Revised July 2009

Southern University - Baton Rouge (SUBR)
Institution Review Board (IRB) for the Protection of Human Subjects

Application for Continuation Review Form

Direction: Provide the information requested below. Submit three hardcopies (and files on diskette – rich text format) of this Application for Continuation Review Form, the Summary or Annual Report for Non-Exempt Research, research protocols (original and revised if changes are to be made), and Research Permission Form or Consent Form and assent form – if applicable (original and revised if changes are to be made) to the Chairperson of the SUBR IRB for the Protection of Human Subjects (Reginald Rackley, Department of Psychology, SUBR, Baton Rouge LA 70813-1241, Voice 225-771-2990, Facsimile 225-771-2082, E-mail irb@subr.edu).

SUBR IRB Number:

Title of Project:

Date of Initial Approval:

Date of Last Continuation Review Approval:

Principal Investigator(s)

Name:
Mailing Address:
E-mail Address:
Telephone Number:
Fax Number (optional):

Other Researchers – Name(s), Mailing Address(es), E-mail Address(es), and Telephone Number(s)

Will the continuation of this research project be supported by a grant or contract?
Yes ___. No ____.

If "Yes," provide the information below.

Grant, Contract, or Funding Agency:

Grant or Contract Title and Number:

Information for federal or state Grant or Contract Contact Person. This is not information for researcher.

Name:
Mailing Address:
E-mail Address:
Telephone Number:
Fax Number:

General Purpose of the Continuation Study

Subjects/Participants for Continuation Study [Place an X in the original approved area(s) and C in area(s) to request a change for this continuation year]

Area	Subjects/Participants are:	Area	Subjects/Participants are:
	1 - SUBR Faculty/Staff/Students		9 – Non-English Speaking
	2 – Minors (If the minors have 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 and/or Pregnant Women		13 – Comatose
	6 – Cognitively impaired		14 – Other Describe Below
	7 – Institutional Residents		
	8 – Prisoners or Parolees		
Other Subjects/Participants – Describe:			

Will new subjects/participants or new private information from databases or files be added this coming year? Yes ____. No _____.

If "Yes" above, provide the requested information.

Number of new subjects/participants to be added: Method for selecting new subjects/participants: New database or file information to be added: Method for obtaining new database or file information:

If new subjects/participants or new private information from databases or files will be added, will the original Research Permission or Consent Form (or Assent Form) be used this coming year?
Yes ____. No _____.

If "No" above, describe the changes that will be made to the research permission/ consent or assent form. <u>Note:</u> A copy of the revised Research Permission Form or Consent Form (or Assent Form) must to be submitted with this continuation application.

Revisions to Original Research Permission or Consent Form: Revisions to Original Assent Form:

Type of Research (Place an X in original approved area[s] and C in area[s] to request a change for this continuation year)

Area	The research involves:	Area	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) -			

Describe in detail below research activities completed this past year.

Describe in detail below research activities to be implemented or completed this coming year.

Will the approved/current protocol(s) be used this coming year (e.g., treatment, instrument[s], data collection, data analysis, anonymity and confidentiality procedures, etc.)? Yes ____. No ____.

If "No" above, describe changes to be made. Note: A copy of the revised protocol(s) must be submitted with this continuation application.

Changes in approved/current protocol(s):

Were there any research-related adverse event(s) this past year (e.g., illnesses, injuries, etc.)? Yes ____. No ____.

If "Yes" above, describe the adverse event(s), resolution(s), and communication(s) with the Chairperson of the SUBR IRB for the Protection of Human Subjects about the adverse event(s)

Adverse event(s): Resolution(s) of the adverse event(s): Communication with Chairperson of the SUBR IRB:

Were any complaints received from subjects/participants or others the past year? Yes ___. No ____.

If "Yes," describe below.

Complaints from subjects/participants: Complaints from others:

Summarize below any recent literature, research findings, or other relevant information, especially information about the purpose, risks, benefits, and procedures, associated with the research to be continued.

Recent literature, findings, or information concerning research focus: Recent literature, findings, or information concerning research risks, benefits, and procedures:

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

1. Will the continuation of the research result in a patent, trademark, copyright, or licensing agreement? **Yes** ___. **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 for continuation purposes? **Yes** ___. **No** ____. 2a. If "**Yes**," describe or explain the financial agreement(s).
3. Is continuation funding from the sponsor of this research project dependent upon the number of subjects/participants enrolled or the findings of the research? **Yes** ___. **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 continuation of the research? **Yes** ___. **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 for continuation approval 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 immediately if research-related injuries or illnesses occur, and submitting to the Chairperson of the SUBR IRB 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 for continuation approval 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.

_____
Name of Course Instructor or Major Professor/Advisor (Type or print)

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

Note: This request for continuation will be reviewed following policies and procedures of the SUBR IRB for the Protection of Human Subjects. SUBR IRB approval for continuation 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.