Consent for Incompetent Persons and Children

There are different versions of signature lines and information to use depending on the type of subjects being enrolled. The different versions are shown below and are labeled. Please include only one version and delete the others.

Version 1: Only Impaired Adults and/or Children who cannot read or understand.

Version 2: Competent Adults and Impaired Adults/Children who can read/understand

Children and Consent of Both Parents: For studies involving children that are greater than minimal risk and no direct benefit to the child, regulations require the signature of both parents. Note the following:

- Include a signature line for Parent 1 and Parent 2.
- This requirement applies unless the second parent is deceased, unknown, incompetent, or not reasonably available or unless only one parent has legal responsibility.

Consent for Incompetent Persons

Under Florida law, several classes of persons can consent for incapacitated/incompetent adults. They are listed below in order of who has the greatest legal authority to consent for an incompetent adult. Consent must be sought first from the person at the top of the list. Only if that option is not reasonably available, does the next option apply, and so on down the list. If the first reasonably available person refuses consent, however, that refusal is final. Indicate in both the Introductory Questionnaire and the ICF whom consent will be sought from, again, starting at the top of the list. If the list is partial, it must still reflect the order required by State law. For example, a health care surrogate and attorney in fact may be listed but a proxy cannot be listed unless all the options before a proxy are also listed.

a) Health care surrogate: Any competent adult expressly designated to make health care decisions for a particular incapacitated individual. The designation should be in writing.
b) **Attorney in fact ("power of attorney"):** A competent adult to whom the subject has delegated authority to make health care decisions by means of a validly executed durable power of attorney.

c) **Judicially appointed guardian:** All persons who have been adjudged incompetent should have a judicially appointed guardian.

d) **Proxy:** If none of the above are reasonably available, then a competent adult who has not been expressly designated to make health care decisions for a particular incapacitated individual but who is available, willing, and able to act is the next option for consent. The following possible proxies should be sought, again in order of priority, working down the list when an option is not available:

i. The subject's spouse;

ii. An adult child of the subject. If the subject has more than one adult child then obtain consent from a majority of the adult children who are reasonably available;

iii. A parent of the subject;

iv. The adult sibling of the subject. If the subject has more than one adult sibling then obtain consent from a majority of the adult siblings who are reasonably available;

v. An adult relative of the subject who has exhibited special care and concern for the subject and who has maintained regular contact with the subject and who is familiar with the subject's activities, health, and religious or moral beliefs;

vi. A close friend of the subject
1. Version 1: Only Impaired Adults/Children Who Cannot Read/Understand:

As a representative of this study, I have explained to the participant’s legally authorized representative the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant’s protected health information will be collected, used, and shared with others:

________________________________________________________________________

Signature of Person Obtaining Consent and Authorization        Date

You have been informed about this study’s purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how the participant’s protected health information will be collected, used, and shared with others. You will receive a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

By signing this form, you voluntarily give your permission for the person named below to take part in this study. You are hereby authorizing the collection, use, and sharing of the protected health information as described in sections 20-29 for the person named below. You are not waiving any legal rights for yourself or for the person you are legally representing.

Print: Name of Participant

Print: Name of Participant’s Legal Representative and Relationship to Participant

[List options that will be used for the study in order shown; see instructions for explanation: health care surrogate, attorney in fact (“power of attorney”), judicially appointed guardian, proxy, participant’s spouse, adult child of participant, parent of participant; adult sibling, adult relative, close friend of the participant]

If you are not the subject, please indicate one of the following:

_____ The participant’s parent
_____ The participant’s guardian
_____ A surrogate
_____ A durable power of attorney
_____ A proxy
_____ Other, please explain:

__________________________________________________
Consent and Authorization Signature of Parent (1)/ Legal Representative

[If the consent of both parents is required, include this additional signature line.]

Consent and Authorization Signature of Parent (2)/ Legal Representative

Date

Date
2. Version 2: Competent Adults and Impaired Adults/Children Who Can Read/Understand:

As a representative of this study, I have explained to the participant or the participant's legally authorized representative the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant's protected health information will be collected, used, and shared with others.

Signature of Person Obtaining Consent and Authorization ____________________________ Date __________

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used, and shared with others. You will receive a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use, and sharing of your protected health information as described in sections 20 – 29 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing ____________________________ Date __________
3. Assent of the Child (to include, if applicable):

CHILD’S ASSENT FOR AGES ___-17 TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Title of Protocol:

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You are being asked to be in a research study. Before you decide to be in it, we want to tell you about it so you can ask questions you have about it.

The doctor in charge of this study is Dr. <fill in PI's name>. The main purpose of this study is to: <fill in with purpose of the study in simple language>

You don’t have to be in the study if you don’t want to, but if you do, this study may help other kids with conditions like yours. You can stop at any time. Stopping or not being in the study will not upset anyone. The doctor and assistant will take care of you as they have in the past. If you have any questions or don’t like what is happening, please tell the doctor or assistant.

Your parent/guardian knows about this study. You have had this study explained to you, and you agree to participate.

__________________________________________________________________________
Patient’s Name Typed/Printed  Patient’s Signature  Date

__________________________________________________________________________
Signature of Person Consenting and Authorizing  Date