Please check one of the following:

\_\_\_\_\_ You are an adult participant in this study.

\_\_\_\_\_ You are the parent or guardian granting permission for a child in this study.

Print child’s name here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or “your ward.”

**Genetic & Blood Markers in Kleine-Levin Syndrome**

**INTRODUCTION TO RESEARCH STUDIES**

A research study is designed to answer specific questions, sometimes about a drug’s or device’s safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

**PURPOSE OF RESEARCH**

You are invited to participate in a research study of Kleine-Levin Syndrome (KLS). We hope to identify the gene(s), protein(s), or other biomarker(s) associated with the development of this condition. If one or more unique gene(s) or biomarker(s) are identified, physicians would have a simple, minimally invasive tool to diagnose KLS. You were selected as a possible participant in this study because you have KLS or because you are a healthy control with no known sleep disorders.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Emmanuel Mignot at 650-725-6517, or Dr. Andrea N Goldstein-Piekarski at agoldpie@stanford.edu.

Stanford University hopes to find approximately 500 individuals with KLS and approximately 400 individuals to act as healthy controls. Enrollment for this study will take place both in the United States of America and internationally.

**DURATION OF STUDY INVOLVEMENT**

This research study is expected to take approximately 5 years – with each subject only actively participating for 1 day.

**PROCEDURES**

If you choose to participate, Dr. Mignot and his research study staff will enroll you in this study. For this research study, the Stanford Center for Narcolepsy Research (SCNR) will ask you to complete a questionnaire (either on-line or on paper) which should take approximately 45 minutes.

The Stanford Center for Narcolepsy Research (SCNR) may also request a sample of your blood in order to identify a gene(s) and other biomarker(s) associated with the development of Kleine-Levin Syndrome and related sleep disorders. SCNR will not use any experimental techniques or drugs in this study, but rather our focus is to use established techniques to identify these markers. A blood sample kit will be mailed to you along with instructions for scheduling a blood draw. In some instances, we may ask you to collect throat/nasal swab samples, complete a short throat swab questionnaire and additional blood samples. We also ask if you would be willing to provide a second blood sample if you experience a KLS episode. Your decision to provide an additional blood sample in the event of a KLS episode is entirely voluntary. If you choose to provide the blood sample, we will send you an additional blood kit upon enrollment. You should have your blood drawn at a time convenient for you at any point during the course of the episode or shortly after the conclusion of the episode. Agreeing to receive a second blood sample kit does not mean you are obligated to provide a blood sample if you experience a KLS episode. You should contact the clinical staff if would like to receive an additional blood kit or if you change your mind about keeping the second blood kit and would then return the blood kit using the prepaid FedEx shipping label. Should we request any additional samples, the appropriate collection kits will be provided.

\_\_\_\_\_\_\_\_\_\_ Yes, I would like to receive an additional blood sample kit.

\_\_\_\_\_\_\_\_\_\_ No, I do not want to receive an additional blood sample kit.

Prior to having your blood drawn, please be sure to have completed the other paperwork provided. Specifically, complete (and date) the questionnaire which should take approximately 45 minutes and fill-in the appropriate information on the “Release of Medical Information” form (remember to sign and date).

The blood will be drawn at a location (e.g. hospital, clinic, lab, doctor’s office) and time convenient for you. The original blood drawing will take a maximum of 70 cc’s of blood (approximately 5 tablespoons or 8 tubes) from adults and children over approximately 80 pounds. For children under approximately 80 pounds, only 50 or less cc’s of blood (approximately 4 tablespoons or 6 tubes) will be collected (not to exceed 1 tablespoon per 16 pounds of body weight). If you choose to provide a second blood sample, the blood drawing will take a maximum of 50 cc’s of blood (approximately 4 tablespoons or 6 tubes) from adults and children over approximately 80 pounds, and it will not exceed 1 tablespoon per 16 pounds of body weight for children under approximately 80 pounds. These amounts are NOT considered harmful to your health. The blood drawing should take about 10 minutes. There is a possibility that the blood draw may cause slight bruising or discomfort and, extremely rarely, infection and/or fainting.

You will be responsible for making the necessary arrangements to have your blood drawn, though you should feel free to ask the SCNR staff to assist you in locating a facility.

In addition to this informed consent form, you should have received the following:

* a blood draw kit
	+ 4-8 vials
	+ 2 needles
	+ 1 blood collection tube
	+ 2 alcohol swabs
	+ 1 non-latex tourniquet
	+ 1 sterile gauze
	+ 2 adhesive bandages
	+ 1 signed veripuncture requisition (blood draw prescription)
	+ 1 pre-address FedEx waybill

You should take these materials with you to your blood draw appointment. Most hospitals have blood drawing clinics where you can simply drop-in without an appointment to have you blood drawn; we suggest that you call beforehand to double-check the procedures at whichever facility you choose.

The Protocol Director (Dr. Emmanuel Mignot) and Dr. Andrea N Goldstein-Piekarski will be available at 650-725-6517 and agoldpie@stanford.edu respectively to help you make arrangements should you have any trouble. The facility where you have your blood drawn may charge you for this procedure. It will be your responsibility to assume this expense initially, but you will be reimbursed by Stanford University (see below).

After the blood is drawn, the tubes go back into the foam box, sealed in the included plastic bag, and tapped shut. The kit then needs to be put in the nearest FedEx pickup box as soon as possible – that same day. The kit comes with a FedEx waybill instructing FedEx to bill the SCNR account (and not you). Whoever draws the blood will help you seal the kit, and they will either tell you the nearest FedEx pickup box or will arrange for the pickup themselves. There are FedEx pickup boxes located at every hospital. If necessary, you can also call FedEx at 800-238-5355 or go to *www.FedEx.com* to find the pickup box nearest you.

Once the samples arrive at Stanford, they will be processed anonymously by SCNR laboratory staff and, eventually, your genetic material will be sent to another academic institution for analysis.

Your samples will be sent outside of Stanford for analysis.

Tissue Sampling for Future Research

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Your tissues will be stored in 1.5 mL plastic tubes in a -80°C freezer. Your tissue will be labeled using a numerical code linked to a key located on a secure Stanford University School of Medicine server.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

Any tissues you have donated which are used in research may result in new products, tests or discoveries. Your cells, DNA and health information may be used by research scientists, including those from private companies. Such companies have a financial interest in using information found from studying patient samples. This includes developing commercial products, tests or discoveries that may later help others by improving the diagnosis and treatment of various medical problems. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the investigators will do genetic testing. Genes are functional units of DNA that contain the instructions for making proteins or RNA in the cells of your body. The genome refers to all of an individual’s genetic material, including all genes.

Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children.

Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, whole genome DNA or RNA sequencing, genetic landmarks, epigenetic changes, individual and family medical histories, reactions to medications, and responses to treatment. We may use your samples to isolate other types of medically important molecules, including RNA, proteins, and metabolic biochemical compounds. Correlation of variation in the levels or character of these molecules may also provide important insights into risk for specific human diseases.

Analysis of Genetic Information:

Primarily, your blood sample will be employed to derive a sample of DNA, the molecule that encodes your genetic information. Studies employing this DNA are aimed at linking genetic information to risk for human disease and response to medical treatments. In most cases this will entail the detailed analysis of your DNA, through the “typing” of individual markers that are known to vary between the genetic makeup of different humans. Such “typing” may look at millions of markers. In addition, the sequence of your entire genome may be determined, through sequencing your DNA, allowing the identification of all the unique markers that exist in your genetic material. By correlating the patterns of these markers in thousands of study subjects with medical features the genetic risk signature for human disease can be determined.

Results Of Genetic Testing:

Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following:

* The information may be too limited to give you particular details or consequences;
* You may be determined to carry a gene for a particular disease that can be treated;
* You may be determined to carry a gene for a particular disease for which there is no current treatment;
* You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

If you wish, in the event the researchers identify genetic information that may clearly impact your health or medical care, clinically-validated testing is available to confirm this finding, and the associated condition can be treated or medically managed, the protocol director will notify your treating physician. While this research data should not be used on its own to direct clinical care, you and your physician may then decide whether you wish to pursue clinically-validated testing.

Given the above considerations, please check [yes or no] at the end of this consent form to indicate whether you wish to be told if the researchers identify results that may significantly impact your health or that of your family.

Sharing of Medical and Genetic Information and Tissue Samples:

It is possible that we will enter into collaborative studies with other academic institutions or private entities that requires the sharing of your medical record information, DNA samples, or other tissue samples. The medical record information will be stripped of all identifying information including your name and hospital number, and a unique study number provided instead. The code linking study number to your name and medical record number will remain confidential at Stanford. Also, it is possible that federal grant funding will be employed for studies using your tissues, and that your genetic information will be deposited along with every other study subject in a large database at the National Institutes of Health. In this case, access to these data would remain highly restricted with only qualified researchers gaining access to the data. Since dbGAP is a federal database, your data will become part of US government records and could be subject to requests under the Freedom of Information Act. NIH plans to contest any such requests for identifiable information, but their decision could be appealed. Although the NIH will not have any direct identifiers, it is conceivable that law enforcement agencies could request access to the de-identified data and search for matches to DNA specimens collected by the police. Again, there would be no information included in the database that could be easily linked to you.

Information from analyses of your coded samples and your coded medical information may also be put into a database called "dbGaP," along with information from the other research participants. Access to these data would remain highly restricted, only researchers who have received approval from an NIH Data Access Committee will receive access. The database will be accessible by the Internet. Only anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

Since dbGAP is a federal database, your data will become part of US government records and could be subject to requests under the Freedom of Information Act. NIH plans to contest any such requests for identifiable information, but their decision could be appealed. Although the NIH will not have any direct identifiers, it is conceivable that law enforcement agencies could request access to the de-identified data and search for matches to DNA specimens collected by the police. Again, there would be no information included in the database that could be easily linked to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

**PARTICIPANT RESPONSIBILITIES**

As a participant, your responsibilities include:

* Follow the instructions of the Protocol Director and study staff.
* Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
* Complete your questionnaires as instructed (approximately 45 minutes).
* Ask questions as you think of them.
* Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study. This is to protect you from possible injury arising from such things as extra blood drawing.

**WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you should elect, at any time, to withdrawal from the study, you may do so. Please notify Dr. Emmanuel Mignot at (650-725-6517) or Dr. Andrea N Goldstein-Piekarski at agoldpie@stanford.edu. Once you have informed the Stanford Center for Narcolepsy Research (SCNR) of your decision, all record of your involvement in the study (save one) will be permanently destroyed. Your biological samples will be removed from storage and destroyed. Your questionnaire and medical records will be destroyed. The information about you entered into SCNR’s secure database will be deleted except for your study code number. At this time, you will be officially removed from the study.

Please note that if you elect to withdrawal from the study prior to submitting a blood sample that you are required to return to the blood collection kit to SCNR. You may use the pre-paid FedEx waybill to return the empty kit.

The Protocol Director may also withdraw you from the study, without your consent for one or more of the following reasons:

* Failure to follow the instructions of the Protocol Director and study staff.
* The Protocol Director decides that continuing your participation could be harmful to you.
* You need treatment not allowed in the study.
* The study is cancelled.
* Other administrative reasons.
* You are unacceptably rude or aggressive with the staff.
* Unanticipated circumstances.

**POSSIBLE RISKS,DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

The blood draw may cause bruising, discomfort and, in exceptionally rare cases, infection or fainting. You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study.

As mentioned above, you are responsible for completing the required questionnaire and if appropriate, scheduling your own blood draw, attending the appointment, and shipping the package to Stanford. These activities take time and may conflict with another activity.

As in all activities, participation in this study may involve risks to you which are currently unforeseeable.

**POTENTIAL BENEFITS**

There are minimal risks proposed in this study and will take all precautions necessary to maintain the low risk nature of the protocol and procedures. By participating in this research you are helping to discover the possible causes of KLS. This information could possibly lead to improved treatment or a cure; this, however, may take many years.

Although you personally will not receive any direct benefit from this study, individuals who might develop KLS in the future, their family members, and future generations may benefit if we can locate genes and/or other biomarkers associated with this conditions, or predictive of responses to treatment. We do not expect to discover any information of direct clinical relevance to your condition or treatment for several years. Because the meanings of research results are not usually fully understood, there results generally are not made available to subjects or their doctors. If, later on, diagnostic tests or new treatments are discovered, this information should be obtained from properly licensed clinical labs or clinics, and will not come from the research team.

**WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY**

**ALTERNATIVES**

The alternative is to not participate.

**PARTICIPANT’S RIGHTS**

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study. You have the right to refuse to answer particular questions on the questionnaire(s).

