|  |
| --- |
| **Instructions:**   1. This consent template **does not** include detailed instructions. Refer to the Consent Form Standards document for detailed instructions about completing each section of this consent template. 2. The areas highlighted in yellow are the areas of the template that need to be completed and/or edited to meet the specific needs of the study. 3. Remove the yellow highlighting and brackets before submission to the IRB. 4. Remove this instructions box before submission to the IRB.   **Last Revision Date: 09-22-2020** |

**CHILDREN’S HOSPITAL LOS ANGELES**

**INFORMED CONSENT/PARENTAL PERMISSION/ASSENT TO PARTICIPATE IN A RESEARCH STUDY**

[Insert title of study]

[If study title is technical, insert lay language title]

[If the study involves using different consent forms for different populations or study groups, identify as a subtitle]

|  |  |  |  |
| --- | --- | --- | --- |
| **Subject’s Name:** |  | **Birth Date:** |  |
| **CHLA MRN#** [remove if N/A] |  |  |  |

A person who takes part in a research study is called a research subject or research participant. If you are reading this consent form as a [parent/legal guardian and/or legally authorized representative, as applicable] “you” also refers to [“your child” (the research participant) and/or the research participant, as applicable].

**KEY INFORMATION**

[The CHLA IRB requires a key information summary section for all consent forms that are longer than 4 pages. **Do not include a Key Information section if the content of this consent document (not including the signature section) is 4 pages or less in length.** This section must come first and should include a concise summary of information that is relevant to why someone might or might not want to take part in the research. The entirety of this section should be no more than one full page in length. A sample key information summary is provided below.]

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.

**What should I know about this research?**

* Taking part in this research is voluntary. Whether you take part is up to you.
* If you don’t want to take part, it won’t be held against you.
* You can take part now and later drop out, and it won’t be held against you.
* If you don’t understand, ask the research team questions.
* Ask all the questions you want before you decide.

**How long will I be in this research?**

Participation will last up to \_\_\_\_. [indicate maximum time of participation, if a subject completes all procedures]

**Why is this research being done?**

This research is being done to find out \_\_\_\_. [keep to a single sentence, such as “… the best way to treat people with Cystic Fibrosis.” or “…how teens think about drug use in their social group.”]

**What happens to me if I agree to take part in this research?**

Study procedures for this research are: [Briefly in simple terms list the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part in the research study. A bulleted list is acceptable.] Examples:

* Take a study drug every week by injection under your skin.
* CT scan(s). If you are not able to lie still during the scan, you will get some medicine to help you sleep.
* Complete questionnaires about your view on drug use in teens and young adults.
* Have blood drawn by inserting a needle into a vein or by using your port.
* Complete a diary every day to record your medication use and any side effects that you experience.
* Let the research team record information from your medical record related to your condition and the treatment you receive.

**Could being in the research hurt me?**

The most important risks or discomforts that you may expect from taking part in the research are: [Briefly list up to 5 main study risks in lay terms most likely to affect someone’s decision about whether to take part in the research study – pick only the most common risks. A bulleted list is acceptable.] Examples:

* Trouble breathing
* Feeling uncomfortable answering personal questions about yourself
* Chemo side effects, such as feeling tired, losing hair, and nausea.
* Allergic reactions
* Irregular heart beat

Please see the POSSIBLE RISKS AND DISCOMFORTS section below for a complete list of expected risks.

**Will being in this research benefit me?**

The most important benefits that you may expect from taking part in this research are: [Briefly list the reasonably expected benefits to the subject most likely to affect someone’s decision about whether to take part in the research study. Keep it to one sentence. If there are no benefits, state: It is not expected that you will personally benefit from this research.]

**What other choices do I have besides taking part in this research?**

Instead of being in this study, your choices may include: [List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, you can eliminate this section from the summary, and include it only in the body of the consent. If there are no alternatives, this section can be omitted. Briefly list the alternatives: 2 maximum.] Examples:

* Get routine care or treatment for your condition.
* Join another clinical research study.

**What else should I know about this research?**

Other information that may be important for you to consider so you can decide whether to take part in this research is: [Describe any additional information that may be important to know for this study, such as study requirements that may burden subjects, e.g., an extensive study visit schedule, time away from work, overnight stays, etc. If this does not apply, this section can be omitted.]

