Informed Consent Form

Title: Building Adaptive Coping and Knowledge to Improve Daily Life (Back2Life): A Pilot Feasibility Clinical Trial for Youth With Chronic Sickle Cell Pain

NCT Number: NCT04602728

IRB Approval Date: September 1, 2021

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 25 patient-parent duos who are being studied at Emory, Children's Healthcare of Atlanta and Children's Healthcare of Atlanta at Hughes Spalding Hospital.

Why is this study being done?

This study will answer the question: does a training program in pain coping skills (also known as cognitive-behavioral therapy) that is tailored to individual needs improve everyday functioning and pain symptoms? You are being asked to participate because you are a teen or parent of a teen with chronic pain and this training may improve your physical and emotional health. The program will be tailored to address challenges related to chronic sickle cell pain.

The program, called Back2Life (Building Adaptive Coping and Knowledge To improve daily Life), may help improve everyday functioning and pain symptoms in teens with chronic pain related to SCD. Our goal is to find out how teens and parents (or "Participants") respond to this program and get feedback about how we can continue to modify it to best fit their needs.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you join the study, you will participate for 6 months (11-15 study visits). The researchers will ask you to do the following:

Baseline Study Visit: You and your teen will complete several surveys at a baseline visit.

Treatment Program: Information from the baseline visit will be used to tailor the program to the needs of you and your teen. Teens will participate in a pain coping skills training program (learning ways to cope with and manage chronic sickle cell pain) that lasts between 6 and 10 sessions that may help with pain issues.

Treatment Sessions: Treatment sessions will be conducted in-person at a CHOA campus or by telehealth. Each session will last about 1 hour, once a week and will teach a new skill to improve chronic pain management and help teens do the activities, they want to do without pain getting in the way. Parents will learn the same skills along with strategies to support their teen's use of skills at home. One booster session will be offered 2 months after completing the program to help problem-solve any difficulties Participants may have had.

Follow-Up Assessments: All Participants will complete the same assessments at the end of treatment, and at 3- and 6-months after the baseline visit.

Qualitative Interview: At the end of the program, Participants will be asked to do a 30-minute interview to share their opinions about the program. This will be used to make the program better in the future.

Blood Draws (Optional): Teens will have the option to complete a blood draw at the time of the baseline visit and 3- and 6-months after the baseline visit. This can be planned during a regular clinic visit when blood draw would already be planned as part of routine care.
Compensation: ALL procedures will be paid for by the study. For your time and participation, you and your teen will each receive $25 for completing the baseline study visit, $30 for end of treatment assessment, $35 for 3-month assessment, and $40 for 6-month assessment and $30 for each completed blood draw. To reimburse transportation costs for attending sessions or cellular data and WiFi usage for telehealth sessions, you and your child will each receive $40 for every attended session (7-11 total). You and your child will also each receive $50 for completing an interview.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Learning how to use coping skills may help to manage chronic sickle cell pain and develop confidence in doing activities without pain getting worse. Although we do not know for certain if the program will help reduce pain, this study will allow us to develop better treatment.

What are the risks or discomforts I should know about before making a decision?
The study will take time. This program may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious like emotional distress, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study
Instead of being in this study, you can choose not to participate. Your usual medical care will not be affected if you choose not to participate.

Costs
You WILL NOT have to pay for any study procedures, including those that medical insurance does not cover. You or your health insurance company will not be billed for any research study sessions.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this, and talk about it with your family and friends.

Emory University, Children's Healthcare of Atlanta, and Grady Health System
Children's Healthcare of Atlanta at Hughes Spalding Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: Building Adaptive Coping and Knowledge to Improve Daily Life (Back2Life): A Pilot Feasibility Clinical Trial for Youth with Chronic Sickle Cell Pain

Principal Investigator: Soumitri Sil, PhD; Aflac Cancer and Blood Disorders Center, Children's Healthcare of Atlanta; Department of Pediatrics, Emory University School of Medicine

Sponsor: National Institutes of Health (NIH); National Heart, Lung, and Blood Institute (NHLBI)

If you are the legal guardian of a child who is being asked to participate, the term "you" may be used in this consent to refer to you and your child. If you are an adult patient, the term "you" may refer to you and your parent.

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.

Introduction:
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to find out how teens with chronic pain and sickle cell disease respond to a new training program called Back2Life and get their feedback about how we can continue to modify the program to best fit their needs. The Back2Life training program focuses on teaching pain coping skills (also known as cognitive-behavioral therapy), that is teaching skills and strategies that may help teens get back into their everyday activities and improve chronic pain management.

Training in pain coping skills along with usual medical care has been shown to improve physical and emotional health in teenagers with chronic pain. As part of our ongoing research studies, we gathered feedback from parents and their teenagers who have both chronic pain and sickle cell disease to develop the Back2Life training program specifically for chronic sickle cell pain. This training program will be tailored to the individual needs of a teen and family to address the specific challenges related to chronic sickle cell pain that might make it hard for teens to engage fully in daily life.

What will I be asked to do?

We are asking about 25 teens and young adults who have chronic pain and sickle cell disease ages 10-18 years old to participate in this study. We are also asking parents or caregivers of the participating patients to be in the study. Parents will answer separate parental surveys, give us information about themselves and about you, and participate with teens in the training program.

If you are eligible and want to be part of the study, you will participate for 6 months (between 11-15 study visits). The study involves a combination of 1) surveys (4 study visits), 2) treatment sessions (7-11 study visits), and 3) a qualitative interview (combined with a survey visit).

Baseline Survey Study Visit: Parents and teens will complete an assessment of surveys at a baseline study visit. We will ask parents and teens to complete brief questionnaires about the teen's pain, sleep, mood, physical functioning, coping, and interest in participating in the program. Parents will also complete a brief questionnaire about stress related to parenting.

Treatment Program: All teens will receive the standard 6-session pain coping skills training program (learning ways to cope with and manage chronic sickle cell pain). The standard program includes topics that were identified by teens with chronic sickle cell pain and their parents as important skills for all teens with chronic pain and sickle cell disease. Some examples of topics include learning how to identify and manage stress, how to stay active and involved in everyday activities without letting pain get in the way, how to talk to others about their pain and what they need that may help, how teens can be a good coach for themselves when pain gets overwhelming or changes their mood, and strategies to help parents be able to support their teens in living the life they want. Research staff will use the information from the baseline assessment to tailor the treatment program to the needs of each teen and family. Teens may receive an additional 1 to 4 study sessions that may help with specific problems related to pain. For example, additional sessions may include topics such as difficulty sleeping, bad moods, or parenting stress. Teens and parents can participate in any of the additional sessions even if they do not have specific problems in these areas.

Treatment Sessions: The treatment study sessions will be conducted in-person at a CHOA hospital campus or by telehealth using a secure audio-video platform. The first treatment session for the study is strongly encouraged to be in-person to help develop a relationship with the provider. All other sessions may be in-person or by telehealth, based on your preference. Each session will last about 1 hour, once a week. Each session will focus on teaching a new skill or strategy to improve chronic pain management. Sessions will be led by a psychology fellow or psychologist who is part of the Aflac Cancer and Blood Disorders Center. Teens will be asked to practice the coping skills at home between sessions and keep a brief diary of their practice, pain symptoms, school attendance, and medication use. At least one parent or guardian is required to attend with their teen. However, all interested family members (parents, grandparents, siblings) are encouraged to attend sessions with their teen. As a parent, you will also receive education and training in the skills your teen will be learning along with behavior management strategies to support your teen's use of skills at home. A booster session will be offered at 2-months after completing the program. Booster sessions focus on problem-solving any difficulties teens or parents may have had with using the skills at home or school. The booster session will be conducted either in-person or by phone, depending on family preference. Sessions may be audio recorded and will only be reviewed by research staff to make sure that the content of the training program is being provided accurately and thoroughly to all participants.

Follow-Up Surveys: All teens and parents will complete the same assessment of surveys after completing the standard 6-session program, and at 3-months and 6-months after the baseline survey study visit. Parents will also report on any changes to their teen's medical treatment or medications. All assessments can be completed in-person or at home using online or paper-and-pencil questionnaires, depending on teen and parent preference.

Qualitative Interview: At the end of the program, parents and teens will be asked for feedback in a one-on-one interview lasting about 30 minutes. Feedback may include how you liked the program, what you thought about the content of the program, and any suggestions or changes to the materials or format. Information from these interviews will be used to refine and modify the Back2Life program. Interviews can be conducted in-person or by telehealth (audio and/or video).

Blood Sample Collection (Optional): As an optional part of the study, we are asking permission to draw samples of blood. Each sample will be about 4 teaspoons (about 20 milliliters) of blood, which will be drawn in the clinic or hospital, and will only take a few seconds. These will be collected at the time of the baseline visit and 3- and 6-months after the baseline visit. We will try to schedule these blood draws during your teen's regular sickle cell clinic visits when blood draws would typically be happening already.

Who owns my study information and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that was already collected may be still be used for this study.

What are the possible risks and discomforts?

Teens or parents may have feelings of emotional discomfort when discussing their experience with sickle cell disease and pain management. Some questions might contain embarrassing or personal questions. Let us know if you have these problems. Teens or parents may choose not to answer a question for any reason. The coping skills training has been used in research and clinical care and is not found to cause any emotional distress to participants or any adverse effects. Dr. Sil, the main researcher, is a licensed psychologist who will closely supervise the delivery of the training.

Some questions we ask may reveal depressive feelings and/or suicidal thoughts. In the event that you or your family member indicates that you have thoughts of harming yourself, you will be contacted by Dr. Sil or a colleague to devise a plan for treatment and/or your safety.

Another possible risk is that someone outside the study might see your or your parent's personal information. We will do everything we can to keep this from happening. Information we collect will be stored securely and only study staff will see it.

If you consent to blood sample collection, you will have a needle stick to get the required blood. This may cause pain, bruising, bleeding, or infection at the site of the needle stick.

There may be other risks that are not known at this time.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about how teens with chronic sickle cell pain respond to the program and if it helps them manage their chronic pain. Although we do not know for certain whether the treatment will reduce pain, the study results will allow us to develop better treatment programs which might be used to help others in the future.

Will I be compensated for my time and effort?

Parents and teens will be compensated for their time and participation for each completed study visit.

Baseline and Follow-up Surveys: Parents and teens will each receive $25 for completing the baseline study visit, $30 for the end of treatment assessment, $35 for 3-month assessment, and $40 for 6-month assessment.

Treatment and Booster Sessions: To reimburse transportation costs for attending each treatment session or to offset the costs for cellular data or WiFi usage for telehealth sessions, parents and teens will each receive $40 for every attended session (between 7-11 sessions).

Qualitative Interview: Parents and teens will also each receive $50 for completing the qualitative interview at the end of the program.

Blood sample collection (optional): Teens will receive $30 for each completed blood draw if they opt in for this optional study.

If you do not finish the study, you will be paid for the visits you have completed. Parents and teens will each receive between $435 to $595 total, if you complete all study visits for the main study. Teens will receive between $525 to $685 for complete all visits for the main study and the optional blood draws. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research. Please speak with your medical care providers for referrals to psychologists or counselors who can offer support for pain management. We will discuss these with you. You do not have to be in this study to be treated for sickle cell disease or chronic pain OR to get psychological or behavioral health services.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results. To protect you, all samples and information about your samples will be stored with numbers instead of your name or other information that identifies you. Only the research team members for this study can link the information that identifies you with the samples. They will have to use passwords to get to this information.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory and Children's Healthcare of Atlanta at Hughes Spalding will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory or Children's Healthcare of Atlanta at Hughes Spalding received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory and Children's Healthcare of Atlanta at Hughes Spalding from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,

- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your data and specimens only for research. We will not sell it. However, the results of this research might someday lead to the development of products (such as a treatment manual for providers working with teens with chronic sickle cell pain) that could be sold by a company. You will not receive money from the sale of any such product.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Medical Record

If you have been an Emory and Children's Healthcare of Atlanta patient before, then you already have a medical record with them. If you have never been an Emory, Children's Healthcare of Atlanta and Children's Healthcare of Atlanta patient, you do not have one. An Emory and Children's Healthcare of Atlanta medical record will be made for you if an Emory and Children's Healthcare of Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Children's Healthcare of Atlanta medical record you have now or any time during the study.

The results of all study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory and Children's Healthcare of Atlanta places may not become part of your Emory and Children's Healthcare of Atlanta medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation and childcare. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:

- Follow-up surveys at the planned end of the program
- Follow-up surveys at 3-months after the program
- Follow-up surveys at 6-months after the program

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory, Grady Health System and Children's Healthcare of Atlanta may use and disclose your PHI to run normal business operations.

- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- National Heart, Lung, and Blood Institute is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory, Grady Health System and Children's Healthcare of Atlanta offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory, Grady Health System and Children's Healthcare of Atlanta IRBs, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including the Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices.

Optional Study: Blood sample collection, Future Contact and Parental Participation:

Authorization for This Use of PHI is Required to Participate in Optional Studies, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI for the optional studies. If you do not authorize the use and disclosure of your PHI for the optional studies, then you may not participate in the optional research studies, but you can still be in the main research study.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your PHI. If you want to do this, you must contact the study team at: Soumitri Sil PhD, Aflac Cancer and Blood Disorders Center, 2015 Uppergate Drive, 4th floor, Atlanta, GA 30322.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Soumitri Sil at [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research.

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Children's Healthcare of Atlanta at Hughes Spalding is owned by the Fulton-DeKalb Hospital Authority (FDHA) and managed by HSOC, Inc., an affiliate of Children's. The FDHA maintains oversight for the Grady Health System.

If you are a patient receiving care at Children's Healthcare of Atlanta at Hughes Spalding and have a question about your rights, please contact the Director of Research Administration at 404-785-7477.

Consent and Authorization

Consent and HIPAA Authorization for Optional Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional studies previously described:

Patient Blood sample collection

_____ No, I do not want to participate in the blood sample collections.
Initials

_____ Yes, I want to participate in the blood sample collections.
Initials

Patient Future Contact

_____ No, I do not want to be contacted about future studies about sickle cell or pain.
Initials

_____ Yes, I give my permission to be contacted about future studies about sickle cell or pain.
Initials

TO BE FILLED OUT BY THE PARENT ONLY

Consent and Authorization for Optional PARENTAL Participation. Please initial below if you opt to participate in and authorize use and disclosure of your **parental IIHI** in the optional studies:

_____ No, I do not want to participate in the parental parts of the study.
Initials

_____ Yes, I want to participate in the parental parts of the study.
Initials

TO BE FILLED OUT BY ADULT SUBJECT OR LEGALLY AUTHORIZED REPRESENTATIVE ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Patient Subject

_____ _____
Signature of Patient Subject (18 or older and able to consent) **Date** **Time**

_____ _____
Signature of Legally Authorized Representative **Date** **Time**

Authority of Legally Authorized Representative or Relationship to Subject

Name of Parent

Signature of Parent **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**