check on the status of a particular application.

Duties of the IRB

See Attachment A, "Duties of the IRB"

The IRB Application

See Attachment B, "Application to the JSU Institutional Review Board"

Completing the Form

See Attachment C, "Instructions for Completing the JSU IRB Application"

Requirements for Submission

See Attachment D, "Requirements for Submission"

Common Concerns

See Attachment E, "Common Concerns Regarding IRB Applications"

Samples of Approved Responses

See Attachment F, "Samples of Approved Responses"

The Review Process and IRB Procedural Flow Chart

See Attachment G, "IRB Procedural Flow Chart"

Informed Consent

See Attachment H, "Informed Consent Checklist"

Consent and Assent Form Samples

See Attachment I, "Consent/Assent Form Samples"

Research Certification Samples

See Attachment J, "Research Certification Samples"

ATTACHMENT A
"DUTIES OF THE IRB"

Duties of the IRB

- To protect the rights of subjects electing to participate in research projects;
- To educate and inform researchers regarding the review process and issues of subject protection;
- To provide researchers with access to federal guidelines for protection of human subjects;
- To provide technical assistance in the area of subject protection to researchers;
- To ensure that all research involving human subjects meets or exceeds subject protection standards set forth in Title 45 Code of Federal Regulations Part 46 (45 CFR 46); and
- To track and follow up on each human research project to ensure continued compliance with 45 CFR 46.

ATTACHMENT B
"APPLICATION TO THE JSU INSTITUTIONAL REVIEW BOARD"

NOTE: No research involving human subjects is to be conducted without the prior written approval of the IRB.

APPLICATION
TO
JACKSON STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Each question should be thoroughly completed. Attachments should be used when appropriate and not in place of completing the application. Please read the instructions and questions prior to completing the application.

□ **Faculty** □ **Staff**
□ **Student** **Anticipated Graduation** _____

FOR OFFICE USE ONLY

Date rec'd._____

Type of Review:
9 Exempt 9 Expedited 9 Full
IRB Action:
9 Approved 9 Disapproved 9 Modification Required

_____ _____
IRB Chair Date
_____ _____
Date
_____ _____

1. **Name:**

   Address:

   City/State/Zip:

   Phone:(daytime)

   Phone:(evening)

   Fax:

   JSU E-mail Address:
   Alternate E-mail Address:

   Department:

2. **Title of Project:**

3. **Research Project Period: from _____ to _____(Do not predate your research. It must be a date after you would receive IRB approval.)**

4. **Funding Source:**

5. **Site(s) of Research:**

6. **Please provide:**

   a. **A brief description of research project:**

b. A brief description of the research design: Qualitative/descriptive (nominal or ordinal data)? Quantitative (interval or ratio data)? True experiment, quasi-experimental, etc.?

1. **Have you conducted a statistical power analysis?**
2. **Have you determined the sample size needed?**
3. **What were the results?**
4. **If you need assistance, go to http://www.psycho.uni-duesseldorf.de/aap/projects/gpower/ or consult your advisor and a statistical text book.**
5. **If you have not conducted a power analysis or determined the sample size needed for statistical significance (inadequate numbers), then you must state your study is a "Pilot Study" in the Title of your project.**

c. A brief description of your proposed data analysis: (T-test, chi-square, correlation, ANOVA, MANOVA, Regression, Discriminant Analysis, etc.)

7. Describe in detail the research procedure related to subjects' participation; minimally, the following information must be included:

a. How will the subject(s) be selected and/or recruited? (Append copy of letter and/or transcript of verbal announcement).

b. Do you supervise, teach, or have direct contact with the participants you plan to recruit? Research conducted with persons whom you have an established relationship could be coercive in nature and represent a conflict of interest.

c. What inducement is offered, if any?

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

e) If a cooperating institution (school, hospital, prison, etc.) is involved, prior written permission must be obtained. (Append approval letter.)

f) Number of times observations will be made or instruments administered?

g) What do the subject's do, or what is done to them, in the study (method of recruitment and how you will collect the consent and the data)?

(1. You must append a copy of questionnaires or test instruments. ❒ Self-designed; ❒ Purchased-name of publisher_____; ❒ Published in a journal-provide citation and permission from the author to use the survey.

2. Description of procedure using the participant in your study.)

h) How is it made clear to the subject that their participation is fully voluntary? (Use the language of the consent/assent form.)

i) How is it made clear to the subject that they may withdraw at any time? (Use the language of the consent/assent form.)

j) How is it made clear to the subjects that they may refuse to answer any specific question that may be asked of them? (Use the language of the consent/assent form.)

k) Cite your experience with this type of research. Student applications must include their own experience, as well as, the advisor's research experience.

