***Title of research study:*** *CONGENITAL HEART DISEASE GENETIC NETWORK STUDY (CHD GENES)*

## ***Key Information:***

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

**If you are 18 years and older**: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

***Investigator:***
*[Insert name of site PI]*

***Contact Info:***
*[insert site PI contact detail]*

***Funding:***
*The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH)*

**COMBINED Parental Permission/Assent:** If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required.

*When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.*

## ***Reason for the study:***

The main reason for this research study is to discover the genetic causes of congenital heart defects (CHD). Congenital heart defects (CHD) are the most common major birth defect. Doctors know little about the causes of these defects but would like to learn more. For this reason, a group of doctors and specialists have come together to search for genes that cause these heart defects or that influence how people with these defects do over time. Genes are the blueprint for how we look, how our bodies work, and how our bodies respond to disease. This study will use blood, saliva and in some cases tissue samples to look closely at the genes, and in some cases to generate stem cells.

This study will include children and adults with congenital heart defects, children and adults without congenital heart defects but who have a condition or syndrome strongly associated with CHD (such as Trisomy or Chr22q deletion), their biological parents and in some cases other biological family members. Pregnant women who have a congenital heart defect or who will deliver a baby with a congenital heart defect can also be included in this study.

## *Procedures:*

If you decide to take part, you may be asked to come to insert name of hospital/clinic for a single study visit. If needed, the procedures/information to be collected at this visit can be split up over more than one visit. We will ask you questions to gather medical and family history information. We may ask your permission to contact your biological family members, or ask you to tell them about this study, to see if they would like to take part in the study as well.

If you agree to participate in this study:

- We will collect a blood sample from you. If you are unable to give a blood sample, we will collect a saliva (spit) sample instead. You may not need to provide a blood or saliva sample if you have already provided a sample for clinical whole genome sequencing purposes. If you have any questions regarding this, you can check with the study team.
- We will review your medical records.
- If you are the patient with CHD or related condition you may also have a physical exam by a geneticist (a specialist who studies genes and traits of people with certain genes).
- We would also like to collect a small piece of your leftover tissue sample if you have any cardiac surgeries scheduled for clinical reasons in the future. This collection of your leftover tissue sample is optional, and you can still participate in this study if you choose not to allow this collection of a piece of your leftover tissue sample.

The sample(s) that we collect (blood, saliva, and/or tissue) will be used for genetic testing.

Some participants may be asked to provide an additional blood sample to generate induced pluripotent stem cells (iPSCs). This extra blood sample is optional, and you can still participate in this study if you choose not to allow this sample collection.

This study is expected to last until 2024, but may last longer if funding is available. As long as the study is still ongoing, we may contact you up to once a year to ask about any updates to your health or family history. As long as the study is still ongoing, we may also continue to review and gather information from your medical record for any updates that may be relevant to this research.

More detailed information about the study procedures can be found under ***"Detailed Procedures"***

## *Risks to Participate:*

The most common risks with this type of research include:

- Loss of confidentiality – information collected about you will be protected as much as possible, but complete confidentiality cannot be guaranteed.

- Pain and discomfort – when collecting blood you may experience temporary pain or discomfort. We will try our best to reduce the amount of pain you may feel.
- Feeling stressed or uncomfortable – when we are asking about your health or family history you may become stressed or uncomfortable. If at any time you feel like this, tell the study team and they can help you. You can stop answering questions at any time.

In addition to these risks, this research may hurt you in ways that are unknown.

## *Benefits to Participate:*

We cannot promise any benefits to you or others from your taking part in this research. However, it is possible that the information gathered during this study may someday be of benefit to future congenital heart patients by helping the researchers understand the genetic causes and clinical outcomes of congenital heart defects. This information may lead to improvements in a doctor's ability to prevent, diagnose or treat people with congenital heart defects.

## *Other Options:*

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive.

This study does not involve treatments. Therefore, your alternative to participating in the study is to not participate.

## *Cost to Participate:*

There is no financial cost to you for being in the study. All activities described in this consent form will be paid for by the study. You and your insurance will remain responsible for all clinical care.

## *Payment:*

You will receive no payment for taking part in this study.

Your information and samples (de-identified) may be used to create products, including some that could be patented/licensed and sold. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

## ***Additional Study Information:***

The following is more detailed information about this study in addition to the Key Information.

