

Knoxville Center for Reproductive Health (KCRH)
1547 W. Clinch Ave., Knoxville, TN 37916 | 1-865-637-3861

Medical Abortion Information and Consent

Initial each line indicating you understand and consent to the abortion procedure. Please do not sign this consent without reading and understanding its contents. You may discuss any questions or concerns you have with our staff, before signing this consent.

The Knoxville Center for Reproductive Health (KCRH) is a private, nonprofit women's health clinic committed to providing quality reproductive health services. The clinic is fully licensed by the State of Tennessee, and has been in operation since 1975. Our medical director, Dr. Morris Campbell, is a Board Certified Gynecologist who has been in practice since 1976. In the unlikely event of an emergency, please call the clinic's local telephone number. After hours, the answering service will take your name and number, and a staff member will return your call.

I, _____, hereby give permission for Dr. Morris D. Campbell and/or such associates and assistants as he may select and supervise to perform a non-surgical/medical abortion with Mifepristone (Mifeprex) and Misoprostol (Cytotec).

_____ I understand I am approximately _____ 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 bleeding from my vagina like a very heavy period or miscarriage. This method usually allows a pregnant woman to have an abortion without putting instruments into the uterus and, in some instances, earlier in the pregnancy than a surgical abortion.

_____ Mifeprex is a drug which blocks the action of progesterone, a hormone needed to continue a 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 "RU486" or the "French abortion pill"). Misoprostol is a drug used in the United States to prevent irritation or ulcers in the stomach of people using aspirin or aspirin-like pain medication. When the FDA approved Mifeprex, it was approved to use in combination with Misoprostol. Studies have shown Mifeprex and Misoprostol, when used together, are approximately 95% - 98% effective in causing an abortion in early pregnancy.

Abortion Procedure:

_____ At the initial assessment, the provider and/or his/her associates will discuss my medical history with me. An ultrasound will be performed to determine how far along the pregnancy is. The ultrasound may be done by putting a probe into my vagina or on my abdomen. I will have my blood checked for Rh factor and anemia. If my blood Rh type is negative, I will need an additional vaccine injection (Rhogam) at an additional cost. I understand the intent of the ultrasound is only to determine the length of the pregnancy, and is not intended to determine any abnormalities of my pregnancy, fetus, or reproductive tract. I understand there are limitations to all imaging techniques, and no technique is 100% accurate or reliable. I release the Knoxville Center for Reproductive Health and its employees from any liability arising from this test, particularly in regards to any abnormalities of my pregnancy, fetus, or reproductive tract that have not been evaluated by this ultrasound.

_____ After consultation with the doctor, I will swallow one (1) tablet of Mifeprex 200mg.

_____ Approximately 12 - 48 hours after swallowing Mifeprex, I will insert four (4) 200mcg Misoprostol tablets (between the gum and cheek). I will follow the provided instructions. It is important I leave these tablets in my mouth to dissolve so all the medication is absorbed into my body. After insertion, I plan to relax for the next several hours when bleeding or cramping will likely begin. I have been advised to avoid work, school, and other responsibilities for at least a couple of days, as the bleeding and cramping may impair my ability to complete these tasks.

_____ I agree to avoid all heavy lifting, pushing, or pulling (25 pounds or more), and all strenuous activity for 10 days. Becoming too active too soon may increase post-abortion bleeding and cramping, and put me at a higher risk for complications. To help prevent infection, I agree to have nothing in my vagina-including no sex, no tampons, no vaginal creams, no sex toys, etc.-until after my follow up exam in three and a half weeks. It is also preferable to avoid tub baths and swimming until after the follow up visit. (Taking a shower is okay.) I will receive written aftercare instructions, and agree to follow all instructions.

_____ I understand the Misoprostol tablets are required to complete the abortion. Failure to use Misoprostol may prevent a complete abortion.

_____ **I will have access to a telephone and my provider's 24-hour emergency contact. I will call the Knoxville Center for Reproductive Health at (865) 637-3861 if: I soak 2 or more overnight-sized maxi pads an hour for more than 2 hours in a row; I have a sustained fever (over 100.4 degrees) that lasts more than 24 hours, or which starts more than 24 hours after inserting Misoprostol; I have severe abdominal pain not helped by Ibuprofen and my prescribed pain medication; or I have no bleeding within 48 hours after Misoprostol, which may require more medication or evaluation for an ectopic pregnancy. I understand that it is my responsibility to contact the clinic should I experience any difficulties following my abortion procedure.**

_____ If I have cramping in my lower abdomen, I can take Advil or Motrin (ibuprofen) 800mg every 8 hours. I will also be given a prescription for Lorcet Plus I can take if needed.

_____ I will return to the office approximately three and one half weeks after taking the Mifeprex. This follow up visit is very important to confirm termination of my pregnancy has occurred and there have been no complications. At this visit I will have a physical examination, pregnancy test, and may have an ultrasound. If the pregnancy is still growing or if there is retained tissue in my uterus, then I will need to have a surgical abortion. I can make arrangements to have my follow-up care with my provider of choice. If I choose to go elsewhere for my follow-up visit, I will arrange for that office to send the Knoxville Center for Reproductive Health a copy of my records.

_____ The follow-up visit is extremely important. If I do not return for this visit, or if I fail to provide the Knoxville Center for Reproductive Health with proof of a follow-up visit completed at another office, I understand that **I will be contacted.** The Knoxville Center for Reproductive Health may call me at home or at my employer, they may call my emergency contact, or send me notification via the US Postal Mail. I can avoid being contacted by keeping my follow-up appointment, and/or by providing the appropriate documentation of my follow-up care.

_____ I will be given a 200mg dose of Mifeprex and 800mcg dose of Misoprostol to be taken buccally rather than the FDA-approved regimen (which includes 600mg of Mifeprex and 200mcg of Misoprostol orally). Current research shows this altered regimen is just as safe and effective in terminating early pregnancy, and it causes less nausea and vomiting. While I have read the *Mifeprex Medication Guide* and *Patient Agreement*, I understand I am consenting to an alternative evidence-based regimen different from what is outlined in this Guide and Agreement. The FDA has recognized evidence-based use of drugs by clinicians is often appropriate and may represent the standard of practice. I have had an opportunity to ask questions about the alternative regimen and based on conversations with my provider, I have chosen the method best for me.

_____ Studies show the alternative evidence-based regimen prescribed by the Knoxville Center for Reproductive Health is approximately 98% effective up to the 49th day (7 weeks) of a pregnancy, and approximately 95% effective up to the 56th day (8 weeks) of a pregnancy.

_____ Terminating pregnancies beyond the 49th day may be associated with a slightly higher rate of complications such as excessive bleeding, incomplete abortion, ongoing pregnancy, and the need for emergency treatment.

Possible Risks:

_____ **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. The risks of an aspiration curettage include a risk of making a hole in the uterus, tearing of the cervix, adverse reaction to local anesthesia that may be used, infection, excessive bleeding, and failure to remove all of the tissue from the uterus.

_____ **Vaginal Bleeding:** As with a surgical abortion, heavy bleeding can occur and blood clots may come out of my vagina. In rare instances, heavy bleeding and the passage of blood clots may occur weeks after treatment, and possibly after I have been checked for my follow up exam. If I have extremely heavy bleeding or dizziness, an aspiration curettage may be necessary to stop the bleeding. If it is not an emergency situation, the aspiration can be performed through this clinic at no additional cost. The risk of having heavy bleeding that results in the need for an aspiration curettage after using Mifeprex/Misoprostol is about 1 per 100 women (1%).

_____ **Excessive bleeding:** In rare situations, hemorrhage (very excessive bleeding) can occur and may require emergency treatment at a local hospital and possibly a blood transfusion. Hemorrhage can occur several days or even weeks after treatment, and can be associated with my next menstrual period. I agree I will call the Knoxville Center for Reproductive Health if I experience any excessive vaginal bleeding within 6-8 weeks after my medical abortion. 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 understand that surgical abortion is strongly recommended to end the pregnancy. The risks of a first-trimester surgical abortion include making a hole in the uterus, tearing of the cervix, adverse reaction to anesthesia that may be used, infection, excessive bleeding, and failure to remove all of the tissue from the uterus.

_____ **Side Effects:** The following side effects are possible: nausea, vomiting, diarrhea, fever, headaches, and chills. Most of these side effects last less than a day. **If these last more than 24 hours or start more than 24 hours after inserting the Misoprostol, I will call KCRH immediately to discuss with treatment staff.** Cramping and bleeding are a normal part of the abortion process. I will likely have cramping in my lower abdomen and I may need pain medication for this reason.

_____ **Ectopic Pregnancy:** A rare condition that is a complication of pregnancy rather than abortion is ectopic pregnancy, or pregnancy in the fallopian tube. In instances where an intrauterine pregnancy cannot be clearly defined, and in extremely rare instances where an intrauterine pregnancy is confirmed, there exists the possibility of an ectopic pregnancy. An ectopic pregnancy can be life threatening. Tools available at this clinic may not be sufficient to confirm ectopic pregnancy, and the Knoxville Center for Reproductive Health in no way purports to provide treatment for ectopic pregnancy. Additional evaluation outside this clinic, at additional expense, would be necessary to confirm ectopic pregnancy and to provide appropriate treatment.

_____ **Infection:** I understand serious infection can occur after medically induced abortion, much as it can occur after childbirth, spontaneous abortion and surgical abortion. The incidence of fatal toxic shock following medical abortion is 1 in 100,000. I understand if I experience the following symptoms of nausea, vomiting, diarrhea, and weakness, with or without abdominal pain, and without fever or other sign of infection **more than 24 hours after taking Misoprostol,** I will immediately contact KCRH for evaluation and possible treatment, if deemed necessary.

Costs and Payment:

_____ I understand both medications are essential in order for my abortion to be complete. If I should vomit within 45 minutes of taking the Mifeprex, I must return to the clinic as soon as possible to retake it. If I lose or forget the Phenergan, Misoprostol, or Doxycycline, I must call KCRH as soon as possible. I understand these medications can be called to a local pharmacy at a cost to me.

_____ If the abortion is not completed by these medications, and a vacuum aspiration (surgical abortion) is required; the Knoxville Center for Reproductive Health will provide the vacuum aspiration at this clinic at no additional charge. However, patients are responsible for any expenses incurred for an emergency room visit or for care at another facility.

_____ If the abortion is not complete at the time of the follow up exam, additional lab testing may be necessary (with additional minimal laboratory fees), to determine the best course of treatment.

Patient Rights:

_____ Each patient has at least the following rights:

- a) To privacy in treatment and personal care;

- b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the appropriate branch of the Tennessee Department of Human Services immediately;
- c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;
- d) To refuse experimental treatment and drugs. The patient's written consent for participation in research must be obtained and retained in his or her medical record;
- e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to the release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's legal representative. The Knoxville Center for Reproductive Health must have policies to govern access and duplication of the patient's record;
- f) To have appropriate assessment and management of pain; and
- g) To be involved in the decision making of all aspects of their care.

Voluntary Consent:

_____ I am aware of other choices during 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 surgical abortion and medical abortion, and the risks of continuing the pregnancy.

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

_____ I understand serious infection can occur after medically induced abortion, much as it can occur after childbirth, spontaneous abortion and surgical abortion. The incidence of fatal toxic shock following medical abortion is 1 in 100,000. I understand that if I experience the following symptoms of nausea, vomiting, diarrhea and weakness with or without abdominal pain and without fever or other sign of infection **more than 24 hours after taking Misoprostol**, that I will immediately contact KCRH for evaluation and possible treatment, if deemed necessary.

Patient's Signature

Date

I have asked this individual questions, and based on the answers she has given me she appears to understand the information being provided.

Staff Signature

Date

Last Updated: 9/8/2008