Student experience:

Faculty experience:

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

9. Justify:

a. Why do you need to use human subjects in this research? Has your topic been research previously? (Consider if your research could be completed with secondary data.)

b. How will your research add to the body of scientific literature?

10. a. What are the benefits gained by the individual for participation in your project? (Remember, most research is conducted for the benefit of the researcher and the participants receive no benefits unless they are involved in treatment or clinical trial research.)

b. Do you see any chance that subjects might be harmed in any way?

c. Are there any physical risks?

d. Psychological risks? (Might a subject feel demeaned or embarrassed or worried or upset? All research has some psychological risk.)

e. Social? (Possible loss of status, privacy, reputation?)

11. Do you deceive them in any way? If yes, explain why deception is justified and provide information about how the participants will be debriefed about your project.

12. How do you ensure confidentiality of the information collected? (By Federal Law, you must state where and who will be responsible for maintaining your data for a period of 3 years.)

13. STUDENT APPLICATIONS ONLY: Has your committee reviewed and approved your proposal prior to submitting your IRB application? Yes No

14. STUDENT APPLICATIONS ONLY: If no, have you reviewed the approval process with your department? Yes No. If you answered no, please see your advisor or chair of your committee for their approval process.

15. Due to recent changes in the Federal Regulations, the IRB is requiring that students, faculty, and researchers obtain a certificate from a tutorial regarding research with human subjects. This may be obtained online.

a. Research Certification
https://www.citiprogram.org/

This requires 1-2 hours and allows you to start and stop until all sections are completed.

b. At the recommendation of OHRP, the Board is requiring that students, faculty, and researchers read "The Belmont Report." This may be found at http://ohrp.osophs.dhhs.gov/educmat.htm. Go to (1) Policy Guidance, and scroll down (2) under Guidance Materials to the link.

c. The final recommendation for the IRB is a requirement that all students, faculty, and researchers read the ethical principals for research with human subjects from their respective disciplines.

Please sign the following, I _____ and my

Advisor _____ have completed all three requirements as of this date _____.

16. As of January 16, 2003, the researcher must use a consent form that has been stamped with an approval date and expiration date. This will be mailed to you along with your approval letter. Failure to use the stamped consent form may result in suspension of data collection until the proper form is utilized. Please notify the IRB when your data collection has been completed.

Applicant's Name (type)	**Faculty Advisor's Name (type)**	**Date**
Applicant's Signature	**Faculty Advisor's Signature**	
	Date	
	Faculty Advisor's Telephone No.	
	Faculty Advisor's Fax No.	
	Faculty Email Address (if available)	

ATTACHEMENT C
"INSTRUCTIONS FOR COMPLETING THE JSU IRB APPLICATION"

INSTRUCTIONS FOR COMPLETION OF THE
-APPLICATION TO THE JSU IRB-

The applicant should answer all questions thoroughly. If questions are not answered in complete sentences, or questions that are pertinent to the proposed research are explained in detail, or if a copy of the research instrumentation, procedures, etc., are not attached, the application will be returned to the applicant or held for receipt of all necessary documentation.

Questions

1. *Name, department, etc.:* Who are you? In what department do you work or study? At what phone number can you be reached? Indicate your local address. Where do you receive your campus mail? If you are faculty or staff, indicate your title. If you are a student, indicate your level of study (i.e., master's student, doctoral student, etc.) and expected date of graduation.
2. *Title of project:* List title of project.
3. *Project period:* Give approximate time period of participant involvement. This is important if your project is a long-term one. The IRB must review ongoing projects every twelve months. The interest here is in the period of participant involvement.
4. *Funding source(s):* If your project is supported, totally or partially, by external funding, the IRB wants to know. (We keep track of sponsored human subject research.) If you are self-funded, enter "N/A". If the proposal has not been funded, but has been submitted, enter the proposed funding source.
5. *Site(s) of research*
6. a. *Research Project:* Present an overview of your study. It is not necessary to include your thesis or dissertation proposal. Provide adequate information so that a reviewer could understand what you intend to do and accomplish.
   b. *Research Design:* Present your information so that a reviewer could determine if your design is quasi-experimental, experimental, quantitative, or qualitative in nature.
   c. *Data Analysis:* Indicate what statistical procedures will be utilized to analyze your data.
7. a. *How were participants selected and recruited?* Where did you get your subject population? Passerby-at-large/Random selection from telephone book? Freshman orientation? Rankin Correction Facility? A nursing home?
   b. *What inducement is offered?* If participants are to receive a stipend, grade points (in this case you must provide the instructions giving the points and how they will be applied to the participants' grade), or any other reward for participation, state what it is. If there is no inducement, enter N/A or None.
   c. *Sample size and characteristics:* How many participants do you plan to involve? Do you plan on distributing 50 or 1,000 survey forms? What is the number of subjects you intend to involve? Also characterize them – females, ages 10-100, high school males, Baptist women. Give any specifics that categorize your participant population.
   d. *Cooperating Institution:* If data are being collected at another site (school, hospital, prison, etc.), then prior permission must be obtained and the IRB must have the original letter.

e. *Number of observations:* Are the participants completing the forms on one occasion or are they repeatedly asked to return for follow-up? Are you asking them to report their diet three times a week for six weeks and take blood samples weekly for six weeks? How much of the participant's time will you need to complete the data collection?
f. *Procedures:* What are you asking them to do? Attach all questionnaires or test instruments and complete description of what tasks they will be doing in your study.
g. *Voluntariness:* You must state that their participation is completely voluntary. Does your informed consent form make this clear to the participants? Is it written in language they can understand?
h. *Withdrawal:* You must state that they may withdrawal from participation in the study at any time without penalty.
i. *Refusal:* Does your consent form state that they may refuse to answer any question or participate in any section of the study?
j. *Experience:* Faculty, please provide a brief description of your research experience. Students, please indicate you are under the direction of your advisor and briefly list their experience.

8. *Informed Consent:* How do you intend to obtain the subjects' informed consent? If in writing, attach a copy of the consent form. If not in writing, include a written summary of what is to be said to the participant(s), and justify the reason that oral, rather than written, consent is being used. (In this case, the researcher and his or her assistant must sign a form indicating that they witnessed the person provide verbal approval.) The consent and/or assent in the case of a minor child must include the following information:
    a. They are being asked to participate in a research project (the word "research" will be used);
    b. The title of the project is stated;
    c. State who is conducting the research and under whose auspices;
    d. Explain what they are being asked to do or what will be done to them;
    e. Tell them how much of their time will be involved in the study;
    f. Explain that participation is fully voluntary; they may stop participation at any time; and they may refuse to answer any question(s).
    g. State how their confidentiality and privacy will be maintained.
    h. Provide name of person who would furnish participants with additional information about the research project.
    i. Offer to answer any questions the participant might have about the study.
    j. Provide the name and phone number of the Vice President for Research Development Support and Federal Relations, Dr. Felix Okojie, to answer questions about their rights as research subjects.

9. *Justify:*
    a. Why is human subjects' participation in this research necessary? Can your research question be answered with secondary data analysis? Has the topic already been exhausted?

    b. What will your research add to the current body of scientific literature?

10. a. What are the benefits gained by the individual for participation in your projects?

b. Do you see any chance that subjects might be harmed in any way?
c. Are there any physical risks? How will you address them?
d. Psychological risks? If your study asks personal questions about certain types of behavior (prostitution, abuse, substance abuse), provide the name and telephone number of persons who could assist them.
e. Social risks? Could your subject lose status if they participate? Could their privacy be jeopardized? Could their reputation be changed?

11. Do you deceive them in any way? If deception is part of your study, then you must include procedures or debriefing them and provide the name and number of someone who could assist with their distress.
12. *Confidentiality:* By Federal law, data must be kept for a period of three years in a locked file cabinet. Also, include who will be responsible for the data and where it will be located.
13. *Student Applications:* If this is a thesis or dissertation, has your committee reviewed the application?
14. *Student Applications:* If this is a research project, has someone in your department reviewed the application and are they assisting you with the process?
15. **RESEARCH CERTIFICATION:** All applicants and advisors must have a certificate from the Office of Human Protection Risks or the National Institute of Health to certify that they have reviewed information regarding the protections of research participants. This certificate must be renewed on a yearly basis.
16. *Consent Form Approval:* As of January 16, 2003, all research must have an officially approved consent letter or assent form that has a date of approval and expiration on the form.
17. **THE APPLICATION MUST BE SIGNED BY ALL RESEARCHERS AND ADVISORS.** Contact numbers and email addresses should be provided. In most cases, the applicant will first be contacted by email to be informed of the status of their application.

