

The University of North Carolina at Chapel Hill
Consent for Storing Biological Samples Without Identifying Information

IRB Study # 08-0423

Consent Form Version Date: 1/10/13

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

Principal Investigator: Anne Z. Steiner, MD, MPH

UNC-Chapel Hill Department: Obstetrics and Gynecology

UNC-Chapel Hill Phone number: (919) 966-5283

Funding Source: URC grant and Department of Obstetrics and Gynecology

Study Contact telephone number: (919) 843-8246

Study Contact email: fertility@unc.edu

What are some general things you should know about this research study?

Research studies are designed to gain scientific information 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.

Research with blood, tissue and/or body fluids (specimens) can help researchers understand how the human body works. Research using specimens can also answer other questions. Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat diseases. In the future, some research may help to develop new products, such as drugs.

You may refuse to allow us to have or store your specimen. If you are a patient with an illness, you do not have to be in the research study in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. 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?

We will be collecting your urine and blood, to see if certain hormone levels can predict if people trying to get pregnant will be able to get pregnant. We are storing your urine and blood so that if we find another hormone that may predict infertility we don't have to repeat the study. Instead we can use your stored specimens and the data from this study. At this point we do not plan to do any genetic research with your specimen, but your stored urine and blood may be used for genetic research in the future.

How will the specimen be collected?

On the second, third, or fourth day of your menstrual cycle, we will obtain approximately 15ml (3 teaspoons) of blood from your vein and will ask you to give us a urine sample.

What will happen to the specimen?

Your urine and blood sample will be used initially to measure levels of FSH, inhibin B, AMH, and estrone glucuronide. The remaining blood and urine will be stored frozen at UNC without any information on it to identify you. Your urine and blood may be used for future studies. The specimens will be destroyed after 20 years. Dr. Steiner, the primary investigator, may release the specimens to other investigators to be used.

What are the possible benefits to you?

There will be no direct benefit to you for letting your specimen be stored for research. Future research with your specimen may provide additional information that will be helpful in understanding factors that lead to infertility.

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.

Will there be any cost to you for storage of the specimens?

There will be no cost to you for the storage and use of the specimens for research purposes.

Will you receive anything for being in this study?

You will be receiving up to \$175 for taking part in this study. Please see the “Consent to Participate in a Research Study” for further clarification. You will not be receiving any additional money for storing your blood and urine.

Who owns the specimens?

Any blood, body fluids, or tissue specimens obtained for the purpose of this study become the exclusive property of Anne Steiner, MD, MPH, primary investigator. The researchers may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

How will your privacy be protected?

The researchers will not have any identifying information about you so there is no risk to your privacy.

Will you receive study results of future research involving your specimens?

You will not receive study results of future research because the researchers have no information that identifies you.

Can you withdraw the specimen from this repository?

You may not withdraw your specimen in the future because there are no identifiers on the specimen and the researchers will not know which specimen is yours.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from having your specimen collected. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

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, 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 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

Subject'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. I agree to my specimen(s) being stored without any identifying code(s).

Signature of Research Subject

Date

Printed Name of Research Subject

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent