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. David Turok, a doctor who works with Planned Parenthood and at the University of Utah. This study is sponsored by the National Institutes of Health (NIH) and is not sponsored by any commercial company. Dr. Turok serves on advisory boards and receives research funding from three of the companies who make IUD's that may be used in this research study. This financial interest has been reviewed by the University of Utah Conflict of Interest Committee and is being managed under their oversight. If you have questions, please ask Dr. Turok for more information.

You are being asked to participate in this study because you came to Planned Parenthood looking for emergency contraception (EC) birth control in the first 5 days after unprotected sex. Plan B and Ella (also known as the morning after pill) are the most commonly used types of EC. They work very well to lower the risk of pregnancy after sex without contraception but they don't do anything to prevent pregnancy for the future. Because women taking EC often also want to start a regular method of contraception we will explain two things for each birth control method we mention: #1) how well it works to lower the risk of pregnancy after sex without contraception (this means how well it works for EC) and #2) how well it works to prevent pregnancy in the future.

An IUD (intrauterine device) is a small, T-shaped piece of plastic that is placed inside the uterus to prevent pregnancy. An IUD is the most effective method of reversible contraception, that is, it works well to prevent pregnancy when it is inside the uterus, but your ability to get pregnant returns after it is removed. Studies show that women who use IUDs are the most satisfied among all people using birth control.

This research study will help us evaluate how well two IUDs work to lower the risk of pregnancy and how satisfied women are with these IUDs when they are placed for EC. Both IUDs work very well to prevent pregnancy when used as a regular birth control method. We know one IUD works extremely well when used to lower the risk of pregnancy after unprotected sex (for EC) and we think the other IUD may work for EC but it has not been tested alone for this. Below is a brief description of the IUDs we are comparing in this study:

The copper IUD (ParaGard®)

- #1) Among all methods of EC this IUD is the very best to keep you from getting pregnant if you have had sex within the last 5 days without using contraception (if 1000 women have sex and have this IUD placed 0-1 will get pregnant within the next month).

- #2) In the first year you use the copper IUD as a regular contraceptive, about 8 in 1000 women will have a pregnancy.
- It does NOT have hormones
- It can last up to 12 years. You will have regular periods, but they may be heavier and you may experience more cramping.

The hormonal IUD (LNG 52mg IUD, commonly known as Mirena® or Lilleta®)

- #1) We think this IUD may work about as well as the morning after pill for EC, but we are not sure. If this IUD works as well as the morning after pill, then *if 1000 women have sex without using birth control and have this IUD placed within 5 days, we expect that about 20 will get pregnant in the next month.*
- #2) In the first year you use the hormonal IUD as a regular birth control method, about 2 in 1000 women will have a pregnancy.
- This IUD contains a hormone (a progestin called levonorgestrel)
- It can last up to 3-5 years
- Bleeding can be irregular in the first 3-6 months. After that you will have less bleeding during your period, or no period at all.

Because you won't know which IUD you have for the first month, you will need to use a backup method of contraception (like condoms or not having sex) for the first 7 days after the IUD is placed in order to avoid pregnancy.

We believe that both IUDs will lower your chance of pregnancy today and will continue to provide highly effective contraception for as long as you have the device. In the long-term, both IUDs work as well as getting your tubes tied at preventing pregnancy. It works for as long as you want (up to 3-5 years for the hormonal IUD or 12 years for the copper IUD). You can have either IUD taken out at any time. During the study, if you would like to switch to the other IUD you can do this at any time. The study will pay to remove and replace the new device.

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still 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 don't 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 include 2-3 clinic visits and completion of 3-4 online surveys over the 12 months you are in the study. We may also use some information we collect from you in this study for other research projects about women's contraception and pregnancy.

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 study guidelines

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.

Randomization
If you meet all of the qualifications above and you agree to participate, you will be randomly assigned (like flipping a coin) to receive either:

- The copper IUD

  or

- The hormonal IUD

You have an equal chance (50%) of being assigned to either IUD. In other words, for every 100 women who join the study, 50 women will receive the copper IUD and 50 women will receive the hormonal IUD. This assignment (randomization) will occur while you are here at the clinic, immediately before you receive your IUD.

This is a blinded study and that means you will not know which IUD you have until you return for your 1 month follow up visit. At that time we will tell you which IUD you received.

If you do not return for your 1 month clinic visit and you want to know which IUD you have, you can call the clinic where you had the IUD inserted and they can tell you. This information can be given to you more than 1 month after your initial insertion date. If you go to any health care provider who inserts IUDs, they will be able to tell you which IUD you have by doing a speculum exam and looking for the IUD strings (each IUD has different color strings).

If you wish to change to the other kind of IUD, this can be done at any time during the year of study participation. Removing the IUD and replacing the other IUD will be paid for by the study for the period of time you are participating in the study.

If you choose to have your IUD removed for any reason during your participation in the study, please contact the clinic. We will arrange to have the IUD removed at a Planned Parenthood clinic at no cost to you. If you wish to change to another form of contraception, the clinic can help you get that birth control method. However, if you choose another type of birth control that will not be paid for by the study.

If your study IUD falls out please contact the clinic. If you would like another IUD we will arrange for a new IUD insertion at a Planned Parenthood clinic. This will be paid for by the study, if the IUD falls out within the first 3 months of your participation in the study.

The specifics of the study visits and follow-up are listed below.

Screening and Enrollment
Before your IUD can be 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 IUD placed.

Placing the 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.

When you leave the clinic on the first day we will give you a home urine pregnancy test to take home with you to use in 1 month.

1 month after you have your IUD Inserted
1 month after you have the IUD inserted we will ask you to do some things at home the day before you come back to clinic for your 1 month follow up visit. We will ask you to complete a home pregnancy test (which we will give to you today), take a picture of the result, and text the picture of the pregnancy test to a phone number we will provide to you. If you do not want to do this, or do not have a phone that can send images, then you won't do this testing at home.

All study participants will come in for a 1 month clinic visit. During this clinic visit we will do a urine pregnancy test and if you desire or if your medical provider recommends, you may have an exam to check for your IUD strings. We will update your contact information, check on any side effects and symptoms, ask about bleeding, or if you are having any problems. We will also ask you about how much you like the method of contraception you are using.

Follow-Up Questionnaires (Telephone, Text or Email)
We will contact you at 3, 6, and 9 months after the IUD was placed to ask you to complete a study survey. The survey can be done either online or over the phone, depending on your preference. The survey will ask questions about: sexual activity, contraception and pregnancy. There will also be a few questions about your income and whether or not you are currently in school. We do everything we can to keep your answers to the survey private. We explain more about the ways we do this later on in the consent.

12-Month Study Visit
Twelve months after the IUD is placed we will ask you to come to the Planned Parenthood clinic for your final study visit. This visit will include a urine pregnancy test, and if you desire or if your medical provider recommends, you will have a pelvic exam to confirm that your IUD is still in

place. And, we will review any side effects that you may have had, including bleeding. We will also ask you about how much you like the method of contraception you are using. If you are unable to meet in person for this visit you can complete the survey online or over the phone, depending on your preference.

The total length of your involvement in the study is 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 the University of Utah for any birth records or Utah State 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) or on Facebook through private messages.** We will give you a card with this information and send you an email today.

RISKS

While the copper IUD is extremely safe and effective for both EC and for preventing pregnancy for the long term, it is not FDA approved for EC. Use of either IUD for EC is considered "off-label" (this means that it is used for another purpose in addition to ones initially approved by the FDA). Many medicines that are prescribed by doctors and used safely everyday are used "off-label."

The American College of Obstetricians and Gynecologists, the leading doctor's group of women's health care providers, recommends using the copper IUD for EC. The risk of pregnancy in the month after having a copper IUD placed (ParaGard®) for EC is 1/1000.

We are not certain about how well the hormonal IUD works as EC but we believe that the risk of pregnancy is about the same as for women who use EC pills, 20/1000 or less. This is based on a study of 105 women at high risk of pregnancy who got both the hormonal IUD and EC pills and there were no pregnancies from EC failure. So, we believe that the hormonal IUD has some EC effect by itself.

If a pregnancy does occur while the IUD is in place there is an increased risk of having a miscarriage. If you are pregnant with the IUD in place it should be removed immediately. If the IUD remains in place during a pregnancy there is a higher risk of infection or early delivery. If you have a pregnancy with an IUD in place you should be evaluated for an ectopic pregnancy (tubal pregnancy) as soon as possible. While the overall risk of pregnancy is very low with both IUDs, if there is a pregnancy does happen with an IUD in place, you are more likely to experience an ectopic pregnancy than you would without an IUD.

Putting in the IUD is a simple procedure, similar to getting a Pap smear.

The risks of having an IUD inserted are:

- Mild cramping at the time of insertion.
- Risk of IUD falling out. This happens rarely (about 5% of the time). You may have increased cramping and heavy bleeding if your IUD is falling out. If you notice these

symptoms or see your IUD come out, we want you to call us. We can replace it in the clinic. Remember that if it isn't in your uterus, it cannot keep you from getting pregnant.

- Risk of change in bleeding patterns. People with both kinds of IUDs can have irregular bleeding within the first month of insertion. You do not need to see a medical provider for this unless it is very heavy and causes you to worry. In that case please call or return to the clinic to discuss this with a clinician.
- Women with the copper IUD have a little heavier bleeding or an additional day of bleeding with their periods. After getting this type of IUD, most women's menstrual periods return to normal within 3-6 months. Women who have the hormonal IUD inserted can have very irregular bleeding for the first 3-6 months and then have very little or no bleeding after that time period.
- IUDs protect against pregnancy. They do not protect against sexually transmitted infections such as Chlamydia or HIV. If you are having sex with more than one person, or with someone who has HIV, or is having sex with other people besides you, condoms are the only way to protect yourself from infection.
- When the IUD is being inserted it is possible to place the IUD or other instruments through the wall of the uterus. This is called uterine perforation and happens about once in 1000 insertions. If that happens you will not be able to have an IUD at this time.
- The copper IUD contains copper. Therefore, women who have an allergy to copper or Wilson's disease cannot have this IUD. If you have any treatments in the future that might be affected by copper, like heat treatments or MRI, tell your doctor first.
- Women using the two different IUDs in this study may experience other rare side effects. These may be different for the different IUDs. Since some of these can be serious please discuss any concerns you have about possible side effects with the staff at this clinic or your regular medical provider.

Completing questionnaires and talking about your sexual history may occasionally be stressful, uncomfortable or embarrassing. You do not have to answer any questions or do anything that makes you uncomfortable. There is also a small risk of loss of privacy, but we make every effort to reduce those risks.

UNFORESEEABLE RISKS

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

BENEFITS

If you choose to participate in this study and have an IUD inserted, the IUD will protect you from pregnancy for up to 12 years for the copper IUD and 3-5 years for the hormonal IUD. You can decide how long you would like to leave it in. A benefit to participating in the study is that you will not be charged for your choice of EC (this includes either the copper IUD or the hormonal IUD). The information we get from this study may help us to treat future patients requesting emergency contraception.

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 some method of contraception. If you want an 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. David Turok or one of his 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.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah Hospital, as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

The University of Utah and Planned Parenthood Association of Utah (PPAU) are both providing services to you as part of this study. Each service provider is only responsible for the services that they actually perform.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't 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.

COSTS AND COMPENSATION TO PARTICIPANTS
There are no costs to you for participating in this research study. You will receive either a copper or hormonal IUD at no cost to you. You will also receive compensation for your participation in the study, as follows:

- $40 electronic gift code will be sent to you after you complete your 1 month follow up visit and survey;
- $10 electronic gift code will be sent to you after you complete each of the 3, 6 and 9-month surveys;
- $40 electronic gift code will be sent to you after you complete your final 12-month clinic visit and survey.

If you do not come in to the clinic for your 1-month or 12-month clinic visits, but you do complete the online surveys, you will receive $10 gift codes for each of those visits, instead of $40 for each visit.

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 850 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, detail 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 and 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;
  - Twilio: Your cell phone number will pass through Twilio when we send you an SMS text message allowing you to complete your follow-up surveys via text messaging. Twilio will not have access to any information that identifies you other than your cell phone number and they will delete your cell phone number within 24 hours of when you receive the SMS message.
  - Utah State Department of Health: infectious diseases that were listed above will be reported to this state agency;
  - 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