ATTACHMENT D
"REQUIREMENTS FOR SUBMISSION"

REQUIREMENTS FOR IRB SUBMISSION

- The IRB application must be fully complete--each item requires a written response in complete sentences.

- The application must be signed by the applicant and, if the applicant is a student, by the appropriate faculty advisor.

- The applicant and the advisor must complete a certificate of training for research with human participants.

- The projected start date for the project must reflect a date that is after the next scheduled IRB meeting (schedules are available from the IRB Assistant and are attached herein).

- The application must be apriori; **applications made after research has begun are not accepted.**

- The proposal described in the application must reflect that the applicant has taken precautions against potential harm to human participants- applications reflecting disregard for human welfare are not accepted.

- The proposal should reflect that the applicant has taken care to ensure:

    - Full protection of participant confidentiality;
    - Complete voluntariness of participation, free from coercion of any kind; and
    - That the potential benefits of the research outweigh any potential risk to subjects.

ATTACHMENT E
"COMMON CONCERNS REGARDING IRB APPLICATIONS"

COMMON CONCERNS REGARDING IRB APPLICATIONS

- Application is incomplete--an item has not been responded to or associated documents (approval letter, questionnaire, etc.) were not included with the application
- The proposed research dates reflect post-hoc application
- The proposal does not adequately address protection of participant confidentiality
- The proposal does not adequately address full voluntariness of participation
- The proposal involves unjustified potential risk to participants (e.g., participants are placed in an experimental situation that is more stressful than is necessary to test the hypothesis)

ATTACHMENT F
"SAMPLES OF APPROVED RESPONSES"

SAMPLES OF APPROVED RESPONSES

- **Item 6:** "150 substance dependent adolescents are randomly assigned to one of three 12-session interventions: comprehensive health education, STD risk reduction, STD risk reduction plus risk sensitization."

- **Item 7a:** "Participants will complete a questionnaire (see attached survey) and participate in a one-hour semi-structured interview (see attached interview schedule). Individuals who agree to be interviewed for the community assessment protocol will respond to a 30-minute interview with the ethnographer. A sample of the types of questions asked and avoided is attached."

- **Item 7g:** "It is specifically stated in the consent form. Any individual may decline to complete the interview or decline to answer any questions within the interview."

- **Item 7h:** "This is specifically stated in the oral consent read to each participant and again prior to assessment."

- **Item 7i:** "This is stated before the instrument is administered and is written on the consent form."

- **Item 8:** "The elements of informed consent are stated prior to the interview in an oral consent procedure and again at the beginning of the interview (see attached consent forms and interview protocols). Oral rather than written consent is used for this telephone survey because the two surveys are anonymous interviews and a signed consent form would violate the assurances of anonymity."

- **Item 9: "**Mississippi has the highest syphilis morbidity in the nation and traditional disease intervention strategies have not been effective in lowering disease incidence in our state. Animal analog research cannot address these issues."

ATTACHMENT G
"IRB PROCEDURAL FLOW CHART"

Protocol Review Process

Upon receipt of the application in the IRB office, each protocol is examined to determine the level of review required for approval. There are three possible levels of review:

1) Exempt or Level I Expedited Review
2) Level II Expedited Review
3) Full Board Review

Exempt and Administrative Review Status

Exempt or Level I Expedited Review Process

1) Adequate protections are in place that ensure full voluntariness of initial and continued participation;
2) The potential subjects are not members of a protected population as identified in 45 CFR 46 (e.g., children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons);
3) The proposed study involves a non- or quasi- experimental method of gathering data (e.g., surveys, questionnaires, record reviews, archival research);
4) Adequate protection of subject confidentiality is ensured by the method of data collection and storage described in the proposal; and
5) The potential benefits of the research outweigh any potential risks associated with the type of research proposed.

The IRB Chair makes the determination of whether an applicant meets the above standards, and, in the event that these conditions are fully met, a letter of approval is issued to the applicant. In the event that minor adjustment to the applicant's proposed procedures will qualify the application for expedited review, the IRB Assistant and/or Chair relay suggested modifications to the applicant.

Level II Expedited Review Process

Three Board members are selected by the Chair to review protocols that require expedited review. Generally these applications have one or more of the following characteristics:

1) The research design is truly experimental, i.e., something is actually done to the subjects other than asking them for information, and all of the above characteristics are met; or
2) Some aspects of the research design raised concerns as to one or more of the characteristics described above, and the research is non- or quasi-experimental.

