**KESSLER FOUNDATION**

INSTITUTIONAL REVIEW BOARD

### PERMISSION TO PARTICIPATE IN A RESEARCH STUDY

*Please remember that this consent form is for the parent or guardian of a minor participating in the study and not for a research professional. Do not cut and paste from the protocol, but rather write the consent form in accessible language at the 8th grade English level.*

*Please DO NOT change the margins of this document as sufficient space is needed for applying the IRB approval stamp on each page.*

*All instructions (shown in red italicized text) should be removed before submitting this form for IRB review.*

**TITLE OF STUDY:** *Insert research study title.*

**RESEARCH STUDY #:** *Insert IRB protocol number, if already assigned.*

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, am being asked to give my permission to allow

my child named \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_to participate in a research study led by Dr(s). *Enter names of Principal Investigator(s).* Other persons who work with *him/her/them* as study staff may be asked to help *him/her/them*. I understand that taking part in this study is completely voluntary; I do not have to give my permission for my child to be part of this study and my child does not have to be part of this study unless he/she chooses to be. My child is free to leave the study at any time if he/she or I change our minds. All research studies carried out at Kessler Foundation are covered by the rules of both the Federal Government and Kessler Foundation.

The Information provided may contain words I do not understand. I will ask the study doctor or the study staff to explain any words or procedures I do not understand.

The table below contains a brief summary of key information about this research study. Additional information can be found throughout this document.

*The summary table below is intended to highlight the most important information a parent/guardian needs to know before giving permission for his/her child to participate. Investigators are strongly encouraged to limit the length of this table so that it does not go beyond page 2 of the consent form.*

|  |
| --- |
| **Study Summary** |
| Why is this research being done? | *Briefly state the purpose/objectives of the research* ***in lay language using 8th grade English. Avoid technical terms and language when at all possible.*** |
| How long does the study last? | *A brief statement of the Duration of the study should be given here.* The study will take *(include the number of visits, actual time for each visit and the total period of time the study will take in weeks/months.)* |
| What will happen during this research study? | *A brief summary of the procedures of the study should be given here. More details of the Procedures can be added in a separate section, below).*While my child is part of this study, he/she will be asked to \_\_\_\_. |
| What risks are associated with participating in this study? | *A brief statement of the major risks and discomforts to the subject while participating in the study should be given here. A more detailed description of Risks and Discomforts can be given later in this document.*  |
| What are the benefits of participating in this research study? | *Describe the benefits (if any) that a subject or others may expect from this research.*The benefits of participating in this study may be:*(Describe potential benefits, to the individual and to society in general, that might result from the research. If the individual participant will receive NO DIRECT BENEFIT, this must be stated.)*However, my child will receive no personal benefit from taking part in this study.*OR*My child will receive no direct benefit from taking part in this study, but the information obtained from this study may help the researchers to better understand \_\_\_\_\_\_.  |
| What other options are available to me if I choose not to allow my child to participate in this study?  | Participation in this study is completely voluntary. If my child and/or I choose not to participate in this study, there will be no effect on my or my child’s medical care or access to benefits to which we are otherwise entitled. |

**The following sections offer more detail about the study.**

**WHY IS THIS RESEARCH BEING DONE?**

*Briefly explain the reason why the study is being done. (What problem is it trying to solve? What new information will it provide?)*

 **WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?**

While my child is part of this study, he/she will be asked to do the following:

*Describe in lay language using 8thgrade English, step by step, what will happen to the participant. This description should include, but not be limited to, such items as:*

1. *The overall design of the study written in lay language.*
2. *Methods and probability of assignment, randomization, controls and placebos.*
3. *Brief summary of blinding procedures, if applicable.*
4. *Procedures to be performed, including frequency and follow-up. (Distinguish between assessments done before and after the intervention and the intervention itself.)*
5. *Distinction between those procedures that are experimental and those that are part of standard care.*
6. *Medications (including placebo) to be administered and the method, dose, and frequency of administration.*
7. *Number, frequency and duration of visits, or time required of participants already on site.*
8. *Specimens to be collected, including frequency and size/amount.*
9. *Specific requirements of the research participant, e.g., post-treatment follow-up, diary cards, questionnaires, etc.*
10. *If pregnancy is an exclusion criterion, ensure that pregnancy testing is mentioned in the procedures. Include the following language regarding sharing of pregnancy test results:* Female children 8 years old and older will be required to have a negative pregnancy test before they can join this study. If a girl less than 13 years of age has a positive pregnancy test, New Jersey law requires that Kessler Foundation notify the New Jersey State Central Registry. A girl 13 and over who has a positive pregnancy test will be told about the test results and will be offered counseling by trained Kessler Foundation staff. The girl will be allowed to decide if she wishes to inform her parent or guardian about the positive pregnancy test.

