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# Informed Consent Form and HIPAA Authorization

**Study Title:** Title of Biorepository

Version Date: Month, Day, 20XX

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

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You, or your child, 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 are being asked to take part in this research study because you have XXX.

The purpose of this study is to collect and store data and samples, such as blood and saliva, for future research (about XXX).

* A collection of medical information (data) and samples of blood, urine or tissue (if applicable) and is called a biorepository.
* The future research will involve various types of genetic testing. Genetic testing looks at pieces of DNA called genes. Genes provide the instructions needed to make our bodies work. (if applicable)
* Add other possible uses of the specimens/data such as looking at proteins, RNA, etc.
* You will not receive results from any of the tests that are performed as part of future research studies. (only if this is the case)

If you agree to take part, you will need to give a blood or saliva samples once (or other frequency). We will also review your medical records once a year (or other frequency).

Your data and samples will be shared with other researchers at CHOP as well as researchers at other institutions or for-profit companies. Before sharing your data or samples, all information that can identify you will be removed. These researchers, who use your samples for future research, will not know who you are. (only if this is the case)

The main risks from this study are related to bleeding or infection from the blood draw and risks related to a possibility of a breach of confidentiality of your samples and data. Every precaution will be taken to secure your personal information to ensure confidentiality.

You will not benefit directly from taking part in this study.

We hope that the information and samples that will be stored in the biorepository will help researchers find the causes and treatments for conditions and diseases (specific disease if applicable) that affect children.

Participation in this study is voluntary and choosing not to participate will not impact your usual clinical care.

If you are interested in learning more about the study, please continue to read below.

### How long will you be in this study?

If you agree to take part in the study, you will come to CHOP for X number of study visits. (There is often the intent to collect specimens multiple times and update the data over a period of years. Be sure that the duration of study participation reflects the duration of all procedures and data collection.)

The samples and information that we collect for the biorepository will be stored and used indefinitely.

## What are the study procedures?

The study involves the following:

Medical History: (explain how the information will be obtained). Information (data) will be collected from your medical records and from a brief interview (if applicable). The information will include your diagnosis, treatments, and medications (and whatever else). (The following is an example for studies where data will continue to be collected over time.) If you are cared for at CHOP, your data will be updated every year until you turn 18 years of age. If you are still cared for at CHOP after you turn 18, we will request that you continue to allow us to update your information.

Questionnaires: You will be asked to complete questionnaires about XXX (e.g. your quality of life, your mood and how you have been feeling, and your daily activities; some of the questions will ask whether you have thought about or tried to hurt yourself or others).

Blood Samples: Up to XXX tubes of blood will be taken and stored in the biorepository. The amount of blood will depend upon your size.

If you are a CHOP patient, the sample will be collected when you are having blood drawn for your medical care. A separate blood draw may need to be done if we cannot coordinate the collection of the research sample with a clinical blood draw.

If you are a relative of a CHOP patient, you will be asked to come to CHOP for a blood draw. Please note that this blood sample is not required in order for CHOP patients to be in the study; your child/sibling/etc. can still be in this study even if you do not give a blood sample. Please note: Relatives and CHOP patient/subjects will need to sign separate consent forms.

Other Specimens: (include one additional entry for each type of specimen that will be collected) We will also request a XXX (urine, saliva, cheek cell, etc.) sample (whatever is applicable). Briefly explain the procedure. Example: Collecting cheek cells involves rubbing a cotton swab on the inside of the cheek for about 10 seconds.

Tissue Specimens: Any tissue or body fluid that is removed during a medical or surgical procedure and is not needed for your medical care will be stored in the biorepository. No extra tissue will be taken for the purpose of this study. The leftover tissue would normally be thrown away.

Genetic Testing:

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.

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.

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

### How will the data and samples be protected and will they be shared?

**When the investigators retain the key to the code but will not share it outside CHOP (most studies), use/modify this statement**

We will remove all information that identifies you, like your name. Identifying information will be replaced with a unique code number. The key that links your code number to your identifiable information will be stored in a safe place at CHOP. This key is necessary since your data may be updated in the future.

When the data and samples are sent to the biorepository, they will only have the unique code number. (only include this statement if it is true)

The data, samples and test results will be shared with other researchers. Research could occur at CHOP, or at outside institutions, which could include for profit companies. We will not ask for your consent before using or sharing them.

When researchers use materials in the biorepository for future studies, they will not be able to identify you, unless you give permission to re-identify you. You can tell us later on this form whether you want to be re-identified. (if applicable)

**When an honest broker will code the samples so that the subjects’ data/specimens can’t be re-linked to their identifiable information by the investigators, use this statement.**

The data and samples will first go to a person who (or system) that will remove all information that identifies you (like your name). Identifying information will be replaced with a unique code number. This person (or system) will keep a separate file (key) that links your code number to your identifiable information. This key is necessary since your data may be updated in the future. The key will NOT be stored in the biorepository.

When the data and samples are sent to the biorepository, they will only have the unique code number. (only include this statement if it is true) None of the researchers who will use materials in the biorepository for future studies will have the key to the code. The person (or system) who removed the identifiers will not be allowed to share the key with anyone else. We will not ask for your consent before using or sharing your data or samples.

The figure below is an example to explain how the data/samples are coded and sent to the repository.



### What will be done with the data and samples?

Researchers will use the data and specimens for future studies. (Explain the various possible uses for the data/specimens)

* A variety of different tests may be done on the samples. (If all specimens will have certain tests, briefly explain/list them. Some repositories perform a number of tests on all specimens.)
* A variety of genetic tests may also be done. Because the field of genetic testing is advancing rapidly, we can’t predict all of the tests that will be done.
* The samples will be used to create cell lines that will be used for XXX (if applicable).
* Anyone who uses the samples and data for future research will not know who you are. They will only get the code number. (If identifiable data and specimens may be shared, modify this statement accordingly).
* Other purposes should also be outlined

You will not be informed of the details of any specific research studies that might be conducted using your identifiable private information or identifiable private biospecimens, including the purposes of the research. You might have chosen not to consent to some of those specific research studies.

### Will I receive any results from any of the tests?

**Note**: Research results can only be returned to subjects if the tests are validated and performed in CLIA-certified labs. Edit the statements below accordingly.

* Because all information and samples will be coded, it will not be possible to share any test results with you or your doctors (only if this is the case).
* The research and genetic tests that are being done are experimental. The meaning of these test results is currently unknown.
* Results that could be important for your clinical care will be shared with you (only if this is the case). We will not share other results with you.

### Could I be re-identified in the future?

(This statement is an example. Revise this to match the protocol.) If researchers want to link the data or samples to your personal information for a research study, they will need to use the key. To do that they will be required to get permission from an ethics committee (IRB). The IRB will review the study to make sure that your rights and welfare are protected. Only then will the investigators be able to use the key to re-identify you. At the end of this form, please indicate whether you will agree to allow this to take place.

## What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

### Risks associated with collection of blood:

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.

If possible, the research blood sample(s) will be collected at the same time you have blood drawn for clinical care or through an existing catheter already inserted into a vein.

### Risks associated with collection of urine, saliva and cheek cell samples:

The physical risks of these procedures are all minimal. Example: A cheek swab could include irritation in the cheek where the swab was taken.

### Risks associated with collection of leftover tissue:

Only tissue that is leftover and that would normally be thrown away will be used for the research. There are no additional risks from the collection of these samples.

### Risks associated with completing questionnaires:

There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable. (Add a statement, if applicable, to discuss any counseling that may be available or any mandatory reporting requirement that must be met as a result of concerns that are raised.)

### Risks to your personal privacy and confidentiality:

Research that uses health information from your medical record (and interviews or questionnaires as applicable) or that involves genetic testing can affect your privacy. Your participation in this research will be held strictly confidential and only a code number will be used to identify the stored samples and data. However, because there will be a link between the code and your identity, confidentiality cannot be guaranteed.

**Risks associated with genetic testing:**

Since future research studies will involve genetic analyses, potential risks include stigmatization of individuals or groups of individuals. It could also affect your insurability. The protections in place (described above) minimize those risks. Only coded samples and data will be stored and used for future research.

There is also a Federal law, called the Genetic Information Nondiscrimination Act (GINA), which generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law may protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

This Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

There may be other risks that are not known at this time. Tell the study investigator or study staff right away if you have any problems.

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

## There will be no direct benefit to you from participating in this study. We hope that the information and samples in the biorepository will help researchers and physicians better understand conditions that affect children. The biorepository may also help researchers develop better ways to diagnose and treat childhood-related disorders in the future.

## 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.

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

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

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.

## 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 medical records and samples. (Include the following two sentences when applicable – i.e., if there are exams, history, and/or tests performed as part of the repository) Information related to your medical care at CHOP will go in your medical record. This could include 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. CHOP 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 (only include if this is going to happen) 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 (include if applicable). 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 (also include UPenn when 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 XXX who is the study sponsor funding this research;
* XXX, who is testing the blood/urine/tissue sample(s); List lab names who receive identifiable specimens
* The Data Coordinating Center at XXX (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)
* The samples/data will be shared with outside researchers and laboratories including XXX, YYY and ZZZ, who will use the samples for future research. They will analyze (and store, if applicable) the samples. The samples/data will be labeled with a XXX (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.

There is no set time for destroying the information that will be collected for this study. 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.

## 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. XXX
The Children’s Hospital of Philadelphia
Division/Department
3401 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 continue to be used for the research. However, no new information will be collected. The key that links your code to your information will be destroyed.

## 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.

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

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

We may share your specimens and data with third parties (other researchers/institutions or for profit companies). If there are patents or products that result from the research, the third parties may make money from the research. You will not receive any financial benefit from research done on your specimens or data.

### Who is funding this research study?

Use one of the 3 statements below depending on which is most applicable.

If there is no external funding source: The Division of XXX at The Children’s Hospital of Philadelphia is funding this research.

or

The National Institutes of Health (or other funding agency) is providing funding for this study.

or

For industry sponsored studies:

This study is supported by the SPONSOR. SPONSOR is giving money to Children's Hospital for some of the costs of the study.

Please ask Dr. XXX 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.

## What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. XXX 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.

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. 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 can 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). If you agree, the data for this study will be made available through unrestricted access.

## Consent to Share Data with the NIH

Please indicate whether you will allow us to share your information with the NIH by putting your initials next to one of the following choices:

\_\_\_\_\_ (initials) No, I do not consent to sharing my de-identified information with the NIH

\_\_\_\_\_ (initials) Yes, I do consent to sharing my de-identified information with the NIH for unrestricted access

## Consent for Re-Linking Samples and Data For Future Research (Optional)

As explained earlier, researchers might want to link your personal information to the samples. They might also want to contact you to see if you are willing to take part in a future research study.

If you agree, we will not ask for your consent before using or sharing your identifiable specimens or data.

Please indicate whether you will allow the data or samples to be relinked to your personal information if needed for future research, by putting your initials next to one of the following choices:

\_\_\_\_\_ (initials) I do **not** want the data and specimens to ever be relinked to my personal information.

\_\_\_\_\_ (initials) Provided that the IRB agrees, I agree to allow the data and specimens to be relinked for future research.

Please also indicate whether we (or other researchers) may contact you about taking part in future studies by putting your initials next to one of the following choices:

\_\_\_\_\_ (initials) I do not wish to be contacted about future research.

\_\_\_\_\_ (initials) Provided that the IRB agrees, I agree to be contacted to take part in future research.

NOTE: If subjects are promised that the sample cannot be re-linked back to them, the selection of subjects for the future research cannot be based on the results of tests performed as part of this 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://irb.research.chop.edu/consent-templates>

## 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:

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| --- | --- | --- |
|  |  |  |
| 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 agreeing to let CHOP use and share your child’s health information as explained above. If you don’t agree to the collection, use and sharing of your child’s health information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child’s participation.*

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|  |  |  |
| 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 |

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.

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| --- | --- | --- |
|  |  |  |
| 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.

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|  |  |  |
| 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.