Diagnosing Down Syndrome by Analyzing Maternal Blood

Study Consent

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

PURPOSE OF RESEARCH

You are invited to participate in a research study of diagnosing fetal Down Syndrome by analyzing maternal blood. We hope to be able to identify fetal Down Syndrome by analyzing fetal DNA found in your blood. You were selected as a possible subject in this study because you are currently at risk for having a child with Down Syndrome.

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. Yair Blumenfeld at 650-269-4665.

This research study is looking for 100 patients with pregnancies at risk for Down Syndrome. Enrollment will only occur at Stanford University.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 3 years.

PROCEDURES

If you choose to participate, Dr. Hudgins and her research study staff will draw 20 mL (5 tablespoons) of your blood for serum analysis and will send it to a lab at Stanford for evaluation. Our goal is to identify a way of diagnosing Down Syndrome without invasive testing. Participation in this study only includes this single blood draw and blood will not be stored for future analysis. The technique used to identify Down Syndrome by blood analysis is experimental and thus you and your doctor will not be notified of the results. We will also follow results from any invasive testing (amniocentesis and chorionic villus sampling) that you should decide to undergo. We will compare these results with the results of blood analysis. Following delivery, experts from the department of genetics will evaluate your neonate for any morphologic signs of Down Syndrome. They may recommend genetic testing following your delivery. We will not perform any tests related to this study on your newborn without your knowledge and permission.

TISSUE SAMPLING FOR GENETIC TESTING

Research using tissues is an important way to try to understand human disease and/or the role genes play in disease. You have been given this consent form because the investigators want to include your tissues in a research project. There are several things you should know before allowing your tissues to be studied:

Your blood will be assigned a unique number and stored without any personal identifiers. Your name or other public identifiers will not be included with any data shared with other investigators.

Once the sample is taken, it will forever be separated or unlinked from your name. This will protect your identity and preserve anonymity. However, once you donate the sample, you will not be able to withdraw your tissues from the research project because the samples will not be traceable.

You and your doctor will not be notified of the test results so that they don't effect any clinical decision making for this pregnancy. The decision regarding whether or not to proceed with the current diagnostic procedures of amniocentesis or chorionic villus sampling will be based on your discussions with

the genetic counselors and doctor. The result of this blood test will not be revealed in the future and thus will not affect any future pregnancies.

Even with special precautions, there is no absolute protection against discrimination on the basis of disease or genetic information. For this reason, the investigator will use the results of this study as research only and not include them in your medical record. Generally, you will not be told the results, even if there might be some potential benefit to you.

Your blood sample will be destroyed after this study.

Any tissues you have donated which are used in research may result in new products, tests, or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests, or discoveries.

SUBJECT'S RESPONSIBILITIES.

- You should 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 all of the Protocol Directors. This is to protect you from possible injury arising from such things as extra blood drawing.

WITHDRAWAL FROM STUDY

If you first agree to participate and then 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 please notify the protocol directors.

The Protocol Director may also withdraw you from the study for one or more of the following reasons:

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.

- There may be some pain/discomfort with the blood draw.
- The blood draw may involve risks to you which are currently unforeseeable.

POTENTIAL BENEFITS

- This study does not have any direct benefit to you or this pregnancy but we hope to use the knowledge gained by this study to assist future pregnacies.
- **WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

ALTERNATIVES

- There are no alternatives to this study. The alternative is not to participate.

SUBJECT'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.

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.

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