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MIFEPREX AND MISOPROSTIL CONSENT FORM

I, _____, hereby give permission to the physician or designated provider to perform a nonsurgical/medical abortion with Mifeprex and Misoprostil.

DESCRIPTION:

_____ I understand that I am fewer than 10 weeks pregnant, and I have decided to have an abortion with the medications Mifeprex and Misoprostil. These medications will cause an abortion by starting cramping and vaginal bleeding like 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 horomone 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"). Misoprostil 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 Misoprostil. Studies have shown that Mifeprex and Misoprostil, when used together, are approximately 95% effective in causing an abortion in early abortion.

_____ The FDA-approved regimen has been altered based on more recent data from clinical research trials 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. Sheo Sharma 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 long 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 for anemia.
_____ I will swallow 200 mg Mifeprex (one tablet). This will be called "day 1"
_____ 8-24 hours later, I will place 800mcg Misoprostil 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 the surgery center 24-hour emergency contact information.
_____ I will contact my provider at 443.394.0523, if I soak 2 or more maxi-pads per hour for two consecutive hours; I have a sustained fever (100.4 F) or onset of fever a few days after Misoprostil I have severe cramping which may require more medication or evaluation for an ectopic pregnancy.
_____ I will return to the office around Day 7 to 14. This follow-up treatment is very important to confirm that termination of my pregnancy has occurred and that have been no complications. At this visit, I will have a vaginal ultrasound. If my abortion has occurred, then no further treatment.

RISKS may include:

_____ Incomplete Abortion: as with a surgical abortion, some pregnancy tissues 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 Misoprostil, or having an aspiration, which similar to a surgical abortion. If I decide to wait or use more Misoprostil, and the abortion is still not complete, I will need aspiration curettage. The risks of 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 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, aspiration curettage may be necessary to stop the bleeding. The risks of aspiration curettage are stated above. The risks of having very heavy vaginal bleeding after having Mifeprex/Misoprostil are about 1 per 100 (1%). The risk of needing a blood transfusion after using Mifeprex/Misoprostil is about 1 per 1,000(0.1%).

_____ Continue pregnancy and birth defects: My pregnancy may not end after receiving the medications. If this happens, birth defects are possible. Because of the risks of birth defects, I know that a surgical abortion is strongly recommended to end the pregnancy. The risks of 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 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/Misoprostil 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 1 in 100,000 risk of developing fatal septic shock. There would be a risk of developing this risk following childbirth, miscarriage, surgical abortion or after other types of surgeries. If more than 24 hours after taking the second medicine (Misoprostil) I have severe abdominal pain or discomfort, or are "feeling sick" including weakness, nausea, vomiting or diarrhea, with or without fever, I will contact the physician right away. If I visit an emergency room or another health care provider who does not prescribe Mifeprex, I will tell then I am undergoing a medical abortion. I understand this risk is higher than surgical.

COSTS AND PAYMENTS

_____ I will receive medical care for my abortion as described above (including information about birth control) at a charge of $400.00. This fee does not include payment for surgical (D&C) abortion if needed, which is $150.00. 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 an early pregnancy including continuing the pregnancy and becoming a parent, continuing the pregnancy and making adoption arrangements, and surgical arrangements. I have been informed of risks involved with a surgical abortion and 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 started 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 questions have been answered to my satisfaction. I certify that I have been given Mifeprex Medication Guide and that I have had an opportunity to read it and discuss it with my provider.

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

□ (please check off) I have received the written information on the following: Centers Policy on Advance Directive, My physician disclosure ownership, Patients' Bill of Rights and how my health information can be utilized.

_____
PATIENTS SIGNATURE

_____
PATIENTS NAME (PRINTED)

_____
MEDICAL PROVIDERS SIGNATURE

_____ Date_____
STAFF SIGNATURE