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| **Study Title:** |  |
| **Qualified Investigator (QI):** | **REB File #:** |

**Date** (yyyy/mmm/dd)**:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Approached:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

(Indicate parents/legal guardians and/or patient’s name)

for participation in the above mentioned study.

**Permission to approach regarding the study was obtained by**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or □ Not Applicable for this study

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| A statement that the study/trial involves research.  An explanation of the purposes of the study/trial. | Describe the extent to which records will be kept confidential and provide examples of people or organizations that may have access to research records (e.g., hospital personnel, study sponsors, staff of the U.S. Food and Drug Administration). |
| The trial treatment(s) and the probability for random assignment to each treatment (if a randomized clinical trial).  A description of the procedures to be followed, including all invasive procedures. | For research that involves more than minimal risk, explain and describe any compensation and any medical treatments that are available if participants are injured as a result of participation in the study, where further information can be obtained, and who should be contacted in the event of a research-related injury. |
| The participant’s responsibilities. | Explain who should be contacted for answers to questions about the research and the participant’s rights (including the name and phone number of the principal investigator). |
| Identification of any procedures that are experimental, and explain the use of research methods such as randomization and placebo controls. | State that participation in the study/trial is voluntary and that declining to participate or deciding to withdraw at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled. |
| An explanation of the expected duration of the participant’s participation and expected number of participants in the trial. | The foreseeable circumstances and/or reasons under which the participant’s participation in the trial may be terminated. |
| A description of any reasonably foreseeable risks or discomforts to the participant and, when applicable, to an embryo, fetus, or nursing infant.  Acknowledge that participation in the study may pose unknown and unforeseeable risks. | That the monitor(s), the auditor(s), the IRB, and the regulatory authorities will be granted direct access to the participant’s original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant’s legally acceptable representative is authorizing such access. |
| Describe the steps that will be taken to prevent or minimize risks or discomforts to the participant. | That the participant or the participant’s legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant’s willingness to continue participation in the trial. |
| A description of any benefits to the participant or to others, which may reasonably be expected from the research. If there is no intended clinical benefit to the participant, the participant should be made aware of this. | State that the participant’s signature will indicate that he or she has decided to participate in the study, having read and discussed the information presented to him or her about the research. |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, and their important potential benefits and risks. |  |

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| **Time alone to review the consent document was provided?**  Yes  No,  if no why not? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Adequate time was given for all questions to be answered to the satisfaction of the participant/parent/legal guardian?**  Yes  No,  if no why not? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ***If the response is NO to the two questions above do not proceed with consent.*** |

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|  | **Obtained from:** | **Date and Time** | **Capacity Assessment \*** |
| **Parent/Legal Guardian** | Yes  N/A | **YYYY / MMM / DD**  **HH:MM** |  |
| **Translator** | Yes  N/A | **YYYY / MMM / DD**  **HH:MM** |  |
| **Participant** | Yes  N/A | **YYYY / MMM / DD**  **HH:MM** |  |
| **Assent obtained** | Yes  N/A | **YYYY / MMM / DD**  **HH:MM** |  |

A copy of the signed consent and assent (if applicable) form was given to the participant and/or parent/legal guardian prior to study procedures?  Yes  No

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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? |

Comments:

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**Informed Consent Discussion Completed By:**

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Printed Name Signature Date (yyyy/mmm/dd)