**Informed Consent/Assent**

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| [ ]  Yes [ ]  No | A waiver of the requirement to obtain consent or waiver or alteration of some elements of consent has been approved by the IRB  |
| [ ]  Yes [ ]  No | A waiver of written documentation of consent (participant signature) has been approved by the IRB |
| [ ]  Yes [ ]  No [ ]  N/A | Investigators obtained consent from each participant prior to the start of any study procedures *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | An IRB-approved study representative obtained consent for all participants *(N/A if the IRB granted a waiver of consent)*  |
| [ ]  Yes [ ]  No [ ]  N/A | Valid (stamped/watermarked) IRB-approved consent forms were used *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | All pages of the consent forms are on file for each participant *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | All yes/no, checkboxes, or similar options on the consent forms are completed and/or initialed *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | Consent forms are free of any handwritten changes or corrections *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | Original copies (not photo copies) of all consent forms signed and dated by participants are on file *((N/A if the IRB granted a waiver of consent or documentation of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | The participant/participant representative signed his/her own consent forms (Exceptions: IRB-approved surrogate) *(N/A if the IRB granted a waiver of consent or documentation of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | An IRB-approved study representative signed/dated the consent *(N/A if the IRB granted a waiver of consent or documentation of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | An IRB-approved study representative entered the same date as the participant/participant representative on the consent form *(N/A if the IRB granted a waiver of consent or documentation of consent)*  |
| [ ]  Yes [ ]  No  | If Short Form Consent is implemented, a witness signed and dated the consent form *(N/A if the IRB granted a waiver of consent or documentation of consent)* |
| [ ]  Yes [ ]  No  | There is documentation of the participant's/participant representative’s receipt of a copy of the consent form (e.g., Enrollment Log or progress notes) *(N/A if the IRB granted a waiver of consent or documentation of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | For protocols that include minors: Parental/guardian permission for the participation for minors was obtained using the IRB approved parent/guardian permission/consent form *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | Parental/guardian permission for the participation for minors was obtained from the IRB approved number of parents/guardians *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | Minors were assented using the IRB approved assent form *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | Enrolled minors that reach local age of majority during the study are consented as adults *(N/A if the IRB granted a waiver of consent)* |
| [ ]  Yes [ ]  No [ ]  N/A | The number of participants who have signed consent / assent forms (i.e., enrolled), is no greater than the IRB-approved enrollment/sample |
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**Informed Consent Disclosures**

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| [ ]  Yes [ ]  No | All required elements of consent are captured within the consent form or informed consent script (checklist on next page) |
| **Required *(\*as applicable)*** |
| [ ]  A statement that the study involves research.[ ]  An explanation of the purposes of the research.[ ]  An explanation of the expected duration of the participant’s participation.[ ]  A description of the procedures to be followed.[ ]  Identification of any procedures, which are experimental.***\****[ ]  A description of any reasonably foreseeable risks or discomforts to the participant.*\**[ ]  A description of any benefits to the participant or to others, which may reasonably be expected from the research.[ ]  A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.***\****[ ]  A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.[ ]  For research involving more than minimal risk an explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.\*[ ]  For research involving more than minimal risk an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained \* | [ ]  An explanation of how to contact the research team for questions, concerns, or complaints about the research.[ ]  An explanation of how to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the participant’s’ rights; to obtain information; or to offer input.[ ]  An explanation of whom to contact in the event of a research-related injury to the participant.[ ]  A statement that participation is voluntary.[ ]  A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.[ ]  A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled |
| **Additional:** *(Include when appropriate)* |
| [ ]  A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.[ ]  Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.[ ]  Any additional costs to the participant that may result from participation in the research.[ ]  The consequences of a participant’s decision to withdraw from the research. | [ ]  Procedures for orderly termination of participation by the participant.[ ]  A statement that significant new findings developed during the course of the research, which may relate to the participant’s willingness to continue participation will be provided to the participant.[ ]  The approximate number of participants involved in the study.[ ]  The amount and schedule of all payments. |
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**Informed Consent/Assent Observation Process**

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| [ ]  Yes [ ]  No | Was the most recently approved version of the informed consent form / assent form used |
| [ ]  Yes [ ]  No | If the consent/assent form was approved for use in more than one language, was the participant given a chance to choose the language he/she prefers? |
| [ ]  Yes [ ]  No | Did the participant receive full explanation of the contents of the informed consent/assent form? |
| [ ]  Yes [ ]  No | Did the participant have ample time to ask any questions and were their questions answered or addressed adequately? |
| [ ]  Yes [ ]  No | Was the informed consent/assent form signed appropriately *(****N/A if the IRB has granted a waiver of documentation of consent)***  |
| [ ]  Yes [ ]  No | Was the informed consent/assent form signed prior to the initiation of any study procedures? *(****N/A if the IRB has granted a waiver of consent or documentation of consent)***  |
| [ ]  Yes [ ]  No | If the subject is unable to read, was a witness or legal authorized representative present throughout the consent process? |
| [ ]  Yes [ ]  No | Was there any evidence of coercion or undue influence during the consent/assent process? |
| [ ]  Yes [ ]  No | Did the participant appear to understand the contents of the informed consent form and was the participant able to convey an understanding of the study procedures? |
| [ ]  Yes [ ]  No | Was the environment suitable for the informed consent/assent process? |
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**COMMENTS:**

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**Monitor’s name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Monitor’s Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_