Consent Form
University of Oklahoma Health Sciences Center (OUHSC)
Antibiotic Prophylaxis to Prevent Obesity-Related Induction Complications in Nulliparae at Term (APPOINT): A Pilot Randomized Controlled Trial
Principal Investigator: Stephanie Pierce, MD
Sponsor: OUHSC Department of Obstetrics and College of Medicine Alumni Association

If you are a parent consenting for your minor child, all references to "you" are applicable to your minor child.

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. Discuss this with your family and friends.

Why Have I Been Asked To Participate In This Study?
You are being asked to take part in this trial because you will be undergoing labor induction at The Children's Hospital at OU Medical and have a body mass index (BMI) of 30 or greater.

Why Is This Study Being Done?
The purpose of this study is to determine if giving antibiotics before labor induction in women with a BMI of 30 or greater will reduce the rate of cesarean section (C-section) and infection.

What is the Status of the Drugs (Devices or Procedures) Involved in this Study?
Cefazolin and azithromycin are antibiotics that are currently approved by the US Food and Drug Administration and given to women before C-sections. They are not currently given to women before labor induction.

How Many People Will Take Part In The Study?
About 300 people will participate, all at this location.

What Is Involved In The Study?
If you agree to participate in the study, you will be randomized to receive either study drugs (cefazolin and azithromycin) or placebo (inactive substances, which will look like the study drugs). Randomization means that you are put in a group by chance. You will have an equal (50/50) chance of being assigned to either group, like the flip of a coin. A computer program at the study sponsor will make this random assignment. Neither you nor your physician will choose which group you will be in.

If you are assigned to the study drug group, you will receive cefazolin (2 grams) through an IV at the start of the labor induction and every 8 hours after for a maximum of three doses **and** azithromycin (500 mg) through an IV once at the start of the labor induction.

You may receive additional antibiotics if your doctor suspects that you have an infection or if you require antibiotics to prevent infections (for example, if you are colonized with group B streptococcus or if you are undergoing cesarean delivery). Any additional antibiotics for such indications are standard treatment and would occur even if you decide not to participate in the study.

If you are assigned to the placebo group, you will receive a saline infusion instead of the drugs listed above.

If you take part in this study, your study doctor will look at your medical history before and up to 30 days after your delivery date. Information about your baby will also be collected, such as your baby's gender, birth weight, overall health, and whether or not your baby was admitted to the Neonatal Intensive Care Unit (NICU).

Whether you have a C-section or additional antibiotics will be determined by your obstetrician, not this study.

You will receive a follow-up phone call from a member of the research team approximately 30 days after delivery.

How Long Will I Be In The Study?
You will be in the study until you are discharged from the hospital. Your direct participation will end after delivery, but we may access your medical records for up to 30 days after that day. Someone from the research team will also call you around 30 days after your delivery.

There may be anticipated circumstances under which your participation may be terminated by the investigator without regard to your consent. You may be removed from the study if new information regarding your condition becomes available, or if the doctor determines it is in your best medical interest.

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks of The Study?
There may be a risk that you have an allergic reaction to cefazolin or azithromycin, however a known allergy to any of the study drugs will be an exclusion criteria for participation in the study.

There are no known specific risks to your baby for the antibiotics used in the study, and they are considered safe to use in pregnancy.

Are There Benefits to Taking Part in The Study?
If you agree to take part in this study, there may or may not be direct medical benefit to you or your baby. We hope that the information learned from this study will benefit other patients in the future.

What Other Options Are There?
You may choose not to participate in the study or receive antibiotics before your scheduled labor induction.

What about Confidentiality?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute

confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration and other regulatory agencies. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, and the OUHSC Office of Compliance may also inspect and/or copy your research records for these purposes.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. However, this website will not include information that can identify you. At most, the website will include a summary of the study and results. You can search this website at any time.

What Are the Costs?
There is no cost to you if you participate in this study.

Will I Be Paid For Participating in This Study?
You will be given a $50 gift card for your participation upon randomization to a study group.

What if I am Injured or Become Ill while Participating in this Study?
In the case of injury or illness results from this study, emergency medical treatment is available. You may contact Dr. Stephanie Pierce at 405-271-8787 if you have any questions or concerns.

You or your insurance may be charged for this treatment.

Complications arising as a result of the natural progression of an underlying or pre-existing condition will be billed to you or your insurance. Please check with the investigator or with your insurance company if you have questions.

No other funds have been set aside by the University of Oklahoma Health Sciences Center to compensate you in the event of injury, illness, or for other damages related to your event of injury or illness.

What Are My Rights As a Participant?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. However, please be sure to discuss leaving the study with the principal investigator or your regular doctor. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare, or willingness to continue your participation in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

Whom Do I Call If I have Questions or Problems?
If you have questions, concerns, or complaints about the study or have a research-related injury, contact Dr. Stephanie Pierce at 405-271-8787.

If you cannot reach the Investigator or wish to speak to someone other than the investigator, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

For questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

Signature:
By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	Printed Name	Date
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date

<u>Child's Assent (ages 15-17)</u>:
The information in the above consent form has been explained to me and I understand it. I agree to participate in this study.

PARTICIPANT SIGNATURE (ages 15-17)	**Printed Name**	**Date**
PARENT (or legal guardian) SIGNATURE	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**