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# Informed Consent and HIPAA Authorization Form

**Study Title:** *Insert Full Title of the Protocol*

Version Date: Month, Day, 20XX

*Consent Name: OPTIONAL if there is more than one consent (e.g. Control Consent)*

|  |  |  |
| --- | --- | --- |
| **Principal Investigator:** | Investigator Name | Telephone: (xxx) xxx-xxxx |
| **Emergency Contact:** | Name | Telephone: (xxx) xxx-xxxx |
| *Omit if minimal risk* | *[should be a phone number accessible 24 hours (i.e. pager, cell) and answered by someone knowledgeable about the study]* | |

You, or your child *(include as applicable)*, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

## Study Overview

*This example is relevant for studies that involve an investigational drug. Additional examples of concise statements (for other types of studies) can be found on the IRB’s website at https://www.research.chop.edu/services/consent-form-templates#collapse-accordion-30904-1.*

You or your child *(include as applicable)* are being asked to take part in this research study because you have XXXX.

The purpose of this study is to find out if drug XYZ works better than drug ABC.

*If the study involves an experimental intervention, agent, device or diagnostic, provide a concise description that includes whether or not the intervention is approved by the FDA. If it is approved, discuss whether it is approved for its proposed use (i.e., for children, for specific disorders, etc.).*

If you agree to take part, your participation will last for XXXX and will involve XXXX study visits. You will need to take the study drug ABC or XYZ or placebo for XXX weeks. A placebo is an inactive substance. There are differences between this study and your usual care. As a participant in the research you will:

(*list the most burdensome and/or main procedures that a reasonable person would want to know*)

* Receive a study drug or a placebo; you will not know which.
* Stop your regular XXX medication;
* Have a research MRI;
* Have research blood tests
* XXX

The main risks of this study are from the study drug ABC or XYZ. These include: death, stroke, hemorrhage, infection, etc. *(include major risks)*

You may benefit if drug ABC or XYZ proves to be more effective. *OR* – You will not benefit directly from participating in this study.

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 study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study *(only if applicable)*.

Please see below for additional details about the study.

### How many people will take part?

*(may be deleted if it won’t impact subject’s willingness to take part)*

(*For single center studies:)* About XXXX *individuals/people/children etc.* will take part in this study.

*(For multicenter studies:)* About XXXX people will take part in the study, including approximately XXXX participants from CHOP.

## What is the current standard of treatment for this disease?

*For clinical trials, if applicable, provide a brief synopsis of what would usually occur at CHOP as part of usual care, i.e. if the subject were not participating in this study (otherwise, this section may be deleted). For example:*

When a cancer comes back (recurs) or does not respond to therapy (is refractory), your doctor may recommend other anti-cancer drugs (chemotherapy), surgery, XXX. For certain cancers, a combination of one or more of these approaches is considered standard treatment. However, for other cancers, the best treatment is not known.

## What is involved in the study?

*If the procedures or study design are complicated (e.g. randomization, crossover design, etc.) a brief description of these procedures can be included. If the procedures are simple, this section can be deleted.*

## What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal. The study involves the following tests and procedures.

*For clinical trials, divide the procedures into “Experimental Procedures” and “Routine Clinical Trial Procedures”. Do not include procedures that would occur as part of clinical care, regardless of study participation.*

*Use standard procedure language when possible from the IRB website:* [*https://www.research.chop.edu/services/standard-language*](https://www.research.chop.edu/services/standard-language)

### Experimental Procedures:

Study Drug or other Intervention: You will need to take the study drug by mouth twice a day for XXXX weeks.

Routine Clinical Trial Procedures (these include exams, tests or procedures that are needed to administer the *study drug/device*, monitor the effects of the *study drug/device*, and prevent or treat complication):

Blood tests: We need to collect blood to measure XXXX *(blood chemistries, blood counts, DNA, etc.). (If repeated, explain the frequency and the amount in teaspoons or tablespoons e.g., Depending on the study visit we will collect between X and Y teaspoons of blood.)* We will do our best to collect the samples at the same time as a clinic blood test. We will try not to stick you more than once.

Interviews: A team member will take your medical history, along with a listing of any medications you are taking. Throughout the study you will be asked to report if you think that anything bad has happened as a result of the study.

Medical Record Review: We will review your medical records throughout the study to collect information about your medical history, current health, diagnosis, treatments, medications, and results of clinical tests.

Genetic Testing *(only include for research involving biospecimens)*:

The study involves genome-wide sequencing: Genome-wide sequencing is the analysis of the complete set of genetic instructions (DNA) in a cell. This analysis looks for small changes (sequence variants) in the genetic instructions. or

The study involves some genetic testing. We will look at some genes to XXX *(e.g. confirm your clinical diagnosis, etc.)* but will not perform genome-wide sequencing.

***If any samples are collected for research purposes, add the following:***

### Samples used for research purposes

During the study, we will collect blood *[urine, tissue etc., include as applicable]* samples from you. By agreeing to participate in the study, you

*[if stored at CHOP]* agree to give these samples to CHOP for research purposes. ***AND/OR***

*[if collected for a sponsor, include the language relevant to the sponsor’s storage and use]*

### Visit Schedule

*Only list the most important procedures for each visit. If there is just a single visit, the table can usually be deleted. If the schedule is lengthy and/or if there are multiple schedules (i.e. different schedules for different cohorts, etc), consider including these as an appendix at the end of the document to avoid unnecessarily breaking up the document.*

The table below provides a brief description of the purpose and duration of each study visit.

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit** | **Purpose** | **Main Procedures** | **Duration** |
| Visit 1 | Screening | Blood tests, MRI scan | 2 hours |
| Visit 2, Day 0 | Start study drug | Distribute study drug | 30 minutes |
| Visit 3, Day 28 | Follow-up | Lab tests, distribute study drug | 1 hour |
| Visit 4, Day 56 | End of study | Return unused drug and quality-of-life survey | 1 hour |

### Will I receive any results from the tests done as part of this study?

*(edit as appropriate)*

Results that could be important for your clinical care will be shared with you. We will not share other results with you.

## What are the risks of this study?

*Include a risk entry for every study procedure described above and combine entries as appropriate (e.g. the minimal risks for questionnaires and interviews can be combined). I*

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

**Risks associated with study drug:**

*Whenever possible, include the risks of drugs/biologis/devices in a table organized by frequency.*

XXXX

Risks of blood tests:

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.

### Risks of Genetic Testing:

The risks related to genetic analyses can be to individuals or to 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.

### Risks of XXXX

*Use standard risk language when possible from the IRB website: https://irb.research.chop.edu/standard-language*

### Risks associated with breach of confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on *(include items as applicable)* data collection forms, blood samples, tissue specimens and in the database instead of names and other private information. A separate list will be maintained that will links each participant's name to the study identification number for futurereference and communication.

## Are there any benefits to taking part in this study?

*For a study with prospect of direct benefit to the individual from the study intervention, use this statement*

You might benefit by XXXX. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help doctors determine XXXX. ***OR***

*For a study without any prospect of direct benefit to the individual, use this statement.*

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help doctors determine XXXX.

## Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

### What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. *(If applicable add)* You will need to follow the study doctor’s instructions, keep all study appointments and take the study drug as directed *(include “study drug” or add other intervention only if applicable).*

### What happens if you decide not to take part in this study?

Participation in this study is voluntary. Your health care provider at CHOP will continue to provide you with health care services even if you refuse to sign this form.

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.

### Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

*If there are consequences of early withdrawal describe them here.*

### Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:   
*(Do not include items that don’t apply. If the study is brief and/or is minimal risk, this section may not be applicable. For example, a study with a single visit cannot be stopped after the subject consents. )*

* Your condition worsens.
* The study is stopped.
* The study drug is no longer available.
* You cannot meet all the requirements of the study.
* New information suggests taking part in the study may not be in your best interests.

### What choices do you have other than this study?

There are options for you other than this study including:   
*(Only include realistic options. If there are no other studies, don’t offer another study.)*

* Participation in another study *(be specific)*.
* Receiving XXXX care outside this study.
* Alternative therapy XXXX.
* Not participating in this study.
* You may discuss other options available to you with your doctor.

## What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from *(include all that apply)* medical records, procedures, interviews and tests. Information related to your medical care at CHOP will go in your medical record. This could include *(include all that apply)* physical exams, imaging studies or tests done in the clinical lab. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Laboratory test results will appear in your medical record with the exception of *(list any exceptions, e.g. genetic tests, non-CLIA approved test results, confidential data which must be protected)* which are performed only for this research study. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

* Members of the research team and other authorized staff at CHOP and UPenn *(include UPenn only if applicable)*;
* People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

*Include the following ONLY if applicable*

* Representatives of XXXX who is the study sponsor funding this research;
* XXXX, who is testing your sample(s); *List lab names who receive identifiable specimens*
* The Data Coordinating Center at XXXX *(multi-center research studies)*;
* Groups monitoring the safety of this study *(e.g. DSMB)*;
* The National Institutes of Health *(or other funding agencies)* who is sponsoring this research;
* The Food and Drug Administration; *(if applicable)*
* Your samples/data will be shared with outside laboratories including XXXX, YYYY and ZZZZ, who will analyze *(and store, if applicable)* your samples. Your samples/data will be labeled with a XXXX *(include whatever is appropriate e.g. study number, date when they were obtained, your initials)*. The outside laboratories will not know who you are. Private information such as your name, birth date or medical record number will not be shared with them; *(if applicable)*
* If you agree, your data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you. You can tell us at the end of this form whether you will allow is to share your data in this way; *(if applicable; include for NIH-funded studies that generate large-scale human genomic data such as GWAS, SNP, genome sequence, gene expression)*.
* Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. *(Only include this statement when applicable – i.e., tests for sexually transmitted diseases, HIV, AIDS, child abuse, etc. )*

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

*CHOOSE one of the next two sentences, whichever applies and insert it at the beginning of the paragraph below.*

There is no set time for destroying the information that will be collected for this study. ***OR*** The identifiable information from this study will be destroyed XXXX years after the study is completed.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.   
*Note: HIPAA requires that consent forms be maintained for 6 years after the study is completed. FDA has separate requirements for maintenance of data.*

*For studies that include a Certificate of Confidentiality (CoC), including but not limited to all NIH funded studies, include the following CoC language edited to be study specific:*

**Certificate of Confidentiality (CoC)**

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

* No one can be forced to share your identifiable information or biological samples for a lawsuit.
* Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data **or biological samples could be shared for:**

* **other scientific research;**
* **XXXXX other purposes;**
* **your medical treatment *(Since CHOP Policy requires all clinically relevant data to be stored in EPIC, this statement will rarely be applicable)*.**

The CoC does not prevent some disclosures.

* **(*Only include the next statement if a US federal or state government agency is funding the research)* The researchers can't refuse requests for information from those funding this research. The [Funding Agency] may need information to assess this project.**
* ***(if applicable, include the following)* The US Food and Drug Administration (FDA) may need information.**
* **You can still share information about yourself. You can also freely discuss your involvement in this research.**
* **The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.**

## Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. XXXXXX  
The Children’s Hospital of Philadelphia  
Division/Department of XXXX  
34th Street and Civic Center Blvd.  
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

### Additional Information (optional, include only if relevant)

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

*Include the following statement if the study involves an intervention or will take place over a period of time and include the DSMB statement first if it applies.*

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

## Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

### Will there be any additional costs?

There will be no additional costs to you by taking part in this study. ***OR***

*If there are costs, explain them*. *This information should match the costs and responsible parties outlined in the billing plan.*

XXX *(study sponsor, CHOP, NIH, whichever is appropriate)* is providing financial support and material for all experimental procedures, as listed above, for this study. The following research procedures, study drugs and study visits will be paid by study sponsor ***OR*** CHOP *(pick whichever is appropriate)*:

* Cost of travel, parking and meals;
* Cost of study drug, etc.;
* MRI of the knee;
* Blood tests for X, Y and Z;
* XXX

*For clinical trials, if subject or insurance will be billed, include the following (as applicable):*

You or your insurance will be billed for the routine costs of a trial, which include procedures listed at “routine clinical trial procedures” above. This includes exams, tests or procedures that are necessary to administer the XXX *(study drug, device – edit as applicable)*, monitor the effects of the drug, prevent or treat complications.

We can help you understand your financial responsibilities.

*(Edit as applicable. Everything below depends on the nature of the study and whether or not billing insurance/subject is permitted or financial assistance is available.)*

* If your insurance does not pay for all the costs, you will be responsible for the remaining costs, including any co-payments and deductibles as required by your insurance.
* If you do not have insurance, you will be responsible for the costs of taking part in this study.

CHOP has programs to help uninsured and underinsured families see if financial assistance is available. If you need financial assistance, you can talk with a financial coordinator.

***Note to Investigators****: If the subject requests or needs to speak with a financial coordinator, The Family Health Coverage Program can be contacted at 267-426-0359 or fhcp@chop.edu. If you need help understanding what charges will be billed to the subject, insurance, or research grant account, contact your CTFM budget analyst.*

**Will you be paid for taking part in this study**?

You will not receive any payments for taking part in this study.

***OR***

Parents/participants will be reimbursed $XXXX for travel, meals and parking *(include as applicable)*. Receipts must be provided for all expenses.***OR***   
Parents and participants will be reimbursed a per diem of $XXXX to offset the costs of meals and incidentals *(include as applicable, in accordance with the* [*www.gsa.gov*](http://www.gsa.gov) *guidance).*

Parents will be paid $XXXX for their time and effort.

Children/participants will be paid $XXXX for their time and effort.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

*(Include only if applicable)* If your travel to CHOP (e.g. flight, hotel) is arranged and paid for by the study team, the agency making the reservations and their representatives will have access to identifiable information.

*NOTE: If payment to an individual could exceed $600 (not including reimbursement for parking, meals, etc. based on receipts) in a calendar year, include a statement that subjects will receive a W9 form.*

***(optional, only include if sharing with a commercial company is possible)***

We may share your specimens and data with third parties (other researchers/institutions or for profit companies). Your specimens and data may be used for commercial profit. You will not receive any financial benefit from the use of your specimens or data.

### Who is funding this research study?

The Division of XXXX at The Children’s Hospital of Philadelphia is funding this research.

***OR***

The National Institutes of Health is providing funding for this study.

***OR***

This study is supported by XXX *(insert sponsor)*. XXX is a drug company that makes the drug being studied in this research project. XXX is giving money to Children's Hospital for some of the costs of the study. The results of the study will be reported to XXX. If the study shows that the study drug/device/intervention *(include as applicable)* may be useful for a new purpose, this could benefit XXX financially. The funding of this study may change over time.

Please ask Dr. XXXX if you have any questions about how this study is funded.

*Include any disclosures mandated by the Conflict of Interest Committee to follow the funding explanation.*

### Conflicts of Interest

*Include any language required by the Conflict of Interest committee here. Examples of conflict of interest language are below:*

*Individual Conflict:*

Some of the investigators on this study, Drs. ABC and XYZ, are paid consultants for XXX, the sponsor of this study.

One of the study doctors, Dr. ABC, has intellectual property/a patent pending on XXX, which is being evaluated in this study. If the study shows that XXX may be useful for XXX, Dr. ABC may receive income from this invention.

*Institutional Conflict:*

CHOP has a significant financial interest in the study drug being evaluated in this research study. In the event that the study drug proves to be effective, CHOP may receive significant financial benefit.

CHOP has a financial interest in intellectual property related to this research (which is licensed by XXX), and may gain financial benefit if the research is successful.

## What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. XXXX at xxx-xxx-xxxx. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children’s Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects’ rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

*For clinical trials that are required to register with clinicaltrials.gov, include*:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## What happens if you are injured during the study? *(Not required for minimal risk research studies.)*

***Wording for non-industry-funded studies***

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call Dr. XXXX at (xxx)-xxx-xxxx. They can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

***Wording for industry-funded studies***

*Do not modify. The language below is required by CHOP Policy* [*(*https://chop.policymedical.net/policymed/anonymous/docViewer?stoken=14de2fa8-d9f5-4188-983b-29545b20809f&dtoken=f52636b5-49e3-4d0d-a63f-701527693206](https://intranet.research.chop.edu/display/IPL/Informed+Consent+-+Subject+Injury+Language+Required+for+Industry-Initiated+Studies+Policy)*).*

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency care. Treatment may be billed to you or your insurer. If your injury is caused by a research procedure or the experimental drug/device/intervention *(include as applicable)*, XXX *(insert sponsor)* may pay for treating the injury. This does not mean that a mistake happened.

The Hospital does not offer financial compensation or payment if you are injured as a result of participating in this research.

If you think you have been injured from taking part in this study, call Dr. XXXX at (xxx)-xxx-xxxx. They can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

*Only include the following section if the study is funded by the NIH and is subject to the 2014 Final NIH Genomic Data Sharing Policy.*

## Sharing Data with the National Institutes of Health (NIH)

### Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH’s goal is to maximize the benefits that come from the research.

The NIH repository stores genetic information and phenotypic data from many studies. The NIH then shares that information with researchers. We will send the information about you and the other participants to a repository at the NIH. The information will be de-identified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual.

The NIH intends to share the collected information with other researchers for future research. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

The goal of genetic studies is to look for genetic connections that may explain how to identify, prevent, and treat health problems. For example, genetic data may be used to find out:

* Who is more likely to develop a certain illness, such as asthma, cancer, or diabetes, or a condition like high blood pressure or obesity;
* What genes affect the progress of a certain disease or condition; and
* What genes may affect treatments which now may or may not work in certain people.

### Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it’s possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.

### Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future.

### Controlled or Unrestricted Access

The data about you will either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access are publicly available to anyone (e.g., The 1000 Genomes Project).

## What will be done with my data and specimens *(if applicable)* when this study is over?

*(Use one of the following three options regarding the use of data for future research.):*

***NO secondary (future) research*** *with or without identifiers:*

Your data and/or samples *(include as applicable)* will not be used for any future research after this study is complete.

*If* ***there is a plan for secondary (future) research*** *with or without identifiers, use one of the following (****without identifiers*** *or* ***with identifiers)****:*

*Statement regarding secondary (future) research* ***without identifiers****:*

We will use and may share data and/or specimens for future research. Information that can identify you or the samples may be kept permanently in a computer database at CHOP.   
Your data and/or specimens may be shared with researchers/institutions at, or outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing your data and/or specimens for future research. We will remove identifiers from them before sharing them with others. This means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. Some of this may not be possible if your samples and data have already been shared.

*Secondary (future) research* ***with identifiers****:*

*If there is ANY chance of using the data and/or specimens for future research and they are linked to identifiers or identifiable information; either*

* *include an “Optional Future Use of Data and/or Specimens” section (see the next section of the template). Or*
* *if future use of individually identifiable specimens/data is mandatory for study enrollment, then this must be explicitly stated below (the header and option to document consent to the future use should be deleted).*

*If identifiable data or specimens will be retained and used for future secondary research, then subjects must consent to its use. Edit the following section as appropriate to indicate whether identifiers would only be maintained at CHOP or might be shared outside of CHOP.*

***Please note that this section does NOT constitute broad consent.***

## Optional Consent for Use of Identifiable Data or Specimens *(include as applicable)* for Future Research

*Edit this section to apply to the research.  
NOTE: Only list the data, images, recordings, and tissue samples that will be used for future research.*

As part of the study, we will collect XXXXX *.* We may wish to use and share this information or samples *(include as applicable)* in a future study about XXX, YYY and ZZZ.   
*(Explain the types of research for which you are seeking approval. HIPAA requires that the consent be specific about the nature of the future use but this may be in general terms, e.g. pediatric heart disease, genetic diseases.)*

The information and samples *(include as applicable)* will be given a unique code and may include information that can identify you. Information that can identify you or the samples *(include as applicable and, if not all samples collected, identify the samples to be used for future research, e.g. blood, urine)* may be kept permanently in a computer database *(add other examples as applicable: lab, repository, registry)* at CHOP or at *(add outside lab as applicable)*.

Future research could occur at CHOP, or at outside institutions, which could include for profit companies.

* Your identifiable specimens or data *(include as applicable)* may be shared with other researchers at CHOP. They will use them for future research. When shared outside of CHOP, no identifiers will be included.

***OR***

* Your identifiable specimens or data *(include as applicable)* may be shared with other researchers at CHOP or outside of CHOP. They will use them for future research.

We may not ask for your consent before using or sharing your identifiable specimens or data *(include as applicable)*. You will not receive any results or financial benefit from the future research done on your specimens or data *(include as applicable)*.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed *(include as applicable)*. You can also ask us to remove information that identifies you from the data or samples *(include as applicable)*. This may not be possible if your data or samples *(include as applicable)* have already been shared.

Please indicate whether you will allow the identifiable data or samples *(include as applicable)* to be used for future research by putting your initials next to one of the following choices:

\_\_\_\_\_ (initials) NO, my identifiable data and samples *(include as applicable)* may not be used for future research. They may be used for this study only.

\_\_\_\_\_ (initials) YES, my identifiable data and samples *(include as applicable)* may be used for other future research studies.

*These statements may require modification depending on the requirements of the study.*

## Consent to Inform Your Doctors of Your Study Participation (OPTIONAL)

Please indicate whether you would like us to inform your non-CHOP doctor(s) of your participation in this study. Please note that this only applies to non-CHOP doctors, as research results will be included in your medical record at CHOP*.   
Edit this language as appropriate, for example, if results of some tests will not be included in CHOP medical records (all other data will be available through Care Everywhere).*

 \_\_\_\_\_ (initials) I request that my non-CHOP doctor(s) **not** be informed of my participation in this study.

 \_\_\_\_\_ (initials) I request that my non-CHOP doctor(s) be informed of my participation in this study.

## OPTIONAL (include other optional components that require additional signatures after the signature page)

*Optional components of the research, such as additional specimens for PK studies or genetic studies should be inserted here. Since these are not required as part of the research, separate signature for each optional study is required.*

\_\_\_\_\_ (initials) I agree to have extra blood taken for the XXXXX study.

\_\_\_\_\_ (initials) I do not wish to take part in this optional part of the research.

**DIRECTION for SIGNATURE PAGE:**

* If only children are participating, delete the signature of subject line.
* When a study is approved under §46.406 then both parents/guardians need to sign the consent document. Signature pages for these situation are available on the IRB website.
* If the study will only enroll adults, edit the paragraph starting with “By signing this form…” to remove references to the parent and to only refer to the subject. Alternatively, a signature pages for adults participants is available on the IRB website.
* If the study may also include adults with diminished capacity, the signature page needs to reflect that a legally authorized representative may consent for an adult who cannot consent for him-/herself. A signature page to include adults with diminished capacity is available on the IRB website
* If the study involves both the child and one or both of the child’s parents, the paragraph must make clear that the parent(s) is consenting for both their own participation as well as the participation of their child. A signature page for situations where both parents + the child are subjects is available on the IRB website.
* The alternative signature pages mentioned above are available at:  
  <https://www.research.chop.edu/services/consent-form-templates#collapse-accordion-30904-2>

***Note:***

* ***Please do not edit the footer of the consent form (e.g. to include the study number). These fields will be automatically populated when the IRB stamps the consent form.***

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

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 research study and you are legally authorized to consent to your child’s participation. You are also authorizing the use of your/your child’s health information as discussed above. If you don’t agree to the collection, use and sharing of health information, you cannot participate in this study. **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 |

*Be sure that the signature page is appropriate for the study population – just children, children & adults, a child and one parent, etc.. See the IRB website for other signature page options designed for these possibilities:* [*https://www.research.chop.edu/services/consent-form-templates#collapse-accordion-30904-2*](https://www.research.chop.edu/services/consent-form-templates#collapse-accordion-30904-2)

*If only children will take part, don’t include a signature line for the subject and remove the “(if different than subject)” from the Name of Authorized Representative line.*

*Be sure that the paragraph includes all subjects (e.g. parent AND child, vs just child).*

## 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.*

**Study Summary SIGNATURE Pages**

**For Subjects with Limited English Proficiency**

## 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 |

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 Subjects with Limited English Proficiency**

### 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: |

**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 “For Subjects with Limited English Proficiency”. 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.