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

NOTE – In lieu of this form, the informed discussion process can also be documented within EPIC via a smartphrase. Refer to the EPIC Research Dashboard on the CRS site: <http://my.sickkids.ca/research/clinical-research-services/Pages/default.aspx>

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

(Parents/legal guardian and/or participant’s name

**Permission to approach regarding the study obtained by:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and position

**CAPACITY ASSESSMENT:**

Capacity for participant consent was assessed.

☐ Participant is able to provide consent for the study

☐ Participant is NOT able to consent for the study; participant will provide assent

☐Capacity for participant consent was not assessed.

If capacity not assessed-why?

**Assessment Completed By:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name and credentials | Signature | Date and Time | Research team role |
|  |  | YYYY/MM/DD  HH:MM |  |

**CONSENT**

The consent was reviewed with the participant and/or parent/legal guardian. The purpose, procedures and alternatives of the study have been were explained as well as the risks and benefits of participating in this study. Issues of confidentiality and the voluntary nature of participating in this study were also explained.

|  |
| --- |
| **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 either or both of the two questions above, do not proceed with consent.*** |

|  |  |  |
| --- | --- | --- |
|  | **Obtained from:** | **Date and Time** |
| **Parent/Legal Guardian** | Yes  N/A  Version: \_\_\_\_\_\_\_\_\_\_\_\_\_ | **YYYY/MM/DD HH:MM** |
| **Participant** | Yes  N/A  Version: \_\_\_\_\_\_\_\_\_\_\_\_\_ | **YYYY/MM/DD HH:MM** |
| **Assent obtained** | Yes  N/A  Version: \_\_\_\_\_\_\_\_\_\_\_\_\_ | **YYY/MM/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

If no, why?

**INFORMED DISCUSSION TEMPLATE COMPLETED BY**:

|  |  |  |  |
| --- | --- | --- | --- |
| Name and credentials | Signature | Date and Time | Research team role |
|  |  | YYYY/MM/DD  HH:MM |  |

Notes:

* This form should be completed immediately after obtaining consent.
* Consent must be done in accordance with the REB approved plan.
* The person completing the form must either: be trained and delegated by the QI to obtain and explain informed consent; or be present during the consent discussion.
* Capacity assessment should be completed by a regulated health care provider
* Refer to the SickKids Policy ‘Free and Informed Consent in Research.’
* This form should be kept within the study binder.