Revised July 2018

Southern University - Baton Rouge (SUBR)

Institutional Review Board for the Protection of Human Subjects

Application for Initial Review Form

Direction: The principal investigator(s) seeking to obtain SUBR IRB approval for a research project must submit three hardcopies of the documents listed below and a thumb drive with digital copies of requisite documents:

The three hardcopies are to include the SUBR IRB Application for Initial Review Form, a research proposal (maximum 10 pages) and necessary attachments (e.g., copies of protocols, questionnaires or researcher-created instruments), a research permission or consent form (also assent form if children are involved), and a human participant protections training certificate. The training certificate can be obtained by registering and completing the modules at the National Cancer Institute Human Participant Protections Education for Research Teams Web site - http://phrp.nihtraining.com/users/login.php and printing and saving as an HTML file the last Web page or certificate.

The diskette should include digital Word files for the SUBR IRB Initial Application Form, the research proposal and attachments, and research permission or consent form (also assent form if children are involved). The human participant protections training certificate is to be saved on the diskette as an HTML file.

The hardcopies and diskette are to be submitted to the Chairperson of the SUBR IRB: Reginald Rackley, Department of Psychology, Southern University - Baton Rouge, Baton Rouge, LA 70813-1241; Voice - 225-771-2990; Facsimile - 225-771-2082; E-mail – irb@subr.edu.

Title of Research Project

Title:

Principal Investigator(s)

Name(s): E-mail Adress(es) Mailing Address(es): Telephone Number(s): Fax Number(s) (Optional):
Other Researchers – Names, e-mail addresses, mailing addresses, and telephone numbers:

Principal Investigator's Status (e.g., SUBR Faculty, SUBR Staff, SUBR Student, or other - describe), Department/Unit, University or Agency

Status: Department/Unit: University or Agency:

Source of Funding and Contact Person

Is this research project funded by a grant or sponsor (Yes or No)? If "Yes," provide the information below for the federal or state agency (or sponsor) and contact person: Funding Agency or Sponsor: Title of Grant or Contract:

Grant or Contract Number:
Contact Person – name, address, telephone number, e-mail address:

Other IRB(s) that will Approve this Research Project

Will this research project be submitted for approval to another IRB (Yes or No)?

If "Yes," identify the IRB or IRB(s):

General Purpose of the Research Project

Describe the general purpose of the research project:

Subjects/Participants for the Research Project (Place X in appropriate area)

Place X	Subjects/Participants are:	Place X	Subjects/Participants are:
	1 - SUBR Faculty/Staff/Students		9 – Non-English Speaking
	2 – Minors (If the minors are incarcerated/detained, check 14 - Other below - and identify these individuals)		10 – Exclusion of Minorities
	3 – Adults (Non Elderly – also see 5, 6, 7, 8, 9, 10, 12, 13, 14-Other)		11 - Fetuses
	4 – Elderly		12 – Terminally Ill
	5 – Pregnant Teens or Pregnant Women		13 - Comatose
	6 – Cognitively impaired		14 – Other Describe Below
	7 – Institutional Residents		
	8 – Prisoners or Parolees		

Other Subjects/Participants – Describe:

Additional Accessible Population and Subject/Participant Information

Accessible Population for Research Project – Describe and give the number:

Subjects/Participants for Research Project - Describe if different from accessible population and give number of subjects/participants for study:

Describe how the subjects/participants will be recruited or selected to ensure an equitable and unbiased representation from the accessible population. For example, if selection is random, what specific procedure will be used (e.g., simple, stratified, systematic)? If selection is not random, what procedure is used and how does this procedure provide a representative, unbiased sample from the accessible population:

Identify the power analysis used to determine the number of subjects/participants needed for the study based on the size of the accessible population. If a power analysis was not used, describe how the sample size is appropriate for statistical purposes and generalizing of results:

Identify individuals who will be excluded from the study and provide the rationale for this exclusion:

Type of Research (Place X in the appropriate area)

Place X	The research involves:	Place X	The research involves:
	1- Interview (Oral or digital)		9 - Clinical HIV/AIDS
	2 – Survey/Questionnaire		10 - Clinical Studies
	3 – Behavioral Observation		11 - Investigational Drugs

	4 – Intervention/Experiment		12 - Investigational Devices
	5 – Deception		13 - Radiation
	6 – Existing Data (e.g., files, databases, etc.)		14 - Controlled Substances
	7 – Human Biological Specimen(s)		15 - Development of Commercial Product from Human Biological Material
	8 – Venipuncture		16 - Genetic Research
17 - Other (Explain) -			

Research Setting and Video/Audio Recording

Setting for Study: Video and/or audio recording to be used during the study and why:

Possible Risks or Discomforts to Subjects/Participants

Expected or possible risks/discomforts during the study:

General and Specific Subject/Participant Benefits

Expected general benefits from study and finding(s): Specific benefits subjects will receive by participating in the study:

Alternative Course(s) of Treatment to what is Proposed

Alternative treatment(s) or procedure(s) that could be used to conduct the study:

Available Medical Treatment for Adverse Experiences - Greater than Minimal Risk

Available medical treatment for subjects/participants:

System and Extent of Confidentiality and Anonymity

Describe in detail the procedure(s) to be used to ensure confidentiality and anonymity for subjects/participants:

Basic and Additional Elements of Consent You have in Your Research Permission Form or Consent Form (Place X in appropriate area)

Place X	Basic and Additional Consent Elements
	1 - Provided title of research.
	2 - Delineated name(s), address(es), telephone number(s), and e-mail address(es) of principal investigator(s)/researcher(s).
	3 - Stated purpose of the research study and described procedures to be used.
	4 - Described possible risks or discomforts.
	5 - Described possible benefits to subjects/participants or others.
	6 - Disclosed available alternative courses of treatment(s) or procedure(s).