Reviewing Board members complete a reviewer checklist designed to direct the reviewer toward validating that various aspects of the issues described above are covered by the proposal. Reviewers may recommend approval, approval with modifications, or full review of the protocol

based on this process. The Chair then compiles the reviewers' comments and relays them to the applicant.

Full Review Process

In the event that a protocol requires Full Board review, copies of the proposal are disseminated to its members at least one week in advance of the upcoming scheduled IRB meeting. Members meet once monthly on the first Thursday of the month, with meetings cancelled in the event that no applications under current review require Full Board scrutiny. Typical of protocols reviewed under such circumstances are:

1) Proposals involving a protected population (e.g., children);
2) Proposals involving complicated experimental manipulation of human subject behavior, such that it is not clear whether potential benefits of the research outweigh potential risks to subjects;
3) Proposals routed to full review at the recommendation of Board members who have performed preliminary expedited reviews; or
4) Proposals sponsored or funded in full or in part by agencies requiring that the research design be approved by an IRB.

The Board uses typical parliamentary procedures to guide and facilitate decision-making, with board members first sharing commentary, then voting to decide final action and any recommendations for or requirements of the applicant. A final vote determines the ultimate decisions of the Board as to the status of the proposal as approved, approved pending modification(s), or disapproval.

Policy and Procedures

At the present time, the IRB employs the manual of the OHRP as a guide to the establishment and enforcement of policies and procedures. The Jackson State University also has a Policies and Procedures Manual that is available upon request for faculty and research units. The ultimate decision-making power rests in the hands of the IRB Chair in the even of an applicant grievance or desire to appeal. Currently, the Board is in the process of reviewing and revising a formal Policy and Procedure statement which clearly outlines steps that can be taken by an applicant who questions the decisions made by the Board. Upon its final revision, this statement will be made available to interested parties through the IRB Assistant.

ATTACHMENT H

"INFORMED CONSENT CHECKLIST"

CHECK	INFORMED CONSENT CHECKLIST – BASIC AND ADDITIONAL ELEMENTS
	A statement that the study involves research
	The title of the research project
	An explanation of the purposes of the research
	The expected duration of the subject's participation (time to complete)
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject (*must be included even if there are no risks to subjects*)
	A description of any benefits to the subject or to others which may reasonably be expected from the research (*must be included even if there are no benefits to the subjects*)
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.
( ) Research Q's	**An explanation of whom to contact for answers to pertinent questions about the research (you and advisor if applicable)**
( ) Rights Q's	**An explanation of whom to contact for answers to pertinent questions about your rights as a participant in human research (the official university contact)**
( ) Injury Q's	**An explanation of whom to contact for answers to pertinent questions about injury, therapy, or appropriate referral sources (medical, counseling, etc.)**
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
	A copy of the consent form must be made available to the subject
	ADDITIONAL ELEMENTS, AS APPROPRIATE
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	The approximate number of subjects involved in the study

ATTACHMENT I

“CONSENT/ASSENT FORM SAMPLE”

Template Consent Form

JACKSON STATE UNIVERSITY CONSENT DOCUMENT FOR
RESEARCH PARTICIPANTS

INVESTIGATOR:	FACULTY ADVISOR:
Your Name	Your Advisor (if student application)
Department	**Department**
Address	Address
City, State, Zip	City, State, Zip
Telephone Number	Telephone Number
JSU E-mail address	**JSU E-mail address**

TITLE OF STUDY:

PURPOSE OF STUDY: You are being asked to take part in a research study to determine ***(describe the purpose of your study)***. The goal of the research project is to determine the relationship (if any) between certain ***(variables, conditions, ideas, etc.)*** and ***(any other procedures as they are explained to the participant).***

METHODS AND PROCEDURES: The entire procedure should take ***(time required for completion of forms/procedures).*** If you agree to take part, ***(explain what they are being asked to do to participate. Follow the example.)*** you will first be asked several questions about personal and background information such as your age, race, education level, and prior ***(describe instruments and what they measure. Follow the example.)*** a brief form of intelligence. The intelligence measure provides only an estimate of intelligence; therefore, results will not be provided to you. You will then be read ***(next requirement for participation until all parts are explained to subject. Follow the example.)*** a story about a person and asked to answer several questions based on the information you are given in the story. Finally, you will be asked to complete two brief self-report forms.

You may ask questions at any time during the study and you are free to contact me or my advisor should you have any questions about the research project.

