UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: VIDPRESAE (VItamin D to PREvent Severe Asthma Exacerbations)

This is a medical research study. The study doctor, Michael Cabana, from the department of Pediatrics or his research coordinator will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about your child's participation. You may discuss your decision with your family and friends and with your child's health care team. If you have any questions, you may ask the study doctor.

Your child is being asked to take part in this research study because he/she has asthma and a low vitamin D levels in his/her blood.

Why is this study being done?

Asthma is a major public health problem in the United States and worldwide. For unclear reasons, there has been an increase in asthma from 1960 to at least the 1990s.

Vitamin D is a vitamin that has known effects on the immune system. The immune system normally protects you against foreign bacteria and viruses. In asthma and other allergic diseases, the immune system may be the cause for worsening symptoms. The purpose of this study is to see if taking vitamin D lessens the number of asthma attacks in the children with asthma who have low blood vitamin D levels.

This research study will look at your child's asthma in relation to vitamin D deficiency and asthma "flare ups". While all of the children will be on a steroid inhaler, half of the children will be given 4000 IU of vitamin D3; the other half will be given a placebo. A placebo is a pill or liquid with no active medicine but looks just like the active medication. The research team also wants to see if taking Vitamin D makes the steroid inhaler more effective.

It is hoped that information gained from this study may help us find out if vitamin D can actually protect against flare-ups of asthma symptoms.

This study is funded by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

Who is being asked to take part in this research study?

Your child is being asked to take part in this research study because he/she has asthma and a low vitamin D levels in his/her blood. Your child's participation will be for approximately 1 year.

This study will enroll approximately 400 children ages 6-14 with asthma and low vitamin D levels. 200 of these children will be enrolled here at UCSF and 200 will be enrolled at Children's Hospital of Pittsburgh.

What will happen if my child takes part in this research study?

Before your child begins the main part of the study he/she will undergo the following screening to determine eligibility:

Visit 1 was a screening visit that your child already completed at week -5.

Visit 2, Week -4

This visit will take about 2 hours at a UCSF Children's Hospital. Your child will be asked not to take his/her albuterol (a breathing medicine that your child may take routinely to control their asthma symptoms) for 4 hours before this screening visit. You have already given your permission either over the phone or in the clinic/ED for this. If your child experiences asthma symptoms and you or your child feel your child needs to use the inhaler, it is OK to do so, just let the study coordinator know.

We will ask you and your child questions about your child's medical history. These questions would include asking you about asthma medicine your child has taken, other medical conditions, and your child's asthma history.

The following are things that will be done at this visit:

- **Physical exam**

A brief physical exam by a doctor or a nurse practitioner and review of medical and smoking history. This will take about 15 minutes.

- **Questionnaires**

Questions that ask about your child's asthma, medicine they have taken, smoking history, doctor and emergency room visits, childhood shots, the health of family members, living conditions in your home, and your child's ability to do things that their friends can do and their feelings will be asked. These will take about 1 hour to complete. Some of these questionnaires will be answered by you and others by your child. If your child is unable to complete a questionnaire on his/her own, you will be asked to fill out the questionnaires for your child.

- **Pregnancy test**

Urine pregnancy tests will be done on all girls of child bearing potential. If your child is of childbearing age (started her period), a urine sample will be collected for a pregnancy test. If the pregnancy test is positive, your child will not be included in the research study. You and your child will be told this result and given the name of an obstetrician/gynecologist or the phone number for the adolescent clinic at Benioff Children's Hospital. If your child is currently breast-feeding an infant, she will not be included in the research study.

- **Spirometry (Before and After Albuterol)**

Spirometry tests are breathing tests that measure the amount of air your child has in his or her lungs and how well your child can move that air by forcefully blowing into a spirometer (the machine that measures how well your child can blow air out of his/her lungs). We will give your child two puffs of albuterol (a medicine that helps relax the muscles around the breathing tubes) and then repeat this breathing test. This will take about 30 minutes.

*If your child's breathing test gets better after the albuterol, he/she is eligible to continue into the study and visit 3 will be scheduled. If not, part A will be scheduled (see below).

