**Header:**

* Title of Protocol
* Font: Times New Roman size 10
* DO NOT USE ALL CAPS

**Document:**

* Font: Times New Roman size 10
* Aligned text to both left and right of margins
* *Italics used here indicate BMHCC IRB examples and optional language. The suggested language is NOT mandatory.*

**Top of first page - centered**: (Required)

* **INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY**

**Footer Top Left**:

* Sponsor’s Version and Date
* BMHCC IRB ICF Template Version and Date
* Font: Times New Roman size 10

Footer Center: Pagination.

* Page # of ##

**Insturctions:**

To complete this consent form, please modify it as appropriate for your study. Generally you will modify the yellow highlighted text as appropriate for your study or remove it if it is a note to you, the author. As you work, please remove all highlighting and prompts to the author.

The table of information below should be as brief as possible. The more detailed information should be included in the additional sections which follow the table. If there is too much information to include in the table, new additional sections may be added.

Please use simple words and short sentences when adding study specific information to this consent form.

If this is being used as a parental permission form, change all appropriate wording such as changing “you” and “your” to “your child” and “your child’s”.

**INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY**

**Title of Study:**

**Protocol No.:**

**Sponsor:**

**Investigator:**

**Participating Investigators:**

**Telephone:**

This form has information about this research. Where it says “See Below”, there is more complete information later in this form. You and the research personnel will discuss this information so you can decide whether or not to take part in this research. Make sure you discuss your concerns and have all your questions answered before deciding to take part in this research.

|  |  |
| --- | --- |
| **Informed Consent** | It is important that you understand this research so that you can decide whether or not you want to take part. This process is called informed consent. To make your decision, you must consider all the information below. You should especially consider:* The purpose of this research.
* How this research differs from standard medical care.
* The procedures and the drug(s)/device(s) involved in this research.
* The risks.
* The alternatives to taking part in this research.
 |
| **Voluntary Participation** | You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled. |
| **Purpose** | The purpose of this research is *explain the purpose of the study using conversational language.* |
| **Number of Participants** | About X people will take part in this research. |
| **Duration** | You will be in this research study for about add duration. |
| **Procedures & Experimental Parts of the Study *(See add’l info Below)*** | While you are in the study you will have different evaluations, tests and/or procedures which involve certain risks. Describe the experimental parts of this study including how the study differs from standard of care and any drugs/devices that are not yet approved or not approved for this particular indication. |
| **Drugs/Devices *(See add’l info Below)*** | The drug(s) used in this study is/are: Insert drug name(s). The device(s) used in this study is/are: Insert device name(s). These drugs/devices involve certain risks.  |
| **Risks**  | Taking part in this study involves certain risks. There may be more or less risks depending on what group you are assigned to. In addition to the risks described below, there may also be risks that are not known at this time. *(Please summarize the most serious risk here)* If you have any medical issues during this study, contact an investigator (*see Contacts below*).**If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are participating in this study.** |
| **Costs** | *Describe any definite costs to the subject*.  |
| **Payment** | *Describe the payment schedule and or reimbursement OR*. You will not receive payment for taking part in this study. |
| **Ending Study Early** | There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reasons if this becomes necessary. If you do leave the study early, you may be asked to have some of the evaluations/procedures described in this form. *Describe any other actions that will occur if the subject has to leave the study early*.  |
| **Contacts** | **If you are having a medical emergency, call 911 or go to an emergency room right away. You should let emergency personnel or providers know that you are taking part in this study.****For questions about the study or research related medical issues:*** Main Investigator-
* Sub-Investigator-
* Research Coordinator-

**If you need to contact someone other than the study personnel about a concern or your rights as a research subject:*** Baptist Institutional Review Board at 901-226-1677 or 901-226-1678

**If you would like to speak to a person who is not affiliated with this research study to discuss problems, concerns or question, or to obtain information or offer input:**Rev. Anthony Burdick, Director of Pastoral Care, Baptist Memorial Health Care Corporation at 901-226-5025 |

# VOLUNTARY PARTICIPATION

(Required):

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you would otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

(Required):

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

[Include for research involving prisoners. Otherwise, delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

# PROCEDURES and their RISKS

(Required):

# List all routine care, related tests/procedures and describe their purpose. Be sure to identify which procedures are experimental. In simple language, using a bullet point format with headers or table, explain the following:

* The tests and procedures that will be done (including medical record abstraction)
* Which procedures/drugs are standard of care and which are for research purposes only
* If research procedures will occur at a standard of care visit, indicate how much additional time will be required to complete the research procedures
* The method of assignment (randomization, etc.)
* The chances of being assigned to various arms
* Whether a placebo will be involved
* The amount of blood to be drawn for research purposes at each visit (in teaspoons/tablespoons)
* Estimate the time required of the subject for each visit

List all experimental related tests/procedures and describe their purpose. List experimental procedures in simple language, using a bullet point format with headers or tables.

# POSSIBLE RISKS

(Required):

In simple language and in simple bullet format, explain the possible risks and discomforts, including:

* Potential risks of investigational agents, devices, procedures, and treatments, as well as known risks of comparative agents, devices, procedures, and treatments used in the study;
* If applicable, psychological, social, or economic risks; and
* Only include the risks associated with procedures and/or treatments being performed solely because the subject is participating in this research study. Risks of routine procedures that would normally be performed even if the subject were not participating in this research study should not be included in the consent form. However, if randomizing to a standard of care treatment when other standard of care treatments/alternatives exist, the risks of the standard of care treatment should be included because the patient may not incur these risks outside of the study.
* If not already done, include a table or description of the timing of drug/device administration
* If applicable, describe the different groups a subject may be assigned to and the probability of assignment to each.

***(Include if applicable)* This research includes or might include whole genome or exome sequencing. This is like taking an inventory of your DNA which contains your genetic information.**

*(Optional):*

*Add the following statement only if the study involves an experimental treatment where some subjects are not randomized to the experimental drug/biologic/device:*

“If you are not randomized to the experimental treatment, you will not be exposed to the risks listed above associated with the experimental drug, [insert name of study drug/biologic/device].

*“If the study includes a placebo, list the potential side effects associated with the placebo immediately following the side effects of the study drugs.”*

**Risks to Pregnant Women and Unborn or Nursing Children**

Reproductive Risks: Include any known reproductive risks and risks to women, pregnant women, men (including the female partners of male subjects), and unborn and nursing children.

Delete the sections below that do not apply.

**Option 1: For studies involving a treatment with known or unknown reproductive risks and other greater than minimal risk studies with possible reproductive risks.**

If you are pregnant, plan to become pregnant or are breast feeding you **cannot** be in this study. You will be required to use birth control during the study and for 30 days after your last dose of the study drug OR modify according to the protocol. Appropriate methods of birth control will be discussed with you. If you are a woman who is able to have children, you will have a pregnancy test to make sure you are not pregnant and may be required to have additional pregnancy tests at other times during the study. Pregnancy tests require a blood or urine sample. You will be told the result of the pregnancy test(s). If you or your partner becomes pregnant during the study, you must tell the study personnel immediately. We will ask to follow you through your or your partner’s pregnancy and the pregnancy outcome.

**Option 2: For minimal risk studies.**

If you are pregnant, plan to become pregnant or are breast feeding you **cannot** be in this study. If you are a woman who is able to have children, you will have a pregnancy test to make sure you are not pregnant and may be required to have additional pregnancy tests at other times during the study. Pregnancy tests require a blood or urine sample. You will be told the result of the pregnancy test(s).

**Option 3: For research involving minors.**

**Children and Pregnancy**

If your child is pregnant, plans to become pregnant or is breastfeeding, she **cannot** be in this study. If your child is able to have children (has started her menstrual periods), she will have a pregnancy test to make sure she is not pregnant and may be required to have additional pregnancy tests at other times during the study. Pregnancy tests require a blood or urine sample. Your child will be told the result of the pregnancy test(s).

Your child should not become pregnant while in this study. If sexually active, your child will be required to use birth control during the study and for 30 days after the last dose of the study drug OR modify according to the protocol. Appropriate methods of birth control will be discussed with your child. By law in Pennsylvania, all minors age 12 or over have a right to talk about birth control and pregnancy privately with their doctor. The desired outcome of these discussions is the sharing of this information with the family. However, the decision to discuss the information with the family is up to your child and alternate support will be provided to your child when necessary.

**ALTERNATIVE TREATMENTS & CHOICES**

(Required):

*Include any alternative treatment(s) that may be available to the subject.*

Example:

You have other options than taking part in this study. Describe other alternatives. OR The alternative to being in this study is to not take part.

# POSSIBLE BENEFITS

(Required):

*In simple language, indicate the possible benefit for both the subject and the ways in which the study has the potential to develop medical knowledge important to society. If there are no direct benefits to subjects associated with participation in the study, then this should be clearly stated.*

Examples:

[If there are benefits to participation] We cannot promise any benefits to you or others from taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Describe the potential benefits of participation. First, describe any direct benefits to the subject, then describe any benefits to others. If benefits from participation may not continue after this research has ended, describe them. Monetary reimbursement for participation is not a benefit and should be described below.]

[Include for a clinical trial with no benefits to participation. Otherwise, delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Describe any benefits to others.]

# COSTS FOR PARTICIPATION

*This section must be consist with contract*

(Required):

State whether there are any costs to the subject/legally authorized representative for participating in the research study.

This section must be consistent with the contract.

The costs of the study visits and tests will be paid by the hospital, your insurance and/or the sponsor of this study. The study drug/device will be provided to you free of charge. (OR) You or your insurance carrier will have to pay for the study drug/device. You will be responsible for paying insurance co-pays, deductibles, out of pocket and other such costs. There is the possibility that you could have a physical injury or illness that is directly caused by a study procedure or drug that is different from your standard medical care. If this happens, you will receive the necessary and available medical care. If physical injury occurs due to any drug or procedure properly given according to the study plan, medical expenses for treating the injury will be billed to your insurance carrier. You may also have to pay some costs, which could be sizeable, that are not covered by your insurance. You should talk to the research personnel and your insurance carrier to find out what costs you need to pay for before taking part in this study.

There is no plan to compensate you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

If you receive a bill that you think is wrong, please contact the investigator or research personnel.

# COMPENSATION FOR INJURY

(Required):

Compensation statement outlining what will be paid and by whom. If compensation for injury language does not apply to the research, delete this entire section.

If you think you have been hurt by taking part in this study, tell the study doctor immediately by calling << insert PI’s name and contact number >>or<< 24 hour number when applicable.

Baptist Memorial Hospital (specify BMH facility i.e., Desoto, Collierville, Memphis, etc.) and/or [insert clinic name] will provide medical and ancillary services ordered by your physician at the established charges for those services and either Sponsor, you, or your insurance will be billed.

*Neither [insert clinic name] nor Baptist Memorial Hospital (specify BMH facility i.e., Desoto, Collierville, Memphis, etc.) has funds for patient compensation of any kind. Therefore, they cannot provide payment for study injuries.*

*(As Applicable):*

*The sponsor will pay for the treatment if your injury is the direct result of your participation in the study, use of the study drug/device and properly-performed research procedures. If the sponsor pays for the treatment of your injury, you will be obligated to provide them with some personal information such as your social security number as they must report the payment to CMS.*

You do not waive any legal rights by signing this consent form.

# COMPENSATION FOR PARTICIPATION

(Required):

*You will not be paid for participating in this research.*

*Or*

[Include if subjects will be paid. Otherwise, delete.] If you agree to take part in this research, we will pay you \_$ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for each research visit completion.] Federal tax law requires to you to report this payment as income to the Internal Revenue Service.

(Required):

If payment will be made, explain the following:

* the amount of the payment, or of each payment if there is more than one
* the total possible payment
* in what form payments will be made (cash, check, type of gift card)
* when payments will be made
* whether payments will be made to the participants OR their legally authorized representatives

# if the amount of payment exceeds $600 in a tax year, the subject will be responsible for paying any state, federal, social security or other taxes. No taxes are withheld from this payment. This payment to you may be considered taxable income by the Internal Revenue Service (IRS) and you may be issued a 1099-Misc Form. This form is sent to the IRS to report any money that is paid to you. To receive payment, you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. Waiver of payment is acceptable if you choose not to complete the W-9 form but continue to participate in the study. You are welcome to decline the payment if you would like.

Please Note: If this research or the information or specimens you provide result in commercial profit, you will not receive any money.

