INFORMED CONSENT DOCUMENT (ICD)

PRINCIPAL INVESTIGATOR: Beth A. Bailey, PhD
TITLE OF PROJECT: Tennessee Intervention for Pregnancy Smoking

INTRODUCTION:

This Informed Consent Document will explain about being a research subject in an experiment. It is important that you read this material carefully and then decide if you wish to be a volunteer.

PURPOSE:

As part of your prenatal care, your health care provider and his/her staff will be providing you with information about smoking and second-hand smoke exposure, as well as general assistance with pregnancy issues. The purposes of the related research study you are being asked to participate in are as follows: First, we hope to find out how useful you find the information your provider gives you. Second, we want to look at how useful you find the information and assistance provided to you by other staff at the provider's office. Finally, we want to look at how your life circumstances may impact the outcomes of your pregnancy and how useful you find the information and assistance you receive.

We hope that the information obtained from this research study will lead to the development of better care for pregnant women.

DURATION:

If you choose to participate in this research study you will be interviewed during four separate visits to your prenatal care provider while you are pregnant. The first interview will last approximately 30 minutes. The subsequent interviews will last 5 to 10 minutes. In addition, you will be contacted for a 10 to 20 minute interview six weeks after your baby is born, and again six to eight months after your baby is born. These interviews after your baby is born will be conducted either over the phone or in person. All eligible women who receive prenatal care here and at other locations throughout Northeast Tennessee will be invited to participate in this study.

PROCEDURES:

If you choose to participate in this research study, you will be asked to participate in four pregnancy interviews. Before the first interview begins, you will be asked to sign this informed consent document as well as other legally required paperwork. Interviews will be individual, private meetings with a project staff person. You will be asked questions about your background and medical history. You will also be given several forms to complete that include questions about smoke exposure, your feelings, and how conflict is dealt with in your home. If health-related or mental health concerns are revealed during participation in this research, you will be referred for further services. Finally, you will be asked to blow in to a carbon monoxide detector that will provide information about the level of carbon monoxide in the air you breathe out. This level is an indicator of the amount of smoke you have been exposed to.

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By the ETSU-VA IRB

11/11/2010

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By Chair IRB Coordinator

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ADDITIONAL DATA COLLECTION:

As part of the research study, project staff will need access to your medical records. By agreeing to participate (indicated by signing below), you are also agreeing to allow research project staff to access your medical records here at your health care provider's office and at the hospital where you deliver your baby. Additionally, project staff will need to access your baby's newborn hospital chart and discharge summary. Finally, you agree to allow us to contact you in the future, using whatever information you provide to us or that we obtain from your medical charts, for participation in a phone interview and other possible follow up studies. If you choose to participate in research interviews after delivery, you will also be asked about your baby's health and development. You will, of course, have the right to refuse participation in any portion of the study or in any future study at that time.

ALTERNATIVE PROCEDURES/TREATMENTS:

There is currently no alternate research study. However, you may choose not to participate.

POSSIBLE RISKS/DISCOMFORTS:

The possible risks and/or discomforts of your involvement include possible discomfort with answering personal questions. Your privacy is important to us. Questions will be asked in private and answers will be kept confidential. However, you may choose not to answer any question that makes you too uncomfortable. There are not other known risks associated with participating in this research study.

POSSIBLE BENEFITS:

The possible benefits of your participation include having someone to talk with about pregnancy related issues. Information from this study may benefit pregnant women and children born to them in the future. Findings from this study will provide health care professionals with information about the effectiveness of the information they give patients, which can help them to better help their patients. Findings from this study may also lead to the development of programs to help women have healthier pregnancies.

COMPENSATION FOR MEDICAL TREATMENT:

East Tennessee State University (ETSU) will pay the cost of emergency first aid for any injury that may happen as a result of your being in this study. ETSU makes no commitment to pay for any other medical treatment. Claims against ETSU or any of its agents or employees may be submitted to the Tennessee Claims Commission. These claims will be settled to the extent allowable as provided under TCA Section 9-8-307. For more information about claims call the Chairman of the Institutional Review Board of ETSU at 423/439-6055.
FINANCIAL COSTS:

There will be no cost to you as a result of participation in this research study. Usual charges related to you prenatal visit will still apply.

COMPENSATION FOR STUDY PARTICIPATION:

You will receive financial compensation for your involvement in this research study, should you choose to participate. You will receive $20 for the first pregnancy interview, $10 for each of the second and third pregnancy interviews, and $20 for the fourth pregnancy interview. You will also receive $20 for each of the two postnatal interviews, for a maximum compensation of $100.

VOLUNTARY PARTICIPATION:

Participation in this research study is voluntary. You may refuse to participate. You can quit at any time. If you quit or refuse to participate, the benefits or treatments to which you are otherwise entitled will not be affected. You may quit by calling Dr. Beth Bailey, whose phone number is (423) 439-6477. You will be told immediately if any of the results of the study should reasonably be expected to make you change your mind about staying in the study.

CONTACT FOR QUESTIONS:

If you have any questions, problems, or research—related medical problems at any time, you may call Dr. Beth Bailey at (423)439-6477, or Dr. Fred Tudiver at (423)439-6738. You may call the Chairman of the Institutional Review Board at (423)439-6055 or at (423)439-6002 for any questions you may have about your rights as a research subject.

CONFIDENTIALITY:

Every attempt will be made to see that information collected as part of this research study is kept confidential. A copy of the records from this study will be stored in the office space within the Research Division of the Department of Family Medicine at East Tennessee State University for at least 10 years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a subject. Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, the ETSU Institutional Review Board, and personnel particular to this research project have access to the study records. Your information will be kept completely confidential according to current legal requirements. It will not be revealed unless required by law, or as noted above.
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AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES:

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects my individually identifiable health information (protected health information). The privacy law requires me to sign an authorization (or agreement) in order for researchers to be able to use or disclose my protected health information for research purposes in the study entitled Tennessee Intervention for Pregnancy Smoking.

I authorize Dr. Beth Bailey and her research staff to use and disclose my protected health information for the purposes described below. I also permit my doctors and other health care providers to disclose my protected health information for the purposes described below.

My protected health information that may be used and disclosed includes:

- Demographic information
- Intake assessment including medical history
- Visit notes and ACOG charting
- Results of all laboratory procedures
- Delivery and newborn chart information

The Investigator, Dr. Beth Bailey, may use and share my health information with:

- The East Tennessee State University Human Research Protections Program (HRPP) Institutional Review Board Administration when the researcher or the research site is undergoing Quality Improvement Program (QIP) auditing.
- Government representatives, when required by law
- Research project staff

Once my health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Dr. Beth Bailey and the State of Tennessee agree to protect my health information by using and disclosing it only as permitted by me in this Authorization and as directed by state and federal law.

I do not have to sign this Authorization. If I decide not to sign the Authorization:

- It will not affect my treatment, payment or enrollment in any health plans nor affect my eligibility for benefits.
- I may not be allowed to participate in this research study.

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by
ChairIRB Coordinator
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After signing the Authorization, I can change my mind and:

- Not let the researcher disclose or use my protected health information (revoke the Authorization).
- If I revoke the Authorization, I will send a written letter to: Dr. Beth Bailey, P.O. Box 70621, Johnson City, TN 37659 to inform her of my decision.
- If I revoke this Authorization, researchers may only use and disclose the protected health information already collected for this research study.
- If I revoke this Authorization my protected health information may still be used and disclosed should I have an adverse event (a bad effect, or experience something unanticipated).
- If I change my mind and withdraw the authorization, I may not be allowed to continue to participate in the study.

This Authorization does not have an expiration date.
If I have not already received a copy of the Privacy Notice, I may request one by contacting the Privacy Officer. If I have any questions or concerns about my privacy rights, I should contact the East Tennessee State University, James H. Quillen College of Medicine Privacy Officer, Paula Wright,, at 423/433-6074 or the Compliance Manager at Phone: (423)439-5651.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.

By signing below, I certify that I have read or had this document read to me. I will be given a signed copy. I have been given the chance to ask question and to discuss my participation with the investigator. I freely and voluntarily choose to be in this research project. In addition, by signing below, I am authorizing the use and disclosure of my protected health information for research purposes as described above.

______________________________    ________________________________
SIGNATURE OF VOLUNTARILY PARTICIPATING PATIENT          DATE

______________________________
PRINTED NAME OF PARTICIPANT

______________________________    ________________________________
SIGNATURE OF INVESTIGATOR/DESIGNEE          DATE

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By           Coordinator

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