RISKS AND DISCOMFORTS: We expect no risks or discomfort for people in this study ***(Explain if there are risks or discomforts. For example, some issues research investigates are private and confidential. Provide the name and number of the facility you will refer them to if the need arises.)*** However, it is possible that you may feel somewhat uneasy answering the questions involved.

BENEFITS: The information obtained in this study may not directly benefit you. However, the results may provide needed information about ***(the purpose of your study and how it relates to the variable, procedures, instruments, etc.)***.

CONFIDENTIALITY OF RECORDS: All information obtained during this study is private. That is, we protect the privacy of people by withholding their names and other personal

information from all persons not connected to this study. Each person will be identified using a code number rather than your name. Raw data will be kept in a locked file cabinet for 3 years as required by federal law. Although the information in this study is private, it may be revealed in certain rare circumstances. Confidentiality will be broken if the information obtained reveals that you intend to harm yourself or another person.

VOLUNTARY PARTICIPATION: **Taking part in this study is completely voluntary. You may refuse to answer any specific question. Participants may withdraw at any time without penalty or prejudice.**

PARTICIPATION CONSENT: I have had the purposes and procedures of this study explained to me and have had the opportunity to ask questions. My signature shows my willingness to allow my child to take part in the study under the conditions stated.

This study has been reviewed by the Institutional Review Board of Jackson State University, which ensures that research projects involving human subjects follow federal regulations. Any questions or concerns about rights as a research participant should be directed to Dr. Felix Okojie, Provost, at Jackson State University, P.O. Box 17057, Jackson, Mississippi, 39217, or (601) 979-2931.

_____ _____

Participant Signature Date

_____ _____

Investigator Signature Date

Sample of HIPAA paragraph to include on consent for studies using protected health information.

Protected Health Information

Protected health information is any personal information that relates to your past, present, or future health or physical condition through which you can be identified. The data collection in this study includes such things as age, race, physical health status, and emotional adjustment. Study information collected solely for this research study and not as part of your regular care will not be included in your medical record. A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept for a period of three years. If you decide to withdraw, the information already collected about you may still be used in this study. While this study is ongoing you may not have access to the research information, but you may request it after the information is completed.

Following are two sample assent forms. They are included as guides to you in construction of a child's assent to be used in your project. Fill in the appropriate information and adjust to the specifics of your research.

NOTE:
***Do not include a statement to the effect that "your parent has agreed to allow you to take part in the study". This implies the possibility of parental pressure for the child's participation. Instead, use "your parent is aware of this project".**
***Make sure you use age appropriate language. For example, do not use the same language for a third grade student as you would for a graduate student.**

Sample Minor Assent Document

Your parent knows we are going to ask you to ***participate in this project/fill out this survey.*** We want to know about kids' ***attitudes/experiences about topic of research.*** It will take ***amount of time*** of your time to complete the task. Your name will not be written anywhere on the ***research instrument.*** No one will know these answers came from you personally.

If you don't want to participate, you can stop at any time. There will be no bad feelings if you don't want to do this. You can ask questions if you do not understand any part of the ***study.***

Do you understand? Is this OK?

Name (Please Print): _____

Signature: _____

Date: _____

Investigator's Signature: _____ Date: _____

Sample Minor Assent Document

Project Title:
Investigator:

We are doing a research study about ***purpose in simple language.*** A research study is a way to learn more about people. If you decide that you want to be part of this study, you will be asked to ***description, including time involved.***

There are some things about this study you should know. There are ***procedures, things that take a long time, other risks, discomforts, etc.***

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be ***description.***

If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you. ***This statement applies to research projects that offer treatment or intervention.***

When we are finished with this study we will write a report about what we learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.
(Print your name here)

(Sign your name here) (Date)

Parts in Italics should be modified for your specific project. Other parts may need to be modified as well depending on your research methods.

ATTACHMENT J
"RESEARCH CERTIFICATION SAMPLE"

2010-2011 IRB Schedule of Deadlines and Meetings	
Deadline for Submission	**IRB Committee Meeting Date**
August 31	September 9
September 30	October 14
October 29	November 11
November 30	December 9
January 28	February 10
February 28	March 10
March 31	April 14
April 29	May 5

Note: The above dates apply only to applications requiring FULL Review (special and protected populations). Applications may be turned in AT ANY TIME to the 6th floor of the Administrative Tower. Please call 979-4197 and/or e-mail vicki.l.prosser@jsums.edu or v.prosser@att.net for questions.