University of North Carolina at Chapel Hill
Consent to Participate in a Research Study

IRB Study #_____08-0423_____
Consent Form Version Date: _____ 1/ 12/2012_____

Title of Study: Time to Conceive: A Study of Fertility: Biomarkers of Infertility

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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.

Research studies are designed to obtain new knowledge that may help other 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.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

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 a way to measure a person's fertility. After 1 year of trying, 1 out of every 7 women will not be pregnant. This is called infertility. This results in significant distress and anxiety. Infertility is common; however, we have no markers to predict who will be infertile. For couples diagnosed with infertility, we have used blood and urine hormone levels (follicle stimulating hormone (FSH), inhibin B, and antimullerian hormone (AMH)) to tell us who will get pregnant with fertility treatment. We don't know if these hormone levels can predict if regular people trying to get pregnant will be able to get pregnant. This study will try to determine if these hormone levels can predict fertility and infertility.

You are being asked to be in the study because you are a woman between the ages of 30 and 44 trying to get pregnant. To participate in this study you must be trying to get pregnant and living with your male partner.

Are there any reasons you should not be in this study?

You should not be in this study if you are currently using birth control or breastfeeding, can not speak English, have been trying to get pregnant for more than 3 months, have used hormone shots for birth control in the past year, have renal failure, or have known fertility problems including but not limited to polycystic ovarian syndrome (PCOS), endometriosis, or a history of pelvic inflammatory disease.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 750 people in this research study.

How long will your part in this study last?

You will be enrolled in the study until you have your early pregnancy ultrasound or until you have been trying to conceive for 12 months. Below is a list of activities during the study and the time it will require to complete them.

Activity	**Time**
Consent and Telephone instructions	**30 minutes**
Questionnaire	**15 minutes**
Blood and Urine collection (Study visit)	**15 minutes**
Fertility Diary (daily up to 3 months, monthly thereafter)	**15 minutes each month**
Telephone call to schedule your pregnancy ultrasound	**5 minutes**
Pregnancy ultrasound	**15 minutes**
Pregnancy outcome questionnaire	**5 minutes**
Total	**1 hour and 40 minutes (minimum)** **4 hours and 25 minutes (maximum)**

What will happen if you take part in the study?

By this time point, we have determined that you are eligible to participate in this study. If you agree to participation, you will complete a questionnaire online. The questionnaire has questions about your medical and reproductive history, your partner, your family history, and your behaviors. If you do not

have access to a computer, you will be provided a paper copy of the questionnaire to complete.

You will also start charting on your online, study, fertility diary. Using the diary you will record days you have bleeding, have intercourse, take medications, and have signs of ovulation. You are not required to monitor for ovulation to participate. However, if you do monitor for ovulation using ovulation predictor kits, basal body temperature monitoring, or cervical mucus testing, we ask that you record your test results. You will login to the online fertility diary daily to chart until you conceive or until you have charted for 3 months (whichever comes first). If you have not conceived after 3 months of charting you will be asked to login once a month thereafter to answer questions regarding your previous month's activities (until pregnancy or 9 more additional months have passed). If you do not have access to the internet at least 5 days a week, you will be provided a paper copy of the diary to complete.

You will call us on the first day of your next period to schedule your study visit. Your study visit will occur on the second, third, OR fourth day of your cycle. We will ask you to provide us with a first morning urine sample the day of your study visit. We will send you in advance a urine collection and transportation kit for you to use to bring in your sample the day of your visit. If you do not bring in your first morning urine, we will collect a urine sample from you during your visit. During the visit, we will obtain approximately 15ml (3 teaspoons) of blood from your vein. These samples will be stored frozen and analyzed at a later time for hormone levels. You must complete the blood draw and provide us with a urine sample to participate in the study, and to qualify for the free ultrasound. You will not be informed of the results of the hormone studies. You will not be asked to provide any additional blood samples.

We ask that you use the pregnancy test we provide on menstrual cycle days 28, 31, 34, 37, 40, and 43 until you have a positive test or your period starts. If your pregnancy test is positive, we would like you to record it in your daily diary and call us at 843-8246 or email us at fertility@unc.edu to set up your ultrasound. If we do not hear from you within 3 months, we will call you to check on you. If we don't hear from you after 6 and 12 months, we will call again to check on you.

You will have a transvaginal ultrasound during your 7^{th} week of pregnancy to look at the size of the baby and look for a heart beat. You will be given a picture of the baby. We will send a copy of our ultrasound findings to your doctor if you desire. You must agree to have a pregnancy ultrasound in order to participate in this study. This ultrasound is only for women who attend their study visit.

You will be asked to complete a short pregnancy update questionnaire online. If you miscarry, we will ask you record the date of your miscarriage. If you do not report a miscarriage, we will contact you between 20 and 22 weeks gestation (around 5 months) to check on you. After delivery you will complete a short online questionnaire about your pregnancy, delivery, and baby. We will send you an email reminder shortly before and following your due date.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from

being in this research study.

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

You may experience minimal discomfort, bruising, and a low risk of infection with the blood draw. You may feel some vaginal pressure during the ultrasound. We understand that you may not want others to know that you are trying to get pregnant. We will do our best to protect your confidentiality. In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation**.**

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 will be removed from subject questionnaires and data sheets, with subjects instead being assigned a study number for identification. Identifiers will be kept separate from data information, again in a password protected or locked location.

No subjects will 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 example, the FDA) for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you start fertility treatment, or because you have not gotten pregnant after 12 months of being in the study, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will receive up to $175 for taking part in this study.

Study Activity	Frequency	Amount per event	Total
Questionnaire	**1**	**$5**	**$5**

Fertility Diary (daily)	**Daily 1-13 weeks**	**$5 (per week) first month; $10 (per week) in second and third months**	**$0-105**
Fertility Diary (monthly)	**0-9**	**$5 (per month)**	**$0-45**
Initial blood and urine sample	**1**	**$15**	**$15**
Pregnancy Outcome Questionnaire	**1**	**$5**	**$5**
Total			**$20-175**

In addition, you will be given a $2 parking coupon on the day of your blood draw, if you have your blood drawn at UNC Hospitals. You will receive up to 60 free pregnancy tests. If you become pregnant during the study, you will receive an ultrasound picture of your baby. You will not have to pay for the ultrasound. The ultrasound results will be recorded in your UNC Medical Record unless you request them not to be placed in your medical record.

Will it cost you anything to be in this study?

If you choose to participate in this study, you will be responsible for paying for your transportation to and from the study site. We will provide a coupon for parking on the day of your blood draw but not the day of your ultrasound. If you use ovulation predictor kits, you will be responsible for paying for them. If you require any care outside of the study protocol, the costs of that care will be billed to you and/or your insurance.

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.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

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, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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

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, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Title of Study: Time to Conceive: A Study of Fertility: Biomarkers of Infertility

Principal Investigator: Anne 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 Research Team Member Obtaining Consent Date

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Printed Name of Research Team Member Obtaining Consent