Revised July 2009

Southern University - Baton Rouge (SUBR)

Institution Review Board (IRB) for the Protection of Human Subjects

Template for Consent Form for Adults

Directions: Use the information below to develop the consent form for adults. This consent form could be in prose or outline format. The specific consent information that you provide should be reflective of needed basic and additional elements of consent and the purpose of your research and protocols to be used, and it should be presented in appropriate written language (readability). If you have any questions about the development of your consent form, contact the Chairperson of the SU-BR 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).

What is the title of Research Project?
Include title of Research Project

Who is/are the principal investigator(s) or researcher(s)?
First, include the principal Investigator(s)'s name(s), address(es), telephone number(s), and e-mail address(es). Then, include this information for other researcher(s), if applicable.

Where is the study being conducted?
Describe the setting(s) where the study will take place.

What is the purpose of this study?
Describe the general purpose of the study.

Who is eligible to participate in the study? Who is ineligible? How were the subjects/participants selected to ensure equality and eliminate biases?
Describe and give the number of subjects/participants that will be involved in the study. Provide inclusion criteria for the subjects/participants. Identify individuals who will be excluded from the study and provide the rationale for this exclusion. Describe how the subjects/participants will be recruited or selected to ensure an equitable and unbiased representation from the accessible population.

What will the subjects/participants do if they take part in the study?
Describe all protocols/procedures in lay language, using simple terms and short sentences. Provide a lay description of the randomization procedure for assigning to groups, if applicable, and describe the chances of being assigned to any one group.

What are the possible risks and discomforts for participating in the study?
If there are risks or discomforts to participation in the study, describe them in detail.

What are the possible benefits for participating in the study or that could occur from study results?
Describe any direct benefits the subjects/participants will receive for participation. Also, describe any benefits other individuals might receive, if applicable, because of the results of the study.

Are there alternative procedures that can be used to conduct the study? If subjects/participants do not want to take part in the study, are there other choices?
Describe alternatives to participation in the study (e.g., survey research could involve an interview instead of completing a questionnaire). State that subjects/participants have the choice at any time not to participate in the study and can withdraw (quit) without penalty.

If subjects/participants have any questions or problems, whom can you call?
State subjects/participants can contact the principal investigator(s)/researcher(s) if they have any questions or problems. If the principal investigator is a student, state that the subjects/participants can contact the student's major professor or advisor (provide contact information). State or add to the consent form the following information:

If you have questions or concerns about your rights as a research volunteer in this study or you want to report a research-related injury, contact Dr. Patrick Carriere, Ph.D., Chairperson, Institutional Research Oversight Committee, P. O. Box 9272, Southern University -Baton Rouge, Baton Rouge, LA 70813-1241; Voice 225-771-5290; Facsimile 225-771-5721; E-mail – patrick_carriere@subr.edu

What subject/participant information will be kept private?
State that every effort will be made to maintain subjects'/participants' anonymity and the confidentiality of their study records. If study findings are to be used for a presentation, report, publication, etc. (contribute to the generalizable knowledge base), also indicate this could happen and state that the private information of the subject/participant, such as your name and other identifying information, will not be included in any presentation, report, or publication.

Can subject/participant participation in the study end early?
State that subjects/participants may withdraw from the study at any time without penalty. Also state that the principal investigator(s)/researcher(s) may terminate the participation of subjects/participants at any time. Describe possible reasons that could result in subjects/participants termination from the study. Also state that the subjects'/participants' failure to complete study procedures or to answer all questions (e.g., on a survey or during an interview) could result in the data not being used in the study.

What charges will the subjects/participants have to pay?
If there are no charges, state "None". If the participant will incur any extra charges beyond those routinely incurred by participants, indicate that those costs must be met by the participant.

What payment will the subjects/participants receive?
If there is no payment, state "None". If the volunteer will be compensated for participating, state: If you agree to take part, we will pay you _____(indicate amount).

If the research involves greater than minimal risk, is medical treatment available for adverse experiences?
Describe available medical treatment for subjects/participants, if applicable.

Does the research involve the collection and use of medical information?
If medical information is collected and used in this study, state the following:

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. (Include this statement if research project involves the obtaining and use of health information)

What signatures should appear on the consent form?
Signatures of volunteer and person administering informed consent must appear on the same page – see below). Also include the statement below:

The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study researcher(s)/investigator(s). I agree with the terms above and acknowledge that I have been given a copy of the consent form. I understand that I have not waived any of my legal rights by signing this form.

(Include the following statement if the study involves the collection and use of medical information) With my signature, I grant authorization (permission) for the use and disclosure of my health information for the purposes of this research study.

_____ _____
Signature of Volunteer (or mark, if unable to sign) Date

_____ _____
Signature of Person Administering Informed Consent Date

_____ _____
Signature of Principal Investigator/Researcher Date

Will the potential volunteer be able to read the consent form?
(If the potential volunteer is unable to read, the Reader must be 18 years of age or older)
If the study potential volunteers are unable to read the consent form and it is read to them, include the text and signature line below. Because this situation is not known until the recruitment and consent processes, principal investigator(s)/ researcher(s) may want to have two consent forms (one with the statement and signature line below and one without).

The study volunteer has indicated to me that the volunteer is unable to read. I certify that I have read this consent form to the volunteer and explained that by completing the signature line above the volunteer has agreed to participate.

_____ _____
Signature of Reader Date