#

# Informed Consent and HIPAA Authorization Form for Screening

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

Version Date: Month, Day, 20XX

*Screening Consent: (A consent identifier is needed if there is more than one consent for the study)*

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

***NOTE for new studies submitted after January 21, 2019 and for studies existing prior to January 2019 which are updated to comply with all of the 2018 Common Rule Regulations:***

*If screening procedures:*

*(1) Only obtain the* ***minimum information necessary for determining eligibility*** *AND*

*(2) Are limited to obtaining information through:*

*(a) Oral or written communication with the subject/LAR and/or*

*(b) Identifiable private information or identifiable biospecimens by accessing records or stored biospecimens,*

*prior consent is* ***not*** *required. If PHI is accessed or used – which it will be for most studies – then the investigators need to either (a) obtain* ***HIPAA authorization*** *using a stand-alone HIPAA authorization form**or (b) obtain a* ***waiver of HIPAA authorization*** *(appropriate if the information will be obtained only from records). More information on these requirements is available on the IRB’s webpage “*[*Recruitment vs Screening*](https://irb.research.chop.edu/recruitment-vs-screening)*”.*

*This consent template should be used when screening involves procedures that go beyond what is listed above in (1) and (2). Examples: fasting prior to main study visit, blood tests, or other additional tests or procedures.*

*More information on these requirements is available on the IRB’s webpage “*[*Recruitment vs Screening*](https://irb.research.chop.edu/recruitment-vs-screening)*”.*

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

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.
This part of the study is to identify individuals who are interested and eligible for the main study.

*Describe the purpose of the research in lay language. Provide the information that a reasonable and responsible parent would want to know before allowing their child to enroll in the study (i.e. focus on the major concepts rather than including detailed explanations of the science behind the research).*

*Don’t include every single detail about the main study. This consent form should focus on screening procedures only.*

If you agree to take part in this screening study, your participation will last for XXXX and will involve XXXX study visits. We will *(include all procedures that are part of screening to determine eligibility)* ask you a few questions about your health history, collect XXX teaspoons of blood, conduct a brief physical exam, measure your vital signs, ask you to collect and send in a small sample of urine, ask you to fast before you come in for your first study visit and review your medical (and previous research) records to see if you are eligible to take part in the main study.

The main risks of the screening are from XXX. These include: XXX. *(include major risks)*

You will not benefit directly from participating in this screening 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 screening 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.

There is a second consent form describing the main study. You will have a chance to review that form before making a final decision about taking part.

Please see below for additional details about the study.

## 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?

The screening study involves the following tests and procedures.

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.

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.

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

***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]*

### 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 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 associated with** *(include all that apply)* **urine collection, physical exams, and questionnaires/interviews:**

There are no physical risks but you might experience momentary embarrassment or discomfort. For questionnaires/interviews, you do not have to answer any questions that make you too uncomfortable.

*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.

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

There will be no direct benefit to you from taking part in this screening study.

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

If you decide to participate in this screening study, you must tell us you agree. You do not have to participate in the main study even if you agree to participate in this screening study.

### What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this screening study.

### 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 screening portion of the study at any time. You do not have to give a reason.

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

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

There are options for you other than this study including not participating in this study.

***Use one of the following sections for Privacy and Confidentiality:***

*The first section should be used if screening uses, accesses, or records PHI (in which case HIPAA applies).*

*The second section should be used if HIPAA does not apply (e.g. the study is about teen driving without using, accessing, or recording any private identifiable information about the subjects past, present, or future health, medical care, or health insurance).*

***If HIPAA applies to the screening, use the following section:***

## 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 *(or verbally agreeing)*, 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:*

## 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.

*If HIPAA does not apply to screening use the following section:*

## What about privacy and confidentiality?

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. People from oversight agencies and organizations such as the Department of Health and Human Services, Office for Human Research Protections may also look at your study records.

By law, CHOP is required to protect your private information. The investigator and staff involved with the study will keep your private information collected for the study strictly confidential.

## Financial Information

There are no costs or payments to participate in the screening part of the study.

### 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.

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.

*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.

## 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.*

**DIRECTION for SIGNATURE PAGE:**

* If only children are participating, delete the signature of subject line.
* When the screening portion 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.***

***Use either the written consent signature page (this page and the next page) or the verbal consent signature page (last two pages), whichever applies.***

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

***If HIPAA does not apply: Delete the statement starting with …and Authorization to Use and Disclose… from the header above and references to sharing health information in the paragraph below.***

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

*Include an assent documentation page only if applicable.*

### 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.*

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

***If HIPAA does not apply: Delete the statement starting with …and Authorization to Use and Disclose… from the header above and references to sharing health information in the paragraph below.***

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

The research study and consent form was explained to:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Providing Consent |  | Relation to subject:[ ]  Parent [ ]  Legal Guardian  |

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 research study.

They confirmed that they were legally authorized to consent to their child’s participation.

They agreed to let CHOP use and share their child’s health information.

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

## Documentation of Child Assent to Take Part in this Research Study

*Include an assent documentation page only if applicable.*

### 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 |

*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, that a particular subject was unable to assent.*