**INTRODUCTION**

You are invited to join a research study led by [insert name and degrees of Principal Investigator] from the [insert department/division affiliation] at Children’s Hospital Los Angeles (CHLA) [insert other institutions as appropriate]. This research is paid for by [Insert name of sponsor and other study support. Delete this sentence if the study is not funded].

You are invited to join this study because [explain succinctly and simply why the prospective subject is eligible to participate, e.g., “you have spina bifida.” or “you have Type1 diabetes that has not responded well to standard treatments.”] Participation in this study is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

**PURPOSE OF THE STUDY**

The purpose of this research is to [explain in simple terms the main purposes of the research. You can use simple illustrations, diagrams or figures if they are helpful in the explanation. Refer to the Consent Form Standards document for detailed instructions and examples for completion of this section.]

**NUMBER OF PARTICIPANTS**

XX people will be asked to take part in this study at CHLA. [Remove the following statement if single-site study only:] YY people will be asked to participate nationwide.

**LENGTH OF PARTICIPATION**

[Describe the time commitment of subject participation. If there is more than one group and the duration of participation varies between groups, describe the length of participation for each group.]

**PROCEDURES**

If you volunteer to be in this study, we will ask you to do the following things:

[Describe all procedures included in the research, including number and duration of visits. Include frequency tables, if appropriate. Refer to the Consent Form Standards document for detailed instructions and examples for completion of this section.]

**POSSIBLE RISKS AND DISCOMFORTS**

[Describe all reasonably foreseeable risks and discomforts, and their likelihood of occurrence when appropriate. Refer to the Consent Form Standards document for detailed instructions and examples for completion of this section.]

[Add for all studies, except those with a completely anonymous data collection method involving no identifiers and no links:]

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see the CONFIDENTIALITY section below for details).

**POSSIBLE BENEFITS TO SUBJECTS**

[Describe any expected direct benefits to the subjects resulting from participation in the study. Do not overstate the benefits. If there are none, state this. Payments and/or the provision of free drugs or medical procedures are **not** considered benefits. Refer to the Consent Form Standards document for detailed instructions and examples for completion of this section.]

**POSSIBLE BENEFITS TO SOCIETY**

[Describe the anticipated benefits to science or society expected from the research.]

This study will help the researchers learn more about [procedure/drug/ intervention/ device]. Hopefully this information will help in the treatment of future patients with [disease/condition].

**YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY**

[Describe the alternatives to participation in the study. For studies that do not involve medical interventions and/or do not offer a potential direct benefit to subjects, it is acceptable to say that the alternative is not to participate in the study.]

**COSTS** **TO YOU FOR BEING IN THIS STUDY**

[Describe any additional costs that the subject could incur as a result of participation, such as parking fees or transportation that will not be reimbursed. If there are no additional costs for participation, state this in the consent form. Use the following language as it applies to the research:]

Taking part in this research study might lead to added costs to you or your insurance company.

(Insert name of investigational drug/device) will be provided to you at no cost while you take part in the study. [The next sentences should be included as applicable:] You and your health plan/insurance company will need to cover the cost of the infusion/injection of the study drug. It is possible that the (insert name of investigational drug) may not continue to be supplied while you are on the study. If this occurs, the research doctor will talk to you about your options.

Most of the tests, procedures, and/or drugs provided to you as part of this study are routinely used to treat your illness/condition. You would receive these tests, procedures, and/or drugs even if you were not participating in this study. You or your health plan/insurance company will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your health plan/insurance company. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs because you are in a research study. If your health plan/insurance company will not pay these costs, you will have additional expenses from being in this study, such as the costs associated with treating side effects.

If you have questions about your insurance coverage, or the items you might be required to pay for, please discuss them with the study team.

[Include for cancer clinical trials:] The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team: www.cancer.gov or 1-800-4-CANCER (1-800-422-6237).

**REIMBURSEMENT FOR YOUR EXPENSES** [This section should be removed if subjects will not be reimbursed for additional costs incurred as a result of participation, or there are no additional costs.]

You will be reimbursed for the following expenses [Complete this sentence, e.g., parking and transportation for study visits.] [Add if applicable:] In order to be reimbursed, please be sure and save your receipts so that you can provide these to the research staff. Reimbursement will be provided through the use of [name payment mechanism, e.g., prepaid debit card, ClinCard].

**PAYMENT FOR PARTICIPATION** [Include this section if subjects will be paid to participate. If subjects will not be paid, either delete this section, or include the following statement: You will not be paid for taking part in this research.]

For taking part in this research you will paid up to a total of $ [insert dollar amount]. You will be paid as follows:

* Describe the payment schedule in terms of amount.
* Describe when and how payments will be made.
* Describe the amount of payment if the subject leaves the study early.

**RESEARCH INJURY** [This section is not required for minimal risk research and may be removed.]

[Use this language for non-industry sponsored or unfunded studies:] If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The research doctor’s name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer.

[Use this language for industry sponsored studies:] If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The research doctor’s name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. [Insert name of sponsor/funding source] will pay your costs for reasonable and necessary care if you have been injured because of taking part in this research study. [Include the next sentences, if applicable:] If you receive Medicare/Medicaid and [insert name of sponsor/funding source] pays for medical treatment for injury relating to your participation in this research, [insert name of sponsor/funding source] will need to collect certain personal information about you, such as your name, date of birth, gender, social security number or Medicare/Medicaid identification number and information related to this research study. By signing this informed consent form, you are giving permission to [insert name of sponsor/funding source] to collect your personal and treatment related information and report it to the Centers for Medicare & Medicaid Services (CMS), while participating in the study and for as long as [insert name of sponsor/funding source] is required by the government to report this information. The sponsor will not use this information for any other purpose.

[Include the following sentence with one of the paragraphs above:]

CHLA [and name of sponsor/funding source, as applicable] has/have no plans to pay you or give you other compensation for injury. You do not give up any rights to pursue a claim through the legal system by signing this form.

**CONFIDENTIALITY**

[Briefly describe how research data/specimens and personal information will be secured to prevent access by unauthorized individuals. Most studies collect data/specimens that are labeled with a unique code. Refer to the Consent Form Standards document for detailed instructions and examples for completion of this section, including sample Certificate of Confidentiality language.]

Add if data/specimens labeled are with a unique code:

The data and specimens [adjust for the study, specify type(s) of specimens, if applicable: blood, urine, tissue, etc.] collected as part of this study will be “coded.” Coded means that the data and specimens [adjust for the study] collected for this study will be assigned a unique code or Study ID. Your research data and specimens [adjust for the study] will not include your name or any other identifying information about you. The code that could be linked back to your identifying information will be kept separate from your research data and specimens. [adjust for the study]

Add if data/specimens are de-identified:

The data and specimens [adjust for the study, specify type(s) of specimens, if applicable: blood, urine, tissue, etc.] collected as part of this study will be “de-identified” or “anonymized.” This means that there will be no way to link the data and specimens [adjust for the study] back to you.

People on the research team [add if treatment study or involves medical procedures: and your doctors and nurses] will know that you are in this research study. All results will be kept confidential. [Add if data/specimens from the study will be sent outside of CHLA:] The data and specimens [adjust for the study] collected as part of this study will be sent to [specify locations].

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. Your private information, data and medical records will be shared with individuals and organizations that oversee this research, including:

* The research sponsor, [insert name of company or delete if no sponsor].
* People who work with the research sponsor [delete if no sponsor].
* Government agencies, such as the Food and Drug Administration (FDA) [if FDA regulated], and the Department of Health and Human Services [if the study is funded by the NIH or other DHHS agency].
* The CHLA Institutional Review Board (IRB) that reviewed this research, and authorized representatives of CHLA.

Add for studies that include treatment or medical procedures:

Because this study involves medical procedures and/or the treatment of a medical condition [adjust for the study], a copy of this consent form will be placed in your medical record. This will allow the doctors that are caring for you to obtain information about any medications and/or procedures [adjust for the study]you are receiving in the study and treat you appropriately.

Add for studies that do not have a Certificate of Confidentiality:

We will take steps to keep your personal information private, but we cannot guarantee complete secrecy. All identifiable information about you will be replaced with a unique code or study ID. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored electronically on a secure network with encryption and password protection to help prevent unauthorized access to your personal information.

We will not release information about you to others not listed above, unless required or permitted by law. For instance:

* if we learn of child or elder abuse, harm to self or others, or
* if you have certain infectious diseases; or
* you are injured and need emergency care.

The results of the research may be presented or published. We will keep your name and other identifying information confidential.

**FUTURE RESEARCH USE OF DATA AND/OR SPECIMENS** [Remove this section if the research does not involve the collection of identifiable (or coded) data/specimens.]

[No Use of Data and Specimens for Future Research: Add if the data/specimens will only be used for the purposes of the study and will NOT be used for future research:] The data and specimens [adjust for the study] collected as part of this study will not be used for future research, even if all identifiers are removed.

[Use of Data and Specimens for Future Research: Add if the data/specimens will be de-identified after the study is completed and then used for future research:] Once this research study is completed, the data and specimens [adjust for the study] collected as part of this study will be “de-identified” or “anonymized.” This means that there will be no way to link the data and specimens [adjust for the study] back to you. Once your data and specimens [adjust for the study] have been de-identified, they may be used by the researcher conducting this study, the study sponsor, or other researchers (at CHLA or elsewhere) for future research projects that are unrelated to the purpose of this study. This future research may be done without consulting you or obtaining consent (permission) for this additional use. Future research [might/will not] include whole genome sequencing.

[Use of Data and Specimens for Commercial Profit: Add if de-identified specimens may be used for commercial research:] Your de-identified specimens may be used for commercial profit. There are no plans for you to share in any profit generated as a result of the use of your data and specimens. [Or explain plans for sharing commercial profit.]

[Use of Data and Specimens for Future Research: Add if coded data/specimens will be used for future research (i.e., a code key will be retained:] Your data and specimens [adjust for the study] collected as part of this study may be used by the researcher conducting this study, the study sponsor or other researchers (at CHLA or elsewhere) for future research projects that are unrelated to the purpose of this study. The data and specimens [adjust for the study] will be labeled with a unique code or Study ID. The link connecting your identity to your study ID will be kept by the research team at CHLA. This future research may be done without consulting you or obtaining consent (permission) for this additional use. Future research [might/will not] include whole genome sequencing.

[Use of Data and Specimens for Commercial Profit: Add if coded specimens may be used for commercial research:] Your coded specimens may be used for commercial profit. There are no plans for you to share in any profit generated as a result of the use of your data and specimens. [Or explain plans for sharing commercial profit.]

**STUDY WITHDRAWAL**

[Describe the circumstances under which subject participation may be terminated without the subject’s agreement, if applicable.]

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers, the FDA, or the study sponsor [adjust for the study] might also decide to stop the study at any time.

[Add if there are any procedures for safe and orderly withdrawal from the study if the subject withdraws or is removed from the study:] If you decide to stop being in the study, or are removed from the study, or the study is stopped, the researcher will ask you to [complete this sentence. For example, return for a final close-out visit or evaluation, return unused study medication, complete an exit telephone interview.]

[Add one of the following statements, as applicable:]

[Add the following language if FDA-regulated clinical trial and/or the data/specimens already collected will still be used for the research in the event that the subject withdraws or is withdrawn from the study:] If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data/specimens collected about/from you up to that point will remain part of the study and may not be removed from the study database.

Add the following language if the data/specimens will be destroyed if the subject withdraws or is withdrawn from the study:] If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data/specimens collected about/from you will be destroyed.

**QUESTIONS ABOUT THE STUDY**

[Choose one:]

[Research that is minimal risk]

If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team:

[Research involving more than minimal risk]

If you have questions, concerns, or complaints about the study, or think this research has hurt you or made you sick, talk to the CHLA research team:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the CHLA Principal Investigator, [Insert Principal Investigator’s name], at [Insert phone number].

[Add a 24-hour contact number for more than minimal risk research:] Evenings, nights, weekends or holidays you may call the hospital number, (323) 660-2450 and ask for the [Insert name of Division or Clinical Service] Service doctor on-call.

[If this is an applicable clinical trial the following statements should be added:] *ClinicalTrials.gov* is a Web site that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Use this language verbatim:]

This research is being overseen by the CHLA Institutional Review Board (“IRB”). An IRB is a group of people who perform ethical review of research studies. You may talk to them at (323) 361-2265, or [hspp@chla.usc.edu](mailto:hspp@chla.usc.edu) if:

* You have questions, concerns, or complaints that are not being answered by the research team.
* You are not getting answers from the research team.
* You cannot reach the research team.
* You want to talk to someone else about the research.
* You have questions about your rights as a research subject.

**FINANCIAL INTEREST OF THE INVESTIGATOR** [Add the disclosure statement required by the Conflict of Interest in Research Committee here or remove this section if there are no conflicts of interest.]

**RIGHTS OF RESEARCH SUBJECTS**

You can agree to take part in this study and stop your participation in the study anytime. You should not sign this form if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know. [Add the following sentence if medical research:] You are not under any obligation to participate in a research study conducted by your doctor.