*If participants will be audio and/or video-recorded, please add the following statement and signature lines:* My child will be *(specify type of recording, audio and/or video)*-recorded during the study, so that the researchers may collect all the information they need correctly. I will indicate below my willingness allow my child to be recorded for purposes of this research study:

[ ] **Yes**, I agree to allow *(specify audio and/or video)* recording of my child’s study sessions.

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] **No**, I do not agree to allow *(specify, as above)* recording of my child’s study sessions.

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**HOW MANY CHILDREN WILL PARTICIPATE IN THIS STUDY?**

*State the total number of participants to be enrolled in the study, the number for each site if a multicenter study, and the number in each arm of the study. State any specific requirements of the participant for inclusion in the study (e.g., age, sex).*

Up to \_\_\_\_\_ children will take part in this study.

**WHO QUALIFIES TO PARTICIPATE IN THIS STUDY?**

*Provide a summary, in lay language, of the criteria for enrollment in this study.* ***Please do not list the same items under both inclusion and exclusion. For example: Inclusion – between 13 and 17 years old – Exclusion – younger than 13 and older than 17.***

*State if any criteria will be determined at screening and describe these criteria in terms that a lay person can understand. For example, do not include details of blood levels of chemicals or numerical scores on tests.*

**WHAT MIGHT MAKE MY CHILD INELIGIBLE FOR THIS STUDY?**

If any of the items listed below are true for my child, I will tell the researcher. To ensure my child’s privacy, I do not have to say which item or items apply to my child. If I choose to tell the investigator which items are true for my child, the information will not be shared with anyone, unless required by law.

*List study exclusion criteria in* ***lay*** *language.*

*If pregnancy is an exclusion, the following statement should be included:* Because of potential risk to a fetus, female children age 8 and over will be required to have a pregnancy test before they can enroll in this study. If my child is female, and has a positive pregnancy test, she will not be enrolled.

**PARTICIPATION IN GENETIC STUDIES: *(remove If not applicable)***

The genetic studies described are for research purposes only. Therefore, you will receive no results from this study (except as described below).  It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. The research tests are not being used as diagnostic tests for any disease or illness. Your participation in this study is not a substitute for your regular medical care or check-ups.

**CONFIDENTIALITY OF GENETIC INFORMATION: *(remove If not applicable)***

A new 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 anyone based on his/her genetic information. This law generally will protect me in the following ways:

        Health insurance companies and group health plans may not request my genetic information that we get from this research.

        Health insurance companies and group health plans may not use my genetic information when making decisions regarding my eligibility or premiums.

        Employers with 15 or more employees may not use my genetic information that we get from this research when making a decision to hire, promote, or fire me or when setting the terms of my employment.

        All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

        Be aware that this new Federal law does not protect me against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**WHAT RISKS ARE ASSOCIATED WITH PARTICIPATING IN THIS STUDY?**

The study described above may involve the following risks and/or discomforts:

*For each procedure/intervention, describe the potential, immediate and long-term discomforts, hazards, and risks - include physical, psychological, social, and reproductive risks. If the incidence or duration of these risks or discomforts is known, it should be stated.*

*(If applicable)* If my child becomes pregnant during the course of the study, I will notify the principal investigator of this fact as soon as possible since the risks to the fetus or my child are unknown.

There also may be risks and discomforts that cannot be foreseen.

**WHAT WILL HAPPEN IF THE RESEARCHERS LEARN NEW INFORMATION ABOUT THE STUDY?**

During the course of the study, I will be told about any new findings that might affect my willingness to have my child remain in the study.

**WHAT WILL BE DONE TO PROTECT INFORMATION ABOUT MY CHILD?**

Every effort will be made to maintain the privacy of my child’s study records.

***Protected Health Information*** *(If the study does not involve the use or creation of PHI, delete this heading.)*

*If the study does not involve the use or creation of PHI, delete this paragraph:* The researchers would like to use information about my child’s health as well as information that identifies my child. This information is referred to as “Protected Health Information” and is given special protections under The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996. The researchers must obtain my permission to use my child’s Protected Health Information.

If my child participates in this research study, information that will be used and/or released may include the following:

*State what protected health and/or research information will be used/disclosed for the study using lay terminology. You must include all protected health and/or research information to be used for the research study. Examples include (remove or revise as needed to correctly reflect the data used or collected in the study):*

* Information from my child’s medical records, such as my child’s diagnoses, medications or other treatments he/she is receiving, laboratory test results, images (such as x-rays or other scans), reported symptoms, ability to function, and other observations made by health professionals as part of my child’s medical care.
* Questionnaires about how my child is feeling physically or emotionally
* Results of tests of my child’s physical or mental function
* Results of laboratory tests or physical examinations given for purposes of the research study
* What study medications my child has been prescribed, my child’s use of the prescribed medication, and whether my child is experiencing any problems that could be related to the study medication
* Other observations made by researchers during the course of the research study

Protected Health Information such as my child’s name, address, date of birth, etc., that is stored electronically is kept in the REDCap system that includes all the protections of my child’s health information required by HIPAA, including requiring users of my child’s information to be pre-approved by the study director and a mechanism that will remove any information that identifies my child in research data that is shared with other institutions.  (My name, address, telephone number, and other forms of contact information will also be stored to enable the researchers to contact me as needed for purposes of the study.) Access to study data will be limited to the members of the study team and will require study team members to submit 2 different access codes to use this data. REDCap/SIMS also tracks access to, and changes made to any study records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that do not hide information that can identify me or my child. Hard copy documents that contain my and my child’s name, phone number, address, date of birth, etc., are kept in locked cabinets that only members of the research team can access.

*If no PHI is being used or created, replace the paragraph above with this version:* Information such as my child’s name, address, date of birth, etc., that is stored electronically is kept in the REDCap system that includes all the protections of my health information required by HIPAA, including requiring users of my child’s information to be pre-approved by the study director and a mechanism that will remove any information that identifies my child in research data that is shared with other institutions. (My name, address, telephone number, and other forms of contact information will also be stored to enable the researchers to contact me as needed for purposes of the study.) Access to study data will be limited to the members of the study team and will require study team members to submit 2 different access codes to use this data. REDCap/SIMS also tracks access to, and changes made to any study records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that do not hide information that can identify me or my child.  Hard copy documents that contain my or my child’s name, phone number, address, date of birth, etc., are kept in locked cabinets that only members of the research team can access.

***Sharing Protected Health Information*** *(If the research study does not involve use or creation of PHI, change this heading to “Sharing Research Information”)*

My child’s health *(replace “health” with “research” if no PHI is being used or created)* information may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research. The researchers may share this information with other people or organizations who are in charge of the research, others who are helping the research study to be done, those who pay for the research, or those who make sure that the research is done properly.

The study team may share a copy of this approval form and records that identify my child with the following people or organizations:

* The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
* Auditors from Kessler Foundation, the sponsor (list name) or government agencies responsible for the conduct of research to make sure the researchers are following regulations, policies, and study plans.
* Members of the study team, including *(insert study team member names)*
* *(If applicable)* The Finance Dept. of the Kessler Foundation, who will prepare subject payments for participation in the study
* Other organizations: *List all study-specific agencies, divisions, companies, labs, etc. who may see research data or PHI-if none, state 'NONE' or select/remove from following:*

FDA (United States Food and Drug Administration) - the government agency that reviews all research information for approval of new drugs and treatments for the public. *(REMOVE if not applicable)*

DHHS (Department of Health and Human Services) - the government agency that oversees and funds research involving human beings. *(REMOVE if not applicable)*

My child and I have the right to look at my child’s study information at the study doctor's office and to ask (in writing) for corrections of any of my child’s information that is wrong.

*Language for blinded study-REMOVE if not applicable:* Because this is a blinded study (neither I nor my doctor will know if my child is receiving study drug or placebo, a sugar pill), I may not see my child’s study information or request corrections to my child’s study information until the study is completed.

If the findings from the study are published, my child will not be identified by name. My child’s identity will remain private unless its release is required by law.

***Removing Approval***

I can change my mind at any time and remove my permission to allow my child’s information to be used in the research. If this happens, I must remove my permission in writing. Beginning on the date I remove my permission, no new information will be used for research. However, researchers may continue to use the information that was provided before I withdrew my permission.

If after signing this form, I want to remove my permission, I can contact the person(s) below. He/she will make sure the written request to remove my permission is processed correctly.

*(Insert Contact Person Name, their Title, Address, Phone and Fax numbers-include ONLY names associated with the study team)*

***Approval Expiration***

This approval has *(state duration it will be kept, should match what is stated elsewhere - if there is no expiration or indefinite, state "no expiration date").* However, as stated above, I can change my mind and remove my permission at any time.

Questions should be directed to the research staff person who is reviewing this form with me. I can also call the Kessler Foundation Privacy Board – *John DeLuca, Ph.D., ABPP at (973) 324-3572.*

**WHERE ELSE CAN I FIND INFORMATION ABOUT THIS STUDY?**

*The following section should be included in the consent form if this is a clinical trial. IRB Policy 5036 requires that all IRB approved trials be registered on the web site <ClinicalTrials.gov>. The definition of a clinical trial is any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome. Medical intervention, as used here, means any intervention used to modify a health outcome.*

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/). This web site will not include information that can identify my child. At most, the Web site will include a summary of the results. I can search this Web site at any time.

**WILL IT COST ANYTHING TO PARTICIPATE IN THIS STUDY?**

Taking part in this study may incur the following (increased/decreased) costs to me on behalf of my child. Some of these costs may be covered by my child’s health insurance provider.

*Indicate who is to bear the expense of tests, procedures, hospitalization, etc., done solely for research purposes. If participation increases/decreases the cost to the subject, so state.*

*OR*

There will be no cost to me or my child for taking part in this study.

**WILL THERE BE PAYMENT FOR PARTICIPATING IN THIS STUDY?**

*Include this statement if subjects are to be paid or reimbursed for participation. Specify the dollar amount and the payment schedule or other forms of reimbursement. Address the matter of prorating payments if the participant withdraws or if the investigator terminates the study.*

I will receive $\_\_\_\_\_\_\_\_\_\_\_ for my child’s participation in this study according to the following schedule:

**WHAT WILL HAPPEN IF MY CHILD IS INJURED IN THIS STUDY?**

*(Choose the appropriate paragraph below)*

*FOR RESEARCH INVOLVING NO GREATER RISK OF PHYSICAL INJURY THAN THAT ENCOUNTERED IN EVERYDAY LIFE:*

Medical treatment will be arranged for my child by the Principal Investigator for any physical injuries suffered as a direct result of my child taking part in this study. My child’s insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. All claims for out of pocket medical expenses for my child’s medical treatment should be made to the Principal Investigator. I understand there will be no cost to my child for the treatment. No financial payment will be provided to me or my child other than my out of pocket medical expenses for physical injuries that happened as a direct result of my child’s taking part in this study.

*FOR RESEARCH ON VOLUNTEERS INVOLVING MORE THAN MINIMAL RISK (for unsponsored research and sponsored research where the sponsor does not agree to reimburse subjects’ out of pocket medical expenses for care for study-related physical injuries ):*

If my child takes part in this study, my child will be exposed to certain risks of physical injury. Medical treatment will be arranged for my child by the Principal Investigator for any physical injury that occurs as a direct result of my child’s taking part in this study. My child’s health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. I understand that I will be responsible for any part of the treatment cost not paid by my child’s insurance or managed care provider. No financial payment is offered to me or my child in the event of physical injuries that happened as a direct result of my child’s taking part in this study.

*FOR RESEARCH ON VOLUNTEERS INVOLVING MORE THAN MINIMAL RISK (for industry-sponsored research where the sponsor agrees to reimburse subjects’ out of pocket medical expenses for care for study-related injuries):*

If my child takes part in this study, my child will be exposed to certain risks of physical injury. Medical treatment will be arranged for my child by the Principal Investigator for any physical injury that occurs as a direct result of my child taking part in this study. My child’s health insurance carrier, managed care provider or other third party payer will be billed for the cost of this medical treatment. (*Name of sponsoring company*) will provide payment for the reasonable costs of medical treatment for the amount that my child’s health insurance, managed care provider or other third party payer does not cover. All claims for costs resulting from medical treatment and not paid by my child’s insurance should be given to the Principal Investigator, who will send the claims to (*Name of sponsoring company*) for payment made directly to me. No financial payment will be provided to me or my child other than my out of pocket medical expenses for physical injuries that happened as a direct result of my child’s taking part in this study.

**CAN I CHANGE MY MIND ABOUT ALLOWING MY CHILD TO PARTICIPATE IN THIS STUDY?**

I understand that giving my permission to allow my child to participate in this research study is my choice, and I may refuse to give my permission for my child to participate, or may stop my child’s taking part in the study at any time, without penalty or loss of benefits to which I, or my child, am/is otherwise entitled. I understand that my child may refuse to take part in this study, or may withdraw from the study even if I give my permission for him/her to participate. I also understand that the investigator has the right to withdraw my child from the study at any time.

*Describe the medical consequences [if any] of the participant’s decision to withdraw his/her child from the research. Indicate the procedures for an orderly termination of participation.*

**WHO CAN I CONTACT FOR MORE INFORMATION?**

If I or my child have any questions about my child’s treatment or the research procedures, we can contact:

*List the name, phone number, and office address of the investigator or other responsible individual who can be contacted by the participant in the research activity.*

*The principal investigator may include this paragraph if he/she believes it is applicable to this study:* If I or my child have medical questions pertaining to this study, there is an on-call resident physician available at the Kessler Institute of Rehabilitation, who can be reached at 973-731-3600. I am aware that this on-call resident physician is not part of the study team and will not be familiar with the study but will be able to direct study-related medical questions to the appropriate member of the study team.

If I have concerns only regarding my child’s **rights as someone taking part in a research study**, I may contact Donna Servidio, IRB Manager, at 1-800-648-0296, extension 6972.

I will receive a copy of this consent form if I agree to give permission for my child to take part in this research study.

**WILL INFORMATION ABOUT MY CHILD BE USED FOR OTHER RESEARCH STUDIES IN THE FUTURE?**

*Federal regulations require that consent/permission documents address the use or non-use of data or biospecimens in future research studies. Select the option below that is most appropriate for your study.*

*Option 1 – No Future Use: If data or biospecimens collected in this study will not, under any circumstances, be used for purposes of any future research studies, include the following statement:* Information and *(if samples are used, specify type - blood, urine, etc, otherwise remove “and samples”)* samples collected in this study will be used for the purposes of this research study only. They will not be made available to researchers for use in future research studies. *Note: Many funding agencies now require researchers to make data available for future use by the research community. If that is the case for the sponsor of your study, do not choose Option 1.*

*Option 2 – Projects Involving Data Repositories: In some cases, the study for which the parent/guardian is providing permission involves future use of data as an integral part of the study itself (examples include the Spinal Cord Injury and Traumatic Brain Injury Model Systems or other projects involving collection of data specifically for purposes of future use). In such cases, delete the section of this template labeled “USE OF INFORMATION COLLECTED IN THIS STUDY FOR FUTURE RESEARCH” and address use of data elsewhere in consent form (in discussion of procedures, confidentiality, or other appropriate sections). Include a description of how data may be used in the future, whether it will be used in identifiable form, and whether and how parents/guardians will be given the option to provide permission for the use of that information.*

*Option 3 – Other Projects in Which Future Use Is Possible: Include the following section:* The information and *(specify type - blood, urine, etc – as applicable)* samples collected in this research study may be useful in future research studies.

In some future studies, the researchers may want to use my child’s information and samples *(delete all references to samples from here forward if not applicable)* in a way that identifies my child. This means that the researchers would have access to my child’s name, contact information, medical record number, or other identifying information, and would know that he/she is the person who provided the information or samples. If, in the future, researchers wish to use information or samples that can identify my child, they will be required to obtain my specific permission, in writing, for the use of my child’s information or samples. (If my child is old enough at the time of the future study, he/she will be approached to provide permission.)

In other cases, researchers may want to use my child’s information or samples in a way that does NOT identify my child. In this situation, the researchers do not have access to my child’s name (or other identifying information) and would not know that my child is person who provided the information or samples. In this section, I am being asked whether it is acceptable to me for researchers to use information or samples that do not identify my child without asking for my specific permission at the time of the future research study.

[ ] **Yes**, I agree to allow information or samples collected in this study that do not identify my child to be used in future research without my specific permission.

Parent/Guardian Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] **No**, I do not agree to allow information or samples collected in this study that do not identify my child to be used in future research without my specific permission.

Parent/Guardian Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Option 4: If the options above do not fit the ways in which data may or may not be used in your study, you may compose new content for this section that addresses:* *(1) whether data may be used in the future (2) whether it may be used in identifiable form and (3) whether and how parents/guardians will be given the option to provide authorization for the use of that information.*

***IF PARTICIPANT IS 12 YEARS OLD OR YOUNGER: Please obtain the Assent form template from the IRB WEBSITE (remove if not applicable)***

**SIGNATURE OF PARTICIPANT IF 13 - 17 YEARS OLD *(remove if not applicable)***

I have read this entire form, or it has been read to me, and I have had all of my questions answered. I agree to take part in this study. I understand that because I am a minor, my parent/legal guardian must also agree to my taking part in this study. I also understand I will not be signed up for this study without my signature on this form. I may stop taking part in this study at any time, with or without my parent's/guardian's permission, by telling the investigator.

Minor’s Name: Signature:

Date:

**SIGNATURE OF PARENT OR LEGAL GUARDIAN**

I am the [ ]  sole parent or [ ]  one of two parents *(check one)* of this participant, *(name).*  I have read this entire form, or it has been read to me, and I have had all of my questions answered to my satisfaction. I have the authority to permit my child to participate in a research study. I hereby give my permission to allow my child to participate in this research study.

Parent #1 Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent #1 Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent #2 Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Leave all Parent #2 lines blank if sole parent is providing permission)

Parent #2 Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Complete date but leave signature line blank if Parent #2 provided permission by alternative means\*)

\*Parent #2 Provided Permission by Alternative Means:

❒ Electronically ❒ by Phone with Witness Present

I am the [ ]sole legal guardian or [ ] one of two legal guardians (*check one*) of this participant, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(*name*). I have read this entire form, or it has been read to me, and I have had all my questions answered to my satisfaction. I have the authority to permit my child to participate in a research study. I hereby give my permission to allow my child to participate in this research study.

Guardian #1 Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Guardian #1 Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Guardian #2 Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Leave all Guardian #2 lines blank if sole parent is providing permission)

Parent #2 Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Complete date but leave signature line blank if Guardian #2 provided permission by alternative means\*)

\* Guardian #2 Provided Permission by Alternative Means:

❒ Electronically ❒ by Phone with Witness Present

:

*Note: If there are 2 parents or 2 guardians, both signatures are required for most research studies of greater than minimal risk. For those studies of greater than minimal risk where the subject may benefit directly from participating in the study, the IRB may vote to allow only one parental signature.*

*For studies requiring 2 signatures, the second signature may be submitted electronically or by phone if witnessed by a member of the study staff.*

**SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL**

To the best of my knowledge, the participant, , (or his /her parent/legal guardian) has understood the entire content of the above consent form, and comprehends the study and its risks as well. The participant’s questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name: Signature:

Date:

**VERBAL CONSENT IF THE PARTICIPANT’S PARENT OR GUARDIAN LACKS UPPER LIMB FUNCTION TO COMFORTABLY WRITE *(remove If not applicable)***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is unable to sign the consent form due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. He/She has also given me permission to initial each page of the consent form with his/her initials as we review it. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.

Person Obtaining Consent:

Name: Signature:

Date:

Witness Name: Signature:

Date:

**SIGNATURE OF READER/TRANSLATOR IF THE PARTICIPANT DOES NOT READ ENGLISH WELL *(remove if not applicable)***

The person who has signed above, , does not read English well. I read English well and am fluent in *(name of the language)* , a language this person (his/her parent/legal guardian) understands well. I have translated for him/her (his/her parent/legal guardian) the entire content of this form. To the best of my knowledge, he/she (his/her parent/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and that these questions have been answered.

Reader/

Translator Name: Signature:

Date:

## SIGNATURE OF WITNESS

I was present when the researcher(s) described the study to the participant (or his/her parent(s) or legal guardian(s)) and I am a witness to the fact that the participant (or his/her parent(s) or legal guardian(s)) provided permission for his/her child to participate.

Witness Name: \_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date: