Document Template #2
Adult/General Informed Consent (Rev. 08/13/2009)

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 approval # (Generated by IRB)

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

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

Institutional Review Board
Nova Southeastern University
Office of Grants and Contracts
(954) 262-5369/Toll Free: 866-499-0790
IRB@nsu.nova.edu

Site Information (if applicable)
Address

Description of the Study:

This section should include a statement that the study involves research, the purpose of the study, the reason for selecting the subject, the procedures to be used and identification of any procedures which are experimental, and the expected duration of the subject's participation, including anticipated follow-up. These procedures should be explained in as much detail as necessary for the subject to understand. Any procedure which is likely to cause stress, pain, or any other unpleasant reaction should be described so that the person understands fully what they are consenting to.

Audio Recording

This section should include information related to audio recording if it is applicable to the project proposed. If there is audio taping, please include the following paragraph:

"This research project will include audio recording of (SPECIFY WHAT IS BEING RECORDED). This audio tape will be available to be heard by the researcher, the university's human research oversight board (the Institutional Review Board or 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 tape will be transcribed by (BE SPECFIIC, including "no one" if no transcription will take place). The tape will be kept securely (SPECIFY WHERE AND HOW). The tape will be kept for XX months (SPECIFY) and destroyed after that time (SPECIFY HOW). Because your voice will be potentially identifiable by anyone who hears the tape, your confidentiality for things you say on the tape cannot be guaranteed although the researcher will try to limit access to the tape as described above."

Video Recording

This section should include information related to video recording if it is applicable to the project proposed. If there is also video recording, please include the following paragraph:

"This research project will include video recording of (SPECIFY WHAT IS BEING RECORDED). This video tape will be available to be seen and heard by the researcher, the university's human research oversight board (the Institutional Review Board or 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 video tape will be transcribed by (BE SPECFIIC, including "no one" if no transcription will take place). The video tape will be kept securely (SPECIFY WHERE AND HOW). The tape will be kept for XX months (SPECIFY) and destroyed after that time (SPECIFY HOW). Because your image and/or voice will be potentially identifiable by anyone who sees or hears the tape, your confidentiality for things you say on the tape cannot be guaranteed although the researcher will try to limit access to the tape as described above."

Risks /Benefits to the Participant:

Subjects should be informed about direct or indirect potential benefits to them or others or the absence of benefits. Elements related to payment (remuneration) are not considered “benefits” to a subject and should be discussed within the Costs/Payments section. Risks should also 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. For research involving more than minimal risk, explanations as to whether compensation or medical (or other) treatments are available if injury occurs. The section must include the following: "If you have any concerns about the risks or benefits of participating in this study, you can contact [name of principal investigator and advisors/collaborators] or the university’s human research oversight board (the Institutional Review Board or IRB) at the numbers indicated above." If there are no direct benefits, indicate, “There are no direct benefits.”

Costs and Payments to the Participant:

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

Confidentiality and Privacy:

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 specify that the university’s human research oversight board (the Institutional Review Board or IRB) and regulatory agencies may review research records.

Use of Protected Health Information (PHI):

Whenever PHI is used, the researcher must obtain a valid authorization from the subject via this section of the consent form. If the study involves collecting PHI, the following format should be used:

"As part of this study, you are asked to authorize (specify the specific person(s) by name who will be requesting this information, usually the researcher(s)) access to your (specify the exact record(s), such as family practice file of Dr. Johnson, or mental health records at the NSU Community Mental Health Center). The purpose of this authorization is to allow the researcher to obtain the following specific information to be used as part of this research study. This information includes: (list here all information you will get, such as EKG results, therapy noted, IQ scores, etc.). You may change your mind and revoke (take back) this authorization at any time, except to the extent that the researchers have already acted based on this authorization. To revoke this authorization you must write to: (list the primary and co-investigators and their contact information). Your treatment at NSU (or other applicable organization) will not be affected in any way by your refusal to give this authorization or to later decide to revoke authorization. You will not be able to participate in the study procedures if you decide that you will not give authorization. If you allow this transfer of information from your medical file, this information will no longer be protected by federal or state law and, thus, it is possible that this information could be re-disclosed. However, we will protect the confidentiality of this information as discussed in the Confidentiality section. You have the right to refuse to sign this authorization and informed consent. This will not affect your treatment in any manner (add, where relevant: but you will be unable to participate in the treatments and procedures associated with this research study.)

If PHI is used, add either of the following paragraphs:

Restriction of Access to Records

"You have the right to inspect or copy your Protected Health Information to be used or disclosed as permitted under federal and state law (whichever gives you greater access rights). You also can refuse to sign this agreement. Participating in this study does not affect your rights to inspect or copy your Protected Health Information."

OR

“Because of the nature of this study, it is necessary to temporarily restrict your access to your medical records in order to insure the validity of the study. You will be restricted from seeing or reviewing the following records during the course of the study: (specify exact records or information). You will be given complete access as defined under federal and state law on (specify exactly when). “

If PHI is not used, the researcher may either add the following paragraph or may eliminate the PHI section:

“This study does not require the disclosure of any Protected Health Information.”

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.

Participant's Right to Withdraw from the Study:

This section must include a statement that the subject understands s/he is free to refuse to participate in or withdraw from the study at any time without adverse affects or loss of benefits. If as a part of withdrawing from the study the participant may request that his/her data may be destroyed when legal, 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 example is provided:

“You have the right to refuse to participate or to withdraw at any time, without penalty. If you do refuse to participate or withdraw, it will not affect your treatment at the medical center in any way. If you choose to withdraw, you may request that any of your data which has been collected be destroyed unless prohibited by state or federal law. Your data will be retained for 36 months from the end of the study.”

The above may be replaced with the following if the data will not (or cannot be) destroyed or that option is not available to subjects. That information must be stated along with the period of time the data will be kept (e.g., “in perpetuity,” “length of the study plus three years,” etc.). The following example is provided:

“You have the right to refuse to participate or to withdraw at any time, without penalty. If you do refuse to participate or withdraw, it will not affect your treatment at the medical center in any way. If you choose to withdraw, your data will not be destroyed and will be kept for the length of this study plus three years.”

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."

Voluntary Consent by Participant:

This paragraph must be included exactly as written in bold face type:

I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate in the research study entitled "(fill in title of study)". All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study they will be answered by (fill in name). (If applicable: I also voluntarily agree to the release of my PHI as described in this document.) A copy of this form has been given to me. This consent ends at the conclusion of this study.

Participant's Signature: _____ Date: _____
Authorized Representative: _____ Date: _____
Authority of Representative is based on: _____
Witness's Signature: _____ 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.