### *If I have Questions or would like to know about:*

| **Who to talk to…** | **You can call …** | **At …** |
|---|---|---|
| • Emergencies<br>• General study questions<br>• Research-related injuries<br>• Any research concerns or complaints | **PI Name**<br>**Principal Investigator** | Phone: xxx-xxx-xxxx |
| • Emergencies<br>• General study questions<br>• Research-related injuries<br>• Any research concerns or complaints | **Lead Study Coordinator Name**<br>**Study Coordinator** | Phone: xxx-xxx-xxxx |
| • Your or your child's rights as a research participant | **Institutional Review Board**<br><br>This is a group of scientists and community members who make sure research meets legal and ethical standards. | Phone: (513) 636-8039 |

### *Detailed Procedures:*

This study is considered a longitudinal study. This means that in addition to the data we collect at your study research visit, we will also continue to review your medical record and collect new data periodically over time as long as the study is still ongoing. If possible, we will arrange the research visit to occur on the same day of a scheduled visit for your regular clinical care. A detailed description of each study procedure is included after the overview list of procedures that may be performed below.

PROBAND (PATIENT) PROCEDURES AND DATA COLLECTION:

- Collect blood (preferred) and/or saliva sample. Providing blood/saliva sample is optional if already collected clinically for Whole Genome Sequencing.
- Ask you questions about your disease
- Collect and ask about pregnancy/birth history
- Collect and ask about family history
- Review medical record and collect data *(including medical and cardiac history)*

- Ask about your family medical conditions and inheritance through generations *(known as genetic pedigree)*
- May perform annual contact *(may be via phone or during your clinical* visits). This will not occur more than once a year.
- Collect demographic information *(collect updated information if changes occur)*
- Collect leftover/discarded tissue and/or samples from medically indicated procedures (Optional)
- Perform genetic physical exam (Optional)
- Collect blood sample for iPSCs, if requested (Optional)

PARENT PROCEDURES AND DATA COLLECTION:

- Collect blood (preferred) and/or saliva sample. Providing blood/saliva sample is optional if already collected clinically for Whole Genome Sequencing.
- Ask you questions about your medical history and your child
- Collect demographic information *(collect updated information if changes occur)*
- Review medical record and collect data about medical history, cardiac diagnoses and history, images and reports
- May perform annual contact *(may be via phone or during your child's clinical visits)*. This will not occur more than once a year.
- Collect leftover/discarded tissue and/or samples from medically indicated procedures (Optional)
- Collect blood sample for iPSCs, if requested (Optional)

FAMILY MEMBER PROCEDURES AND DATA COLLECTION:

- Collect blood (preferred) and/or saliva sample. Providing blood/saliva sample is optional if already collected clinically for Whole Genome Sequencing.
- Ask you questions about your and your family's medical history
- May perform annual contact (may be via phone). This will not occur more than once a year.
- Review medical record and collect data about medical history, cardiac diagnoses and history, images and reports
- Collect demographic information (collect updated information if changes occur)
- Collect leftover/discarded tissue and/or samples from medically indicated procedures (Optional)

Your and Your Family's Medical History Collection

We will ask you questions about: your date of birth, sex, race and ethnicity; medical history, including cardiac history and lifestyle; biological mother's pregnancy history; and a family history of biological relatives such as parents, grandparents, brothers, sisters and others. The family information collected will include (as you are able to provide) their date of birth, their heart health history and other health conditions, and their cause of death if they are no longer alive.

Medical Records Review and Data Collection

Information will be collected from medical records at this medical center. You may also be asked if health related information can be used from other outside doctor's medical records. If outside records are to be used, we will ask you to sign a separate *Medical Release Form.* As part of a long term follow-up, public databases will be periodically reviewed, to learn if any of the participants have died. The data collected may include:

- Diagnosis, procedures, surgeries, reports and images related to your cardiac or other diagnosis
- Clinical Whole Genome Sequence data (if available)
- Demographics (date of birth, sex, race, ethnicity)
- Medical history, including pregnancy and birth history of the patient, information on selected medical conditions and common pregnancy exposures, neurodevelopmental history, and medications,
- Family history of CHD and other conditions
- Genetic pedigree (this is a tracing or tracking of family conditions and inheritance of such conditions)
- Address for the patient and/or parent(s) to study the relationship between place-based information (such as how close you live to major roadways or services) and health outcomes. Your address will not be shared with anyone outside of the hospital/clinic who enrolled you into the study.

Data collection about you from your medical records will continue until this study ends unless you contact us to request data collection to stop.

Blood Collection for Use in This Research

A blood sample may be taken. If possible, blood will be taken from an indwelling line (in place for a clinical procedure) or at the time of a regular (clinical) blood test. The blood draw may be scheduled for another time that is more convenient for you.

The amount of blood taken for each collection is based on age and weight. Estimates of these amounts are:

- Teenagers and adults, about 4 teaspoons

- For children aged 6-10 years, about 2 teaspoons
- For children aged 1 day to 5 years, about 1 teaspoon

If there is left over blood available from clinical testing, we may collect some for use in this research. If for any reason the sample taken is not enough, we may request for you to provide an additional sample.

Additional Blood Collection for iPSC Growth (OPTIONAL)

For patients with CHD/related conditions and/or their parents, if the study testing reveals the presence of genes that are likely related to the cause of the congenital heart defects we are studying, then we may ask you to return to study site to collect an additional optional blood sample.

If you agree to this additional blood collection, we will collect the sample as described above.

Some of the cells in the blood will be processed to obtain stem cells. These are called "Induced Pluripotent Stem Cells" (iPSCs). Stem cells are special types of cells that will keep growing and renewing themselves in a petri dish indefinitely. Pluripotent stem cells are cells that have the possibility of changing to become any cell type in the body (heart cells, brain cells, etc.)

With the iPSCs, the study researchers can then make many other cell types, such as heart cells. This type of research has been done around the world for years already. The cells can be frozen until analysis, or until experiments are done in the future. All of the iPSCs generated under this protocol will be kept indefinitely and may be used for future studies related to CHDs.

If we ask you to provide this additional blood sample, it is optional, and you can still participate in this study if you choose not to allow this sample collection.

Saliva (spit)

A saliva sample may be collected. Saliva will be collected by asking you to spit numerous times into a small tube.

Leftover/Discarded Samples from Medically Indicated Procedures (OPTIONAL)

If you are scheduled for a medically indicated procedure, we may ask to collect leftover/discarded tissue and/or samples. This may include blood, muscle and/or cardiac tissue, discarded amniotic fluid, or umbilical samples. If you agree to this optional part of the study, no additional samples will be collected during your surgery, only leftover/discarded samples will be collected.

Genetic Testing

The sample(s) that we collect (blood, saliva, and/or tissue) will be used for genetic testing to search for genes that cause these heart defects or that influence how people with these defects do over time.

Physical Exam (OPTIONAL)
For patients with CHD or related conditions of interest (as described on page 1), we may ask a clinical geneticist to briefly evaluate you. You do not have to agree to have a physical exam performed. You can indicate your preference later in this form.

Information from Other Biological Family Members (grandparents, brothers and sisters, extended family)
We may ask you to tell other family members about this research study to see if they will agree to take part and to give their samples. If you agree to contact your family members, you may get some written information for them to read.
You do not have to ask your family members to be in the study. Whether you ask your family members or not, you can still take part in this study. If you ask your family members and they choose not to participate, you can still take part in this study.

Follow-up Contact
During the study, the study doctor/staff may contact you again to ask for health and medical updates. The types of information collected may include general health questions and questions about your heart related medical changes since the last interview. This contact could occur via phone or during scheduled clinical visits for you and/or your child.

## *Detailed Risks*

**Medical History Collection Risks**: Answering questions and sharing information about yourself and your family may be uncomfortable, cause stress, or make you nervous. You do not have to answer any question that makes you nervous.

**Blood Collection Risks:** During blood collection, you may experience minor discomfort, bruising, or rarely dizziness or fainting. There is also a very small risk of infection at the site. Taking the research sample at the same time as a routine blood test will not cause any additional discomfort. There is no pain or discomfort if the blood sample is drawn from an indwelling line. We may use a numbing medication or treatment to reduce the amount of pain you feel during the insertion of the needle.

**Saliva Collection Risks:** There are no known risks to collecting spit. With infants and children, a special sponge may be used to obtain spit from the mouth. This may cause a strange feeling in the mouth and the child may start to cry.

**Leftover Tissue Collection Risks:** There is no risk to collecting tissue that would otherwise be discarded after the surgery and clinical testing.

**Genetic Exam**: There are no risks to having the genetics exam, but the exam may discover new medical conditions that were not known to you.

**Genetic Testing Risks:** Doing genetic testing may detect or discover medical conditions you/your family were not aware of. Some people in genetic studies feel anxious if they think they might have a gene that puts them at risk or that may be passed on to

children. If you have these feelings at any time during the study, you may contact us and we will arrange for you to speak with someone who can help you. You can opt out of receiving your genetic test results if you choose.

## *Change of Mind/Study Withdrawal*

You can leave the research at any time; it will not be held against you.

If you stop being in the research, data already collected from you will remain in the study database but we will not collect any new information. Samples that have already been collected will continue to be used for the research unless you notify, in writing, the study doctor named on page 1 that you want your samples destroyed.

## *Privacy:*

Efforts will be made to limit the use and disclosure of your personal information, including research and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and review your information include the Cincinnati Children's Hospital Institutional Review Board (IRB), site name and other representatives of these organizations, and the funding sponsor (NHLBI) and/or their representatives overseeing this study, including the Administrative Coordinating Center (Cincinnati Children's Hospital Medical Center).

Samples and/or data collected for or generated from this study may be shared and used for future research without your additional consent. Samples and /or data may be shared with research collaborators, who may be at another institution or for-profit company.

Genetic Testing Protection:
A federal law, called the Genetic Information Nondiscrimination Act (GINA), 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 protects you as follows:

- 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.

However, you should be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-

term care insurance. For this reason, we will take several steps to keep all data private and confidential.

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

Federal Certificate of Confidentiality:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that is required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

## *Future Research*

Your collected data will be shared with national databases (hosted by the National Institute of Health) throughout this study. This data will be de-identified and nobody will be able to tell the data came from you. At the end of this study, all of your de-identified data will be shared with a public national database.

At the end of this study, any of your stored leftover samples will be sent to a central repository (hosted by the National Institute of Health). No identifiable information about you will be shared with these samples.

As part of your participation in the study, a unique subject number will be assigned to you that will allow researchers to see if you have been involved in more than one research study or database for patients with congenital heart disease. If you have

participated in more than one CHD study or database, this unique subject number may prevent any incorrect duplication of findings. This subject number will also allow your de-identified data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this subject number and not your personal identifiable information will be accessible to other investigators.

Data and samples from these storage sites will be available to other, future researchers for study of cardiovascular and other diseases. Before a researcher can get any study data or samples, they must obtain NIH approval. The researchers will not have access to any identifying information such as your name or medical record number. With this security measure, researchers will not be able to link samples or information back to you. Knowing that samples may be used by a research team in the future to study the heart or other conditions may cause stress to some people. If you believe you will be bothered by this, talk with the study doctor/staff before you sign this form.

All future researchers will be given the least amount of information needed to meet the goals of their research project. Researchers that use these samples and information must agree to never try to re-identify a participant from a coded dataset. Researchers will only be allowed to use the provided samples and information for approved research purposes. Any researchers planning to do research with information that may identify you will need to have extra review and approval by the Institutional Review Board (IRB). An IRB is a group of scientists and non-scientists who look at research projects like these and make sure research participants' rights and welfare are protected.

## *Return of results:*

Most tests done on samples or images obtained in research studies are only for research and have no clear meaning for healthcare. If the research with your information or samples gives results that do have meaning for your health, the researchers will contact you and ask you if you would like to know what they have found. You can say No to hearing about the results at that time if you desire.

The genetic research community has come to realize two types of genetic results that might be appropriate to share with patients that want these results:

1. Genetic results that are the likely cause of congenital heart disease
2. Genetic results that indicate another disease unrelated to congenital heart disease for which there are medical tests or treatments that might be taken to prevent and/or lessen the impact of the condition. These genetic results could indicate an existing condition or the risk for a future condition (such as an increased risk of certain types of cancer).

You need to know that, given the purpose of our study, we are not looking at every known gene for important changes that could affect your health. Our study does not substitute for a clinical test ordered by your doctor. However, if we come across a genetic result that might significantly impact your health and medical care and if we

know you are interested in learning about these findings, we can share what we have found with you.

Only a small number of study participants will have a genetic result to share. You will not be contacted unless we find one of these results. Also, if we do not have results to share now, there is still a chance that your congenital heart disease was caused by a genetic change that has not yet been identified. In addition, you may have another medical condition or be at risk for developing one that was not identified by our limited genetic analyses. Due to these issues, the genetic results from this research study do not take the place of a clinical evaluation. If we find results and you choose to allow us to return the genetic results to you, we will refer you to a genetic counselor for clinical testing. This genetic counselor may not be associated with your research study doctor or enrolling center. If you choose to receive results, the genetic counselor will have access to your personal information such as your name, date of birth and research test result.

This is an on-going study and even if we do not identify results on your research sample immediately, we might contact you with results in the future as our understanding of genes for congenital heart disease and other conditions improves. On the next page(s) you will have the option to select whether you are interested in receiving your genetic results. Regardless of your selection on the next page(s), you may change your mind later by notifying the study team.

The CHD GENES study team will not return results for samples that were provided clinically for whole genome sequencing.

Please initial your choice below:

If there are reportable results from a research sample now or in the future:

_____Not Applicable (a research sample was not provided)

_____I **do not** want any genetic-testing results from a research sample shared with me.

_____I **do** want genetic testing results from a research sample shared with me.

If you want genetic results from a research sample (initial all that apply):

_____Not Applicable (a research sample was not provided)

_____I want congenital heart disease-related results from a research sample shared with me

_____I want non-congenital heart disease-related results from a research samples shared with me (for example, genes that increase risk for cancer)

I understand that in order to receive the genetic results from a research sample I will be referred to a genetic counselor.

## PARTICIPATION FOR OPTIONAL PROCEDURES

### INDUCED PLURIPOTENT STEM CELLS (iPSC)

As previously described, we may ask to collect an additional blood sample for iPSC. Please initial your choice below:

_____YES, I agree to take part in the iPSC part of the study as described earlier in this form. I understand that if my testing shows that I have a gene that qualifies for this part of the study an additional blood sample will need to be taken and sent to a laboratory for the development of iPSCs. I understand this part of the study is OPTIONAL.

_____NO, I do not agree to take part in the iPSC part of the study. My blood samples from this study cannot be used to generate iPSCs.

### LEFTOVER TISSUE SAMPLES

As previously described, we would like to collect leftover tissue samples from any surgeries you may have performed for clinical purposes. Please initial your choice below:

_____YES, if I have surgery for clinical reasons, I agree to the collection of my leftover tissue samples for research.

_____NO, I do not agree to the collection of my leftover tissue samples.

### AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

*<NOTE: Sites may insert their own institutional HIPAA langue in place of the language below. Remove this blue text >*

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

**What protected health information will be used and shared during this study?**

Site Name will need to use and share your PHI as part of this study. This PHI will come from:

- Your Site Name medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

**Who will share, receive and/or use your protected health information in this study?**

- Staff at all the research study sites (including Site Name and Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The National Institute of Health (NIH)
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

**How will you know that your PHI is not misused?**

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

**Can you change your mind?**

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

**Will this permission expire?**

Your permission will never expire.

**Will your other medical care be impacted?**

By signing this document, you agree to participate in this research study and give permission to Site Name and Cincinnati Children's to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

While you/your child are participating in this research study you may not be able to access some of your/your child's health information that is related to the study. Any request for this information can be fulfilled once the study is completed.

## SIGNATURES

Signature below is for:

□ Proband/Adult
□ Parent Permission for Child Proband
□ Biological Mother
□ Biological Father
□ Extended Biological Family Member/Adult (family member other than parent)
□ Parent Permission for Biological Family Member/Child

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.
You will receive a copy of this signed consent document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Minor Participant (ages 11-17) Indicating Assent — Date

_____ _____
Signature of Adult Research Participant Indicating Consent (18 years and older) — Date

_____ _____
Signature of Parent or Legally Authorized Representative* — Date

*If signed by a legally authorized representative, a description of such representative's authority must be provided: _____

_____ _____

Signature of Person Obtaining Consent Date