



Consent to Participate in a Research Study

The proportion of hyperglycosylated hCG to total hCG in the urine of women with ectopic and normal pregnancy and subsequent promotion of progesterone production by the corpus luteum

You are being asked to take part in this research study because you have an early pregnancy. Research studies include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Thomas Price, M.D. will conduct the study and it is funded by the Department of Obstetrics and Gynecology and Division of Reproductive Endocrinology and Fertility at Duke University Medical Center.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Thomas Price, M.D. and Dr. John Crochet, M.D. will be your doctors for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to further understand why ectopic (tubal) pregnancies are associated with lower levels of the hormone progesterone.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately thirty-two (32) people will take part in this study at the Duke Fertility Center (DFC).

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You are being asked to participate in this study because you have an early pregnancy and your pregnancy blood hormone level (quantitative hCG) has normally increased over 2 days. Your participation in this study will include the following:

- Allow the use of blood that has already been collected as part of your routine care to be used for research purposes.
- Provide a one-time urine sample of 2-3 mL.
- Allow the investigators to look at your medical records pertaining to this pregnancy until you are 24 weeks pregnant.

Participation in this study is voluntary and refusal to participate involves no penalty or loss of benefits to which you are otherwise entitled. You may terminate your participation in this study in writing or



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verbally to study personnel at any time. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

HOW LONG WILL I BE IN THIS STUDY?

Your active participation in this study concludes when you give the urine sample. We may access your pregnancy medical records until 24 weeks to see how your pregnancy is progressing. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We hope that in the future the information learned from this study will provide a better diagnostic test for ectopic (tubal) pregnancy.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Thomas Price's office.

In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board. If any groups review your research record, they may also need to review your entire medical record.

As part of this study, Dr. Thomas Price and his study team may review the results of testing done for your pregnancy which may include blood, urine and ultrasound studies. These studies would have been done as part of your regular care. He will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.



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The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS?

The only additional costs to you as a result of being in this study are the cost of returning to DFC to give a urine sample. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. In order to make sure that tests and studies done solely for research purposes are charged correctly, we will carefully monitor your Duke Hospital and Clinic charges as long as you are participating in this study. Please ask the research personnel if you would like to know more about which tests and studies are being done solely for research purposes.

WHAT ABOUT COMPENSATION?

There is no compensation for this study.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Thomas Price or Dr. John Crochet at (919) 572-4673 during regular business hours and at (919) 684-8111 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.



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Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Thomas Price or Dr. John Crochet in writing and let him know that you are withdrawing from the study. The mailing address is 5704 Fayetteville Road, Durham, NC 27713.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at anytime without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

If you agree to allow your blood and urine to be used as part of this research, you are free to change your mind at any time. We ask that you contact Dr. Thomas Price or Dr. John Crochet in writing and let him know you are withdrawing your permission for your urine to be used for research in this study. The mailing address is 5704 Fayetteville Road, Durham, NC 27713. At that time we will ask you to indicate in writing if you want the unused blood and urine destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. Thomas Price or Dr. John Crochet at (919) 572-4673 during regular business hours and at (919) 684-8111 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Subject

Date



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Signature of Person Obtaining Consent

Date