Document Template #1
Parent/Guardian Consent Form (Version: 9/20/2011)

Parent/Guardian 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):
Name, degree
Complete mailing address
Contact phone number

Co-investigator(s):
Name, degree
Complete mailing address
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 research about?
This section should include a statement that the study involves research. It should then state either that the parent is being asked for permission for his/her child to participate or for his/herself and his/her child. For example, "You are being asked to let your child participate in a research study" or if the parent will also be participating then it should read "If you agree, both you and your child will participate in the research study." This section should then give the purpose of the study and the reason for selecting the subject(s). If the study involves both the parents and the children, all sections of the consent form should reflect the two groups (see parenthetical items below). This section should also include the approximate number of subjects involved in the study.

What will (I and/or) my child be doing?
Describe the procedures to be used and identify of any procedures that are experimental, and the expected duration of the subjects participation, including anticipated follow-up. 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 parent 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 dangers are there for (me and/or) my child?
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. Research with children that presents greater than minimal risk also has an impact on consent requirements. Please contact the IRB office for more information or your center representative.

The section must include information as to 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 or your research rights, or (you or) your child has a research-relate 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.”

What good things might come about for (me and/or) my child?
Parents should be informed about direct or indirect foreseeable benefits to them or others or the absence of benefits. If there are no direct benefits indicate, “There are no direct benefits.” Elements related to payment (remuneration) are not considered “benefits” to a subject and should be discussed with the payment section.

Do I have to pay for anything?
Costs should be addressed explicitly. If there are no costs, then you may state “There are no costs for (you or) your child’s participation in this study.”

Will I or my child get paid?
Payments to the participant should be addressed explicitly, including a statement that payments will not be given if that is the case. If there are no payments involved you may state, “There are no payments made for participating in this 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.

How will my (and/or my child’s) information be kept private and confidential?
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 data will be retained (NOTE: a minimum of 36 months from the conclusion of the study is required). The confidentiality statement must include 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 or your child. 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 to 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 my child to be in the study or my child doesn't want to be in the study? (What if I do not want to be in 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 the parent is consenting also for his/her child to participate, then he/she must also be able to refuse to allow the child to participate or withdraw the child at any time without penalty. If as a part of withdrawing from the study the participant may request that his/her data (or the child's 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 refuse for your child to participate or withdraw your child at any time. Your child may also refuse to participate or withdraw. If you do withdraw your child, or your child decides not to participate, neither you nor your child will experience any penalty or loss of services that you have a right to receive. If you choose to withdraw your child, or he/she decides to leave, any information collected about your child **before** the date of withdrawal 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 refuse for your child to participate or withdraw your child at any time. Your child may also refuse to participate or withdraw. If you do withdraw your child, or your child decides not to participate, neither you nor your child will experience any penalty or loss of services that either of you has a right to receive. If you choose to withdraw your child, or he/she decides to leave, any information collected about your child **before** the date of withdrawal 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."

If the parent is also participating in the research, then the following examples are provided.

"You have the right to refuse for you and your child to participate or withdraw yourself and your child at any time. If you do withdraw your child, neither you nor your child will experience any penalty or loss of services that either of you has a right to receive. If you choose to withdraw yourself or your child, any information collected about either of you **before** the date of withdrawal 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 refuse for you and your child to participate or withdraw yourself and your child at any time. If you do withdraw your child, neither you nor your child will experience any penalty or loss of services that either of you has a right to receive. If you choose to withdraw yourself or your child, any information collected about either of you **before** the date of withdrawal 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 have your child continue to participate, this information will be provided to you by the investigators."

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 for (you and/or) your child to participate in the study entitled "XYZ" [FILL IN TITLE OF STUDY]

Child's Name: _____

Parent's/Guardian Signature: _____ Date:_____

Parent's/Guardian Name: _____ Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

NOTE: If the study involves greater than minimal risk, the signature of both parents may be necessary in keeping with applicable regulations.