CONSENT/ASSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

PARTICIPANT/SUPPORT PERSON/ YOUTH/PARENT/GUARDIAN

Sponsor / Study Title:	**Planned Parenthood of Southwest and Central Florida / "Friends/Family in the Abortion Procedure Room (FAIR): Assessing pain level, patient, staff and support person satisfaction with support person in abortion procedure room: A randomized controlled trial"**
Principal Investigator: (Study Doctor)	**Sujatha Prabhakaran, MD, MPH**
Telephone:	**941-567-3818 (24 Hours)**
Address:	**Planned Parenthood of Southwest and Central Florida** **236 E Bearss Ave** **Tampa, FL 33613** **Planned Parenthood of Southwest and Central Florida** **8068 N 56th St. T** **Tampa, FL 33617**

Please note: If you are reading this document to decide whether your child may participate in this study, the terms "you" and "your" refer to your child.

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

We are asking you to take part in a research study called:

Friends/Family in the Abortion Procedure Room (FAIR): Assessing pain level, patient, staff and support person satisfaction with support person in abortion procedure room: A randomized controlled trial

The person who is in charge of this research study is Dr. Sujatha Prabhakaran, MD, MPH. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be conducted at Planned Parenthood of Southwest and Central Florida's Tampa Health Center.

Purpose of the study

The purpose of this study is to find out if having another person, such as a family member or friend, in the abortion procedure room will help people who are getting an abortion with pain and anxiety. To figure this out, we will collect answers to questionnaires and surveys today from you if you choose to participate.

Why are you being asked to take part?

We are asking you to take part in this research study because you are having an in-clinic abortion procedure, or you are here today supporting someone who is having an in-clinic abortion procedure.

Study Procedures:

If you take part in this study, your participation in the study will only be the length of your appointment today. During this time, you will be asked to complete one or more surveys or questionnaires that we estimate will take from 5-30 minutes of your total time, and should not add additional time to your day here at the health center (you can complete these surveys throughout today's already scheduled visit).

Total Number of Participants

About 400 individuals will take part in this study at Planned Parenthood of Southwest and Central Florida' Tampa Health Center.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study. You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or change in your medical care if you stop taking part in this study. If you want to stop taking part in this study, contact the study doctor or the study staff at the telephone number listed on the first page of this form.

Your part in the research may stop at any time for any reason, such as, the sponsor or the study investigator decides to stop the study. You will be told about any new information found during the study that may affect whether you want to continue to take part.

Benefits

You may or may not receive any benefit from being in the study. The possible benefits of participating in this research study include:

- decreased pain during the procedure
- decreased anxiety during the procedure
- higher satisfaction with the procedure and care
- Supporting a friend or relative during their abortion procedure

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known risks to those who take part in this study. There is a possibility that some of the survey or questionnaire items may cause some slight discomfort. If there are questions that you do not want to answer, you do not have to answer them. You may also stop your participation in the evaluation at any time.

Compensation

You will receive a $10 gift card as compensation for your time and participation today.

Costs

It will not cost you anything to take part in the study. However, routine care for the procedure (care you would have received whether or not you were in this study) will be charged to you and/or your insurance company.

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.
- Certain government people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- Any agency of the federal, state, or local government that regulates this research.
- The Chesapeake Institutional Review Board (CIRB) and related staff who have oversight responsibilities for this study.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an unanticipated problem, call Dr. Sujatha Prabhakaran at: 941-365-3913 x 1118.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00019968.

NEW INFORMATION

You will be told about any new information found during the study that may affect whether you want to continue to take part.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting Planned Parenthood of Southwest and Central Florida to use your health information for research purposes.

The following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;

- Each research site for this study including Planned Parenthood of Southwest and Central Florida Tampa Health Center
- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- The Chesapeake Institutional Review Board (CIRB) and Planned Parenthood of Southwest and Central Florida and its related staff who have oversight responsibilities for this study
- Data Safety Monitoring Boards or others who monitor the data and safety of the study

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, Planned Parenthood of Southwest and Central Florida may collect, use, and share the following information:

- Your research record

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this form, please write to:

Principal Investigator: Dr. Sujatha Prabhakaran, MD, MPH
736 Central Avenue, Sarasota, FL 34236

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by Planned Parenthood of Southwest and Central Florida policies. You will receive a signed and dated copy of this form.

STATEMENT OF CONSENT

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this signed and dated form to take with me.

_____ ____/____/____
Signature of Research Subject (if subject is age 18 or older) Date

_____
Printed Name of Research Subject

STATEMENT OF ASSENT

I have talked to my parent(s) or guardian(s) about this study, and I would like to be in this study. I will be given a copy of this form to keep.

_____ _____
Printed Name of Subject Age

_____ ____/____/____
Signature of Subject (if capable of signing) Date

_____ ____/____/____
Signature of Parent/Legal Guardian (if subject is under age 18) Date

_____
Printed Name of Parent/Legal Guardian (if subject is under age 18)

_____
(Authority of Legal Guardian to act on behalf of Subject)

*Authority to act on behalf of another includes, but is not limited to parent, guardian, or durable power of attorney for health care.

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

_____ _____

Signature of Person obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent