GUIDELINES FOR PARENT/LEGAL GUARDIAN CONSENT FORMS

1. The written parent/legal guardian consent form must be in a language easily understood by the parent/legal guardian of the subject. It is the documentation of an ongoing process that occurs at every contact between researcher and subject, not solely prior to the commitment to participate. Use of technical terms should be avoided, or if they must be used they should be defined or explained thoroughly in simple lay language. Consent forms should be written at an eighth-grade reading level.

2. The form should contain the basic elements of informed consent. The following guidelines and the parent/legal guardian consent form template are provided to assist in the writing of a clear, easily understandable consenting document.

FORMATTING
- All margins should be a minimum of one inch.
- Font size should be 12-point or larger.
- Version date of the consent form and page numbering should be inserted in the footer of each page.
- A line for parent/legal guardian’s initials may be placed at the bottom of each page (optional).
- The heading of the form should be followed by the title of the project (this can be a shortened form of the official title if it accurately reflects the study purpose).
- The sections of the consent form should be titled separately as shown in the template.
- The following paragraph should be bolded and in lower case after the project title as shown in template).

You are being asked to read the following material to ensure that you are informed of the nature of this research study and of how your child will participate in it, if you consent for him/her to do so. Signing this form will indicate that you have been so informed and that you give your consent. Federal regulations require written informed consent prior to participation in this research study so that you can know the nature and risks of your child’s participation and can allow him/her to participate or not participate in a free and informed manner.

The information below relates to each of the required consent form sections with specific suggested language included in the consent form template.

PURPOSE
Explain the goals and objectives of the project, including the rationale for performing the study. This section should address issues related to the overall research, not to individual participants.

SELECTION CRITERIA
- Provide a brief description of study population including age range, gender (if restricted), and membership in a group (i.e., enrolled in a class, employed at or living in a specific location, normal healthy individuals, or those diagnosed with a particular disease).
- State approximate number of subjects to be enrolled (this will include local enrollment AND if applicable, national/international study populations).
ALTERNATIVE TREATMENT(S)
Include a brief description of other treatment(s) available as an option if the potential subject does not wish to participate in the study.
Note: If the project does not include a treatment or intervention, delete this section.

PROCEDURE(S)
• Describe each procedure in simple lay terms.
• Listing procedures in the consent form is adequate only if an oral description is provided to comply with the requirement for "fully informed consent".
• State time requirements (total length of participation as well as time involved for individual procedures).
• List measurements in lay terms (i.e., inches, pounds, etc.)
• If the study is blind or double-blind, describe the groups clearly.
• If subjects will be assigned (randomized) to a group by chance (this may be defined as "like the flip of a coin"), the groups and randomization procedure must be described clearly.

RISKS
• List the most common serious risks.
• Potential of psychological and/or social risks involved in study participation must also be stated clearly.
• If the study is placebo-controlled, subjects must be informed that there is a possibility they will receive no treatment, and the consequences, if any.

BENEFITS:
A benefit is a valued or desired outcome. Benefits associated with participation in research can be classified as those that accrue to the subject directly, such as improvement in health status, acquisition of useful information from the treatment, as well as those that may be important societally and provide generalizable information.

• If there are no benefits, simply state, “There is no direct benefit to you (your child) from his/her participation.”

Note: Financial or other forms of compensation are not a benefit to be derived from the research. Compensation should be listed under the “Participation Costs and Subject Compensation” heading.

CONFIDENTIALITY
Explain how confidentiality will be maintained (include information concerning database security, retention of data, time and method of destruction of paper records and/or links to subjects’ names). List people by category and/or by name who will have access to the data.

PARTICIPATION COSTS AND SUBJECT COMPENSATION
It is considered unethical (in most cases) to have a research subject pay for experimental drugs, research-related procedures or the laboratory costs involved.
• State clearly the costs to the subject and/or to third party payors (including hospital stay). If
there are no costs, so state.
• If subjects will be paid, state the amount (add proration for partial completion of the study).
  This will usually be commensurate with time lost and expenses, and must not be in amounts excessive enough to represent potential financial coercion.
• Specify any compensation provided to the subjects (e.g., gift certificates, training sessions, etc.).
• If they will not be paid or compensated, so state.

CONTACTS
Contact information must provide subjects with easy access to the Principal Investigator, directly or through appropriate study personnel. Avoid telephone numbers linked to menus that do not include the Principal Investigator’s name or a specific option for “individuals participating in research studies.”

LIABILITY
This section must be included for projects involving minimal or greater than minimal risk. It is in addition to the Contacts section.

Note: Names of individuals in the Contacts and Liability sections should be followed by their degrees (M.D., Ph.D., Pharm.D., Ph.D. Candidate, etc.).

AUTHORIZATION
This section is to be used verbatim in ALL consent forms with two exceptions:
! delete words "or by the sponsor" if unfunded and no sponsor is involved.
! delete words "or affecting your child’s mental health care" if no mental health treatment is involved and subjects are not being recruited from a mental health setting.
Note: The paragraph should be bolded and in lower case.

SIGNATURE LINES
• All individuals signing the consent form must date their own signatures.
• The Witness Signature line may be deleted if not applicable to the project.

INVESTIGATOR'S AFFIDAVIT
• Only individuals who are indicated on the Verification of Human Subjects Training form as being eligible to consent subjects may sign as presenter.

• The Principal Investigator or Co-Principal Investigator must sign as investigator unless prior Committee approval has been obtained to allow other designated study personnel to sign as investigator (investigator’s signature to be obtained within 7 days of subject’s signature).

GUIDELINES FOR MINOR’S ASSENT FORM
For enrollment of minor subjects, an assent form must be signed by those subjects capable of reading and understanding a simplified version of the Parent/Legal Guardian Consent Form.
• For ages 6 - 14, a simple paragraph will normally be adequate (see example at end of Parent/Legal Guardian Consent Form template).

• For 15-17 year olds, depending on the complexity of the project, EITHER
  1. a Subject’s Consent Form signed by both the minor and the parent/legal guardian
  OR
  2. an Adolescent’s Assent Form would be used to document assent. The Adolescent’s Assent Form should follow the same format as the Subject’s Consent Form (section headers, etc.) but at a language level consistent with the study population.

For those subjects who are too young to read an assent form, but who would be capable of understanding an oral explanation of the procedures, a copy of the oral explanation should be submitted for approval. A signature line and date line to be signed by the individual responsible for the oral explanation should be included.

**Note:** The age, maturity, and psychological state of the subjects must be taken into account by the principal investigator when designing an assent form or an oral explanation form.