ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called ***Mifepristone Induction for Fetal Demise***. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Dr. Jessica Atrio. You can reach Dr. Atrio at:
1695 Eastchester Rd, suite 505
Bronx, NY, 10461
718-405-8260
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by Montefiore Medical Center, Department of Family Planning.
The study drugs, Mifepristone and Placebo are provided by Danco Pharmacies.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Why is this study being done?

This research study is being done so that we can find out if using one more medication (mifepristone) will help your procedure happen more quickly. If you agree to participate in this research study, you will receive all the standard medications (misoprostol) and hospital care for women who have a fetus that passes away in the uterus, plus as a study participant you will receive an additional pill (mifepristone or placebo). A placebo is a pill with no active medication. Researchers use placebos to see if the study drug works better than receiving nothing at all. Neither you nor your study doctor will be able to decide which pill you receive, mifepristone or placebo.

Mifepristone and misoprostol are used together for pregnancy termination (abortions) in early pregnancy (20 weeks or less). Most women, like yourself, who have a fetus that passes away in the uterus are given one medication (misoprostol) to bring on contractions and delivery for a pregnancy at 13 weeks gestational age or greater.

The U.S. Food and Drug Administration (FDA) has approved Mifepristone for pregnancy termination, but the FDA has not approved mifepristone to bring on contractions after a fetus has passed away. The reason for this research study is to learn if Mifepristone will help women deliver faster than without mifepristone.

We are not sure which is the best way to help women deliver a pregnancy that has passed away and no longer alive. We are asking women who are experiencing this condition to volunteer for this research study. Our goal is to improve treatment options for women in the future by understanding which method is most effective.

Why am I being asked to participate?

You are being asked to participate in this study because you are a healthy woman between 16 to 50 years of age, with a pregnancy that passed away or died in the uterus after about 20 weeks or five months.

How many people will take part in the research study?

You will be one of about 74 people who will be participating in this study at Montefiore Medical Center.

How long will I take part in this research?

You will be involved in the research during your admission to the hospital. You will be asked to schedule a routine post-partum follow up with a Montefiore provider anywhere between 2-6 weeks postpartum depending on the type of procedure you have.

What will happen if I participate in the study?

Before any study-related procedures are performed, you will be asked to read and sign this consent document. If you agree to take part in the study, you will be assigned, by chance, to either one of two study groups, the **mifepristone group** or the **placebo (pill without any medication) group**, prior to the start of the induction of labor. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to either study group. The rest of your care will be the same as any other patient in your situation.

Mifepristone Group

If you are assigned to the Mifepristone group, you will be asked to take one mifepristone pill by mouth prior to additional medications as indicated by the doctors in charge of your care.

Placebo Group

If you are assigned to the placebo group, you will be asked to take one placebo pill by mouth prior to additional medications as indicated by the doctors in charge of your care.

Both study groups

In addition, if you agree to be a part of this research study, we will review your medical record to collect demographic data such as age, ethnicity, education, household, and health information about you and your delivery, such as your treatments on labor and delivery and how long you have been pregnant.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study

Will it cost me anything to participate in this study?

Taking part in this study will not involve any added costs to you. All study drugs will be given free of charge by the sponsor, company or the drug makers. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Atrio at 718-405-8082.

Are there any risks to me?

Confidentiality
We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information and specimens will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them
- clinicians and staff at Montefiore who review your records for your care
- the organization that funded the research
- organizations and institutions involved in this research: The Einstein School of Medicine.

- groups that review research (the Einstein IRB, and the Office for Human Research Protections, and the US Food and Drug Administration)

These people, who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Risks of Taking Mifepristone

Mifepristone may cause bleeding, cramping, diarrhea, nausea, vomiting, headache, dizziness, back-pain, and tiredness. These are also common side effects of the medication misoprostol and of the process of induction of labor. Therefore, if you develop any of the above listed side effects - it will be difficult to determine if they are cause by the other medications used to induce labor, the labor process itself or the study medication (mifepristone). The medical team can offer medications to help you with these side effects. Very rarely, the amount of blood loss may be life-threatening and it may be necessary for you to receive a blood transfusion. You may occasionally experience some discomfort during the pelvic exams and with delivery of the pregnancy or placenta.

Occasionally, the medications and induction of labor treatment may not cause all of the pregnancy or placenta to come out of the uterus. In that case you may need an exam in the operating room for emptying of the uterus by a clinician, or to complete a dilation and evacuation procedure (or dilation and curettage); this is a procedure that empties the uterus of pregnancy tissue. Very rarely, it is also possible that a woman may need a surgery like a cesarean section to remove the pregnancy from her uterus.

Additionally, there is small chance that during the induction process you may get an infection in your uterus or develop sepsis (the body's overwhelming response to infection). Sepsis is a known risk related to any type of spontaneous or induced abortion or intrauterine pregnancy demise. There have been reports of deaths due to sepsis in women who have had induced abortion with mifepristone and misoprostol. Most of these women were infected with the same type of bacteria, known as Clostridium sordellii. The symptoms in these cases of infection were not the usual symptoms of sepsis. We do not know whether using mifepristone and misoprostol caused these deaths. Reports of fatal sepsis in women undergoing medical abortion are very rare (approximately 1 in 100,000).

Other Risks

The other risks include symptoms and situations similar to what was mentioned above and are expected to happen in women who are inducing labor because of pregnancy demise, many of which you would likely experience whether or not you chose to participate in the study. It is normal to feel very sad and distressed when faced with this situation. The hospital staff has experience taking care of women in your situation and can offer support.

Allergic Reaction to Study Drug

Any drug can cause an allergic reaction which could be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. There is hospital staff available throughout your time in the hospital, who will be checking in on you often. If you are experiencing any of these symptoms – alert a member of the staff immediately.

Unknown Risks
We have described the risks we know about. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. The unknown risks of participation could be permanent, severe or life threatening. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. If you are enrolled into the Mifepristone group, the possible benefit of taking part in this study includes the possibility of safely shortening the length of labor induction and therefore a faster time to delivery of the fetus. We hope you will participate because the study will generate important information about which labor induction medications have the greatest chance of success and fewest side effects in women who have a pregnancy that passes away in the uterus after 20 weeks or 5 months.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Your other choices are:
- To receive treatment with misoprostol only and not participate in the study

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility.

Can the study end my participation early?

We will not let you participate in the study any more if the Primary Investigator feels it is necessary for your health or safety, or if you have not followed study instructions**.** In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

Information Banking (Future Use and Storage)

We will store information about you in a "bank", which is a library of information from many studies. This information can be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy the information in the bank but if the information was already shared with other researchers, we cannot get it back.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility**.**

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. The information will be destroyed at the end of the study.

INITIAL YOUR CHOICE BELOW
I consent to be contacted in the future to learn about:
_____ New research protocols that I may wish to join.
_____ General information about research findings.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your information or for any tests, treatments, products or other things of value that may result from the research.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time