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: _____

☐ Verify that the most currently approved version of the ICF is being used. The correct version must have the IRB approval stamp, and the expiration date of approval must not be prior to the date consent is obtained.

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 03282022**