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| **INFORMED CONSENT AUTHORIZATION TO PARTICIPATE** **IN A CLINICAL INVESTIGATION**

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| --- |
| **Family Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

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| --- |
| **Title:** (Protocol #1) Study of the Genetic Causes of Neurologic and Psychiatric Disorders  |
| **Principal Investigator** | Reid Robison, MD, MBA |
| **Sites of Investigation:** | **Place a check(√) at which site participant will be seen****□** Utah Foundation for Biomedical Research 1208 East 3300 South, Suite 100 Salt Lake City, Utah 84106 Phone: 801-449-1246 Fax: 909-474-8883 Website: <http://www.utahresearch.org/>  □ Steinmann Institute  10 West Broadway Suite 820     Salt Lake City, Utah 84101     Phone: 801-716-4284 □ CRI Lifetree, Center for Neuroscience Research 3838 South 700 East, Suite 202 Salt Lake City, UT 84106 Phone: 801-269-8200□ Participant will submit sample to Sponsor |
| **Sponsor:** | Utah Foundation for Biomedical Research1208 E. 3300 S. Suite 100Salt Lake City, UT 84106801-449-1246 (24 hour telephone number) |

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|  |

**Introduction**

You, or your child, are being asked to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Before you decide to participate (or permit your child/legal dependent) to participate in this research study you should read this form carefully. If you are a parent or legal guardian of a study participant that is not legally permitted to consent to be in a research study on his/her own behalf, than it is necessary that you sign this informed consent form. Parents or legal guardians, who are giving permission for a child, please note: in the sections that follow, the word 'you' refers to 'your child.' If there is anything in this form you do not understand please ask questions. Please take your time.

You do not have to take part in this study if you don’t want to. If you do take part, you can withdraw at any time.

If your child participates in this study and becomes of legal age while the study is ongoing, the researchers will contact him/her by letter and/or telephone to obtain consent for their sample to remain in the study. If the researchers are unable to contact your child, their de-identified sample and clinical information will remain in the research study database.

**What is the nature and purpose of this research study?**

Human nucleic acid (DNA and RNA) is organized in pieces called genes. Genes are what provide the instructions needed to make our bodies work and contributes to a person’s unique characteristics such as eye and hair color. There are over 6 million known ways that human DNA and RNA can vary from one person to another.

There are many new technologies that help scientists study sections of genes. This allows them to look at hundreds to thousands of variations at one time. The Sponsor is using this technology to examine the nucleic acids of you and/or your child. This will allow the Sponsor to:

* Find sections of DNA and RNA that might be responsible for different diseases;
* Look at sections to find specific genes and their variations. This may help understand and diagnose different diseases.
* Analyze cell lines derived from blood.
* Look at how people respond to treatment and/or medications.
* Try to discover ways to try to prevent diseases from happening.

The Sponsor is doing this research study to understand the mechanistic basis of many neuropsychiatric diseases. This information may improve the understanding of genetic causes of neurologic and psychiatric disorders, including but not limited to: Attention Deficit Hyperactivity Disorder (ADHD), Intellecutual Disability, Tourette Syndrome, Autism, Bipolar Disorder, Obsessive Compulsive Disorder (OCD), Developmental Delay, Schizophrenia, Depression, Multiple Sclerosis. The study will evaluate what gene or gene combination may cause neurologic and/or psychiatric disorders in children and adults who have one or more of these conditions compared to those who do not.

**Why are you asking me to take part in this study?**

You are being asked to take part in this research study because you or your family member has been diagnosed with a neurologic or psychiatric condition or you do not have a neurologic/or psychiatric condition.

**How many people will take part?**

We expect that over the next 20 years, approximately 10,000 people of all ages will take part in this multiple-site study.

**What will you expect from me if I take part?**

If you agree to take part the Sponsor will collect a blood or saliva sample, ask you about your medical and psychiatric health history, and review your past medical records. Your active participation will take about 30 minutes, unless you agree to participate in other voluntary assessments, which could take a few hours longer. **If you do not want to complete these assessments, you can still provide a blood or saliva sample for the study.**

Blood Sample

About 2-6 teaspoons of blood (10-30 ml) will be taken from adults to obtain DNA, RNA and make cell lines. A cell line is a cell that is duplicated (cloned) to make more of the same cells. If you are participating in this study from a distance, a special collection tube and mailing envelope will be sent to you so you can go to your doctor’s office or a laboratory to have a blood sample collected. About 8ml (a little more than 1 ½ teaspoons) will be collected from children weighing less than 55 pounds. Children weighing between 55-110 pounds will have 8-16 mls (about 1 ½ to 3 teaspoons) of blood collected. Your blood sample will be given a special coded number and will not contain your name or other identifying information.

Saliva Sample/Cheek Swab:

Saliva sample/cheek swab will be obtained when:

1. One of the parents is not available, and the opposite parent and the child have submitted a blood sample.

2. It is not possible to obtain a blood sample from the child and the parents have submitted a

 blood sample.

3. Both parents have donated blood samples and the child/parent prefer(s) not to have blood

 drawn from the child.

4. You are participating in this study via the telephone/fax from a distance, in which case a saliva collection kit may be mailed to your home for you to use and mail back to us.

Review of Your Medical Records:

If you decide to consent to this part of the study, information about your health from medical records (Private Health Information PHI) will be used for this study. You will be asked to sign a medical records release form to allow your medical records to be given to the research doctor. PHI will not be shared with anyone outside of UFBR.

Parent Samples

We would like to have blood or saliva samples from one or both parents. The research staff may choose to visit you in your home in order to collect these samples. Blood samples require about one teaspoon (6 ml) of blood. We also ask for parent permission to obtain the parent’s medical records. Parent samples will be coded with the same code as their child’s. This will hopefully allow us to better understand genetic makeup of children.

Additional Assessments

In some cases, additional assessments on research participants with certain neurologic and psychiatric disorders may be done. Depending on the disorder, the study doctor may ask you to participate in a more detailed assessment, including asking many questions. This information will be kept confidential, and any information sent to our collaborators will NOT include your name, date of birth or any other identifying information. These additional assessments can take an hour or more, and can often be emailed or faxed. In person assessments that are taking too long can be divided up into two visits (at a clinic or at your home), plus you may be able to finish some of the assessments over the phone. **If you do not want to participate in these additional assessments, you can still provide a blood or saliva sample for the study.**

**What will you do with my samples and information that you collect?**

The Sponsor will use a computer program to give your samples a unique code that won’t contain any of your identifying information. Your samples will be stored in a secure laboratory affiliated with the Utah Foundation for Biomedical Research for an indefinite period of time. By signing this informed consent form, you are acknowledging that you are donating your blood or saliva samples, DNA, RNA, proteins, and cell lines to this research study. These donated samples will, therefore, become the property of the Utah Foundation for Biomedical Research.

The Sponsor will be using some of your sample to obtain DNA, RNA and cell lines. Your DNA and RNA will allow the Sponsor to examine your genes for a possible link with the conditions being studied. Another part of your sample may be stored in order to measure the levels of some of the proteins that your genes make based on your DNA results. The rest of the blood/saliva will be stored in such a way that the Sponsor can access more DNA (or RNA, or protein, which are molecules produced downstream from the DNA) if the Sponsor needs to do more studies in the future to better understand the diseases being studied. Your blood may also be used to obtain peripheral blood mononuclear cells (PBMCs), and we might use these to make induced pluripotent stem cells for further study of your condition. Your DNA results will be matched up by the computer system with the initial information from your medical records in a way that only researchers at UFBR with access to the DNA will be able to identify you. The Sponsor will collaborate with research scientists at other institutions, and your blood, DNA, cell line and non-identifying data derived from them could be sent to them for further research, but no personal identifying information will be sent to collaborators. We might submit your DNA sequence information in a de-identified manner to genomic repositories, such as dbGAP, and other data hosting agencies. This will be done in a manner where there will be a very low risk of anyone identifying you based on your DNA.

**Will I be provided with the results of the genetic testing?**

You will not be provided with the results of this testing unless a significant finding is made in which case the findings will be provided to your primary care physician for further testing and genetic counseling at the discretion of your doctor. The Sponsor will not provide genetic counseling. We want to be clear that this is a research study, not a clinical test, so we cannot necessarily guarantee that we will return any lab results. However, if we find anything that is medically actionable, we will do our best to return this information to you.

**PERMISSION TO CONTACT YOU IN THE FUTURE**

We hope to keep in contact with you and your family in the future. If you give us permission to update your records or contact you in the future regarding future research studies, information that can identify you will be kept permanently in a separate computer database at the Utah Foundation for Biomedical Research for an indefinite period of time.

**What are the risks to me if I take part?**

Taking part in a research study involves risks, or side effects, and inconveniences. Talk to your study doctor about the possible risks of being in this study. Below is a list of the known risks.

If you sign this consent form, you agree to participate in this study. This means that you have agreed to fill out questionnaires, have a sample of blood or saliva taken. There is some risk of loss of privacy.

**Blood Sample:**

You may experience some pain, bleeding or bruising from the needle stick if you have your blood drawn as part of this study. Rarely, taking blood may cause fainting or infection.

**Saliva Sample/Cheek Swab:**

There is no risk in collecting a saliva sample or a cheek swab.

**Risks to Personal Privacy and Confidentiality:**

This study uses information from medical records (PHI). It also involves genetic testing. This can affect your privacy. Your participation in this research study will be held strictly confidential. Coded numbers will be used to identify specimens and research records. While it is impossible to absolutely guarantee that information in our secure system will never be known by others, we are taking every possible precaution to protect your privacy.

The procedures that have been put in place by the Sponsor are designed to make it very difficult for the results from the research study to be linked to you. However, there is always a chance that information from you taking part in this study would adversely affect you or your family in some way where applicable law does not protect against discrimination on the basis of genetic information, such as obtaining life or long term care insurance, or employment.

For more information about risks, you may talk to Dr. Robison at 801-449-1246 or the co-investigator, Gholson Lyon, at cell phone 646-872-1219.

**UNKNOWN/UNFORESEEABLE RISKS**

In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated this study. You will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

**What are the benefits to me if I take part?**

There are no direct benefits to you from taking part in this study. The knowledge gained from this study may help us better understand the causes of neurologic and psychiatric disorders and conditions. It may also help the Sponsor to develop better ways to diagnose these disorders and to develop new and better medicines to treat them in the future.

**What are the alternatives to participating in this study?**

Your alternative is not to participate in the study

**What happens if I decide not to take part in this study?**

Taking part in this study is your decision. If you are being told about this study at a clinic where you seek care, it is important that you understand that you don’t have to take part in order to receive care by your doctors. Your participation in this study is completely optional. 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. Your choice will not affect the availability of care you receive from your doctors.

You agree that the study doctor in charge of the study can remove you from this study without your consent for any reason, including, but not limited to:

a. His/her judgment that any condition or circumstance may jeopardize your welfare such as increased risk, change in potential benefit, or the integrity of the study.

b. Your failure to follow the instructions of the study doctor(s).

c. If the study is stopped by the sponsor and/or doctors participating in the study prior to completion.

d. The child/legal dependent indicates that they do not wish to participate in this study.

**Do I need to give my consent in order to take part?**

Yes, you must give your permission or consent to take part in this study. If you are participating in this study in person, you will be asked to sign this form only after you have had all of your questions answered and have decided to take part. A signed copy will also be given to you to keep as a record.

You may also take this form home to talk to your family and friends about it before deciding.

**What about privacy and confidentiality?**

Your health information will be collected in order to do this study. The Sponsor has measures in place to keep your personal information private and confidential. However, the Sponsor cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

People and organizations that may inspect and/or copy your research records to conduct this research, to assure the quality of the data, and/or to analyze the data include:

* 1. Members of the research team at the Utah Foundation for Biomedical Research
	2. People who oversee or evaluate research and care activities here at the Utah Foundation for Biomedical Research
	3. People from agencies and organizations that perform independent accreditation and oversight of research.
	4. Ethical Review Boards, including Institutional Review Boards (IRBs)

The results of this research study may be shown at meetings or published in journals to inform others about what is learned. None of your personally identifying information will be revealed in meetings or publications, unless we obtain your written permission to do so.

The Sponsor is required by law to protect your health information. By signing this document, you are authorizing the Utah Foundation for Biomedical Research to obtain and use your health information (PHI) as needed for this research study. However, our experience is that most health care organizations require written consent on their own forms prior to releasing any PHI, due to HIPAA requirements, so we fully expect that you will have to sign those forms as well, prior to us being able to receive any PHI from any healthcare organization.

This authorization does not expire.

**When will my information be destroyed?**

There is no set time for destroying any of the information that we will collect for this study. The Sponsor is planning on being able to collect and analyze the data for many years.

**What are my rights as a research participant?**

You may request to withdraw your participation in this study at any time by mailing a written request to the Utah Foundation for Biomedical Research, or emailing info@utahresearch.org. If you request to discontinue participation in this study, any information collected from you (including DNA samples) will be destroyed.

As a research participant you will be asked to complete the study procedures for this study, come to the study clinic for all of your scheduled visits, follow the instructions listed in this informed consent form, and notify the study doctor if any information regarding your health or availability to participate in this study changes.

**Will it cost me to take part?**

No, there is no cost to you for taking part in this study.

**Will I be paid for my time?**

We can pay each participant (adults and children) $10 each for participation in the study, if you request it. This is to compensate you for the time and effort that you are expending to participate in our study. You are under no obligation to accept this compensation, but it is available to you, if you request it.

**Who is paying for this research study?**

The Utah Foundation for Biomedical Research is paying for the needs of this study. In the future the Sponsor may look for additional support from outside sources for the ongoing costs of the study.

**Who can I contact if I have questions, complaints or concerns?**

If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, you may contact:

 **Dr. Robison of the Utah Foundation for Biomedical Research**

(801) 449-1246 between 8 am and 5 pm Monday thru Friday.

If you have any questions regarding your rights as a research participant, please contact the Independent IRB, Inc. at toll free 1-(877) 888-iirb (4472) during regular working hours. You can also contact the Independent IRB, Inc if you would like to report problems in a research study, express concerns, ask questions, request information, or provide input. The Independent IRB, Inc is a committee established for the purpose of protecting the rights of participants in a research study. For more information about your rights and role as a research participant you can visit the Research Participant section of the IIRB, Inc. website at [www.iirb.com](http://www.iirb.com).

**AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION (PHI)**

Signing this document means you allow the Sponsor and the researchers at UFBR to access your deidentified medical information about your health. You may be asked to participate in other research studies. You can choose whether or not you will participate in any research studies that you are contacted about. However, in order to be eligible to be contacted, you have to sign this consent and authorization form that indicates you are willing to be contacted.

This is the information that will be used:

-Name

-Contact information

-Information from your medical records

Others who will have access to your information for this research project are the Utah Foundation for Biomedical Research and authorized members of the study team who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research).

If we share your information with anyone outside the Utah Foundation for Biomedical Research, you will not be identified by name, date of birth, address, telephone number, or any other information that would directly identify you, unless required by law.

You may withdraw your permission for us to use your protected health information. When your child(ren) turns 18 they may also withdraw their permission. **This must be done in writing.** You must give your written notice of withdrawal in person or by mail. If done in person, it may be given to the research doctor or the research doctor’s staff. If you prefer to mail it, please send it to:

Dr. Reid Robison

Utah Foundation for Biomedical Research
1208 East 3300 South, Suite 100

Salt Lake City, Utah 84106

If you withdraw this permission, we will not be able to collect new information about you, and you will be withdrawn from the research registry database.

**IN CASE OF INJURY**

In case of injury, contact Dr. Reid Robison at 801-449-1246 or the Independent IRB, Inc. at toll free 1-(877) 888-4472.

If during the course of this study any injury occurs to you as a direct result of the study participation, the study sponsor agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the investigators.

Financial compensation for such things as lost wages, disability or discomfort due to injury is not routinely available.

You **DO NOT** waive any of your legal rights by signing this form.

**Consent to Take Part in this Research Study and Authorization to Disclose Health Information**

**CONSENT FOR PARENT OR ADULT PARTICIPATION**

I confirm that I have read this consent and authorization document in a language I understand well and have had the opportunity to ask questions. I will be given a copy of the consent and authorization form to keep. By signing this informed consent form, you are acknowledging that you are donating your blood or saliva samples, DNA, RNA, proteins, and cell lines to this research study. These donated samples will, therefore, become the property of the Utah Foundation for Biomedical Research. By signing this form, you have had your questions answered and you agree to take part in this research study. You also agree to let the Utah Foundation for Biomedical Research collect your health information as explained above. If you don't agree to our collecting, using and sharing your health information, you cannot participate in this study. If you indicate that you are the legal guardian, you are certifying you are legally authorized to consent to medical care for this child.

**YES / NO - I also agree to allow my medical records to be obtained for this study,**

 **and reviewed for future research studies.**

**YES / NO - I also agree to be contacted in the future about taking part in research**

 **studies.**

**YES / NO - I also agree to have additional assessments performed by the study**

 **doctor (if applicable to my condition)**

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Adult’s Name (or Parent) Phone number(s) (to contact you)

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Adult’s Signature (or Parent) Date

**If a second parent present:**

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Second Parent’s Name Phone number(s) (to contact you)

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

Adult’s Signature Date

**PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT FOR PARTICIPATION OF MINORS IN THIS GENETIC STUDY:**

I confirm that I have read this consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. By signing this informed consent form, you are acknowledging that you are allowing for the below minors under your care to donate blood or saliva samples for DNA, RNA, proteins, and cell lines in this research study. These donated samples will, therefore, become the property of the Utah Foundation for Biomedical Research. I am willing and authorized to serve as the parent or surrogate decision maker for

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Child’s Name #1 Child’s Name #4

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Child’s Name #2 Child’s Name #5

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Child’s Name #3 Child’s Name #6

Indicate the legal representative’s authority to act for the individual:

[ ]  Parent

[ ]  Spouse

[ ]  Adult (18 years of age or over) for his or her parent

[ ]  Individual with power of attorney

[ ]  Guardian appointed to make medical decisions for individuals who are incapacitated

**YES / NO - I agree to allow my children’s medical records (PHI) to be obtained**

 **for this study, and reviewed for future research studies.**

**YES / NO - I agree to be contacted in the future about my child or children**

 **taking part in other research studies.**

**YES / NO - I agree to have additional assessments performed on my child by**

 **the study doctor (if applicable to his/her condition)**

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

Parent’s Name (or Authorized Rep) Phone number(s) (to contact you)

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

Parent’s Signature Date/Time

**Child Assent**

***For children age 7 to the age of legal consent***

This study has been explained to me and I agree to take part.

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Child’s Name #1 Child’s Name #4

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

Child’s Signature #1 Date Child’s Signature #4 Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Child’s Name #2 Child’s Name #5

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Child’s Signature #2 Date Child’s Signature #5 Date

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Child’s Name #3 Child’s Name #6

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

Child’s Signature #3 Date Child’s Signature #6 Date

**OFFICE USE ONLY regarding child assent:**

**For children unable to assent:**

I certify that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ was (were) not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

**OFFICE USE ONLY: SIGNATURE REQUIRED FOR PERSON OBTAINING CONSENT**

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

Person Obtaining Consent and Assent Signature of Person Obtaining Consent and Assent

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Copy of consent form given to participant on (date) \_\_\_\_\_\_ by (initials) \_\_\_\_\_\_\_