Alternative Treatment Plan and Consent for Medical Abortion with Mifeprex (Mifepristone) and Misoprostol

I, _____, hereby authorize and consent to the performance of a medical abortion with Mifeprex and Misoprostol by and under the supervision of Dr. _____. I understand that I am pregnant and the purpose of the medical abortion is to terminate this pregnancy. I have been informed of the alternatives to this type of medical abortion, including other medical abortion options, surgical abortion, and continuing this pregnancy to term. I have had the opportunity to ask questions and I understand these options. I voluntarily request a medical (non-surgical) abortion using Mifeprex and Misoprostol. I give my consent freely and without coercion.

Philadelphia Women's Center Alternative Regimen	**FDA Approved Regimen**
Mifeprex 200mg orally (in the clinic)	**Mifeprex 600mg orally (in the clinic)**
Misoprostol 800 mcg buccally (at home)	**Misoprostol 400 mcg orally (in the clinic)**
Home use of Misoprostol	**Clinic administration of Misoprostol**
Misoprostol 24-48 hours after Mifeprex	**Misoprostol 48 hours after Mifeprex**
Up to 63 days LMP	**Up to 49 days LMP**
2 clinic visits (rarely more)	**3 clinic visits (rarely more)**

The difference between the Philadelphia Women's Center alternative regimen and the FDA regimen are as follows:

- Smaller dose of Mifeprex
- Different route of administration of Misoprostol
- More flexibility of time between the use of the two medications
- More privacy for the abortion since the second medication is used at home
- Fewer office visits

Description

I understand that I am 9 or fewer weeks pregnant. 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, much like a very heavy period or miscarriage. This method allows a pregnant woman to have an abortion without putting instruments into the uterus.

1. I have read the "Medication Guide for Mifeprex" provided by Danco Laboratories, which describes the medications that will be used, along with the risks and side effects. I have also read and understand the alternative treatment plan. I have discussed the procedure with a staff member who has answered my questions to my satisfaction. I have had any questions posed to the physician answered to my satisfaction.

2. I understand that Mifeprex, along with Misoprostol, has been approved by the FDA for the purpose of inducing abortion.

3. I have been advised NOT to proceed with the abortion using Mifeprex and Misoprostol if :
    a. Have liver or kidney disease.
    b. Have a confirmed or suspected ectopic pregnancy.
    c. Have an undiagnosed adnexal mass.
    d. Have an IUD in place.
    e. Take long-term corticosteriod therapy.
    f. Have a history of allergy to mifepristone, misoprostol, or other prostaglandin.
    g. Have a bleeding disorder or take anticoagulant therapy.
    h. Have an inherited porphyria.

    I hereby state that none of the above apply to me _____ (initial here)

4. I understand that I may have an undiagnosed ectopic pregnancy, which is a pregnancy in the fallopian tubes. In this situation, medical abortion will not end the pregnancy. I understand that follow-up is required and that the treatment for ectopic pregnancy may require hospitalization and surgery that cannot be performed at the Philadelphia Women's Center.

5. I agree to allow the Philadelphia Women's Center to perform all necessary diagnostic tests, ultrasounds, and procedures which may be required to monitor my health prior to, during, and after my abortion, including a physical examination and vaginal probe ultrasound which is required to accurately date my pregnancy. I understand that ultrasound is for dating purposes and not for diagnosing fetal conditions or anomalies.

6. I understand that if I am eligible for a non-surgical abortion and I request this method for terminating my pregnancy, I will receive 1 (one) 200 mg tablet of Miferprex orally. Side effects include abdominal pain, uterine cramping, nausea, headache, vomiting, fatigue, and dizziness. I understand I should also experience vaginal bleeding.

7. I understand that I am responsible for taking 4 (four) 200 mcg tablets of misoprostol buccally, and that I will be instructed on

the most appropriate time to take the medicine. I understand that I may pass the pregnancy at any time, or fail to pass the pregnancy. I will probably experience abdominal pain, including uterine cramping and bleeding. I may also experience nausea, vomiting, diarrhea, dizziness, or fainting.