**CONFIDENTIALITY**

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Some of your data may be sent to the database of Genotypes and Phenotypes (dbGaP) which was developed by the NIH to archive and distribute the results of studies that have investigated the interaction of genotype and phenotype. Your identity will not be disclosed.

**Authorization To Use Your Health Information For Research Purposes**

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

**What is the purpose of this research study and how will my health information be utilized in the study?**

You are invited to participate in a research study of Kleine-Levin Syndrome (KLS). We hope to identify the gene(s), protein(s), or other biomarker(s) associated with the development of this condition. If one or more unique gene(s) or biomarker(s) are identified, physicians would have a simple, minimally invasive tool to diagnose KLS. We will use your health information to confirm your diagnosis of KLS or hypersomnia. Please know that your identity and health information will never be released or published.

**Do I have to sign this authorization form?**

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study

**If I sign, can I revoke it or withdraw from the research later?**

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Emmanuel Mignot, MD PhD

Stanford University Center for Narcolepsy Research

3165 Porter Drive

Palo Alto, CA 94304

**What Personal Information Will Be Used or Disclosed?**

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: sleep study results (MSLT, PSG, MWT), physician impressions relating to Kleine-Levin Syndrome or hypersomnia, HLA typing results, self-reported medical information.

**Who May Use or Disclose the Information?**

The following parties are authorized to use and/or disclose your health information in connection with this research study:

* The Protocol Director: Emmanuel Mignot, MD, PhD
* The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
* Research Staff
	+ Clinical team, including the clinical coordinator and her assistant(s)
	+ Lead Research Scientist

**Who May Receive or Use the Information?**

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services
* The National Institutes of Health (NIH)
* Collaborating Research Teams at Stanford
* Collaborating Laboratories and Research Teams outside of Stanford University
* The database of Genotypes and Phenotypes (dbGaP) which was developed by the National Institutes of Health (NIH)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

**When will my authorization expire?**

Your authorization for the use and/or disclosure of your health information will expire December 31, 2158.

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

Signature of Participant Name of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Legally Authorized Representative (if applicable) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Description of Representative's Authority to Act for Subject (if applicable)

 **FINANCIAL CONSIDERATIONS**

Payment

You will not be paid to participate in this research study.

Costs

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.

The study will pay for those services, supplies, procedures, and care directly associated with this study that are not a part of your routine medical care. For example, if you are charged a fee for the blood-draw, parking or providing copies of KLS related medical records, you will be reimbursed. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

Sponsor

The Kleine-Levin Syndrome Foundation is providing financial support and/or material for this study.

**COMPENSATION for Research-Related Injury**

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

**CONTACT INFORMATION**

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about thisresearch study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Emmanuel Mignot. You may contact him now or later at 650-723-6601

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Emmanuel Mignot at 650-723-6601.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906.  You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact

Dr. Andrea N Goldstein-Piekarski at agoldpie@stanford.edu

**EXPERIMENTAL SUBJECT’S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

* be informed of the nature and purpose of the experiment;
* be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
* be given a description of any attendant discomforts and risks reasonably to be expected;
* be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
* be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
* be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
* be given an opportunity to ask questions concerning the experiment or the procedures involved;
* be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
* be given a copy of the signed and dated consent form; and
* be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I consent to my samples being saved for future research [ ]  Yes [ ]  No

 [ ]  No Restrictions [ ]  Restrictions (Please specify in space below)

Please attempt to contact me about results that may significantly [ ]  Yes [ ]  No
impact my health or my family’s health.

Are you participating in any other research studies? [ ]  Yes [ ]  No

May we contact you about future studies that may be of interest to you? [ ]  Yes [ ]  No

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

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| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Adult Participant |  \_\_\_\_\_\_\_\_\_\_\_ Date |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Print Name of Adult Participant

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

Signature of Parent, Guardian or Conservator *(if applicable)* Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Print Name of Parent, Guardian or Conservator Authority

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

Authority to act for participant

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

(If available) Signature of Other Parent *(if applicable)* Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Print Name of Other Parent

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

Authority to act for participant

*The IRB determined that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404, in accordance with 45 CFR 46.408(b).*

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject’s Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_
Signature of person obtaining consent                   Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Print Name of person obtaining consent