*This template is for an addendum to the consent form. This form should be used when the Sponsor or Investigator need to provide specific limited new information about the project to subjects rather than having subjects sign an entire revised consent form.*

*Please note, the reviewing IRB and/or the Sponsor have the authority to request a full consent form rather than an addendum.*

**Instructions**

To stand out both on your computer screen and in black/white copies, instructions are in bold, italic, and blue type. Instructions are in gray boxes and should be deleted in final consent.

IRB-required template language is in black type and should not be changed.

Rarely, changes to the required language may be necessary. To petition for a change in required language, submit proposed changes with justification on the “ICF Template Change Form” to the IRB office.

Sample language, which can be used, modified, or deleted as appropriate for your project, is in blue type. Please maintain the blue color to distinguish your project-specific information from the required template language.

* Arrows are used to show alternative choices. In the final consent, arrows can be deleted and the usual margin maintained.

**<Medical College of Wisconsin><Children’s Wisconsin>**

**ADDENDUM TO THE CONSENT FORM**

<Title>

<Principal Investigator>

<Department>

<Telephone Number>

Medical College of Wisconsin

8701 Watertown Plank Road

Milwaukee WI 53226

(*insert if research activities are occurring at CW*)

Children’s Wisconsin

8915 W Connell Ct

Milwaukee, WI 53226

***Insert brief overview of project.***

***Insert new/revised information.***

**CONSENT TO CONTINUE PARTICIPATING**

**By signing my name below, I confirm the following:**

* I have read (or had read to me) this entire addendum, including Attachment 1.   
  All of my questions have been answered to my satisfaction.
* The project’s purpose, procedures, risks and possible benefits have been explained to me in the main consent form for this project.
* I agree to continue letting the research team use and share the health information and other information gathered for this project.
* I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

**IMPORTANT:** You will receive a signed and dated copy of this addendum. Please keep it where you can find it easily. It will help you remember what we discussed today.

***Signature line instructions:***

*Generally, the subject's signature is sufficient. Thus, the following signature lines are* ***optional*** *to include: Legally Authorized Representative, Witness, Principal Investigator or designated representative. These should only be included when the Investigator chooses to include them, or when required by the Sponsor.*

***Date or Date & Time: Time is optional to include; if included, must be completed by each signer.***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Subject's Name** *please print* | **Subject's Signature** | **Date** OR **Date**/**Time** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Legally Authorized Representative, if applicable**  *please print* | **Signature of Legally Authorized Representative** | **Date** |
|  |  | |
| ***Name of Subject*** *please print* | ***Relationship to Subject*** *(e.g. Court-appointed guardian, healthcare power of attorney, next of kin, etc.)* | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Witness, if applicable** *please print* | **Signature of Witness** | **Date** |
| **Rationale for Use of Witness**  Subject has limited/no literacy  Subject has limited English proficiency  Subject has limited/no vision | Sponsor requirement  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **\* Name of person discussing/ obtaining consent** *please print* | **Signature of person discussing/obtaining consent** | **Date** |

*\* A member of* *the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol.* *The Principal Investigator is responsible and accountable for the research project.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Principal Investigator** *please print*  \_\_ I participated in consent process  \_\_ I acknowledge enrollment of this subject into the project | **Signature of Principal Investigator** | **Date** |

|  |  |  |
| --- | --- | --- |
| **Consent of Adult Subject (18 years or older)** | | |
|  |  |  |
| **Subject's Name** *please print* | **Subject's Signature** | **Date or Date/Time** |

|  |  |  |
| --- | --- | --- |
| **Assent of Minor Subject (17 years old or younger)** | | |
|  |  |  |
| **Name of Minor Subject** *please print* | **Signature of Minor Subject** | **Date or Date/Time** |
| **If child’s assent is not obtained above, please indicate reason below (check one):**  Assent is documented on a separate IRB-approved assent form  Child is under the IRB-approved age range for assent  The IRB granted a waiver of assent, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Consent of Parent(s)/Guardian(s) of Minor Subject** | | |
|  |  |  |
| **Name of Parent/Guardian** *please print* | **Signature of Parent/Guardian** | **Date or Date/Time** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Name of Second Parent/Guardian** *please print* | **Signature of Second Parent/Guardian** | **Date or Date/Time** |
| **If the signature of the second parent/guardian cannot be obtained, please indicate the reason:**  Second parent/guardian is deceased  Second parent/guardian is not reasonably available  Second parent/guardian is incompetent  Only one parent/guardian has legal responsibility for the care and custody of the minor  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

***Attachment 1 is optional. Delete if not needed***

Attachment 1 – Details of project schedule and procedures