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked to sign a new consent form.

* You have a right to have all of your questions answered before deciding whether to take part.
* Your decision will not affect the medical care you receive from CHLA.
* If you decide not to take part, you can still receive medical care from CHLA.
* You will be given a copy of this signed and dated consent form [and the “Experimental Subject’s Bill of Rights”] to keep.
* [You will be asked to sign a separate CHLA HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information.]

[Add if there are optional procedures included in the research:]

**OPTIONAL PROCEDURES**

May the researchers [describe optional procedure in simple language]? Please provide your initials beside your decision.

\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_No [Subject] [Add if minors 14 years and older are included]

\_\_\_\_\_\_\_Yes \_\_\_\_\_\_\_No [Parent/Legal Guardian/Legally Authorized Representative (for children or adults unable to consent)]

[Add the following signature section for documentation of consent from adults who are capable of providing consent, and/or documentation of assent from children ages 14 to 17 years old:]  
**SIGNATURE OF RESEARCH SUBJECT**

(*For adults who are capable of providing consent; children ages 14 to 17 years old who are capable of providing assent*)

Your signature below indicates:

* You have read this document and understand its meaning;
* You have had a chance to ask questions and have had these questions answered to your satisfaction;
* You consent/assent to your participation in this research study; and
* You will be given a signed copy of this form.

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

Print Name of Subject

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

Signature of Subject Date

[Add the following signature section for documentation of parental permission from the parent(s) or legal guardian(s) of children:]

**SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S)**

(*For all subjects under the age of 18*)

Your signature(s) below indicates:

* You have read this document and understand its meaning;
* You have had a chance to ask questions and have had these questions answered to your satisfaction;
* You agree to your child’s participation in this research study;
* [Include the following statement if the parent completes any questionnaires or participates in other research activities related to the child:] You agree to your own participation in this research study; and
* You will be given a signed copy of this form.

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

Print Name(s) of Parent(s)/Legal Guardian(s)

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

Signature of Parent/Legal Guardian Date

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

Signature of Parent/Legal Guardian Date

[Add the following signature section for documentation of consent from a legally authorized representative for adults lacking the capacity to consent:]

**SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE**

(*For adult subjects who are not capable of providing consent*)

Your signature below indicates:

* You have read this document and understand its meaning;
* You have had a chance to ask questions and have had these questions answered to your satisfaction;
* You consent to allow the subject to participate in this research study; and
* You will be given a signed copy of this form.

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

Print Name of Legally Authorized Representative

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

Signature of Legally Authorized Representative Date

[Add the following signature section for documentation of obtaining consent/permission/ assent:]

**SIGNATURE OF INDIVIDUAL OBTAINING CONSENT**

I have explained the research to the subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

[Add this information when children and/or adults lacking the capacity to consent are subjects:]

**Assent Instructions:** All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.

Subjects ages 7 to 13: If assent is obtained, subjects must be given a simplified assent form.

Subjects ages 14 to 17: If assent is obtained, have the subject sign this consent form, unless the investigator determines that the subject is not capable of signing.

Adults subjects who are not capable of providing consent: If assent is obtained, subjects must be given a simplified assent form, or the subject can sign this consent form.

* I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.

OR

* The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

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

Print Name of Individual Obtaining Consent

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

Signature of Individual Obtaining Consent Date

[Add the following signature section for documentation of a witness signature:]

**SIGNATURE OF WITNESS (if applicable)**

Your signature below indicates:

* You were present for the entire consent conference;
* The information in the consent document and any other written information was accurately explained to the subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable];
* The subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] had an opportunity to ask questions and those questions were answered; and
* The subject and/or the subject’s parent(s)/legal guardian(s)/[legally authorized representative, as applicable] voluntarily signed the consent/permission/assent form in your presence.

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

Print Name of Witness

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

Signature of Witness Date

[Sample table – It is recommended that a table such as this be included for studies involving multiple visits:]

**APPENDIX - Schedule of Study Procedures**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Visit 1**  (start of study) | **Visit 2**  (1 week after start) | **Visit 3**  (1 month after start) | **Visit 4**  (6 months after start) |
| Blood draw | X | X | X | X |
| MRI | X |  |  | X |
| Questionnaires | X |  |  | X |
| Bring unused pills/empty pill bottles back |  | X | X | X |
| Physical exam | X | X | X | X |