8. I understand that it is possible to have heavy vaginal bleeding during a medical abortion. I also understand that surgery may be required to help treat my bleeding. In the event of an excessive loss of blood, or a dangerous change in my condition, I may have to be transferred to another facility where I may need additional monitoring treatment, including blood transfusion.

9. I understand that I may pass an embryo (pregnancy) at an unpredictable or inconvenient time and that I may see the embryo.

10. I may experience emotional distress and/or depression following the abortion.

11. I understand that the only way to be assured that I am no longer pregnant is to return to the Philadelphia Women's Center for my scheduled follow-up. I understand that if I have no bleeding within 48 hours after the administration of misoprostol, I may still be pregnant. In this case, I agree to notify the Philadelphia Women's Center and return prior to my scheduled follow-up.

12. I understand that if I have heavy bleeding or severe pain, a suction curettage may be advised to complete my abortion. This condition has been reported to occur less than 1% of the time. I understand that failure to proceed with a suction curettage under these circumstances could result in serious complications, including death. **I agree to have a surgical abortion at Philadelphia Women's Center under such circumstances if I am so advised, at no additional cost to me.**

13. I have been told that medical abortion has a failure rate of 5% and that both medications used could cause serious birth defects if the pregnancy were to continue after the use of the medications. I understand that if the medications do not work, or if I chose to withdraw from the treatment and do not have a surgical abortion, it is possible that birth defects will develop in the fetus. **If the medical abortion fails to terminate the pregnancy, I agree to have a surgical abortion at Philadelphia Women's Center, at no additional cost to me.** I acknowledge that no guarantee has been made to me about the result of this treatment and that unforeseen complications may arise that will require additional treatment and/or hospitalization. **I understand that treatment not received at Philadelphia Women's Center will be at my own expense.**

14. I understand that it is essential that Philadelphia Women's Center be able to contact me by telephone during my treatment, if necessary, and that I have given a phone number where they may both call me and/or leave messages regarding my treatment.

15. I understand that the physician and the Philadelphia Women's Center staff will rely upon statements that I make, the medical history that I provide, and other information in determining the course of treatment and whether or not I am eligible for a medical abortion. I have made a full, complete, and truthful disclaimer of all such information. I understand that if I withhold or falsify information that might affect my medical care, the physician and the Philadelphia Women's Center staff cannot accept any responsibility for any problems that may result.

16. I have been given the 24-hour emergency telephone number for Philadelphia Women's Center. I understand that I should call the center if I have any questions or concerns. I agree to notify the Philadelphia Women's Center immediately if I develop a fever of 100.4º or higher, heavy bleeding (soaking 2 heavy flow pads in one hour), severe cramping or abdominal pain, weakness, nausea, vomiting or diarrhea. My failure to give this notice, or failure to notify the Philadelphia Women's Center if I seek medical care elsewhere, releases the physician and the Philadelphia Women's Center from any further responsibility to me.

17. I have read (or had read to me) and fully understand this consent form and the information given to me about the process of medical (non-surgical) abortion, including alternative methods of treatment, risks and discomforts I may encounter. I am aware that the possibility of complications from both known and unknown causes may arise as a result of this procedure. I voluntarily accept the responsibility to follow instructions and return for follow-up appointments as well as accepting the risks associated with the procedure.

18. I authorize Philadelphia Women's Center to release my medical records to any provider of medical services I may need as a result of this procedure. I also authorize any provider of medical services necessary after my abortion to release my complete medical records to Philadelphia Women's Center. Those records shall extend to all aspects of treatment, including testing and/or treatment for sexually transmitted disease, substance abuse, or mental health conditions, unless expressly limited by me in writing.

Patient Signature: _____ Date: _____

Parent Signature: _____ Date: _____

Staff Signature: _____ Date: _____

Physician Signature: _____ Date: _____

Mifeprex Agreement

I understand that requesting a non-surgical abortion ("abortion by pill" or "medical abortion") carries some additional obligations on my part. *Please initial the lines below.*

I agree to:

_____ Live within a one-hour radius of Philadelphia Women's Center ("PWC") at least until the abortion is complete.

_____ Be available to come to several appointments at PWC.

_____ Have a working telephone number that PWC may call

_____ Allow PWC to leave messages regarding my health care at this number: _____

_____ Come back to PWC for a follow-up exam and ultrasound. I understand that my abortion is not complete until a clinician has examined me.

Additionally, I agree to the following Patient Agreement for Mifeprex:

1. I have read the Medication Guide provided by Danco Laboratories and the Alternative Treatment Plan using Mifeprex and Misoprostol to end my pregnancy.
2. I discussed the information with my health care provider.
3. My provider answered all my questions and told me about the risks and benefits of using Mifeprex and Misoprostol to end my pregnancy.
4. I believe I am no more than 63 days (9 weeks) pregnant.
5. I understand that I will take a 200 mg dose of Mifeprex in my provider's office.
6. I understand that I will be given the Misoprostol to take home with me to be taken buccally no sooner then 24 hours, and no later than 48 hours, after I have swallowed the Mifeprex.
7. My provider gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
8. Bleeding and cramping do not mean that my pregnancy has ended. Therefore, I must return to my provider's office about two weeks after taking the Mifeprex to be sure my pregnancy has ended and that I am well.
9. I know that, in some cases, the treatment will not work. This happens in about 5 to 8 women out of 100 who use this treatment.
10. I understand that if my pregnancy continues after any part of the treatment, there is a chance that there may be birth defects. If my pregnancy continues after treatment of Mifeprex and Misoprostol, I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy.
11. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or need a surgical procedure to stop bleeding, my provider will do the procedure or refer me to another provider who will.
12. I have my provider's name, address, phone number, and know that I can call if I have any questions or concerns 24 hours a day, 7 days a week.
13. I have decided to take Mifeprex and Misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
14. I voluntarily request the Alternative Treatment Plan for Medical Abortion using Mifeprex and Misoprostol from the Philadelphia Women's Center.
15. I agree to be available to speak with a nurse after I have inserted the Misoprostol. I also agree to return to the Philadelphia Women's Center approximately 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well.

Patient Name (please print): _____

Patient Signature: _____ Date: _____

Parent Signature: _____ Date: _____

Staff Signature: _____ Date: _____

RHOGAM

ALLERGY

Philadelphia Women's Center

Mifeprex Treatment Report

Name: _____ DOB: _____ Age: _____ GA by u/s: _____w_____d LMP: _____

Patient Visit – Day 1

Date: _____

Physician Orders:

- ❑ Mifeprex 200 mg PO stat
- ❑ Cytotec 200 mcg #4 to take buccally at home in 24 to 48 hours
- ❑ Rx Tylenol 3 with Codeine, one PO q 4-6° prn for severe cramps, disp #10
- ❑ Doxycycline 100 mg BID x 7 days, disp #13. Take with breakfast and dinner.
- ❑ Rx Ibuprofen 800 mg. Take one PO q 6-8 prn for cramps, disp #10
- ❑ Patient given Mifeprex 200 mg PO. Lot/Serial # : _____ Exp. Date: _____ Time Given: _____
- ❑ Patient given Doxycycline 100 mg po stat
- ❑ Danco Mifeprex Medication Guide given to patient.

- ❑ Rhogam given IM. Site: _____ Lot # : _____ Exp. Date: _____ Given by:_____

MA Signature: _____

Physician Signature: _____

Counseling:

- ❑ Educated pt on Mifeprex and Misoprostol regimen with side effects. Pt verbalized understanding.
- ❑ Patient to RTC on: _____ for follow-up examination.
- ❑ Emergency information and warning signs reviewed.
- ❑ Instructed pt to call PWC with any questions or concerns.

Counselor Signature: _____

Follow-Up Visit – Day 14

Date: _____ Time: _____

Hgb: _____ U/S: _____

Bleeding:

- ❑ None
- ❑ Mild
- ❑ Moderate
- ❑ Severe

Cramping:

- ❑ None
- ❑ Mild
- ❑ Moderate
- ❑ Severe

BCM dispensed:

Abortion Complete?

- ❑ Yes
- ❑ No (See notes)

Notes:

Physician Signature: _____