**Introduction:** As the parent and/or legal guardian of \_\_\_\_\_\_\_\_\_\_\_\_ (the Child), you have the right to decide who may review or use the Child’s Protected Health Information (PHI). The type of information that may be used is described below. When you consider allowing the Child to take part in a research study, you must give permission as the parent and/or legal guardian to allow the Child’s PHI to be released from his/her doctors, clinics, and hospitals to the research team, for the specific purpose of this research study.

**This authorization relates to the following study**:

|  |
| --- |
|  |
| **TITLE OF THE RESEARCH** | **IRB PROTOCOL #** |
|  |  |
| **PRINCIPAL INVESTIGATOR (in charge of Research Team)** | **SPONSOR #** |
|  |  |
| **NAME OF RESEARCH PARTICIPANT** | **BIRTHDATE** |
|  |  |
| **STREET ADDRESS** | **CITY, STATE & ZIP CODE** |
|  |  |

**What information will be used for research purposes?** This form is to allow the release of the Child’s health information to be used for the research described above. The Child’s health information includes information that can identify him/her. For example, it can include the Child’s name, address, phone number, birthdate, and medical record number.

This permission is for health care provided to the Child [describe the date range or time period from which PHI will be accessed for the purposes of this research. If the research involves only the study of a specific medical condition and only records related to that condition will be accessed for research purposes, describe the condition here.

*Examples*: January 1, 2019 through December 31, 2021; the last 5 years; from the time of your last heart attack until the end of this research study; or health information related to your heart attack].

I understand the information listed below will be released and used for this research study:

[Provide a description of the PHI to be used by customizing the list below. Delete information that is not applicable and add any other applicable categories of PHI. HIPAA requires the information requested be limited to the minimum necessary to accomplish the purpose of this research.]

* All records *[If you select this option, you must be able to justify the reason for this request in the event of a HIPAA or privacy audit.]*
* Information provided by you or the Child
* Hospital discharge summary
* Radiology records
* Medical history/treatment
* Medications
* Consultations
* Radiology films (such as X-rays or CT scans)
* Laboratory/diagnostic tests
* EKG reports
* EEG reports
* Psychological testing
* Pathology reports
* Operative reports (about an operation)
* Pathology specimen(s) and/or slide(s)
* Diagnostic imaging reports
* Dental records
* Other: [specify other here]

In the event of an adverse event, such as injury related to the research, other records may be accessed for the purposes of the Child’s treatment and/or for reporting purposes. This may include records from other health care providers from which the Child has received medical care, but who are not specifically listed in this Authorization.

Specific Authorizations**:** I understand that this release also pertains to the Child’s records concerning hospitalization or treatment that may include the categories listed below. I have the right to specifically request that the Child’s records **NOT** be released from his/her health care providers to the Research Team. However, I understand that if I limit access to any of the Child’s records listed below, the Child [**will not** OR **will still**] be able to participate in this research study. Check limitations, if any, below:

|  |  |
| --- | --- |
| [ ]  Mental health records | [ ]  Sexually transmitted diseases |
| [ ]  Psychotherapy notes | [ ]  Alcohol/substance abuse |
| [ ]  HIV (AIDS) | [ ]  Sickle cell anemia |
| [ ]  Other:       |  |

**Who will be allowed to release this information?**

I authorize the following persons, groups or organizations to disclose the Child’s information described in this Release of Information/Authorization for the above referenced research study:

[Describe the organizations which will release PHI by including the following as applicable. Delete organizations from this list that are not applicable.Be as specific as possible. You and/or the subject may also write in the name of his/her health care organization.]

* + Indiana University Health
	+ Indiana University Health Physicians[include specialty]
	+ Eskenazi Health
	+ IUMG – Primary Care Physicians
	+ Eskenazi Health Physicians
	+ Indiana Network for Patient Care (INPC)
	+ Other: [name of health care organization(s) or provider(s)not listed above]

**Who can access your PHI for the study?** The people and entities listed abovemay share the Child’s PHI with the following persons or groups for the research study:

* + The researchers and research staff conducting the study
* The Institutional Review Boards (IRB) that review the study
	+ Indiana University
	+ U.S. or foreign governments or agencies as required by law

[Include the following as applicable. Delete all lines that do not apply.]

* + Federal agencies with research oversight responsibilities including but not limited to:
* Office for Human Research Protections (OHRP) *[for federally-funded and/or VA research]*
* National Institutes of Health (NIH) *[for NIH sponsored research]*
* The United States Food and Drug Administration (FDA) *[for FDA regulated research]*
	+ Research teams at other institutions or research site(s): [list]
* The following research sponsor(s): [list]
* Contract research organization(s): [list]
* Data safety monitoring boards and others authorized to monitor the conduct of the study

**Expiration date of the authorization:** This authorization is valid until [insert one of the following:] the research ends and required monitoring of the study has been completed **OR** [date] **OR** [description of event or other circumstance (e.g. one year after your diagnosis, one year after birth)].

Efforts will be made to ensure that the Child’s PHI will not be shared with other people outside of the research study. However, the Child’s PHI may be disclosed to others as required by law and/or to individuals or organizations that oversee the conduct of research studies, and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. Thus, the Research Team cannot guarantee absolute confidentiality and privacy.

**As the Child’s parent and/or legal guardian, I have the right:**

1. To refuse to sign this form. Not signing the form will not affect the Child’s regular health care, including treatment, payment, or enrollment in a health plan or eligibility for health care benefits. However, not signing the form will prevent the Child from participating in the research study above.
2. To review and obtain a copy of the Child’s personal health information collected during the study. However, it may be important to the success and integrity of the study that persons who participate in the study and their parents and/or legal guardians not be given access until the study is complete. The Principal Investigator has discretion to refuse to grant access to this information if it will affect the integrity of the study data during the course of the study. Therefore, my request for information may be delayed until the study is complete.
3. To cancel this release of information/authorization at any time. If I choose to cancel this release of information/authorization, I must notify the Principal Investigator for this study **in writing** at [name and mailing address]. However, even if I cancel this release of information/authorization, the Research Team, Research Sponsor(s), and/or the Research Organizations may still use information about the Child that was collected as part of the research project between the date I signed the current form and the date I cancel the authorization. This is to protect the quality of the research results. I understand that canceling this authorization may end the Child’s participation in this study.
4. To receive a copy of this form.

I have had the opportunity to review and ask questions regarding this release of information/authorization form. By signing this release of information/authorization, I am confirming that I have the authority to execute this authorization on behalf of the Child.

|  |  |
| --- | --- |
| Printed name of Parent and/or Legal Guardian |  |
|       |  |
| Signature of Parent and/or Legal Guardian       | Date       |

**\*Legal Authority:**

 [ ]  Parent

 [ ]  Legal Guardian