IRB #: 24-04-FB-0086
IRB APPROVAL DATE: 07/02/2025
EXPIRATION DATE: 03/09/2026

# *Subject Consent Form*

*Macon & Joan Brock Virginia Health Sciences at Old Dominion University Institutional Review Board*

STUDY TITLE

COMBINATION OXYTOCIN/FOLEY VERSUS OXYTOCIN ALONE FOR INDUCTION OF LABOR IN PATIENTS WITH PRETERM PRELABOR RUPTURE OF MEMBRANES

**Key Summary of Information**

We are inviting you to take part in a research study about methods for induction of labor in pregnant women who have experienced preterm prelabor rupture of membranes (PPROM). This page is intended to provide you with key information to help you decide whether to participate. The detailed consent form follows this page. Please ask the research team questions. If you have questions later, the contact information for the principal investigator in charge of this study is below.

## WHAT IS THE PURPOSE, WHAT ARE THE PROCEDURES, AND WHAT IS THE DURATION OF THIS STUDY?

The purpose of this study is to determine the best method for labor induction for pregnant women who have experienced PPROM.

There are multiple methods used for labor induction. One is oxytocin: a hormone that our bodies normally release to cause contractions when we are in labor. This is given intravenously to start contractions. The other is a Foley catheter: a thin rubber tube with an inflatable balloon at the end of it. This is placed through the cervix, and the balloon is inflated, allowing the cervix to dilate.

There are currently no good studies to guide the best way to induce labor in patients with PPROM.

You will be in the study from the time you are admitted to the hospital until you deliver your baby. You will be randomized to one of two study groups. The first group will undergo induction of labor with only IV oxytocin, the second group will undergo induction of labor with IV oxytocin and a Foley catheter. All study participants will have data collected on demographics, medical history, pregnancy history, and on maternal and infant delivery outcomes.

## WHAT ARE SOME REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY?

You might choose to participate in this study because you would like access to the possibility of receiving a Foley catheter as part of your induction of labor. You might also choose to participate in the study because you wish to contribute to the field of science and help the study team learn new information that may help future pregnancies.

## WHAT ARE SOME REASONS YOU MIGHT CHOOSE NOT TO PARTICIPATE IN THIS STUDY?

You may choose not to participate in this study because of the inability to select the method of induction due the nature of randomization in the study or because you do not want to receive a Foley catheter as part of your labor induction.

For a complete description of the risks of this study, please refer to detailed consent form.

## DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer for it. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. You are free to withdraw from the study at any time.

## WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

For questions about the study, contact the investigator, Marwan Ma'ayeh, MD, at 757-446-7900.

For questions about your rights as a research participant, contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423.

*Please continue to the next page for detailed information about the study.*

## Study Title

Combination Oxytocin/Foley versus Oxytocin Alone for Induction of Labor in Patients with Preterm Prelabor Rupture of Membranes

## INVESTIGATORS

Marwan Ma'ayeh, MD; George Saade, MD
Macon & Joan Brock Virginia Health Sciences at Old Dominion University, Department of Obstetrics and Gynecology

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find the best method to use for labor induction for patients who have experience preterm prelabor rupture of membranes (PPROM).

## WHY ARE YOU BEING ASKED TO TAKE PART?

You are being asked to participate in this research project because you have experience preterm prelabor rupture of membranes and will be undergoing an induction of labor.

This is a research study. This study includes only people who choose to take part. Please take your time to make your decision and feel free to ask any questions you might have.

## WHAT ARE SOME IMPORTANT DETAILS ABOUT THIS STUDY?

At this local site about 80 people will take part in this study. We will need you to be in the study for until you deliver your baby.

Clinically relevant research results will not be disclosed to participants, including any that might apply individually.

## WHEN SHOULD YOU NOT TAKE PART?

If you have any of the following conditions or are taking any of the medications listed below, you should not take part in this study:

- Spontaneous labor
- Known allergy to latex;
- Cervical dilation >2cm;
- Infection;
- HIV
- If your doctor believes you should not have an induction of labor or use a Foley catheter for induction of labor
- Known or suspected fetal anomaly or chromosome abnormality;

## WHAT IS INVOLVED IN THE STUDY?

You will be "randomized" into one of the study groups described below. This means that you will be assigned into a group by chance. It is like flipping a coin. A computer program may do this - neither

you nor the investigator will be able to choose what group you will be in. You will have an equal chance of being placed in any group.

The following are standard procedures that will be done because you will be in this study:

For the oxytocin only group:

- Receiving IV oxytocin for induction of labor

The following are experimental procedures that are being tested in this study:

For the oxytocin and Foley catheter group:

- Receiving a Foley catheter in addition to oxytocin for induction of labor

## WHAT ARE THE RISKS OF THE STUDY?

A risk associated with allowing your data to be saved is the release of personal information from your study record. We will strive to protect your records so that your personal information (like name, address, social security number and phone number) will remain private.

Data is mixed on whether a Foley catheter increases the risk of infection; however, larger studies have shown no increased risk of infection associated with Foley catheter. You may have some discomfort when the Foley catheter is being placed.

Oxytocin is a medication frequently used for induction of labor. It may cause you to contract too frequently, and in very high doses it may be associated with water toxicity. This is why this medication will be given in a low gradual dose according to the Sentara Norfolk General Hospital Labor and Delivery protocol.

While on the study, you are at risk for these side effects. You should discuss these with the investigator and/or your regular doctor or healthcare provider.

