Consent and Authorization Document

BACKGROUND

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you want to volunteer to take part in this research study.

This study is being conducted by Dr. Lori Gawron, a doctor who works with Planned Parenthood and at the University of Utah.

You are being asked to participate in this study because you came to Planned Parenthood for emergency contraception (EC) and may be interested in a contraceptive implant or an IUD for ongoing birth control.

This research study will help us understand why a person may chose an implant or IUD at the same time as EC, as well as help us understand the risk of a pregnancy when oral EC and an implant are initiated on the same day. We are also interested in finding out about satisfaction and continued use of an implant over the 1st year after insertion at the time of EC.

We do not know if the implant alone can work for EC, so we will give you oral EC ("Plan B") at the same time we insert the implant. Both IUDs (hormonal and copper) will lower your chance of pregnancy without oral EC. The implant and either IUD will continue to provide highly effective contraception for as long as you have the device. In the long-term, the implant and both IUDs work as well as getting your tubes tied at preventing pregnancy. They work for as long as you want (up to 5 years for the implant, 3-7 years for the hormonal IUD or 12 years for the copper IUD). You can have the implant or either IUD taken out at any time. All methods of contraception being offered in this study are being used according to their FDA approval.

It is up to you to decide whether or not to take part in this study. If you decide to take part, you are free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you do not take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other clinical staff, nor decrease the standard of care that you receive as a patient.

STUDY PROCEDURES

If you agree to participate in the study, your participation will require completion of an enrollment survey and then you will receive the contraception method of your choice (the implant with Plan B or either IUD, at no cost to you). If you chose the implant, you will be asked to complete a 1-month pregnancy test at home and report the results back to us through an electronic survey link. You will also be asked to complete surveys about your satisfaction with the implant and any problems you may be having with the implant. These surveys will be sent to you at 3, 6, 9, and 12 months from the date of implant insertion.

Study Eligibility
Before you can enter this study, you must be:

- between 18-35 years old
- in need of EC (had unprotected intercourse in the last 120 hours/5 days)
- fluent in English and/or Spanish
- willing to comply with all study procedures

AND

- have had a regular menstrual cycle (period every 21-35 days) over the last 3 months
- know your last menstrual period (±3 days)
- desire to prevent pregnancy for at least 1 year
- have a working phone (that we will test today) and be willing to provide the names and contact information of 2 other people who always know how to contact you.
- For those choosing an implant, you need to agree to abstain from unprotected intercourse for 7 days after insertion

Screening and Enrollment
Before your implant or IUD is placed, you will need to have a urine pregnancy test. Once you ask any questions you may have and decide to be part of this study, you will be asked to sign this consent form and then have the implant or IUD placed.

Placing the implant involves cleansing the upper arm, injecting some local anesthetic, and using a special inserter to place the implant under the skin.

Placing an IUD involves a vaginal speculum exam (like a Pap smear). After this the cervix will be cleaned with soap, some local anesthetic may be placed in the cervix, and the IUD will be placed in your uterus.

We will ask you to complete a questionnaire about prior sexual activity, use of contraception, pregnancies and sexually transmitted infections. If you chose an IUD, your participation in the study is now complete.

If you chose the implant, we will give you a home urine pregnancy test to take home with you to use in 1 month.

1 month after the implant insertion, you will receive an electronic link to a survey to record the response of the home pregnancy test. We will also ask you about your satisfaction with the implant, any unprotected intercourse in the 1st 7 days after insertion, and any problems you may have experienced involving the implant.

Three-, six-, nine- and twelve- month follow-up will include an electronic survey asking about your satisfaction with the implant and any problems you may have experienced involving the implant.

If you chose an IUD, your study involvement will end after today's clinic visit.

If you chose an implant, your study participation will last 12 months. If you get pregnant at any time within a year of starting the study, we will contact you to find out the outcome of the pregnancy. This may require us contacting you up to 22 months from today to see what happened with the pregnancy. We will verify the outcome of any pregnancy by checking with the hospital where you delivered your baby. This may include verifying with Utah State for birth certificate records. **Keeping in touch with you is very important for the next year. If you wish to contact us at any time you can contact us by email or phone (call or text).** We will give you a card with this information and send you an email today.

RISKS
The clinical care you receive in this study is currently the standard of care for an implant or IUD. You may chose an IUD or an implant with Plan B even if you chose to not participate in this study. Regardless of your study participation, EC may not work to prevent a pregnancy. If you have an IUD in place and become pregnant, the IUD could increase risks of miscarriage or ectopic pregnancy. An implant would not interfere with a developing pregnancy but, if you chose to continue the pregnancy, we would recommend removal of the implant to avoid fetal exposure to the hormone. The healthcare provider will discuss the known risks of implant or IUD insertion with you as part of your clinical consent.

Participation in the implant arm of the research study requires us to contact you over time and potentially review your medical records, if you experience a problem with the implant. There is a possible risk of loss of confidentiality due to participation in this study, but we take measures to keep this from happening.

UNFORESEEABLE RISKS
In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS
There may be no direct benefit to you for your participation in this study. However, the information we collect from this study will help us counsel individuals in the future about the pregnancy rate when the implant and Plan B are used together at the time of EC. While this is currently the clinical standard of care, we do not know if the combined use may improve or worsen the EC effect. The study will also inform policies and clinic procedures, when we better understand which methods are preferred and whether those who chose them are satisfied and continue them.

ALTERNATIVE PROCEDURES
You may choose not to be in this study. If you choose not to be in this study, the clinic staff will assist you in getting EC and the method of contraception you desire. If you want an implant or

IUD for contraception, but do not want to participate in the study, it can still be done here at the clinic.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, you can contact Dr. Lori Gawron or one of her partners 24 hours/day at the University of Utah at (801) 581-6170.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION
Research studies include only people who choose to take part. You can tell us that you do not want to be in this study. You can start the study and then choose to stop the study later. We will still give you medical care and answer any questions you have. Your decision will not affect your relationship with your doctor or the study team in any way.

RIGHT OF INVESTIGATOR TO WITHDRAW
The investigator can withdraw you without your approval. Possible reasons for withdrawal include deciding you do not want an IUD or implant.

COSTS AND COMPENSATION TO PARTICIPANTS
There are no costs to you for participating in this research study. You will receive the implant or IUD of your choice at no cost to you. If you chose an implant and agree to complete the surveys for this study, you may receive up to $80. You will receive $40 when you return the one-month pregnancy test and then $20 at 6 months (after completing both the 3 and 6 month surveys) and $20 at 12 months (after completing both the 9 and 12 month surveys).

NEW INFORMATION
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research doctor will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

NUMBER OF PARTICIPANTS
We expect to enroll up to 300 participants for this study at Planned Parenthood Clinics in Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.
This is the information we will use and include in our research records:

- Demographic and identifying information like name, address, telephone number and email address;
- Contact information for 2 people who can always contact you;
- Related medical information about you like: current or past medications or therapies, prior illnesses, surgeries or pregnancies, allergies, detailed information about your recent periods;
- Information from a physical examination such as: blood pressure reading, heart rate, breathing rate, temperature, weight;
- All tests and procedures that will be done in the study;
- Answers to all phone or online surveys that are completed in the study;

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- A description of this clinical trial will be available on http://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.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team at Planned Parenthood Association of Utah and University of Utah Health Sciences Center;
  - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
  - Food and Drug Administration: a federal agency that needs to confirm the accuracy of the results submitted to the government.

- If we share your identifying information with groups outside of Planned Parenthood Association of Utah or University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share

your information again with others not described in this form.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at Planned Parenthood Association of Utah.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

FUTURE CONTACT
From time-to-time we have studies that might be of interest to you. Can someone from the University of Utah, Department of Obstetrics and Gynecology, contact you by phone/mail if we have a study in the future that may be of interest to you?

_____Yes _____No

CONSENT
I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date