******

# Study Summary Document (non-English Speakers)

## Consent to Take Part in this Research Study and Authorization to Disclose Health Information for Research

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Subject |  |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Authorized Representative (if different than subject) |  | Relation to subject:[ ]  Parent [ ]  Legal Guardian |

The research study and consent form have been explained to the subject or parent/legal guardian.

By signing this form, you are indicating that you have answered the subject’s or parent’s/legal guardian’s questions, they have agreed to take part in this research study and they are legally authorized to consent to their or their child’s participation. They have also agreed to let CHOP use and share their or their child’s health information as explained above. If they don’t agree to the collection, use and sharing of their or their child’s health information, they cannot participate in this study.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Consent |  | Signature of Person Obtaining Consent |
|  |  | Date: |

**Witness/Interpreter**

By signing this form, you are indicating that

* The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
* The subject’s questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
* At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Witness/Interpreter |  | Signature of Witness/Interpreter |
|  |  | Date: |

## Child Assent to Take Part in this Research Study

### For children capable of providing assent:

I have explained this study and the procedures involved to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in terms he/she could understand and that he/she freely assented to take part in this study.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Obtaining Assent |  | Date |

**Witness/Interpreter**

By signing this form, you are indicating that

* The information in the Summary Document as well as any additional information conveyed by the person obtaining assent was presented to the subject in a language preferred by and understandable to the subject; and
* The subject’s questions were interpreted and the responses of the person obtaining assent were presented in a language preferred by and understandable to the subject.

At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining assent (including responses to the subject's questions) and responded affirmatively.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Witness/Interpreter |  | Signature of Witness/Interpreter |
|  |  |  |
|  |  | Date |

**Delete the “Unable to Assent” block (below) when either:**

* All subjects will assent; or
* When the Unable to Assentdocumentationis included as part of the ICF signature block as part of a *Combined Consent Form/Study Summary Document*.

### For children unable to assent:

I certify that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Responsible for Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Responsible |  | Date |

**COMMENTS**

1) Delete assent lines if none of the children will be old enough to assent (e.g., neonates) or if the study only involves subjects capable of consenting for themselves.

2) If some may be old enough and some not, include both statements so that the investigator can document on the Assent page, why a particular subject was unable to assent. **NOTE:** If the study summary document is combined with the consent form, only one “Unable to Assent” block is needed.