Document Template #1
Adult/General Informed Consent (Rev. 9/20/2011)

Consent Form for Participation in the Research Study Entitled XYZ (or can be written "in the XYZ study")

Funding Source: List complete identification for funding source or None.

IRB protocol #:

Principal investigator(s)	Co-investigator(s)
Name, degree	Name, degree
Complete mailing address	Complete mailing address
Contact phone number	Contact phone number

For questions/concerns about your research rights, contact:
Human Research Oversight Board (Institutional Review Board or IRB)
Nova Southeastern University
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information (if applicable)
Address

What is the study about?
This section should include a statement that the study involves research. The purpose of the study should also be included.

Why are you asking me?
The reason for asking the subject to participate. This section should also include the approximate number of subjects involved in the study.

What will I be doing if I agree to be in the study?
The procedures to be used and identification of any procedures that are experimental, and the expected duration of the subject's participation, including anticipated follow-up, should be discussed. These procedures should be explained in as much detail as necessary for the subject to understand. Any procedure that is likely to cause stress, pain, or any other unpleasant reaction should be described so that the person understands fully what he/she is consenting to.

Provide a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. If there are any anticipated

circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent, for example, if it appears that the subject may be in danger or no longer meets the inclusion criteria of the study, this should also be included in this section.

Is there any audio or video recording?
This section should include information related to audio or video recording if it is applicable to the project proposed. If there is audio and/or video recording, please include the following paragraph:

"This research project will include audio (and/or video if applicable) recording of (SPECIFY WHAT IS BEING RECORDED AND HOW). This audio (and/or video) recording will be available to be heard by the researcher, the IRB), any granting agencies (IF APPROPRIATE also SPECIFY which agencies), and the following (SPECIFY: such as dissertation chair or committee, other researchers, classes, or no one else or as appropriate). The recording will be transcribed by (BE SPECIFIC, including "The recording will not be transcribed." if no transcription will take place). The recording will be kept securely (SPECIFY WHERE AND HOW). The recording will be kept for XX months (SPECIFY) and destroyed after that time (SPECIFY HOW). Because your voice (or your image and your voice) will be potentially identifiable by anyone who hears (or hears and sees) the recording, your confidentiality for things you say (or do) on the recording cannot be guaranteed although the researcher will try to limit access to the tape as described in this paragraph."

What are the dangers to me?
All foreseeable risks or discomforts should be specified. All studies are considered to have some risk. Therefore risk should always be described as at least minimal. Never suggest that there is no risk. As some research may have unknown risks, it may be appropriate to also include "The procedures or activities in this study may have unknown or unforeseeable risks".

For research involving more than minimal risk, include explanations as to whether compensation or medical (or other) treatments are available if injury occurs. If such treatment will be provided, indicate what it consists of, or where further information may be obtained.

The section must include information about who to contact with questions or concerns about the study, as well as who to contact about research-related injuries. For example, include a sentence such as "If you have any questions about the research, your research rights, or have a research-related injury, please contact [name of principal investigator and advisors/collaborators]. You may also contact the IRB at the numbers indicated above with questions as to your research rights."

Are there any benefits for taking part in this research study?
Subjects should be informed about direct or indirect foreseeable benefits to them or others or the absence of benefits. Please do not include the benefits of research knowledge to the scientific literature. Elements related to payment (remuneration) are not considered "benefits" to a subject and should be discussed within the Costs/Payments section. If there are no direct benefits, indicate, "There are no direct benefits."

Will I get paid for being in the study? Will it cost me anything?
Costs and payments to the participant should be addressed explicitly, including a statement that payments will not be given if that is the case. Describe how payments are made if the subject elects to discontinue participation during the study. If payment will be by generated check and the subject's information may need to be provided to an accounts payable or other similar office, that information should be provided.

If there are no costs or payments involved you may state, "There are no costs to you or payments made for participating in this study."

How will you keep my information private?
Confidentiality must be specified as well as a description of procedures for protecting privacy, including specific information regarding how data will be stored to ensure security and confidentiality and how long the data will be retained (NOTE: a minimum of 36 months from the conclusion of the study is required). The confidentiality statement must include in the statement a clause that reads "all information obtained in this study is strictly confidential unless disclosure is required by law." This section must also specify that the IRB, regulatory agencies, and if the PI is a student that the dissertation chair/thesis adviser may review research records.

For research involving FDA regulated drug (including biological products) and device clinical trials, the following specific statement that clinical trial information will be entered into a databank must be included. The statement is as follows: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Use of Student/Academic Information:
If information will be collected from educational records, this section must discuss what information will be extracted and how it will be used.

If no student/academic information will be used in the study, this section may be eliminated.

What if I do not want to participate or I want to leave the study?
This section must include a statement that the subject is free to refuse to participate in,

or withdraw from, the study at any time without adverse affects or loss of benefits to which the subject is otherwise entitled. If as a part of withdrawing from the study the participant may request that his/her data not be used if that is legally permitted, that too should be included. Information related to data retention must also be included (e.g., "in perpetuity," "length of the study plus three years," etc.). The following examples are provided:

"You have the right to leave this study at any time or refuse to participate. If you do decide to leave or you decide not to participate, you will not experience any penalty or loss of services you have a right to receive. If you choose to withdraw, any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the conclusion of the study and may be used as a part of the research."

If the participant may request that his/her data not be used, then it should read:

"You have the right to leave this study at any time or refuse to participate. If you do decide to leave or you decide not to participate, you will not experience any penalty or loss of services you have a right to receive. If you choose to withdraw, any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the conclusion of the study but you may request that it not be used."

Other Considerations:
This general statement should be included (in the appropriate person):

"If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigators."

NOTE TO INVESTIGATORS: FINAL VERSIONS OF CONSENT OR ASSENT FORMS SHOULD BE STRUCTURED IN SUCH A MANNER AS TO MINIMIZE "WHITE" SPACE.

Voluntary Consent by Participant:
By signing below, you indicate that

- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it
- you voluntarily agree to participate in the study entitled “XYZ” [FILL IN TITLE OF STUDY]

Participant's Signature: _____ Date: _____

Participant’s Name: _____ Date: _____

Authorized Representative: _____ Date: _____

Authority of Representative is based on: _____

Signature of Person Obtaining Consent: _____

Date: _____

***Please note that if the study does not include individuals who are being represented by an authorized individual then the lines in red may be eliminated—leaving only the Participant’s Signature line and Date and the Witness’s Signature line and Date.