

**University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Participants Social Behavioral Form**

THIS CONSENT DOCUMENT SHOULD BE USED ONLY
BETWEEN 9-28-09 AND 9-27-10
APPROVED BY
INSTITUTIONAL REVIEW BOARD, UNC-CHAPEL HILL

IRB Study # 08-1839
Consent Form Version Date: 09/25/2009

Title of Study: Periconceptional Changes in Thyroid Function: A Pilot Study

Principal Investigator: Anne Z. Steiner, MD, MPH
UNC-Chapel Hill Department:
UNC-Chapel Hill Phone number: (919)966-5283
Funding Source and/or Sponsor: University of North Carolina

Study Contact telephone number: (919) 843-8246
Study Contact email: fertility@unc.edu

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn about changes in thyroid function in early pregnancy. Some studies have suggested that abnormal thyroid function in early pregnancy may lead to miscarriage. It is thought that women with thyroid antibodies are more likely to have thyroid dysfunction in early pregnancy increasing their risk for miscarriage.

You are being asked to be in the study because you are pregnant and provided a blood sample for research prior to conceiving.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 60 people in this research study.

How long will your part in this study last?

If you participate in this study, you will provide a blood sample today. You will not be asked to do anything further for the study. The blood will be analyzed after all 60 subjects have been enrolled.

What will happen if you take part in the study?

If you agree to participate in this study, we will obtain approximately 10ml (2 teaspoons) of blood from your vein. These samples will be stored frozen and analyzed at a later time for thyroid hormone levels and for presence of thyroid antibodies. You must provide blood to participate in this study. You will not be informed of the results of the blood results. Any residual blood will be discarded at the conclusion of this study.

We will also analyze the blood you provided for *Time to Conceive* for the same thyroid hormone and compare the values.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

You may experience minimal discomfort, bruising, and a low risk of infection with the blood draw. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will your privacy be protected?

Confidentiality will be protected by keeping data in both a locked location and in a password-access computer program, with only the study investigators and research coordinator having access to the data. In addition, personal identifiers including name, contact information, date of birth and medical record is not included on blood samples and data sheets, with subjects instead being assigned a study number for identification.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Will you receive anything for being in this study?

You will be receiving \$15 for taking part in this study.

Will it cost you anything to be in this study?

There will be no costs for being in the study

What if you are a UNC student?

You may choose not to be in the study or to stop being in the study before it is over at any time.

This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?

Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Principal Investigator: Anne Z. Steiner, MD, MPH

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent