

Mifeprex and Misoprostol Abortion Consent Form

I, _____, hereby give permission for Gabrielle Goodrick, M.D. or designated provider to perform a nonsurgical/medical abortion with Mifeprex and Misoprostol.

DESCRIPTION:

_____ I understand that I am fewer than 9 weeks pregnant, and I have decided to have an abortion with the medications Mifeprex and Misoprostol. These medications will cause an abortion by starting cramping and vaginal bleeding like a heavy period or miscarriage. This method allows a pregnant woman to have an abortion without putting instruments into the uterus.

_____ Mifeprex is a drug which blocks the action of progesterone, a hormone needed to continue the pregnancy. Mifeprex has been approved by the U.S. Food and Drug Administration (FDA) for early abortion, and has been used by millions of women in Asia and Europe (it has been referred to as "RU-486" or the "French abortion pill"). Misoprostol is a drug used in the United States to prevent irritation or ulcers in the stomach. When the FDA approved Mifeprex, it was approved for combination with Misoprostol. Studies have shown that Mifeprex and Misoprostol, when used together, are approximately 95% effective in causing an abortion in early pregnancy.

_____ The FDA-approved regimen has been altered based on more recent data from clinical research trials here in the U.S. The alternative evidence-based regimen has the same efficacy (i.e., it works 95% of the time), and is better tolerated by patients. For these reasons, Dr. Goodrick as well as many abortion providers across the U.S. are using this alternative regimen.

PROCEDURE:

_____ The provider will take my medical history, and examine me to assess how many weeks pregnant I am. An ultrasound will be done to determine how far along my pregnancy is. The ultrasound will be done by putting the ultrasound probe in my vagina. I will have my blood drawn to check my blood type and for anemia.

_____ I will swallow 200 mg Mifeprex (one tablet). This will be called "day 1".

_____ 24-48 hours later, I will place 800 mcg Misoprostol in your mouth as instructed.

_____ I will remain at home and plan to relax for the next 6 hours when bleeding or cramping will likely occur. I understand that I will have access to a telephone and Dr. Goodrick's 24-hour emergency contact information.

_____ I will contact my provider at 602-279-2337 if: I soak 2 or more maxi-pads per hour for 2 consecutive hours; I have a sustained fever (100.4 F) or onset of fever a few days after Misoprostol; I have severe abdominal pain not helped by pain medicine; or I have no bleeding within 24 hours after Misoprostol, which may require more medication or evaluation for an ectopic pregnancy.

_____ I will return to the office around day 7. This follow-up appointment is **very** important to confirm that termination of my pregnancy has occurred and that there has been no complications. At this visit, I will have a vaginal ultrasound and urine pregnancy test. If my abortion has occurred, then I am done.

RISKS may include:

_____ Incomplete Abortion: As with a surgical abortion, some pregnancy tissue may remain in my uterus. If this occurs, the provider will discuss my treatment options, which may include waiting one or more weeks, using more Misoprostol, or having an aspiration, which is similar to a surgical abortion. If I decide to wait or use more Misoprostol, and the abortion is still not complete, I will need an aspiration curettage. The risks of an aspiration curettage include a risk of making a hole in the uterus, tearing the cervix, adverse reaction to anesthesia that may be used, infection, excessive bleeding, and failure to remove all of the tissue from the uterus.

_____ Vaginal bleeding: As with the surgical abortion, heavy bleeding can occur and blood clots may come out of the vagina. If I have extremely heavy bleeding or dizziness, an aspiration curettage may be necessary to stop the bleeding. The risks of the aspiration curettage are stated above. The risks of having very heavy vaginal bleeding after Mifeprex/Misoprostol is about 1 per 100 (1%). The risk of needing a blood transfusion after using Mifeprex/Misoprostol is about 1 per 1000 (0.1%).

_____ Continued pregnancy and birth defects: My pregnancy may not end after receiving the medications. If this happens, birth defects are possible. Because of the risk of birth defects, I know that a surgical abortion is strongly recommended to end the pregnancy. The risks of a first-trimester surgical abortion include a risk of making a hole in the uterus, tearing the cervix, adverse reaction to the anesthesia that may be used, infection, excessive bleeding, and failure to remove all the tissue from the uterus.

_____ Side effects: The following side effects are possible (10-15%): nausea, vomiting, diarrhea, fever, headaches, and chills. Most of these side effects last less than a day. I will have cramping in my lower abdomen and may need pain medications for this reason.

_____ Ectopic pregnancy: A rare condition which is a complication of pregnancy rather than the abortion is an ectopic pregnancy or a pregnancy in the fallopian tube. I understand that if the pregnancy is in the fallopian tube or outside the uterus, neither a surgical abortion nor a Mifeprex/Misoprostol abortion will remove the pregnancy, and due to the possible threat of rupture of the fallopian tube, hospitalization may be necessary as soon as it is discovered.

_____ Infection: There is a very rare risk of serious bacterial infection after a medical abortion. There is a 1 in 100,000 risk of developing fatal septic shock. There would be a risk of developing this infection following childbirth, miscarriage, surgical abortion or after other types of surgeries. If more than 24 hours after taking the second medicine (Misoprostol) I have severe abdominal pain or discomfort, or are 'feeling sick' including weakness, nausea, vomiting or diarrhea, with or without fever, I will contact Dr. Goodrick right away. If I visit an emergency room or another health care provider who does not prescribe Mifeprex, I will tell them I am undergoing a medical abortion. I understand this risk is higher than surgical abortion and accept this risk.

_____ It is unknown if antibiotic use might prevent this very rare infection. Dr. Goodrick feels it could help and recommends Doxycycline 100mg twice a day for 5 days. Many providers are doing this and they will be provided for you to take as directed.

COSTS AND PAYMENTS:

_____ I will receive medical care for my abortion as described above (including information about birth control) at a charge of \$_____. This fee includes payment for a surgical abortion if needed. The fee does not include charges incurred for an emergency room visit or for care at another facility.

VOLUNTARY CONSENT:

_____ I have been informed of other choices during early pregnancy including continuing the pregnancy and becoming a parent, continuing the pregnancy and making adoption arrangements, and surgical abortion. I have been informed of the risks involved with a surgical abortion and a medical abortion, and the risks involved with continuing the pregnancy. I understand that I may choose to have a surgical abortion at any time after I start the medical abortion, although I will need to pay for this care if it is not medically necessary.

_____ I have fully disclosed my medical history including the date of my last menstrual period, allergies, blood conditions, prior medications or drugs, and reactions to medications or drugs. I certify that I have read this form or that it has been read to me. I understand its contents, and any questions have been answered to my satisfaction. I certify that I have been given the Mifeprex Medication Guide and that I have had an opportunity to read it and discuss it with my provider.

_____ I understand why Dr. Goodrick is recommending the alternative evidence-based regimen and I understand that this consent form amends the signed Patient Agreement. I understand that Dr. Goodrick thinks this is the best regimen for me. I will be given a 200 mg dose of Mifeprex and an 800 mcg dose of buccal Misoprostol rather than the FDA-approved regimen of 600 mg Mifeprex and 400 mcg oral Misoprostol because current research shows that this is safe and effective and causes less stomach upset. Based on conversations with Dr. Goodrick and the information she has provided, I have chosen the method that is best for me.

PATIENT'S SIGNATURE

PATIENT'S NAME (PRINTED)

MEDICAL PROVIDER'S SIGNATURE

STAFF SIGNATURE

DATE