Children's Wisconsin
Kids deserve the best.

Children's Wisconsin **Informed Consent Discussion Documentation** **DO NOT upload into IRBNet**

Protocol Number: _____ PI: _____

Abbreviated protocol title: _____

Study Participant's Name: _____

Date of Discussion: _____ Time of Discussion (24 hr. clock): _____

Persons present at discussion: _____

The Participant (check all that apply):

- ☐ Has decision making capability ☐ Does not have decision making capability
- ☐ Is unable to formulate/communicate decision for reason(s) as described in IRB approved protocol
  Note reason: _____
- ☐ Under guardianship. Guardianship verified by the following means: _____
- ☐ Is a minor (Parent/LAR consent/permission is required)
- ☐ The IRB has required assent for this study starting at age: _____

The following items have been discussed with the participant and/or LAR (check all that apply):

- ☐ The content of the informed consent document and the purpose of the study
- ☐ Indications, Risks, Benefits, Alternative Treatments, and participant's responsibilities
- ☐ The Participant and/or LAR was offered an opportunity to ask appropriate questions of the Investigator regarding the study and satisfactory answers were given.
- ☐ The following steps were taken to protect privacy
- ☐ The following methods were utilized to confirm understanding (e.g., open ended questions, teach back, etc.):
  _____
- ☐ The potential subject/family was given time to review the consent materials and consider their decision

The Participant and/or LAR (check all that apply):

- ☐ Consented freely and without fraud, duress, or coercion
- ☐ Refused consent
  - ☐ Reason known (list): _____
  - ☐ Reason unknown
- ☐ Was notified of available alternatives to study participation

The consent was signed/dated by the participant? ☐ yes ☐ no ☐ NA Waiver of Documentation already approved by IRB or minor

Parental permission form signed/dated by participant's LAR? ☐ yes ☐ no ☐ NA Waiver of Documentation already approved by IRB or all adults

The witness (if required) signed/dated the consent? ☐ yes ☐ no ☐ NA

Assent of participant obtained? ☐ yes ☐ no ☐ NA
Documented on ☐ Separate assent ☐ Parental permission form ☐ NA Waiver of Documentation already approved by IRB

HIPAA Authorization obtained? ☐ yes ☐ no ☐ NA
Signed and Dated? ☐ yes ☐ no ☐ NA

☐ Signed copy of consent/assent/HIPAA Authorization given to the participant and/or LAR

☐ Consent was signed prior to any study specific procedures being performed.

LAR Information:

Name: _____ Relationship to participant: _____

Signature and Date of person conducting the consent discussion:

_____ _____
Signature Date

Comments: _____

_____

_____

_____

_____

Form completed by: _____ **Form Version 03.11.2020**