There also may be other side effects that are unknown and we cannot predict.

For more information about risks and side effects, ask the investigator or contact 757-446-7900.

## 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 benefit to you. There is no guarantee that you will personally benefit from taking part in this study. We hope the information learned from this study will benefit other people with preterm prelabor rupture of membranes in the future.

## WHAT OTHER OPTIONS DO YOU HAVE?

You may receive oxytocin and/or a Foley catheter even if you do not take part in the study, depending on the treatment plan from your regular doctor.

Please talk to your regular doctor or health care provider about these and other options.

## WHAT ABOUT CONFIDENTIALITY?

In conducting this research study, it may be necessary for the research team to send information about you and your health to persons in other organizations. This information may include what we call "protected health information (PHI)," which includes personal information about you. It will be shared with others only as described below:

| Description of Your PHI to Be Disclosed | Organization and Person (or their title) Disclosing Your PHI | Organization and Person (or their title) Receiving Your PHI | Purpose of Disclosure |
|---|---|---|---|
| Maternal medical, surgical, obstetrical, and social history | Sentara EPIC and Macon & Joan Brock Virginia Health Sciences at Old Dominion University Allscripts medical records | Principal investigator and research team members | Conducting the research study |
| Maternal and fetal outcomes | Sentara EPIC and Macon & Joan Brock Virginia Health Sciences at Old Dominion University Allscripts medical records | Principal investigator and research team members | Conducting the research study |

All protected health information will be maintained in strict confidence as required by law. However, your protected health information may be disclosed if required by law. Once your protected health information is disclosed for research, such as to the sponsor, federal privacy laws may no longer protect the information.

- If you refuse to give your approval for your personal information to be shared as described in this consent form, you will not be able to be in this study. However, your choice will not affect any medical benefits to which you are entitled.
- By signing this consent form to participate in the study, you are allowing the research team to share PHI, as described in this consent form.
- You have the right to cancel your approval for the sharing of PHI. If you cancel your approval, you will have to leave the study. All information collected about you before the date you cancelled will continue to be used. To cancel your approval, you must notify *Marwan Ma'Ayeh, MD* in writing at *825 Fairfax Avenue, Suite 310, Norfolk, VA 23507.*
- Your approval for the sharing of personal information about you for this study expires at the end of the study.

- You also have the right to review your research records, or someone you designate may review your research records on your behalf, once the study has ended unless prohibited by law.
- Any research information in your medical record will become a permanent part of that document.

Your study records may be reviewed and/or copied in order to meet state and/or federal regulations. Reviewers may include, for example, an Institutional Review Board, the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP)

Information learned from this research may be used in reports, presentations and publications. None of these will personally identify you.

## What Will Participation in the Study Cost or Pay?

There are no additional costs to you associated with taking part in this study.

You will not receive payment for taking part in this study.

If any new products, tests, or discoveries resulting from the research have potential commercial value, you will not be compensated or benefit financially.

## What If You Get Injured?

In the case of injury or illness resulting from this study, emergency medical treatment is available and will be provided by Sentara Norfolk General Hospital and paid for by your insurance. Further medical care and/or hospitalization resulting from this injury or illness will be charged to your insurance.

Macon & Joan Brock Virginia Health Sciences at Old Dominion University and Sentara Norfolk General Hospital will not provide free medical care for any sickness or injury resulting from being in this study. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, you do not waive any legal rights by signing this consent form.

## What About the Collection of Data?

You are in a study where data is collected as part of your participation in the research study. These data will not be used or distributed for future research studies by the investigator or other researchers. After all of the study testing is complete, the data and specimens will be destroyed.

## What Are Your Rights as a Participant?

Taking part in this study is your choice. If you decide not to take part, your choice will not affect any medical benefits to which you are entitled. You may choose to leave the study at any time. If you do leave the study, discuss it with the investigator who will help you do so in the safest way. If you leave, the study it will not result in any penalty or loss of benefits to you.

The investigator may decide to take you off this study if you cancel your approval or it is in the best interest of your health.

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

Virginia law says that if you or anyone associated with the study is exposed to the other person's body fluids that might transmit the virus that causes AIDS or the Hepatitis B or C virus:

- The person whose body fluids were involved is deemed to have consented to testing for those viruses so that no further consent is necessary to test the person for these diseases; and,
- Those test results will be released to the person who was exposed and to the health department as required by Virginia law.

## WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the investigator, Marwan Ma'ayeh, MD, at 757-446-7900 or the research coordinator at 757-446-0529.

For questions about your rights as a research participant, contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423.

If you believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Marwan Ma'ayeh, MD at 757-446-7900. You may also contact Betsy Conner, director, Macon & Joan Brock Virginia Health Sciences at Old Dominion University Human Subjects Protection Program and IRB office at at (757) 446-5854.

## SIGNATURE

You will get a copy of this signed form. You may also request information from the investigator. By signing your name on the line below, you agree to take part in this study and accept the risks.

| _____ | _____ | _____ | ___/___ /___ |
|---|---|---|---|
| Signature of Participant | Typed or Printed Name | Relationship to Subject | MM/ DD/ YY |

## STATEMENT OF THE INVESTIGATOR OR APPROVED DESIGNEE

I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

| _____ | _____ / _____ / _____ |
|---|---|
| Signature of Investigator or Approved Designee | MM/ DD/ YY |

v.1