

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

A Randomized Trial Comparing Coconut Oil as a Low-Cost Alternative to Commercial Ultrasound Gel IRB: #12932

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent and Authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

This study is being done to compare the quality of obstetrical ultrasound images obtained using coconut oil to those obtained using commercial ultrasound gel. We will be using organic refined coconut oil in this study. In this study, coconut oil is an investigational device because it is not FDA approved as an ultrasound gel.

We are asking you if you want to be in this study because you are pregnant with only one baby and are here for your regular ultrasound appointment.

The study is being conducted by Dr. Caroline Rouse and Dr. Claire Edelman with the department of Maternal Fetal Medicine at IU School of Medicine.

WHAT WILL HAPPEN DURING THE STUDY?

After obtaining your consent and answering any questions you may have, you will be randomized (like flipping a coin) to either starting the ultrasound by first obtaining the 3 required study images with coconut oil and then proceeding to the standard ultrasound using commercial ultrasound gel (Arm 1) or by starting with the scheduled ultrasound using the commercial ultrasound gel and ending by obtaining the 3 required study images using coconut oil (Arm 2). The ultrasound images will be obtained by running an ultrasound device over your abdomen to obtain different views of your baby.

Whether assigned to Arm 1 or Arm 2, prior to the collection of the study images using coconut oil, you will be handed a small plastic cup with a pre-measured amount of coconut oil and you will be asked to warm it in your hand for at least 2 minutes. You will then apply the coconut oil to your abdomen with your hands prior to the ultrasound technician obtaining the images required for the study.

The ultrasound technician will collect 3 extra images for study purposes only. This will only require 5-10 extra minutes of your time.

At the end of the image collection period, you will be asked to complete a short 10-question survey about your experience.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

- There is a risk someone outside the study team could get access to your medical information from this study. More information about how we will protect your information to reduce this risk is below.
- There is a risk of allergic reaction to the coconut oil if you have coconut allergy which is rare. There is also the risk of skin irritation from the coconut oil or standard ultrasound gel if you have an inflammatory dermatologic condition such as dermatitis, eczema, or psoriasis. Medical care will be provided if skin irritation or allergic reaction occur.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We don't think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured as a result of participating in this study, you will be responsible for seeking medical care and for the expenses associated with any care received. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

HOW WILL MY INFORMATION BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include making sure you meet the criteria to be in this study and gathering information about your medical history to include in the research data.

The information released and used for this research will include:

- BMI
- Allergies
- Past medical history/treatment
- Diagnostic imaging reports

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- The United States Food and Drug Administration (FDA)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher, Dr. Claire Edelman, at 317-650-9107.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you.

If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with IU Maternal Fetal Medicine.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please inform Dr. Claire Edelman in person or at ceedelma@iu.edu at any time.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Claire Edelman at ceedelma@iu.edu. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name	Date
Participant's Signature	
Participant's Address	

Printed Name of Person Obtaining Consent	Date
Signature of Person Obtaining Consent	

