ALTERNATIVE TREATMENT PLAN AND CONSENT FOR MEDICAL ABORTION WITH MIFEPREX™ (MIFEPRISTONE) AND MISOPROSTOL

The FDA gave it's approval status to Mifepristone in 1996 based on research up to that time. Extensive research has continued since then that shows there are alternative treatment plans that are equally safe and effective, minimize side effects and risk and enhance privacy and convenience for women. Atlanta Women's Center offers the following alternative treatment plan for medical abortion with Mifeprex™:

Atlanta Women's Center Alternative Regimen	**FDA Approved Regimen**
Mifeprex ™ 200 mg orally (in the clinic)	**Mifeprex™ 600mg orally (in the clinic)**
Misoprostol 800mcg buccally (at home)	**Misoprostol 400mcg 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 Office visits (rarely more)	**3 Office visits (rarely more)**

The difference between the Atlanta Women's Center Alternative regimen and the FDA regimen are as follows:

- Smaller dose of Mifeprex™
- More flexibility of time between the use of the two medications.
- More privacy for the abortion since the second medication is used at home.
- Maybe used later in pregnancy (63 Days LMP v. 49 Days LMP).
- Fewer office visits.

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

2. I have been advised not to proceed with a Medical Abortion if I:
    a. have liver or kidney disease;
    b. have a confirmed or suspected etopic pregnancy;
    c. have an undiagnosed adnexal mass;
    d. have an IUD in place;
    e. take a long-term corticosteroid therapy;
    f. have a bleeding disorder or take anticoagulant therapy;
    g. have an inherited porphyria;
    h. have inflammatory bowel disease;
    i. have severe anemia or history of blood clotting defect;
    j. am breast feeding;
    k. have a history of sickle cell disease;
    l. have known allergy to Mifeprex™, Misoprostol or other prostaglandin;

m. cannot commit to returning to the clinic for all recommended follow-up visits;
n. am unwilling to have a surgical abortion;
o. have no telephone or transportation;
p. do not have support at home while undergoing this procedure or;
q. do not live in the metro area.

I hear by state that none of the above conditions applies to me. _____
(*initial here*)

3. I consent to diagnostic studies, tests, a physical examination, an abdominal ultrasound or a vaginal probe ultrasound, if necessary, which are made for the determination of gestational age only and not for detection of abnormalities or defects of treatment relating to the diagnosis of my conditions or procedures set forth herein. I also consent to the disposal of any tissue or other parts of the contents of my uterus (womb) which may be removed during the abortion at the discretion of the physician or the center, if a vacuum aspiration is necessary. I also consent to the administration of RhoGam (or equivalent) should my blood be Rh negative. I agree that the doctor or clinic staff may need to contact me or my emergency contact regarding additional laboratory findings. My confidentiality will be respected where possible.

4. I understand that an etopic pregnancy (pregnancy in the fallopian tubes) is a rare condition, which is a complication of pregnancy rather that of the abortion. I understand that if the pregnancy is in the fallopian tube or outside the uterus, neither surgical abortion nor a Mifeprex™/Misoprostol abortion will remove the pregnancy, and that due to the possible threat of rupture of the fallopian tube, hospitalization may be necessary as soon as it is discovered.

5. Test and or/ exams have indicated that I am pregnant.

6. I understand that the purpose of an abortion is to end my pregnancy.

7. I understand that if I am eligible for a non-surgical abortion and I request this method of terminating my pregnancy, I will receive 1(one) 200mg tablet of Mifeprex™ orally. Side effects include: abdominal pain; uterine cramping; nausea; vomiting; diarrhea; headache; dizziness; chills; and/or fever. I understand I may also experience vaginal bleeding.

8. I understand I am responsible for taking 4 (four) 200mg tablets of Misoprostol buccally on _____. Possible side effects of this medication are: nausea; vomiting; diarrhea; abdominal pain; dizziness; hot flashes; cramping and or bleeding. Bleeding may continue for as long as six weeks. I also understand that the possible risk include: hemorrhage; continuing pregnancy with risk of fetal anomaly if not terminated; incomplete abortion requiring an aspiration or surgical procedure; infection; or other rare complications including death.

9. I understand that one to five hours I take the Misoprostol I will experience cramping bleeding. The cramping can be very strong and painful for several hours, but usually does not last more than 24 hours. The bleeding can be quite heavy and there may be clots for several hours.

10. I understand that I may pass the embryo at an unpredictable or inconvenient time or place, and that I may see the embryo.

11. I understand that I will be given prescriptions for pain medications and a telephone number to reach the clinic and on-call person if I experience any problems or have any questions after I leave the clinic.

12. I understand that it is possible to have heavy bleeding or severe pain, and that a suction curettage may be advised to complete the abortion. The condition has been reported to occur less than 1% of the time, but failure to proceed with a suction curettage under these circumstances could result in serious problems. Rarely a blood transfusion may be needed as well.

13. I have been told that Medical Abortion has a failure rate of approximately 5%, and that the medications used could cause serious birth defects if a pregnancy were to continue after use of medications. If the medications do not work, or if I choose to withdraw from treatment, and I do not have a surgical abortion, it is possible that birth defects will develop in the fetus. I understand that incomplete expulsion of the pregnancy tissue may increase the risk of uterine infection.

14. I understand that it is important that the abortion be completed because the Misoprostol can cause serious birth defects.

15. I understand that I should return for my two-week check-up to be sure that abortion is complete. At this visit an ultrasound will be performed and if the abortion has not been completed, I will have the option of taking another dose of the Misoprostol or having a vacuum aspiration (a suction procedure to empty the uterus) to complete the abortion.

16. I agree to have a surgical abortion at Atlanta Women's Center under such circumstances if you so advised me at no additional cost to me.

17. It has been explained to me, and I understand, that the operation consist of stretching open the mouth of the uterus (cervix), and with surgical instruments, removing the contents of my uterus.

18. It has been explained to me that pregnancy terminations of less than 6 (six) weeks can be performed, but intra-operative and post-operative examinations may be necessary to confirm successful completion of the procedure. I have been informed that there is a slight chance the pregnancy may be missed during the surgical procedure due to the early gestational size of the pregnancy. This could occur because of the miniscule size of the pregnancy or if the pregnancy is in the fallopian tube (ectopic pregnancy). It has been explained to me that in rare instances, the sonogram may visualize what appears to be a pregnancy during the initial examination. I understand that all tissue removed during the procedure will go outside the laboratory for a microscopic examination by a pathologist if a vacuum aspiration is complete. I understand that depending on the results of my lab report, AWC may need to contact me by phone. If I do not respond, a certified letter will be sent to my home. I have been informed that further follow-up is available to me if necessary. If I do not return as requested, I release AWC and the employees/physicians of all financial and medical responsibility.

19. I acknowledge that no guarantee has been made to me about the result, and that unforeseen complications may arise that will require additional treatment of hospitalization. I understand that treatment not received at Atlanta Women's Center will be at my own expense.

20. I understand that it is essential that Atlanta Women's Center is able to contact me by telephone during my treatment if necessary, and that telephone number is _____.

21. I understand that the purpose of this procedure is to terminate this pregnancy. I affirm this to be my personal choice in light of the alternative of continuing the pregnancy to term. No one has coerced or compelled me to make this decision.

22. I understand that the alternatives to abortion are either to have the baby and keep my child, or have the baby and give the child up for adoption. I have considered these alternatives and the staff here have offered to make referrals to appropriate agencies for birth and or/ adoption. I reject these alternatives and request that the abortion procedure be performed.

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

24. I understand that I should call Atlanta Women's Center if I have any questions and/or concerns. If I develop a fever, heavy bleeding, severe cramping or pain, or other symptom, I agree to notify Atlanta Women's Center immediately by telephoning the 24-hour emergency line. My failure to give this notice releases the physician and the clinic from any further responsibility to me.

25. I have read (or have had read to me) and fully understand this consent form and the information given to me about the process of Medical Abortion with Mifeprex™/Misoprostol, including alternative methods of treatment, risks and side effects reasonably to be expected, and the possibility that complications from both known and unknown causes may arise as a result of this procedure. I voluntarily accept the risks associated with a Medical Abortion.

26. I voluntarily request a Medical Abortion using Mifeprex™ and Misoprostol from Atlanta Women's Center. I give my consent freely and without coercion.

27. I authorize Atlanta Women's Center to release my medical records to any provider of medical services that 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 Atlanta 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 condition, unless expressly limited by me in writing.

Patient Signature: _____ Date:_____

Staff Witness:_____ Date:_____
(*Agent for Physician)*

Physician:_____ Date:_____