	7 - Described available medical treatment for adverse experiences (greater than minimal risk).
	8 - Described the extent of confidentiality and anonymity for subjects/participants.
	9 - Whom to contact about the research—Include the following statements: For additional information about this research study contact –name(s), address(es), and telephone number(s) of principal investigator(s). If you have questions or concerns about your rights as a participant in this research study or to report a research-related injury contact Dr. Patrick Carriere, Ph.D., Chairperson, Institutional Research Oversight Committee, P. O. Box 11241, Southern University -Baton Rouge, Baton Rouge, LA 70813-1241; Voice - 225-771-5290 Ext 183; Facsimile – 225-771-5721; E-mail – patrick_carriere@.subr.edu
	10 - Stated the following: Participation is voluntary; refusal to participate involves no penalty or loss of benefits that the subject is otherwise entitled; Subjects may discontinue participation without penalty or loss of benefits that the subjects are otherwise entitled.
	11 - Stated the procedure may involve currently unforeseeable risks to the subjects or fetuses, if the subjects become pregnant.
	12 - Described anticipated circumstances under which subject participation may be terminated by the principal investigator(s) without regard to the subject's consent.
	13 - Disclosed additional cost to subjects as a result of participation in the study.
	14 - Described circumstances under which subjects can withdraw from the study and procedures for orderly termination.
	15 – Stated that significant new findings that may relate to subjects' willingness to continue participation in the study will be disclosed to the subjects.
	16 - Stated the possible number of subjects involved in the study.
	17- Stated subjects will receive a signed copy of the consent form.

If you indicated above that you are not including Basic or Additional Consent Elements in your Research Permission Form or Consent Form, identify the element(s) by number(s) and provide the rationale(s) for a request for waiving the element(s).

Element Number	Rational for Waiver Request

Research Project Involving the Obtaining and Use of Health Information and the Health Insurance Portability and Accountability Act (HIPAA) of 1996

Does your research project involve the obtaining and use of health information (Yes or No)?

If "Yes," you are to include in your research permission or consent form the following statement:

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health related information that could identify you.

If you sign this consent form, you are giving permission for the use and disclosure of your health information for the purposes of this research study. You do not have to give this permission. However, if you do not, you will not be able to participate in this study.

Instrument Validity and Reliability Data

Did you include in your proposal the validity and reliability data for all instruments to be used to generate data (Yes or No)?

If "No," provide the validity and reliability data for the instruments here:

Descriptive and Inferential Statistics

Did you describe in your proposal the descriptive and inferential statistics (and related assumptions) to be used to analyze the data collected in this research project (Yes or No)?

If "No," describe both the descriptive and inferential statistics to be used and the assumptions you will meet to use the inferential statistics:

Conflict of Interest Declaration: All items must be addressed, and YES responses must be described or explained

1. Will the proposed research result in a patent, trademark, copyright, or licensing agreement (Yes or No)?

1a. If "Yes," describe or explain the patent, trademark, copyright, or licensing agreement.

2. Have you, research project personnel, or your department or agency entered into or expect to enter into any financial agreement with the sponsor of the research (Yes or No)?

2a. If "Yes," describe or explain the financial agreement(s).

3. Is funding from the sponsor of this research project dependent upon the number of subjects/participants enrolled or the findings of the research (Yes or No)?

3a. If "Yes," describe or explain the funding arrangement(s).

4. Is there any other conflict(s) of interest that could result from the proposed research (Yes or No)?

4a. If "Yes," describe or explain the conflict(s) of interest.

Principal Investigator's Assurance

I, the principal investigator, assure that the information presented in this application is complete and correct, and I will abide by all SUBR and federal policies and procedures involving the use of human

subjects/participants in research and Louisiana legal statutes. As principal investigator, I also understand that I am responsible for conducting the study, ensuring the ethical recruitment-selection-treatment of subjects/participants, securing a new SUBR IRB review for changes in protocols or procedures, notifying the Chairperson of the SUBR IRB for the Protection of Human Subjects immediately if research-related injuries or illnesses occur, and submitting to the Chairperson of the SUBR IRB for the Protection of Human Subjects the required review or summary report when the study is completed or within one year (12 months) if the study is not completed.

_____ _____
Signature of Principal Investigator Date

If the Principal Investigator is a Student, Course Instructor or Major Professor/Advisor's assurance

By my signature below (course instructor for class research project or major professor/advisor for capstone/research projects, thesis, or dissertation), I assure that the information presented in this application is complete and correct, and the student is knowledgeable in policies and procedures involved in using human subjects/participants and has been advised to abide by SUBR and federal research guidelines and Louisiana legal statues. I also agree to meet with the student on a regular basis to monitor the research project and to support the submission of the required review or summary report to the Chairperson of the SUBR IRB for the Protection of Human Subjects.

If the student's research is a thesis or dissertation, my signature below also affirms that the student's thesis or dissertation prospectus has been approved by his or her thesis or dissertation committee.

_____
Type or Print Name - Course instructor or Major Professor/Advisor

_____ _____
Signature of Course Instructor or Major Professor/Advisor Date

Note: This research proposal will be reviewed following policies and procedures of the SUBR IRB for the Protection of Human Subjects. SUBR IRB approval does not signify that the approved proposal conforms to other IRB or research-site requirements or that the proposal documents conform to accepted professional/academic standards for the use of the written language.