- We will give you your child's study medication (placebo), and instruct you/your child how to use the electronic pill cap device (MEMS) on keeping track of daily use of medication. A placebo is a look-alike (fake or inactive) medication. Your child will take the placebo medication for 4 weeks. This period of the study is known as the run-in. It will be used to track your child's compliance with the study medication and his/her ability to follow the study instructions.

- Instruct your/child on how to take his/her steroid inhaler. All children participating in this study will be taking the same steroid inhaler (Flovent). Children 11 years and younger will take 88 mcg twice a day, and children 12 years and older will take 110 mcg twice a day. If your child is currently using a different asthma medication we will ask you to switch him/her to Flovent for the duration of the study.

- Nasal blows for baseline assessment of viral infections.

Visit 2A (Part A only necessary if breathing tests from visit 2 do not improve with albuterol)

If your child's breathing test (spirometry) did not improve after the albuterol was given during Visit 2, your child will be asked to come to UCSF medical center for Visit 2A. This visit should take between 2 and 2.5 hours and will be scheduled within 2 weeks after Visit 2.

The tests that will be done at this visit will be:

Methacholine Challenge Test

A methacholine challenge is a common test often used to find out if a person has asthma. Methacholine, also known as Provocholine, is a medicine that makes the breathing tubes narrow or tighten. The test is done by breathing in a mist, then after 3 minutes, blowing into a tube attached to a machine that can tell if your child's breathing tubes have started to narrow (spirometry). The dose of this medicine will keep getting higher until the breathing tests show that your child's breathing tubes have started to narrow or tighten or your child has reached the highest dose. The test will be stopped when this happens. This medicine (Methacholine or Provocholine) is approved by the Food and Drug Administration (FDA) for children in the doses used for this research. Your child will receive albuterol (an inhaler medicine that relaxes the airways) after the test is done to reverse any narrowing or tightening of the breathing tubes. This test may take up to 2 hours to complete. Your child will be asked to repeat the spirometry testing after the Methacholine Challenge until the investigators are assured that your child's breathing has returned to baseline. Your child will not be discharged until his/her spirometry testing has returned to baseline (what it was before the methacholine challenge).

Your child will be able to continue on in this study if he/she has changes that show that his/her breathing tubes have started to narrow in the breathing tests during the Methacholine Challenge Test. Please understand after performing Visit 2 (parts A and/or B) your child is NOT eligible to continue into the study:

- If he/she has normal or very low levels of vitamin D. If your child has very low levels of vitamin D (<10ng/ml), he/she will be referred to a pediatric endocrinologist for evaluation and treatment.
- Your child does not qualify to participate in the study if the Methacholine Challenge Test is negative.

Visit 3, Week 0

This visit will take about 2 hours at a UCSF Children's Hospital. Your child will be asked not to take his/her albuterol (a breathing medicine that your child may use for symptoms of asthma) for 4 hours before this visit.

- Review of study medications
- Questionnaires
- Spirometry (before and after Albuterol)
- Your child will be asked to give a urine sample to test their kidney function and calcium level
- Blood draw: a total of about 2.5 tablespoon of blood will be taken by putting a needle into a vein in your child's arm. The blood samples will be used to test your child's vitamin D level, immune allergy studies that are important in asthma, calcium level, complete blood count, and blood for DNA and RNA extraction, to be banked and saved for later testing. Collection of blood for DNA and RNA is optional; if you decide to opt out then the total amount of blood will be about one tablespoon. This may take up to 15 minutes.
- Included in this consent form is a place for your permission to obtain blood from your child to test for genes that may be important in asthma.
- Your child will be randomized (like a flip of a coin) to either 4,000 IU of Vitamin D3 or placebo in the treatment phase of the study. Your child has an equal chance of being in either one of the two groups. You will be called by the research coordinator about 4 weeks after your visit to ask if your child has had any new symptoms or changes in medication.

Visit 4, Week 8, Visit 6, Week 24 and Visit 8, Week 40

These visits will take about 1-1.5 hours at a UCSF outpatient clinic and/or Mission Hall or your child's home. Your child will be asked not to take his/her albuterol (a breathing medicine that your child may use when having an asthma attack) for 4 hours before this visit.

- Questionnaires
- Review study medications
- Height and weight (Visit 6)
- Spirometry
- Give more study medications
- You will be called by the research coordinator about 4 weeks after each visit to ask you if your child has had any new symptoms or changes in medication.

Visit 5, Week 16 and Visit 7, Week 32

These visits will take about 2 hours at a UCSF outpatient clinic, phlebotomy clinic, and/or Mission Hall or your child's home. Your child will be asked not to take his/her albuterol (a breathing medicine that your child may use for asthma symptoms) for 4 hours before this visit.

- Questionnaires

- Review study medications
- Height and weight
- Spirometry
- Urine Sample to check kidney function and calcium level
- Blood sample for measurement of vitamin D level (A total of about 1 teaspoon of blood will be taken by putting a needle into a vein in your child's arm)
- Give more study medications
- You will be called by the research coordinator about 4 weeks after each visit to ask you if your child has had any new symptoms or changes in medication.

Visit 9, Week 48

This visit will take about 2 hours at UCSF Children's Hospital. Your child will be asked not to take his/her albuterol (a breathing medicine that your child may use for asthma symptoms) for 4 hours before this visit.

- Questionnaires
- Review study medications
- Spirometry(before and after albuterol)
- Urine Sample to check kidney function and calcium level
- Blood sample for measurement of vitamin D level, immune allergy studies that are important in asthma, complete blood count, and blood for DNA and RNA extraction, to be banked and saved for later studies. Collection of blood for DNA and RNA is optional; this may take up to 15 minutes. (A total of about 2.5 tablespoons of blood will be taken by putting a needle into a vein in your child's arm. If you decide to opt out the genetic testing, then the total amount of blood will be about one tablespoon.)
- Included in this consent form is a place for your permission to obtain blood from your child to test for genes that may be important in asthma.
- Physical exam

Asthma flare-ups:

Any time your child has an asthma flare-up you should seek appropriate medical attention, as you normally would. We do ask that if your child has an asthma flare-up, please also contact the research coordinator within 12 hours. The coordinator will then come to your home within three days to collect a nasal sample after your child blows his or her nose. Any time your child has an asthma flare up, a short visit to the home or the clinic will be necessary within 7 days for a physical exam, a brief interview and spirometry.

If your child would withdraw from the study before completing all study visits, your child will be asked to complete an early termination visit.
The early termination visit will take about 2-2.5 hours at a UCSF clinic.

The following procedures will be done at the early termination visit:

- Review of adherence with study medications
- Questionnaires
- Spirometry (before and after albuterol)
- Urine sample to check kidney function and calcium level
- Blood sample for measurement of vitamin D level, complete blood count, immune

allergy studies that are important for asthma, blood for DNA and RNA extraction, to be saved for later genetics testing. This may take up to 15 minutes. (A total of about 2.5 tablespoons of blood will be taken by putting a needle into a vein in your child's arm. Collection of blood for DNA and RNA is optional, if you decide to opt out then the total amount of blood will be about one tablespoon.).

How long will I be in the study?

Participation in the study will take a total of about 1 year.

What are the possible risks, side effects and discomforts of this research study?

Risk of Study Drug (Vitamin D):
The dose of vitamin D that we will use in this study have been safely tolerated in children participating in prior studies. Taking too much vitamin D can rarely lead to side effects such as nausea, vomiting, poor appetite, weakness, headache, bone pain and weight loss. Very rarely, too much vitamin D can also cause hypercalcemia (high blood levels of calcium), causing mental status changes such as confusion. High blood levels of calcium can cause heart rhythm abnormalities, and kidney problems.

Risk of Placebo Medication:
Children with very low vitamin D levels (<10 ng/ml) will not be allowed to participate in this study (see above). Treatment is not currently recommended for most children whose vitamin D levels are low (between 16 ng/ml and 29 ng/ml) but not low enough (below 16 ng/ml). If your child has a level between 10 ng/ml and 15 ng/ml, and he is assigned to the control medication, he will receive a placebo, which is lower than that recommended for treatment. Because of this your child would have a small risk of rickets (a disease of the bones). If your of rickets and a diagnosis of rickets is confirmed, his/her participation would be discontinued and he would be referred to a pediatric endocrinologist. All children whose vitamin D level is low (below 16 ng/ml) at the end of the study will be referred to their primary care physician for further evaluation.

Risk of Methacholine Challenge:
This test commonly causes temporary wheezing, cough and chest tightness. If this occurs, your child will be given a bronchodilator (albuterol) to make these symptoms better. There is a small risk that severe chest tightness and difficulty breathing can occur, requiring emergency rescue treatment. In the case of an emergency, qualified persons and emergency equipment will be available at all times.

Risk of Blood draw:
Bruising, bleeding, and discomfort occur in 10-25% of people undergoing venipuncture. Infection and fainting occur in less than1% of patients. Every effort will be made to combine at least one blood draw with your child's routine blood work in order to minimize the number of blood draws.

Risk of Spirometry:
Your child may commonly have some coughing or shortness of breath after spirometry, but there is no pain expected to be associated directly with these tests.

Risk of Step-down therapy:

Step-down therapy is when the dosage of your child's asthma medication is reduced to the smallest dosage that still controls symptoms. Your child may have a worsening of symptoms when stepping down therapy. This risk is low since only children who have been well controlled for 3 months would be eligible for step- down. National guidelines recommend this step down in therapy because the risk of continuing controller therapies in well controlled patients outweighs the benefit of the therapy.

Risk of Breach of Confidentiality:
There is the risk of breach of confidentiality. Samples (blood) will be sent to the laboratory without patient identifiers, the sample will be identified only by your child's ID number. Any information linking your child's identity to your child's ID number will be kept in a password protected database in the locked office of the investigator and/or research coordinator. Data obtained from this study may be published, or presented at scientific meetings, but your child's identity will not be disclosed.

Risks of albuterol*:*
Albuterol, at higher doses, may commonly cause nausea, shakiness and rapid heart rate.

Risk of Questionnaires:
Some of the questions may make subjects feel uncomfortable. In addition, subjects commonly may feel tired from answering the questions.

Risk of nasal blows:
There are no risks to the nasal blows.

Risk of Genetic testing: Risks may include: a) finding out about previously unrecognized genetic diseases, and b) loss of patient confidentiality. Labels for blood samples will not have any personal information. The blood will be used only to look for genes related to asthma and allergies. There is a risk that participating in a genetic study may influence insurance companies and/or employers in the future regarding your health. We will not place information about this study or the results of study tests in your medical record.

What are possible benefits from taking part in this study?

Since there is a 50% chance of your child receiving a placebo, he/she may not benefit directly from the study medication, which may or may not prove to be beneficial at the end of the research study. However, we will provide education to your child on his/her asthma and its triggers. This knowledge is likely to be of direct benefit to you child. Through asthma education and close monitoring, your child may have some improvement in his/her health. The information collected will help the investigators and research team to advance the understanding of asthma and the role that vitamin D plays in this disease. It may also help to develop new research studies that may possibly help individuals diagnosed with asthma in the future. Vitamin D levels will be reported to you and your child at the end of the research study.

If my child agrees to take part in this study, will my child be told of any new risks that may be found during the course of the study?
You and your child will be promptly notified if, during this research study, any new information develops which may cause you and your child to change your minds about

continuing to participate.

Will I or my insurance provider be charged for my child's participation in the Vitamin D Asthma Study?

There will be no costs to you or your insurance provider to participate in the Vitamin D Asthma study. All medications (Vitamin D or placebo) and procedures performed for this study (spirometry with albuterol, methacholine challenge, blood tests) will be paid for by the study. If you receive a bill for any of these procedures or think that your insurance company has been charged for any of the study procedures, please contact the study coordinator.

You and/or your child's insurance will be billed in the usual manner for any routine standard care or treatment your child receives that is unrelated to the research study. Medical care needed to treat your child's asthma outside of the study visits (including physician visits, ER or urgent care visits or hospitalizations) during the study will need to be paid for by you or your child's healthcare insurer. If your child is already on an age appropriate dose of Flovent at the beginning of the study then he/she will continue this. If your child is on a different medication your child's prescription will be changed. If your child is on a different dose of Flovent we will provide a prescription for the new dose. If these changes result in a co-pay being incurred, please provide the receipt to us and we will reimburse the co-pay amount.

Will my child be paid if he/she takes part in this research study?

Participants will be compensated for their time with gift cards based on the time spent in each visit: $30/1st hour and $20/hour after the 1st hour. Parking validation will be provided and taxi vouchers will be made available for families that prefer not to drive.

Your child's biological sample or genetic material may lead, in the future, to new inventions or products. There are currently no plans to share with you any money or other rewards that may result from the development of such commercial tests or treatments.

Who will pay if my child is injured as a result of taking part in this study?

If you believe that the research procedures have resulted in an injury to your child, please seek medical care for your child, as you normally would. Please also contact your study doctor, Michael Cabana, as soon as you can. You can tell the doctor in person or call him/her at 415-514-2660. Emergency medical treatment for injuries solely and directly related to your child's participation in this research study will be provided to you by the hospitals of UCSF. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you if this emergency treatment is provided by a UCSF facility. If your child's research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. For further information about this, you may call the office of the Committee on Human Research at 415-476-1814.

Who will know about my child's participation in the Vitamin D Asthma Study?

Any information from your child's medical records that is used in the Vitamin D Asthma Study will be kept as confidential (private) as possible. All data that identifies your child will be kept in a password protected database on a secure computer. Only the investigators and designated research staff will have access to this information. Your child will not be identified by name in any publication or research results unless you sign a separate form giving your permission (release). The investigators may continue to use and disclose, for the purposes described in this document, identifiable information related to your child's participation in this research study indefinitely or for at least 7 years following final reporting or publication of the project.

Who will have access to my child's identifiable medical record information contained in the Vitamin D Asthma Study?

In addition to the study investigators, the following individuals will or may have access to identifiable information (which may include your child's identifiable medical record information) related to his/her participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office and the FDA may review your child's identifiable research information (which may include identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information (which may include your child's identifiable medical information) related to your child's participation in this research study in response to an order from a court of law. If the investigators learn that your child or someone with whom your child are involved is in serious danger or potential harm, they will need to inform, as required by California law, the appropriate agencies.

Other investigators may request access to the Vitamin D Asthma Study to identify subjects for their research studies. If Dr. Cabana approves the request, the research staff will search the Vitamin D Asthma Study database to identify potential subjects. A member of the research staff will then contact you to inform you that you may be a possible candidate and ask your permission to have that investigator contact you directly about their study. Your contact information will only be provided to an outside investigator following your approval. Data obtained from this study may be shared with other investigators interested in lung diseases or Vitamin D. However, the shared information will not contain personal identifiers such as your child's name or birthdate.

Will this research study involve the use or disclosure of my child's identifiable medical information?

This research study will involve the recording of past, current and/or future identifiable medical information from your child's hospital and/or other (e.g., physician office) records. The information that will be recorded or obtained will be limited to information concerning your child's diagnosis of asthma, medical history, medications you are taking, and laboratory tests. This information will be used for the purpose of determining if your child can be included in the study. This research will result in identifiable information that will be placed in your child's medical records held at UCSF. The nature of the identifiable information resulting from your child's
participation in this research study that will be recorded in your child's medical record includes any medication your child received, laboratory (blood and urine tests, pulmonary function, tests) results, and a reference to the discussion where you gave your consent to have your child participate in this study. If your child does not have medical records at a UCSF facility, one will be created after enrollment.

May I have access to my medical information that results from his/her participation in this research study?

You and your child are permitted access to information (including information resulting from your child's participation in this research study) contained within your child's medical records filed with your child's health care provider. The results of the genetic studies will not be disclosed to you or your child.

Is my child's participating in the Vitamin D Asthma Study voluntary?

Your child's participation in this study, including the use of your child's medical record

information for the purposes described above, is completely voluntary. Whether or not you provide your consent for participation in this Vitamin D Asthma Study will have no effect on your child's current or future medical care at UCSF. Whether or not you provide your consent for participation in this research study will have no effect on your child's current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my child's consent for participation in this study?

You may withdraw, your consent for your child's participation in the Vitamin D Asthma Study at any time. This includes withdrawal of consent for additional collection of your child's medical record information and its further use for the research purposes described above. However, any research samples and medical record information collected prior to the date you formally withdraw consent for your child to participate will continue to be used for the research purposes described above. The link between your child's identity and your child's research code will be destroyed.

Your child's doctor may be an investigator in this research study, and as both your child's doctor and a research investigator, s/he is interested both in your child's medical care and in the conduct of this research. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your child's care with another doctor who is in no way associated with this research project. You are not under any obligation to participate in any research study offered by your doctor.

If I agree to take part in this research study, can I be removed from the study without my consent?

The investigators may withdraw your child from the study without your consent. The investigator may wish your child to stop the study early if she becomes pregnant or if your child experiences symptoms that cause the investigator to feel that it is not in his/her best interests to continue. The Primary Investigator may also stop the study early if an unexpected pattern of side effects is observed.

Banking or Storing Samples/Specimens

Storing samples/specimens for future research use is called "banking". This type of bank is kind of like a regular bank. Only, instead of keeping money, this bank keeps different kinds of samples, such as blood and urine. The reason researchers bank specimens is to use them for later research studies of their own or to share them with other researchers.

In this study, we will be storing or "banking" your child's blood and urine specimens for future research use. The samples in the bank will be used for future research studies to learn more about asthma. The research study in which your child's specimens may be used has not yet been determined. The goal of these studies is to help us to understand asthma better. Understanding more about asthma may help us in designing future asthma research studies and may help us to take better care of people who have asthma.

Specimen Banking

____ I agree to allow my child's specimens (blood, urine, nasal cells) to be stored indefinitely for future research about asthma. The stored specimens will not be identified by my child's name or any personal identification, but by an assigned code (de-identified). The information linking the code with your child's identity will be stored in a separate secure location.

____ I do NOT want to allow my child's specimens (blood, urine, nasal cells) to be stored for future asthma research

Collection and Banking of DNA and RNA Material

The blood and nasal cells that are collected and banked for future asthma research contain chemicals called deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). Almost every cell in a person's body contains DNA and RNA. DNA and RNA are like a big instruction book that tells your body how to grow and develop. A segment of DNA is called a gene. Differences in genes help to explain difference between people and can help explain some diseases. Each person gets half of their DNA from their mother and the other half from their father. When DNA is copied from parents to children, it isn't always copied exactly the same. Sometimes the DNA has changes. These are called mutations. Mutations can be good or bad. Some cause birth defects or other diseases. Others don't affect anything and go unnoticed.

It is possible that future researchers can look at the genetic information (DNA) in the blood that is banked. Changes in genes that contribute to better or worse outcomes for people with Asthma could be found. It is important to note that any DNA or RNA information collected from your child's samples in future research will **NOT** be shared with you.

DNA and RNA Sample Banking

____ I agree to allow my child's DNA and RNA to be collected and stored indefinitely. The stored specimen will not be identified by my child's name or any personal identification.

____ I do NOT want my child's DNA or RNA to be collected and stored.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of my child's participation in this study at any time, and that such future questions will be answered by the physicians associated with the University of California or their research staff. I understand that a copy of this consent form will be given to me.

I understand that any questions which I have about my child's rights as a participant in the Vitamin D Asthma Study will be answered by the University of California Office of the Committee on Human Research at 415-476-1814. By signing below, I agree to have my child participate in this study and provide my authorization to share my child's medical records with the research team.

_____
Child's Name

_____
Printed Name of Parent/Guardian

_____
Relationship to Child

_____ _____
Date Parent/Guardian Signature for Consent

_____ _____
Date Parent/Guardian Signature for Consent

_____ _____
Date Person Obtaining Consent

Assent

This research has been explained to me, and I agree to participate.

Signature of child-subject: _____

Printed name of child-subject: _____

I believe that my child understands what this research involves and that he/she has given assent for his/her participation.

Printed name of Parent: _____

Signature of Parent: _____

Certification of Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed."

_____ _____

Signature of Person Obtaining Consent Date