We are inviting you and your child(ren) to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

CONSENT, PaReNTAL Permission, and Authorization Document

The Utah NeoSeq Project

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| **Voluntary Participation** | Participating in this research is completely voluntary. You and your child(ren) are free to decide to join this study or not to join this study. You and your child(ren) do not have to be in this study to get medical care. |
| **Study Procedures & Authorizations** | In this study, you and your child(ren) will have blood drawn for whole genome testing. You will also be asked to authorize the use of your and your child(ren)'s health information, genomic data, and samples for research by the study team and storage of your information and samples for future research.  All of the study procedures and authorizations will be explained in more detail later in this document. |
| **Benefits** | You and your child(ren) may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this research study |
| **Risks** | There are some risks and discomforts from the blood draw. There is a risk of loss of confidentiality. All the risks will be described in more detail later in this document. |
| **Conflict of Interest** | Two study team members have a financial interest in the company that creates the natural language processing tools used in this research, and one study team member’s licensed intellectual property (called VAAST) will be used in this project. This is a conflict of interest as determined by the University of Utah. |

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| What is the purpose of this research study? |

The overall purpose of the Utah NeoSeq Project is to develop and evaluate a new rapid whole genome sequencing (WGS) test to provide a genetic diagnosis to critically ill patients in the University of Utah neonatal intensive care unit (NICU). In addition, the study will enable us to learn about the benefits and limitations of WGS testing for different health conditions, help us discover new genetic diseases, and improve the tools used to analyze genetic data.

WGS is a test that involves sequencing all of a person's DNA. DNA codes for genes that make proteins for the body. WGS detects DNA variants.. A DNA variant is a change in our DNA sequence (also known as our genetic code) that is different from what is typically seen in the general population. We all have thousands of DNA variants (changes in the sequence) that will be detected with WGS. The majority of these variants are harmless or have an unknown effect. However, some DNA variants may cause disease.

For this study, we are looking for variant(s) that cause your child's disease. Determining a genetic diagnosis may help improve your child's care. The goal of the "rapid" WGS test is to return a genetic diagnosis in a shorter timeframe.

In this research study, the WGS test is an investigational device, meaning that it has not been approved by the Food and Drug Administration (FDA). For this study, your and your child(ren)'s DNA will be sequenced in a research laboratory and analyzed using research tools and methods. Risks, benefits and limitations of research-based WGS are discussed below.

This study is being conducted by researchers and clinicians at the University of Utah and ARUP Laboratories.

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| Why are we being asked to take part in this research? |

You and your family are being asked to participate in this study because your child is critically ill and his/her condition may be explained by an underlying genetic condition. Diagnosis of your child's genetic disease is the main goal for the WGS test.

Biological parents of the child enrolled in this study ("study child") are asked to participate in the study and be analyzed in the WGS test. A sibling with a similar clinical condition to the study child, and/or a healthy sibling may also be invited to participate in the study. Genetic data from family members can improve the ability of the WGS test to identify the genetic cause of the study child's disease, but the test can be completed for the study child alone without the participation of any family members.

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| What will we be asked to do if we decide to take part in this research? |

If you decide to participate, you and your child(ren) will go through research-based WGS testing for the purpose of identifying medically relevant variants in your DNA. Genetic counseling will be offered to you and your family.

Following counseling and consent, your and your child(ren)'s blood will be collected for WGS testing and future research. If cord blood is available, we may be able to use this blood instead of drawing blood from your child.

For mothers who are pregnant, we will collect additional blood samples. During pregnancy, maternal blood contains DNA from the child. This DNA from the child present in maternal blood during pregnancy is called circulating cell-free DNA (ccfDNA). We will store these maternal samples for future research that evaluates genetic testing on ccfDNA present in the maternal blood sample.

As needed, a qualified member of the care team may ask some additional medical and family history questions and complete a physical exam for your child and/or other participating family members. This may include taking photographs, if the team feels a picture helps document your baby's condition.

Test results will be returned to you and your child's health care provider. More information about the types of results that will be provided is included on following pages.

Throughout the course of this study, you may be asked to complete questionnaires related to you or your child’s medical history, family history, lifestyle, and about your decision-making, understanding, opinions and feelings as they relate to genetic testing. These questionnaires may take anywhere from 10 to 60 minutes. You can decide to complete or not complete each questionnaire when it is given to you.

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| How long will it take to participate in this research study? |

You may only need a few hours to complete all of the parts of this research, and you do not need to complete everything in one visit. Your and your child(ren)'s data and biological samples will be part of the research study for many years to come.

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| What results will be returned for the WGS test? |

**Under federal law, research participants have a right to request their data from research projects.**

**By agreeing to participate in this research, you are requesting access to research information.**

You and your child's physician will receive a research letter from the study team describing the results of the test. The results will be reviewed with you by a genetic counselor or other qualified health provider. The following sections (A-D) outline which results will or will not be included in this letter.

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| 1. What results are included for the STUDY CHILD? |

* Variants related to your child's medical issues are reported. If your child develops additional signs/symptoms in the future, the sequencing done for this study may be looked at again to see if variants can be found to explain these new symptoms. It is also possible that additional testing may be recommended.
* Variants in genes associated with your child's medical issues may be reported even if it is uncertain if the variant causes disease. These are called variants of uncertain significance. In some cases, variants in genes with uncertain function may also be reported. Only variants of uncertain significance that are thought to be related to your child's medical issues will be reported. Because genetic knowledge continues to advance at a rapid pace, interpretation of the result may change in the future.

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| 1. What results are included for FAMILY MEMBERS? |

* The presence or absence of variants detected in genes associated with your child's medical issues will also be reported in tested family members. If a variant is detected in your child, further genetic counseling and testing in other family members that are not part of this study may be recommended. The costs associated with additional counseling and testing are not covered by this study.
* If a family member has symptoms of a condition, separate testing should be ordered as part of their care, as the analysis of genes for this study is incomplete and based on the your child's medical issues. Only variants identified in your child will be reported in family members.

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| 1. What results are optional for the STUDY CHILD and FAMILY MEMBERS? |

* Variants in genes that can cause or increase the risk of medical issues that are unrelated to your child's current medical issues may be discovered during the analysis. Variants that are unrelated to your child's current medical condition, but are determined to be medically actionable by the study investigators, are called incidental findings. "Medically actionable" means that there is some treatment, surveillance or care that may help reduce the health risks associated with a variant. This may include variants associated with both childhood and adult-onset conditions. Common examples include variants that are associated with an increased risk for cancer and cardiovascular disease.
* Incidental findings not associated with your child's symptoms are only included in the research letter if you opt-in below.

Please decide whether you would like to receive (**opt-in**) or NOT receive (**opt-out**) medically actionable incidental findings that are unrelated to your child's current diagnosis.

Each family member should initial under opt-In or opt-out to show their choice.

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| --- | --- | --- | --- |
| **Relationship To study child** | **Name** | **Opt-in** | **Opt-out** |
| Study child |  |  |  |
| Mother |  |  |  |
| Father |  |  |  |
| Sibling 1 |  |  |  |
| Sibling 2 |  |  |  |

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| 1. What results are not included? |

* Variants unrelated to your child's medical condition that are not considered medically actionable will not be reported. If your child is determined to be a carrier for a condition but is not at risk for having a condition, this will not be reported.
* Variants in genes related to your child's medical issues, but not suspected to cause disease, are not reported. These are called benign or likely benign variants.

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| What results could be available in the future? |

As part of this research your and your child(ren)'s medical and genomic data may be re-analyzed in the future for the above described research purposes. In the event we discover something that might be important to a current health condition or that may be important for future health, we will attempt to contact you to ask if you would like to receive this information.

If receiving results in the future is important to you, we encourage you to update the study team if your contact information changes. Contact information for the study team is listed at the end of this consent. If we do not have your current contact information, we may not be able to contact you.

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| What other information can I receive from this research? |

**Raw Genomic Data.** You may request to receive the unprocessed data from the analysis of your DNA and other tissues.

**General Study Results.** You may also receive a newsletter describing discoveries from the research. This newsletter will not identify you or describe your personal results. It may be sent via the myHealth portal, by unencrypted email to your email address if you gave us one, or by US mail to your home address.

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| Can our results be used for medical care? |

Laboratory tests for regular medical care are required to be done in a CLIA certified lab. This certification ensures quality, safety, and oversight. Since this genetic test is only available through research at this time, it is not considered CLIA-certified. Research results should be validated (if possible) in a CLIA-certified laboratory prior to using them for medical care. Confirmatory sequencing in a CLIA-certified lab may take several weeks. It is possible that some types of results from research-based WGS tests cannot be confirmed in a CLIA-certified laboratory because there is no method available to do so.

Your child's health care provider could recommend using the research results to make medical decisions **if no CLIA-approved confirmation is available, or if immediate changes in medical care are indicated**. If this happens, you will be counseled on the risks and benefits of the specific medical intervention indicated. You will be able to decide if you do or do not want your child's health care provider to use the research result for medical decisions.

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| What are the limitations of research-based WGS tests? |

* Although genetic test results are usually accurate, the following can cause testing errors:
  + Use of research-based tools to sequence and analyze genomic data,
  + Clinical misdiagnosis of a condition,
  + Inaccurate information provided regarding family relationships,
  + Sample mislabeling or contamination,
  + Transfusion or bone marrow transplantation, and
  + Maternal cell contamination of prenatal or cord blood samples.
* Some disease-causing variants are not detectable using this method. This test may not find the cause of your child's condition, and may not identify every disease-causing variant.
* Disease-causing variants may be found for which there is no effective medical treatment.
* Variants may be found that may be associated with the disease, but require more research to understand.

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| What are the risks of participating in this study? |

**Blood Draw.** You or your child(ren) may be nervous about needles, and having blood drawn may sting.  There could be a little bleeding or bruising.  There is a very small chance of fainting or infection with any blood draw.

**Confidentiality.** There is a risk of possible breach of confidentiality.  We will, however, make every effort to protect your confidential information to minimize this risk. There is a small risk that your information could be matched against other genomic databases to identify you. How your data Is shared and protected is described in detail below.

**Using Research Results for Clinical Care.** This WGS test is done in a research environment and results should be confirmed in a clinical certified (CLIA) laboratory, whenever possible, before being used in patient care. However, your health care provider could recommend to use the research results to make medical decisions **if no CLIA-approved confirmation is available, or if immediate changes in medical care are indicated**. In these cases, there is a risk of an incorrect diagnosis leading to changes in medical care (including the start or stop of procedures, drugs, or treatment) that could be unnecessary, ineffective, or harmful. You will be counseled on the risks and benefits of the specific medical intervention indicated.

**Unexpected Results.** There is a risk that you may receive unexpected results from genetic testing, including:

Identifying a genetic risk unrelated to the original reason for testing,

Predicting another family member has, is at risk for, or is a carrier of a genetic condition,

Revealing non‐paternity or non-maternity for the study child or other tested siblings (i.e. revealing the person stated to be the biological father or mother is not, in fact, the biological father or mother),

Evidence that the parents of the individual tested are blood relatives.

**Emotional Distress from Results.** You could experience confusion or negative feelings such as anxiety or guilt from the results. In some cases, these results may be unexpected. The study team can help connect you with a genetic counselor to discuss these results, or additional counseling or mental health evaluation if needed. The costs of these additional services will not be covered by the study and will be billed to you and your health insurance as in standard care.

**Insurability.** If results are returned, the information from the genomic tests could be used to discriminate against you. The Genetic Information Nondiscrimination Act (GINA) protects your access to health insurance and protects against discrimination from employers. You cannot have your health insurance rates raised or denied because of any results from genomic testing. This does not apply if you or your family receive care through the Tricare military health system, Veteran's Administration, Indian Health Service or through the Federal Employees Health Benefits Plans. GINA's provisions prohibiting discrimination by employers based on genomic information generally do not apply to employers with fewer than 15 employees.

Please note that information placed in your or your child(ren)'s medical record may be viewed by health insurance companies. Theoretically, life insurance, disability, or long-term care insurance companies could use information from genetic testing to deny coverage or raise the rate to applicants. Therefore, if you decide to participate in this research study, you may wish to consider the impact of these possible results on your or your child(ren)'s insurability.

**Unknown Risks.** Additionally, there may be risks that are currently unknown.

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| What are the benefits of taking part in this research? |

There may or may not be a direct benefit to you or your child(ren) for taking part in this research. It is possible you or your child(ren) could receive a medically actionable result from the study. If this is the case, this result could improve your doctors’ ability to prevent, detect, or treat the disease.

The research has great potential to benefit society by improving genomic testing for the future.

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| Will I get paid for taking part in this research? |

No. You and your child(ren) will not be paid for taking part in this research.

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| What are the costs to me for taking part in this research? |

You will not be charged, nor will your or your child(ren)'s insurance company be charged, for any test, procedure or visit that is completed solely for the purpose of this research.

If you or your child(ren) receive a result from the research WGS test, follow up testing may be needed in a certified clinical laboratory. The costs of any follow up testing, associated counseling or other services, will NOT be covered by the study and will be billed to you or your/your child(ren)'s insurance company.

Any other tests, procedures or visits would normally be done as standard medical care will be billed to you or your/your child(ren)'s insurance company.

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| What if we do not want to take part? |

Participating in this research is completely voluntary. You and your child(ren) do not have to participate. No matter what you decide it, it will not affect your or your child(ren)'s relationship with your health care providers. You may ask a member of the study team or your health care provider to discuss other options that may be available to you and your child(ren), such as clinical genetic testing.

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| What information about us will you use? |

**AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION.** Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your and your child(ren)'s health for this research study. **This authorization does not have an expiration date.**

**If you do not want us to use information about your or your child(ren)'s health, you should not be part of this research.** If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

This is the information about you and your child(ren) that we may use and disclose (release) for this research:

* **Identifying information** such as name, date of birth, address, and telephone number.
* **Medical information** such as results and notes related to physical examinations, lab tests, genetic/genomic tests, and any health information indicating or relating to a particular condition. This could be information that you share with us or is listed in your or your child(ren)'s medical record.
* **Photos** taken as part of physical exams, either by the clinical care team or the study team.
* **Family and medical history** that you may share with us or is listed in your or your child(ren)'s medical record.
* **Genetic information** from the testing and analysis of your and your child(ren)'s DNA as part of this study, or as part of past or future tests.

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| Will you store our biological samples for future use? |

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As part of this study, we will put some of you and your child(ren)'s blood and/or DNA in a tissue bank so that other researchers can use it in the future.  Future genetic research may be done on your or your child(ren)'s blood/DNA and it may help us learn more about genetic diseases.  The information listed above may be shared with these future researchers. You may be contacted by us or other future researchers to obtain consent for future research projects.

**If you do not want your or your child(ren)'s blood/DNA to be saved for future research, you should not participate in this study.** No matter what you decide to do, your decision will not affect your or your child(ren)'s medical care.

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| How will you protect our information? |

We will do everything we can to keep you and your child(ren)'s information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your and your child(ren)'s medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

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| Where will you store our samples and information? |

Your and your child(ren)'s blood/DNA will be stored at the University of Utah Cellular Translational Resource Core and ARUP Laboratories. These samples will be coded so that your names are not on the samples. All identifying information and testing information will be kept and protected on password protected computers and servers at the University of Utah.

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| How will our information and samples be used? |

Our research team may use your medical and genomic information for multiple research purposes including:

* Discovering medically important genetic variants. This may include re-analyzing the data in the future to detect important genetic variants, not found in the initial analysis.
* Improving data analysis tools
* Developing natural language processing tools (computer programs that are able to "read" and understand written words) that use electronic medical record data to evaluate and improve the use of genetic testing
* Developing clinical genomic tests (genetic tests available as part of regular medical care) and evaluating performance on different samples types, including peripheral and cord blood samples and circulating cell free DNA (ccfDNA) samples from maternal plasma
* Evaluating the benefits, limitations and value of genomic testing in patients with different health conditions.
* Learning more about genetic diseases.
* Studying how medical providers and patients use, understand and feel about genomic testing.

Your and your child(ren)'s data and samples may be used in the development of commercial products. There are no plans to provide financial compensation to you or your child(ren) should this occur.

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| Who will use our information and samples? |

* Members of the research team, the University of Utah, and ARUP Laboratories.
* The University of Utah Institutional Review Board (IRB), the board that oversees research to make sure your rights are protected.
* Funding agencies, who may review study records to guarantee the quality and accuracy of research but will not remove records identifying you from the University. An example is the National Institutes of Health (NIH), the nation’s medical research agency.
* Other academic research centers, hospitals, or industry partners we work with now or may work with in the future to improve genomic testing through research. This includes Rady Children's Hospital, Intermountain Healthcare, and Illumina, but may include others in the future. If we share your identifying information with groups outside of the University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.
* The Food and Drug Administration (FDA), who may inspect records.
* De-identified information may be shared with national genomic databases that are managed by institutions other than the University of Utah. These databases are used by researchers to combine and share information. These databases must abide by national regulations to protect data and respect the permissions you have granted us. Rarely, other researchers who use these databases may contact our study because they have information or a study that you could benefit from. If this is medically important, we will try to contact you with this information. These repositories include:
  + A database called dbGaP that is maintained by the National Institutes of Health (NIH).
  + The Newborn Screening and Translational Research Network (NBSTRN)
  + A database called ClinVar that is maintained by the National Center for Biotechnology Information (NCBI)
  + A database called GeneMatcher that connects researchers interested in the same rare disease genes

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| How do we withdraw from the study? |

You can tell us anytime that you and/or your child(ren) do not want to be in this study and do not want us to use your or your child(ren)'s health information.  You can also tell us in writing.  The decision to withdraw from this study will involve no penalty or loss of benefits to which you and your child(ren) are otherwise entitled. This will not affect the relationship you have with your or your child(ren)'s doctor or other staff, nor decrease the standard of care that you or your child(ren) receive as a patient.

If you decide to withdraw yourself or your child(ren) from the study, your biological samples will be destroyed and we will not be able to collect new information about you or your child(ren). However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.  Also, once your and your child(ren)'s samples and data are shared outside of the University of Utah, we will not be able to remove or destroy them.

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| Who do we contact if we have questions about this study? |

**RESEARCh Team**

If you have questions, complaints or concerns about this research, or think you or your child(ren) have been injured from being part of this study, you can contact the research team:

**Sabrina Malone-Jenkins, MD**

Phone: 801-581-7052

Monday thru Friday, 9am – 5pm

**RESEARCH PARTICIPANT ADVOCATE**

You may also contact the Research Participant Advocate (RPA):

Phone: (801) 581-3803

Email: [participant.advocate@hsc.utah.edu](mailto:participant.advocate@hsc.utah.edu)

3803

**INSTITUTIONAL REVIEW BOARD (IRB)**

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator.

Phone: (801) 581-3655

E-mail: irb@hsc.utah.edu

**CONSENT, Authorization,**

**and Parental Permission**

**I confirm that I have read this consent, authorization, and parental permission document and have had the opportunity to ask questions. I will be given a signed copy of this form to keep.    
  
(Study Child/Patient).** I agree to allow my child to participate in this research study and authorize you to use and disclose health information about my child for this study, as you have explained in this document. I authorize the study researchers and partner laboratories to perform research-based whole genome sequencing on my child's sample, as you have explained in this document. The risks, benefits, and limitations have been explained to my satisfaction by a qualified health professional.

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Study Child’s Name

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Parent/Guardian’s #1 Name Relationship to Child

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Parent/Guardian’s #1 Signature Date

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Parent/Guardian’s #2 Name Relationship to Child

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Parent/Guardian’s #2 Signature Date

Permission cannot be obtained from the second parent/guardian because (please check which one applies to the situation, 45 CFR 46.408):

□ The parent/guardian is deceased. □ The parent/guardian is incompetent.

□ The parent/guardian is unknown. □ The parent/guardian is not reasonably available.

□ Only one parent has legal responsibility for the care and custody of the child.

**Person Obtaining Authorization and Consent**

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Name of Person Obtaining Authorization and Consent

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Signature of Person Obtaining Authorization and Consent Date

**Test completed as**: € Proband € Trio

€ Duo € Quad

**Biological Parents and Adult Sibling.** I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document. I authorize the study researchers and partner laboratories to perform research-based whole genome sequencing on my sample as part of my family member's test, as you have explained in this document. The risks, benefits, and limitations have been explained to my satisfaction by a qualified health professional.

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Adult Family Member #1 Name Relationship to Patient

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Adult Family Member #1 Signature Date

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Name of Person Obtaining Signature of Person Obtaining Date Authorization and Consent Authorization and Consent

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Adult Family Member #2 Name Relationship to Patient

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Adult Family Member #2 Signature Date

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Adult Family Member #3 Name Relationship to Patient

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Adult Family Member #3 Signature Date

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Name of Person Obtaining Signature of Person Obtaining Date Authorization and Consent Authorization and Consent

**Child Sibling.** I agree to allow my child to participate in this research study and authorize you to use and disclose health information about my child for this study, as you have explained in this document. I authorize the study researchers and partner laboratories to perform research-based whole genome sequencing on my child's sample, as you have explained in this document. The risks, benefits, and limitations have been explained to my satisfaction by a qualified health professional.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Child Sibling's Name (1) Relationship to Patient

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Child Sibling's Name (2) Relationship to Patient

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian’s #1 Name Relationship to Child

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian’s #1 Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian’s #2 Name Relationship to Child

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian’s #2 Signature Date

Permission cannot be obtained from the second parent/guardian because (please check which one applies to the situation, 45 CFR 46.408):

□ The parent/guardian is deceased. □ The parent/guardian is incompetent.

□ The parent/guardian is unknown. □ The parent/guardian is not reasonably available.

□ Only one parent has legal responsibility for the care and custody of the child.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Obtaining Signature of Person Obtaining Date Authorization and Consent Authorization and Consent

**NATIONAL INSTITUTES OF HEALTH**

Reporting Race and Ethnicity Data

This Information Is requested for the (study child/patient):

|  |
| --- |
| Age: |

\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| Sex/Gender: |

* Male
* Female

|  |
| --- |
| Ethnicity: |

Do you consider your child to be Hispanic or Latino? (See definition below)

[Hispanic or Latino: A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin” can be used in addition to “Hispanic or Latino.”]

Select one:

* Hispanic or Latino
* Not Hispanic or Latino

|  |
| --- |
| Race: |

What race do you consider your child to be?

Select one or more of the following:

* American Indian or Alaska Native. A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.
* Asian. A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)
* Black or African American. A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black” or “African American.”
* Native Hawaiian or other Pacific Islander. A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
* White. A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
* Check here if you do not wish to provide some or all of the above information.