UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: *Alternative Provision of Medication Abortion via Mail-order Pharmacy Dispensing*

Principal Investigator:	Daniel Grossman, MD, Professor, Department of Obstetrics, Gynecology & Reproductive Sciences Director, Advancing New Standards in Reproductive Health (ANSIRH). 1330 Broadway, Suite 1100, Oakland, CA, 94612 Phone: (510) 986-8941; e-mail: daniel.grossman@ucsf.edu

This is a clinical research study. Your study doctor(s), listed above, will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are seeking a medication abortion, or the abortion pill, which includes the drug, mifepristone, or Mifeprex®.

Why is this study being done?

The goal of this study is to see what patients think about receiving abortion pills in the mail from a pharmacy, and to collect information on the health outcomes of patients after they receive the abortion pills by mail.

The U.S. Food and Drug Administration (FDA) has approved Mifeprex® (used together with misoprostol) for termination of pregnancy, but the FDA has not approved the dispensing of Mifeprex® outside of the clinic or hospital setting. This study is being conducted with approval from the FDA.

This study is being paid for by a grant from the Society of Family Planning.

How many people will take part in this study?

You will be one of up to **650** people across the country who will be participating in this study. The study will be conducted at approximately **15-20** locations.

What will happen if I take part in this research study?

The Screening Visit will take about 15 minutes. During this visit, we will determine if you are eligible to take part in this research study. If you are not eligible, the study doctor will tell you why. At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Draw a blood sample
- Ask you for a urine sample
- Test your blood/urine for pregnancy, if you are a female able to become pregnant.
- Ask for your contact information, preferred mailing address where you would like to receive the medications, your email address and phone number.

If you are eligible for the study:

- You will receive your abortion medications by mail at the address you provided within 2 business days.
- You will take the mifepristone and other medications according to the instructions from your clinician.
  - Mifepristone comes as a tablet to take by mouth. You will take one tablet of mifepristone once on the first day. Within 24 to 48 hours after taking mifepristone, you will apply four tablets in total of another medication called misoprostol buccally (between the gum and cheek) by placing two tablets in each cheek pouch for 30 minutes, then swallowing the remaining content with water or another liquid. Make sure that you are in an appropriate location when you take misoprostol because vaginal bleeding, cramps, nausea, and diarrhea usually begins within 2 to 24 hours after taking it but could begin within 2 hours.
- If you do not receive the medication for whatever reason, you should call or return to the clinic for more information.

Three days after your clinic visit:

- You will receive an email with a link to an online survey asking about your experience obtaining the medication. The survey will take about 10 minutes to complete.
- You don't have to complete the survey immediately. But if you don't respond within 2 days, you may be contacted by telephone or text message (according to your preferences) to complete the survey.
- The survey will ask about your experience receiving the medications, including when they arrived and in what condition, as well as your experience taking the mifepristone.

Two weeks after you take the mifepristone:

- You will receive an email with a link to another online survey asking about your overall satisfaction with the medication abortion process and whether your abortion is now complete. If

you are unsure if the abortion is complete, we will ask permission to contact you one week later. The survey will take about 10 minutes to complete.
- You will be contacted by email, text, or telephone (according to your preferences) each day for three days in a row to remind you about the survey.

Four weeks after you take the mifepristone:

- If you do not visit the clinic for an in-person follow-up, you will be advised to take an at-home urine pregnancy test four weeks after taking the mifepristone. After you take the pregnancy test, you will be asked to complete a final survey (2-3 questions) asking about the results of the pregnancy test.

A description of this clinical trial is available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you agree to participate in the study, clinical information about your visits regarding the medication abortion will also be reviewed from the medical records at the clinic you visited and, with your authorization, any other health care provider or health care facility you visited after receiving the medication abortion. This includes information about whether the abortion was complete and any problems you may have experienced. This information will not personally identify you.

How long will I be in the study?

You will be asked to participate in the study for approximately two weeks and in some cases up to four weeks. Everyone will be asked to complete a survey three days after being prescribed mifepristone and a second survey two weeks after being prescribed mifepristone. If the follow-up for your abortion is not yet complete, we will contact you again.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor or researchers if you no longer want to participate.

What side effects or risks can I expect from being in the study?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. There is also the risk that someone may see or open your mail and learn about the medication. Only your name will be listed on the package and it is illegal to open someone else's mail. The study team plans to protect your privacy – see the Confidentiality section below for details.

Your doctor or clinician will talk with you about any side effects or risks you can expect during a medication abortion. Involvement in this study will not affect the medications you receive, side effects, or risks, only the location in which you receive the medication.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors and researchers learn more about how patients feel about obtaining the medication, mifepristone, by mail. It is hoped that this information will help increase access for future patients seeking a medication abortion.

What other choices do I have if I do not take part in this study?

If you do not wish to participate in the study, you can continue your regular care with your doctor (and receive referral for abortion care). Participation in the study will not affect the care you receive at the clinic. Please talk to your clinician about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

Certificate of Confidentiality

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. For example, we will voluntarily disclose information about incidents such as child abuse, and intent to hurt yourself or others. In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the

Federal government needed for auditing or evaluating federally funded projects or information needed by the FDA.

Are there any costs to me for taking part in this study?

No. The patient will not pay any additional costs to participate in the study. The sponsor will pay for the abortion medication (mifepristone and misoprostol). All other services associated with the medication abortion will be billed as they would be otherwise.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or over the phone.

Treatment and Compensation for Injury:
If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

Will I be paid for taking part in this study?

You could receive a total of up to $65 in gift cards for one initial clinic visit plus two surveys completed at home. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

Can I be withdrawn from the study without my consent?

You may be withdrawn from the study if the site PI or the PI feels that it is not in your best interest to continue. You are free to withdraw from participation at any time, for any reason, specified or unspecified, and without any effect on your medical care. Reasonable attempts will be made by the site PI to provide a reason if you are withdrawn.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) listed on the front page of this form.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the UCSF Office of the Institutional Review Board at 415-476-1814 or the study's Project Manager. You may also contact your local IRB, listed on the front page of this form.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent