# Addendum to the Informed Consent and HIPAA Authorization

**Study Title:** XXXX

**Principal Investigator:** Investigator Name Telephone: (xxx) xxx-xxxx

**IRB#:** XX-XXXXXX **Version Date:** MM-DD-YYYY

In the past, you or your child agreed to take part in the XXXX Study at The Children’s Hospital of Philadelphia. This is a research study looking at XXXX.

We are asking for you or your child to take part in an additional study procedure, which was not included in the consent form you originally signed.

Parents or legal guardians who are giving permission for a child, please note: in the sections that follow the word ‘you’ refers to ‘your child’.

**What is involved in the additional research procedure?**

Edit/use the following statements (or add others) as applicable:

Recent studies show that XXXX (*provide a brief rationale for the proposed additional studies, e.g. your genes may influence whether you develop asthma*).

We are asking for your permission to collect a blood sample/use a left-over blood sample previously taken for the study and do genetic testing. Doing genetic tests on your blood sample will allow us to learn more about XXXX. We will share these samples with XXXX, who will do the tests…. *(explain what is being done with the samples, what information is being shared with other researchers, and disclose that results are not being returned).*

The genetic testing of your sample was not included as one of the procedures in the consent form for the study you are taking part in.

OR

We are asking for your permission to review your medical records for an additional XXXX months/years to get additional information about your diagnosis, treatment, follow-up, clinic visits and results from tests and procedures. This was not included as one of the procedures in the consent form for the study you are taking part in. (*Provide a rationale for why charts are being reviewed for an additional period of time).*

OR

We are asking for you to complete a questionnaire about XXXX. This was not included as one of the procedures in the consent form for the study you are taking part in. (*Provide a rationale for the questionnaire and explain what kind of questions subjects will be asked).*

This consent form is in addition to the consent and HIPAA authorization you already provided for this research study. The additional data/samples collected will be covered by the HIPAA authorization you already provided for the main study. Except as stated below, no changes are made in the information described in the original consent document. If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this additional study procedure if you do not want to. You can still participate in the main study even if you do not want to complete this additional procedure.

**What are the risks of participating in this additional procedure?**

Edit/use the following statements (or add others) as applicable:

**Questionnaire Completion:** There are no physical risks but you might experience momentary embarrassment or discomfort when answering the questions. You do not have to answer any questions that make you too uncomfortable.

OR

**Blood Samples:** Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection. *OR* As the sample has already been taken in the past for the study, there are no physical risks associated with this additional procedure.

**Breach of Confidentiality:** As with the all information collected for this study, we will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality.

**Genetic Testing:** The risks related to genetic analyses can be to individuals or groups. These harms include stigmatization and insurability. To reduce this risk, only coded samples will be stored and used for future research. Information about this study will not be recorded in your medical record.

The Genetic Information Nondiscrimination Act is a Federal law that makes it illegal for some groups to discriminate against you based on genetic information. This law applies to all health insurance companies, group health plans, and employers with 15 or more employees. This law does not apply to companies that sell life insurance, disability insurance, or long-term care insurance.

**What are the benefits of participating in this additional procedure?**

There will be no direct benefit to you from taking part in this additional procedure/assessment. The knowledge gained from this additional procedure may help doctors understand XXXX.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled. You can stop being in the study at any time. You do not have to give a reason.

**Are there any additional costs for participating in this additional procedure?**

There is no cost to you for participating in this additional study procedure.

## Verbal Consent to Take Part in this Additional Part of the Research Study and Authorization to Use and Disclose Health Information for the Research

## (if obtained over the phone)

The person who provided consent confirmed that all of their questions had been answered and they agreed to their/their child’s participation in this additional procedure. They confirmed that they were legally authorized to consent to their child’s participation.

They agreed to let CHOP use and share the health information that will be collected for this portion of the study and acknowledged that the additional data/samples collected will be covered by the HIPAA authorization already provided for the main study.

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

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

## Consent to Take Part in this Additional Part of the Research Study and Authorization to Use and Disclose Health Information for the Research

## (if obtained in person)

The research study and consent form have been explained to you by:

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

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this additional part of the research study and if you are giving permission for a child to participate in this research study, you are legally authorized to consent to the child’s participation.

**NOTE:** *A foster parent is not legally authorized to consent for a foster child’s participation.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Subject |  |  |
|  |  |  |
| Signature of Subject (18 years or older) |  | Date |
|  |  |  |
| Name of Authorized Representative  (if different than subject) |  | Relation to subject:  Parent  Legal Guardian |
|  |  |  |
| Signature of Authorized Representative |  | 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 |

This study has been explained to me and I agree to take part.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Subject (optional) |  | Date |

*Delete the following if all subjects will assent.*

### **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.*