# CONFIDENTIALITY (HIPAA)

# *(Required):*

**What is the HIPAA Privacy Rule?**

The “Privacy Rule” is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information. It was issued by the government to make sure that your medical and health information is protected and not shared with others without your permission. Participants in research studies may be protected by this regulation. Most participants in research studies will need to sign an informed consent form which includes an Authorization for the use and release of certain health information.

**What is “Protected Health Information” (PHI)?**

Protected health information (PHI) is information about you and your health. Examples of protected health information (that may be collected and used in this study) are:

* Personal information such as your name, initials, social security number, date of birth, age, address, race and sex
* Information that describes your disease and/or condition
* History and treatment of your disease and/or condition
* Past and current medical history
* Other medical conditions that may affect your treatment
* Medications that you may be taking or have taken in the past
* Medical data like laboratory test results, tumor measurements, CT scans, MRIs, X-rays, EKGs, and pathology results
* Information about side affects you may have and how they were treated
* Follow-up information about your general health and disease after your treatment.

**Why this information is being used and/or given to others?**

Information is collected for this study:

* To do the research
* To study the results of the research, and
* To see if the research was done right.

# PRIVACY AND CONFIDENTIALITY: HIPAA Authorization

HIPAA (Health Insurance Portability and Accountability Act)

In order to take part in this study, we need to obtain your health information from your medical providers. Your signature on this form which includes this HIPAA Authorization will allow us to get access to that information. We are committed to respecting your privacy and to keeping your personal and health information confidential. When choosing to take part in this study, you are giving us permission to use your personal information that includes health information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, medical diagnoses, or social security number. Your health information and personal information we may collect and use for this study includes:

List all information being collected for this study. Examples: demographics including race and ethnicity (required if the research is federally funded), labs, imaging results (e.g. x-rays), questionnaires, photos, video, audio and any other information/results collected for this study.

This also includes any information collected about a medical issue caused by a study activity.

**Cancellation of Authorization**

(Required):

Your authorization for the use and/or disclosure of your health information will end on (date) or when the research project ends, whichever is earlier. List a specific date on which the authorization will expire, e.g., “will end on December 31, 2045”). If you are uncertain, choose a date that provides plenty of time for your work to be completed.

If you terminate this authorization, continued use of your PHI already obtained before the termination is permitted and its use is necessary in completing the research. However, PHI collected after your termination of this authorization may not be used in this study. If you refuse to sign this authorization, you will not be able to participate in this research study. If you terminate this authorization, then you will be withdrawn from the study. You may terminate this authorization in writing at any time by contacting the principal investigator or study staff by sending a letter to this address:

* Trial Site Name
* Address
* City/State/Zip

I understand that the medical provider may not make my treatment conditional on whether or not I sign the authorization.

I understand that this authorization is voluntary and that I may refuse to sign this authorization. I understand that my refusal to sign this authorization does not affect payment for services, my ability to obtain treatment, or my eligibility for benefits or enrollment.

*If the research involves treatment include the following statement:*

*To maintain the integrity of this research study, your right to access your health information that is created or obtained by your health care providers as part of this research study may be suspended until the study has been completed.  Your right to access your health information related to the research study will be reinstated upon completion of the research study.  If you authorize release of your medical record to a third party after the conclusion of the research study, please be aware that your medical record will likely contain information about your participation in the research study.*

For this study, certain people will need access to your personal information. All the people who will need access to your personal information may not be required by law to protect it. However, they will all protect it to the best of their ability. Therefore, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

The following people may have access to your personal information:

Modify the list below as necessary.

* Research personnel employed at Baptist Memorial Health Care Corporation or any of its affiliates which include: insert all that apply
* Institutional Review Boards (ethics committees that review research)
* Health insurance providers
* Insert Sponsor (sponsor) which is providing money to the researcher to carry out this research
* Research monitors hired by the sponsor to oversee the study and review health care records to ensure study-related information is correct
* Government Agencies like the Food and Drug Administration (FDA)
* An organization such as a contract research organization (CRO) that has been hired to coordinate the study Specify
* A data and safety monitoring committee
* Others as required by law
* Add others as necessary

To the extent allowed by law, we limit the viewing of your personal information to people who have to review it. We cannot promise complete secrecy.

**Research records/specimens**

(Required):

Explain how paper research records will be maintained.

*For example, “All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and the specified entities listed in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”*

(Required):

Explain how electronic research records will be maintained.

*For example, “All your electronic research records will be computer password protected and accessible only to research personnel and the specified entities listed in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”*

***[OR]***

*“All your electronic research records will be kept on an encrypted computer where your information is replaced with a code and password only known to the research personnel, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”*

**Medical Records**

(Required):

[*Explain if documentation of the participation of the subject in the research study, such as a copy of the consent form or other notation, will be placed in the subject’s medical record. For example:*]

Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record; as such, this information could be made available to your employer or insurer.

[***OR***]

Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

**Presentations/Publications**

(Required):

Explain whether or not individual subjects will be identified in any presentations or publications based on the research.

*For example, “While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.”*

*If the research involves treatment include:*

You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study and the results of any study test or procedure may be included in your health records and may be seen by your insurance company.

If you authorize release of your medical record to a third party after the conclusion of the research study, please be aware that your medical record will likely contain information about your participation in the research study.

**STUDY WITHDRAWAL**

(Required):

If you choose to withdraw you should talk to your doctor about the potential risks and discuss the best way to withdraw from the study. Once you withdraw you will not be able to continue in the study. No new data will be added to the database once you withdraw, but all data collected prior to withdrawal may still be used as part of the study.

(Required):

 Include specific procedures for withdrawal and circumstances under which a subject may be terminated from the study.

**NEW FINDINGS:**

(Required):

[Include if incidental findings may be communicated to the participant] This *(provide imaging procedure (e.g. MRI))* is done for research purposes rather than for diagnosis. The *(provide procedure)* will not be routinely examined by health professionals for potential structural and functional clinical abnormalities. However, in the event an abnormality is detected by the investigators or the *(administer of the procedure* *(e.g. MRI technician)),* the *(named procedure)* will be further examined by a *(name appropriate clinician* (e.g. a radiologist)) and the investigator may encourage you to consult your physician.

***[add below language if applicable]***

[The blood, saliva, tissue that is obtained from you will be tested and/or stored for future use and potential laboratory, genomic and proteomic studies. The material will have your name, medical record number and other identifying information associated with it. Please indicate if you wish to be contacted in the future regarding any test results that may be obtained.]

[Include if incidental findings will not be communicated to the participant] The *(named procedure)* we collect are for research purposes only and we cannot provide a (*name* *appropriate clinician)* clinical interpretation of the results. However, if your healthcare provider would like to use the *(type of data e.g. scans)* for comparison with another clinical *(applicable types of data)* that has already been obtained or may be obtained in the future, they may request these *(type of data)* if they are still available.

***[add the below language if applicable]***

[The blood, saliva, tissue that is obtained will be tested and/or stored for future use and potential genomic and proteomic studies. However, the material will be de-identified (will not have your name, medical record number or other identifying information associated with it. Therefore, we will not be able to contact you in the future regarding any test results that may be obtained.]

Any new findings that may impact your decision to continue participation will be [fill in method].

CONSENT SIGNATURES TO FOLLOW ON NEXT PAGE

# CONSENT TO PARTICIPATE

The research study, procedures, risks and benefits have been explained to me. I have read and understand all of the above, been given the opportunity to ask questions, and my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I will be given a copy of this signed and dated consent form for my own records. I do not give up any of my legal rights by signing this consent form.

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

Name of Adult Participant (printed)

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

Signature of Adult Participant Date/Time

Or

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

 \*Legally Authorized Representative (printed)

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

Signature of the Legally Authorized Representative Date/Time

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

Relationship to patient

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

Name of Person Obtaining Consent (printed)

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

Signature of Person Obtaining Consent Date/Time

\*If authorization is to be obtained from a legally authorized representative (e.g., parent(s), legal guardian or conservator) a description of his/her authority to act for the participant is also required.

**Signature Block for Child Subject**

|  |
| --- |
| Your signature documents your permission for the child named below to take part in this research. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  |  |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
|  |  |  |
| Signature of second parent  |  | Date |
|  |  |
| Printed name of second parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |
| Signature of person obtaining consent |

* ***[Add the following block if you will document assent of children using the consent document.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |