

**Whole Woman's Health of Austin**  
*Transforming healthcare one woman at a time*  
8401 N IH 35 Suite 200 \* Austin, TX 78753  
(512) 250-1005

## Consent for Mifepristone Abortion

**I certify the following to be true (please initial each line):**

- \_\_\_\_\_ I take responsibility for making the decision to have an abortion.
- \_\_\_\_\_ I am sure of my decision and understand that once I take Mifepristone, I have started the abortion process, and I can NOT change my mind.
- \_\_\_\_\_ I understand and agree to the medical abortion process using mifepristone and misoprostol. I understand these medications usually interrupt the growth of the pregnancy and cause an abortion.
- \_\_\_\_\_ I understand that mifepristone is an FDA approved drug for abortion and that misoprostol has FDA approval for preventing stomach ulcers.
- \_\_\_\_\_ I realize there are possible side effects of the drugs mifepristone and misoprostol. Mifepristone may cause nausea, diarrhea, bleeding, and infection or "toxic shock syndrome." Possible side effects of misoprostol include but are not limited to nausea, vomiting, diarrhea, temperature, and abdominal pain and cramping. There is also a slight (less than 1%) chance but possible risk of hemorrhage with Misoprostol that may require emergency treatment, hospitalization, and blood transfusion.
- \_\_\_\_\_ I understand the use of misoprostol pills usually results in moderate to severe cramping that can last several hours, and pain pills may not provide complete relief.
- \_\_\_\_\_ I understand that the intended result of using the misoprostol pills is to abort the pregnancy and has about a 95-97% success rate. I understand I may or may not be able to see the egg sac, embryo or fetus, placenta, and pregnancy-related material, and that it is not exactly predictable when the pregnancy will be aborted.
- \_\_\_\_\_ I understand that for my safety, in case of hemorrhage, I should have a support person with me or "on-call" that can drive and has an available car during the time I am using the Misoprostol.
- \_\_\_\_\_ I have been advised to be within one hour's drive from an emergency room and have a phone at the time I insert the misoprostol pills in case of the hemorrhage.
- \_\_\_\_\_ I consent to receive all medications, shots, pelvic exams, blood and urine tests, and ultrasounds to be performed at Whole Woman's Health in the course of my treatment.
- \_\_\_\_\_ I have been advised to contact Whole Woman's Health's emergency number if I have signs of hemorrhage, fever, infection, or severe diarrhea and vomiting.
- \_\_\_\_\_ I understand a co-existing (twin) pregnancy in my fallopian tube is possible, and that mifepristone will not abort a tubal pregnancy. Tubal pregnancies can burst and may result in death if not treated.
- \_\_\_\_\_ I understand that more than one visit to Whole Woman's Health is **absolutely** necessary to make sure the abortion has occurred and that I am not still pregnant. I agree to return to Whole Woman's Health for my follow-up appointment.
- \_\_\_\_\_ I realize that medical abortion has about a 5% failure rate and that the drugs can cause serious birth deformities, such as deformed arms and legs, paralyzed face, and nerve damage.
- \_\_\_\_\_ I agree to have a surgical abortion if the mifepristone-misoprostol abortion fails. I understand that there is a slight risk of the following possible complications with a surgical abortion:
- |  |  |
|--|--|
| <input type="checkbox"/> infection           | <input type="checkbox"/> scar tissue in the uterus                                 |
| <input type="checkbox"/> hemorrhage          | <input type="checkbox"/> tear or puncture of the uterus, cervix, bowel, or bladder |
| <input type="checkbox"/> incomplete abortion | <input type="checkbox"/> death   |
| <input type="checkbox"/> anesthetic reaction |  |
- \_\_\_\_\_ I understand that the risk of death or (mortality) is much greater for childbirth than for a first trimester surgical or medical abortion, but that a mortality risk exists for any outcome of pregnancy.
- \_\_\_\_\_ I understand that I must return to Whole Woman's Health for a follow up visit 7-10 days from when I take the Mifeprex.
- \_\_\_\_\_ I understand the patient consent for mifepristone abortion.

Patient Signature \_\_\_\_\_ Date \_\_\_\_\_

Staff Witness \_\_\_\_\_ Date \_\_\_\_\_

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**To the best of my knowledge, I do NOT have any of the following:**

- \_\_\_\_\_ Sickle Cell Anemia, Leukemia, or Thalacemia
- \_\_\_\_\_ Heart Disease that is AHA class 3 or higher
- \_\_\_\_\_ Adrenal insufficiency
- \_\_\_\_\_ An IUD in place
- \_\_\_\_\_ Blood clotting disorders
- \_\_\_\_\_ Liver or kidney disease
- \_\_\_\_\_ Seizure disorder or Epilepsy that is not controlled by medication
- \_\_\_\_\_ Inflammatory bowel disease (such as colitis, Crohn's, irritable bowel syndrome)
- \_\_\_\_\_ Allergy to mifepristone or misoprostol (Cytotec)
- \_\_\_\_\_ Any medical condition that requires me to take "blood thinners" such as Aspirin (ASA), Coumadin (Wayfarin), or Heparin
- \_\_\_\_\_ High blood pressure not controlled by medication
- \_\_\_\_\_ Long term use of corticosteroids
- \_\_\_\_\_ Respiratory disease
- \_\_\_\_\_ Known or suspected tubal pregnancy (ectopic)
- \_\_\_\_\_ Immune Deficiency Disorder?
- \_\_\_\_\_ Alcohol or drug addiction?
- \_\_\_\_\_ Take any of the following medications on an every day basis (If so, please circle)?  
 Aspirin    Coumadin    Ibuprofen    Heparin

### **Using Mifepristone "Off-Label"**

The "off-label" or evidence based alternative dispensing of a medication involves giving instructions for use of a prescription medication that differ from the written instructions that the pharmaceutical company and the FDA have agreed upon when the drug was released. The "off-label" use of medications is perfectly acceptable and legal. It is commonly done by physicians when they have knowledge and experience in the use of the drug in a manner different than the written labeling, and that the "off-label" use will result in a more effective and efficient result with no significant increase of risks or side effects. The "off-label" use of mifepristone (RU486) and misoprostol is based on the NAF protocol and U.S. clinical trials of these medications involving over 6,000 patients.

Our protocol differs from the FDA regimen by the administration of one tablet (200mg) of mifepristone rather than the three tablets (600mg), by the administration of 800mg of misoprostol rather than 400mg, by the administration of misoprostol buccally rather than the oral route, by the administration of misoprostol at home rather than in the office, and by the inclusions of patients up to six gestational weeks (42 days) rather than five gestational weeks (35 days).

By my signature below, I confirm that I have read and understood this information on the "off-label" use of mifepristone and misoprostol, and have had an opportunity to ask any questions I might have regarding the use of these medications.

Patient's Signature \_\_\_\_\_ Date \_\_\_\_\_

Counselor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Physician's Signature \_\_\_\_\_ Date \_\_\_\_\_