******

**Study Summary SIGNATURE Pages**

**For Non-English Speaking Subjects**

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

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

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

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

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

##  Assent to Take Part in this Research Study *(Non-English Speaking Subjects)*

### For children (or adults with diminished capacity) 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 |

### For children (or adults with diminished capacity) 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 Conducting Assent |  |  |
|  |  |  |
| Signature of Person Responsible |  | 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 if they were capable of providing assent in a language preferred by and understandable to the subject; and

• The subject’s questions, if they were capable of providing assent, 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, if they were capable of providing assent.

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

**INSTRUCTIONS (REMOVE WHEN CONSENT IS DRAFTED FOR IRB REVIEW):**

1) The last two pages are completed for research studies when a “short form” and the regular consent document is utilized as a “Study Summary Document” for “Non-English Speaking Subjects”. The person obtaining consent and the Witness are required to sign the two Signature Pages above.

2) The short form consent form is also required to be completed, and is a document, translated into the subject's native language, that contains a description of the required elements of informed consent and notes that these elements, as they pertain to the study, will be presented orally to the subject or legally authorized representative. The short form document templates are available on the Consent Form Templates page on the IRB website. The subject (or legally authorized representative) and the Witness is required to sign the Short Form.