Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here:

_____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

****

Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

The study doctor wants to know if you would like to be part of a research study. This form describes the study in order to help you decide if you want to participate. This form will tell you what you will have to do during the study and the risks and benefits of the study.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information not clear to you.

Joining a research study is an important decision. You should ask the study team any questions you may have about the study and this consent form before making a decision.

Participant ID:

STUDY

Also, you should have your personal treating physician call the study doctor to ask any questions he or she feels are necessary to evaluate the study and your possible participation in it.

You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. Do not sign this form unless the study doctor or study staff has answered your questions and you decide that you want to be part of this study.

When reading this form, please note that the words "you" and "your" refer to the person in the study rather than a parent or guardian who might sign this form on behalf of the person in the study.

PURPOSE OF RESEARCH

Diamyd Therapeutics AB has begun a research study evaluating the effect of a new investigational drug, Diamyd, as a possible treatment for type 1 diabetes. An investigational drug is one which has not been approved for sale in the United States by the US Food and Drug Administration (FDA).

Type 1 diabetes is an autoimmune disease, which means that pancreatic beta cells—the body's insulin-producing cells—are destroyed by the body's own immune system. Although many people diagnosed with type 1 diabetes manage their disease with insulin therapy, it can still be difficult to control the blood sugar level. To stop or delay the immune system's destruction of beta cells would therefore be of great value in controlling the blood sugar levels.

Studies have shown that people with diabetes who continue to produce their own insulin have less trouble with low blood sugar and fewer complications from their diabetes than people who no longer make any insulin. A previous study in children and adolescents with type 1 diabetes demonstrated that beta cells were protected after receiving Diamyd.

The Diamyd vaccine is an investigational drug aimed at saving a person's ability to make their own insulin for as long as possible. Its active substance is a protein called glutamic acid decarboxylase (rhGAD65).

The goal of this study is to see if the Diamyd vaccine shots may help to preserve insulin producing capacity. Diamyd or placebo shots will be given to study participants under the skin to see (at the end of the study) if receiving Diamyd is better than receiving placebo. Placebo is a substance that looks like Diamyd but has no active drug. The study will also further evaluate the safety of the vaccine.

In this study, 4 vaccinations will be given to all participants over a period of nine months

The study doctor will ask participants to attend 8 clinic visits for routine examinations and for taking blood and urine samples. Also, at 6 of these visits, a test will be performed to evaluate the body's ability to produce insulin. The total duration of the study is about 2 ½ years.

Direct positive effects of the Diamyd vaccination cannot be guaranteed.

You were selected as a possible participant in this study because you were recently diagnosed as having Type 1 diabetes.

Your participation in this study is entirely voluntary.

Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Darrell Wilson at 650 723 5791.

This research study is looking for about 320 people with type 1 diabetes between 10 to 20 years of age from several study sites are expected to participate in this study. You are being asked to participate because you are between 10 and 20 years of age and have been diagnosed with type 1 diabetes within the past 3 months. All drug research studies have guidelines about who can be in a study. The study doctor will determine if you meet all of the requirements for being a part of this study.

Stanford University expects to enroll about 15 research study participants.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 2 ½ years for each subject.

PROCEDURES

If you choose to participate, the Protocol Director and his research study staff will do the following:

The first part of the study is the screening visit. After this visit, the study doctor will decide if you qualify to be in the main part of the study.

Before you can start the study, the study doctor or study staff will talk to you about the study. Then you have to sign this form before the study doctor or study staff can begin the screening to see if you qualify to be in the study.

If you are approved for entry into the study, you will be assigned by chance to 1 of 3 groups to receive Diamyd and/or placebo (inactive substance). You will return to the clinic within 2-4 weeks after the screening visit and receive the first of the 4 injections of study drug (this visit will be Day 1). The other 3 injections will be given after 1 month, 3 months, and 9 months, at clinic visits. The injections are given subcutaneously, under the skin, in the same way that insulin injections are given.

You will be assigned by chance (like pulling a card out of a hat) to 1 of the 3 study groups:

- Group 1: Four subcutaneous injections of Diamyd at a dose of 20 micrograms each
- Group 2: Two subcutaneous injections of Diamyd at a dose of 20 micrograms each (the first two injections) and two subcutaneous injections of placebo (the last two injections)
- Group 3: Four subcutaneous injections of placebo

Neither you nor the study doctor or study staff will know who receives Diamyd, placebo, or both, until after the study is finished and the results have been assembled. After each injection, you will need to stay at the clinic for at least an hour so that the study doctor's staff can examine the injection site.

You will visit the clinic for a total of 8 times over a period of 2 ½ years. You will need to be fasting (no food or beverages for greater than 10 hours, although water is allowed) when you arrive at the clinic in the morning, and you must not have injected your morning insulin yet. If you have an insulin pump, you must continue with your basal dose of insulin but not add any bolus dose in the morning before the visit.

At clinic visits, you will undergo physical examinations and have blood and urine samples taken. You should ask the study doctor about what will happen during the physical exams. During some of the physical exams, the study doctor will check to see what stage of sexual maturity (puberty) you are in. Ask the study doctor if you have any questions about this.

The study staff will test your urine to see if you are pregnant. You will only have pregnancy testing if you are a woman. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study. Please note that if you are the parent or guardian of a child in this study, the study doctor or study staff may or may not tell you the results of your daughter's pregnancy testing, depending on state law.

The study doctor or study doctor's staff will interview you about how you are feeling and will answer any questions you might have about your study drug and experiences. The study staff will ask you to answer questions about your health,

your medical history, and the medications you take. The study staff will check your blood pressure by putting a band around your arm. This will squeeze your arm for about a minute. The study staff will see how tall you are, and see how much you weigh.

At some visits, the study staff will do a neurological exam (shake hands, walk on a line etc.). You should ask the study doctor about what will happen during this exam.

At four clinic visits, the study staff will give you a dose of study drug (Diamyd or placebo) at the clinic.

The study staff will also give you a study diary and tell you how to use it. Between the clinic visits, you will be asked to record any hypoglycemic episodes (low blood sugar) and any injection site reactions in this diary. The study staff will ask you to bring the completed diary back to the study center at each visit.

The study staff will also ask you to call the clinic every day for 4 days before every visit to report how much insulin you injected during these 4 days.

At 6 of the 8 clinic visits, the study doctor will perform a tolerance test to evaluate your body's ability to produce insulin. Each of these tests involves taking blood samples before and after you have ingested a drink composed of sucrose, soy protein, casein, and soy oil. (It also contains milk protein.) To avoid needing to prick the skin with a needle several times for samples, the study doctor's staff will place an intravenous plastic tube (catheter) in your arm. Each test will take approximately 2 hours.

The maximum amount of blood drawn for tests at each visit will be based on your age and weight (approximately 1-3 tablespoons depending on the visit).

Your regular medical care might include some of the study tests and procedures. The study doctor or a member of the study staff can answer any questions you may have about which tests and procedures are not part of your regular medical care.

Overall, clinic visits will take 2-3 hours.

When the study is completed, the groups of participants who received Diamyd will be compared to the group who received placebo.

Diabetes care

If you decide to be in this study, you will be expected to keep your blood sugar as close to normal as possible by managing your diabetes actively. During the whole study you will be responsible for receiving your own diabetes care as usual.

What do I have to do?

During the study, you will have the following responsibilities:

- Attend all scheduled visits.
- Inspect the injection site daily for a week after each injection.
- Use the study diary to record how the injection site looks and feels and to record all hypoglycemic episodes.
- On the 4 days prior to each clinic visit, call the clinic each day to report how much insulin you injected in the previous 24 hours.
- Notify the study doctor of any illnesses or injuries, unexpected or troublesome side effects, or problems that occur during the study.
- Notify the study doctor if you plan to have surgery or any other medical treatment or procedure.
- Follow the instructions you are given.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

Pregnancy and Breastfeeding

Researchers do not know if or how Diamyd affects the fetus during pregnancy. Neither do researchers know if Diamyd is absorbed into the breast milk and if this could harm the child. You must therefore not be pregnant or breastfeeding when you enter this study. Nor can your plan to become pregnant within 1 year and 9 months after the first injection. During this period of time you will need to use an effective form of birth-control when having sexual contacts. Some methods of birth control will not work when you are taking certain drugs. Be aware that you can still become pregnant even if you use an acceptable birth control method.

A pregnancy test will be performed at every visit to the clinic. A pregnancy test does not keep you from becoming pregnant. If you become pregnant, you must tell the study doctor right away.

If you are a man, there may be risks to an fetus you father during or after the study. The study doctor will talk to you about the birth control options you and/or your partner must use during the study and for 1 year after the last study drug administration.

If you think you are or your partner is pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you are not allowed to receive further injections of study drug. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with the sponsor and Quorum Review.

OPTIONAL GENETIC STUDIES

The sponsor wants to use some of your blood to look at your genes, which are often called "DNA." Genes are in your blood, and they are what make you different from anyone else. Some genes control things like the color of your hair or eyes. Other genes might make you more likely to get certain diseases like type 1 diabetes.

Some researchers want to look at your blood to find out if any of your genes make you more likely to have type 1 diabetes, and to find out if your genes affect your response to the study drug you may be taking in the main study. This is called a "genetics research study."

The sponsor will not use your blood for any other tests without your permission. No one other than the sponsor (and/or people or companies the sponsor works with) will test your blood. The sponsor (and/or people or companies the sponsor works with) will not give or sell your blood to other people or companies.

You do not have to be in this genetics study if you don't want to. You can still be in the main study even if you don't want to be in this genetics study.

WHAT WILL HAPPEN TO ME IN THIS GENETICS STUDY?

If you want to be in the genetics study, you will come to the study center for Visit 3 during the main study. At that time, all the procedures for Visit 3 of the main study will be done. In addition, the study doctor or study staff will obtain an extra tube of blood (about 1 teaspoon). This will be done at the same time as other blood tests for the main study are taken, so there will be no additional sticks.

None of the genetics study procedures are a part of your regular medical care.

The estimated recovery time of your participation in this genetics study will be the same as the recovery time of the main study visit when blood is taken.

ARE THERE RISKS TO ME IF I AM IN THIS GENETICS STUDY?

There is not another needle stick for the genetics study. This blood sample will be in addition to the other samples that will be taken for the main study at Visit 3.

Your test results are private. However, if your test results got into the wrong hands, the privacy of your health information may be lost. The sponsor, Diamyd Therapeutics AB, will make every effort to make sure no

one gets your test results except those people or companies you read about in this form.

WILL BEING IN THIS GENETICS STUDY HELP ME?

Being in this study will not help you. Information from this study may help researchers understand type 1 diabetes and come up with new tests or medicines to help others in the future.

WILL IT COST ANYTHING TO BE IN THIS GENETICS STUDY?

You will not have to pay for the study visit or test that are part of this genetics study.

WILL I GET PAYMENT?

You will not receive any additional payment for this part of this genetics study.

WILL I GET PAYMENT IF THE SPONSOR MAKES NEW TESTS AND MEDICATIONS?

The blood you give for this genetics study might help the sponsor come up with new tests or medications in the future. If the sponsor makes new tests or medications, you will not get any money for these tests or medications. The sponsor will own the results of this study and any new tests or medications the sponsor makes because of this study.

HOW WILL THE SPONSOR PROTECT MY IDENTITY?

Your blood will not have your name on it. Your blood will have a code on it. The code will link your blood sample to information about the test results. People who work for the sponsor will be able to find your study number from the code so they can destroy your blood if you change your mind later.

WHERE WILL MY BLOOD GO?

People who work for the sponsor will store your blood in a secure laboratory. They will store your blood for 1 year after completion of the study and then the sponsor will destroy your blood.

DO I HAVE TO BE IN THIS GENETICS STUDY?

Your decision to be in this genetics study is voluntary. You do not have to be in this genetics study if you don't want to. You can still be in the main study if you don't want to be in this genetics study.

If you don't want to be in this genetics study, there will be no penalty to you, and you won't lose any benefits. Your regular medical care at this study center will not change if you decide not to be in this genetics study.

The tube with your blood in it will have a code that connects it to you. If you change your mind about being in this genetics study later, you must tell the study doctor you want the sponsor to stop testing your blood. The sponsor will then destroy your blood sample. If the sponsor did any testing before you changed your mind, the sponsor will still use the test results.

If you tell the study doctor you want the sponsor to stop testing your blood, this is not the same as canceling your permission to use and share your records. You must follow the directions in the section titled, "Who will use and share information about my being in this study?" to cancel your permission to use and share your records.

The study doctor or sponsor can remove you from the genetics study at any time, even if you want to stay in the study. This could happen if:

- *The study doctor believes it is best for you to stop being in the study.*
- *You do not follow directions about the study.*
- *The sponsor stops the study for any reason.*

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more tests.

WILL I GET THE RESULTS OF MY GENETIC TESTS?

Your test results are for research only. You will not get your test results. The test results will not be put in your medical records. The sponsor will not give your test results to any insurance company, your employer, your

family, the study doctor, any other doctor, or anyone else, except as specified below. The test results are not for personal use.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

I agree to be part of the genetic study YES NO (circle one)

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study. This is to protect you from possible injury arising from such things as extra blood drawing, the possible interaction(s) of research drugs, or other similar hazards.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you withdraw from the study, or the study medication is stopped for any reason,

The Protocol Director may also withdraw you from the study and the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Previous studies have demonstrated Diamyd to be safe and well tolerated. Side effects reported by participants who have received Diamyd include discomforts such as headache, nausea, diarrhea, local skin reactions showing redness and swelling, increased white blood cell counts, hypoglycemia, and muscle- neck- joint- or back pain. The follow-up periods have been at least 5 years for adults and 30 months for children and adolescents. The prior dose has been 2 injections (not 4, as some participants in this study may receive). Up to this point, the participants who have received 2 injections of Diamyd have not experienced any serious side effects related to the study drug. As a precaution, participants will stay in the clinic for observation for 1 hour after each vaccination.

Early in the development of the vaccine it was discussed whether the vaccine could give problems with the nervous system. This has however not been seen in any study with the vaccine to date. As a precaution, everyone in the study will be tested (shake hands, walk on a line etc.) to be sure they do not have any neurological problems.

Could I have an allergic reaction?

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some other things that could happen during an allergic reaction are:

- a rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

Diamyd may involve risks to the participant (or the embryo, fetus, or nursing infant if the participant is or may become pregnant) which are currently unforeseeable.

What if I am receiving placebo instead of active drug during the study?

Some people in the study will get placebo instead of Diamyd. Receiving placebo is the same as not receiving study drug. As long as you maintain your standard diabetic care as usual, receiving placebo will not worsen your diabetes. Please ask the study doctor or study staff if you have any questions about placebo.

Could I have any other problems with my health if I do this research study?

It is possible that you could have problems and side effects of Diamyd that nobody knows about yet. If the study doctor learns any new information about Diamyd that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

It is possible that receiving Diamyd with your regular medications or supplements may change how Diamyd, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study.

What are the risks of giving blood for this study?

The study doctor or study staff will take your blood by sticking a needle in your arm. The risk of serious side effects from these procedures are very small:

- It may hurt.
- You may get a bruise.
- You may feel dizzy.
- You may get an infection.

Ask the study doctor or study staff how much blood you will give during this study.

POTENTIAL BENEFITS

If you decide to take part in this study, there is no guarantee that your health will improve. If you receive the Diamyd vaccine, it may help the body to continue to produce some insulin, but there is no guarantee. Even if Diamyd can protect the insulin producing cells that are left, you will still need to take insulin shots. If the injections with Diamyd produce a positive effect, the preservation of your body's ability to produce some insulin may help you control your blood sugar levels. Studies have shown that people who continue to make insulin have less trouble with low blood sugars and fewer complications from their diabetes than people who no longer make their own insulin. The study doctor and study staff will follow your health and diabetes closely.

You will also be helping others by contributing to medical research.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

Before you decide to take part in this study, the study doctor or study staff will talk with you about the other options available to you, including the important risks and benefits. You may choose not to participate in this study. At present, there is no approved medical treatment that will preserve beta cells, and the ability to make insulin, for people with type 1 diabetes. There may be other research studies that you can choose to be in.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.
If you decide not to participate, tell the Protocol Director. You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of Diamyd; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization

form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this research study is to obtain data or information on the safety and effectiveness of Diamyd; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Darrell M Wilson, MD, G313 Medical Center, Stanford, CA 94305-5208.

What Personal Information Will Be Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, any information about you that the study doctor needs to do the study, including information from the tests described above. Your records also will include other identifying information about you, such as your name and address.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Darrell M Wilson, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff at Stanford

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Diamyd Therapeutics AB; people who work with or for the sponsor; and other researchers involved in this study. These people will use your records to review the study, to check the safety and results of the study, and to seek government approval of the study drug. Examples include the data safety monitoring board, collaborators at other institutions, and outside data analysts.
- The Food and Drug Administration and other regulatory agencies in the United States and other countries.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will expire 14 June 2114.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until

it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Participant Date

_____ _____
Signature of Legally Authorized Representative Date

PARENT (change if needed)_____
Description of Representative's Authority to Act for Subject

FINANCIAL CONSIDERATIONS

Payment

You will get $50 for each study visit you finish. The study doctor or study staff can tell you more about when you will get paid.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

Costs

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits.
The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. If you would like to review the list of such covered services, supplies, procedures and care, please tell us now or at any time during the study.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. **You will be responsible for any co-payments and/or deductibles as required by your insurance.**

Sponsor

A company called Diamyd Therapeutics, the sponsor of the study, is paying for this study. Diamyd Therapeutics is also paying the study doctor to do this study.

The National Institutes of Health are providing some financial support for the facility and staff where part or all of the study is taking place.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, care will be provided to you. You will **not** be responsible for any of these costs.

Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr Wilson. You may contact him now or later at 650 723 5791.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr Wilson. You may contact him now or later at 650 723 5791.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, Stanford, CA 94305-5401.

Appointment Contact: If you need to change your appointment, please contact Adriana Soto at 650 7235 6577.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

We may contact you about future studies that may be of interest to you unless you check this NO – DON'T contact about future studies ☐.

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your child's regular doctor or specialist of your child's participation in this study.

☐ Yes, I want the study doctor to inform my child's regular doctor/specialist of my child's participation in this study:

_____ _____
Name of Doctor Phone

☐ No, I do not want the study doctor to inform my child's regular doctor/specialist of my child's participation in this study.

☐ My child does not have a regular doctor/specialist.

Participant ID:

STUDY

☐ The study doctor is my child's regular doctor/specialist.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____ _____
Signature of Adult Participant Date

_____ _____
Signature of LAR (Parent, Guardian or Conservator) Date

__ **PARENT** (change if needed)_____
Authority to act for participant

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Authority to act for participant

The IRB determined that the permission of two parents is required for research to be conducted under 21 CFR 50.52, in accordance with 21 CFR 50.55 unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child. Not reasonably available means that the other parent is not present during the consenting process, or will not be available prior to the start of research procedures.

Participant ID:

Person Obtaining Consent
I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of witness Date

Participant ID:

STUDY