UNIVERSITY OF WASHINGTON
CONSENT FORM
COPPER IUD TREATMENT OBSERVATION STUDY (CITROS)

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24-hour Emergency Contact: Please call UWMC Paging Operator: (206) 598-6190 and ask to have Dr. Godfrey paged

What is "informed consent"?

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide if you want to be in the study. We will go over this form with you out loud, you may also want to read this form carefully before deciding. You may ask questions about the research like, what we will ask you to do, the risks and benefits, your rights, and anything else. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form.

What is this study about?

We want to know if a medication you can buy at the drug store, like Aleve, can help Copper IUD users have less heavy bleeding when they first get their IUD. Most copper IUD users have bleeding changes for the first six months after getting their Copper IUD. We want to know if taking these medications can help women cope with these bleeding changes and increase women's satisfaction with their copper IUD. We expect to enroll 86 women in this study in Seattle and Chicago.

Why are you asking me to be in this study?

You are being asked to participate in this study because you are considering having a Copper IUD inserted for birth control.

How does this study work?

In this study women who use the Copper IUD will be split into two different groups. You and the study doctor will not know which group you are in. Women in both groups will be asked to take a medication for the first seven days of their period for 3 months. One group of women will be taking a medication call sodium naproxen- this medication is known by the brand name Aleve. The other group of women will be taking a "placebo" pill. A placebo pill is a sugar pill that is made to look exactly like the sodium naproxen pill.

This study will take place at the University of Washington and Stroger Hospital of Cook County, Chicago, IL. The study will take place over about 18 months, but we are only asking you to participate for 6 months.

What will I have to do to be in the study?

This study includes three doctors office visits over 6 months, answering online and in person questionnaires, and writing down your bleeding every day for 4 months.

1) Your IUD Consultation/Insertion Visit

At your IUD insertion visit or birth control visit with your doctor, if you and your doctor decide that you will have a TCu380A IUD inserted, you may be eligible to enroll in this study. We will figure out if you are eligible to participate by asking you some questions about your medical history and contact preferences. If you are eligible and you decide to participate you will complete several study questionnaires after your regular doctors' visit. The study questionnaires will ask about:

- Contact information and general demographic information.
- Your sexual desire, arousal and satisfaction.
- Your quality of life including your satisfaction with your relationships, work and other areas of life.
- Your history and experience with menstrual cramping and bleeding.
- A member of the research team will ask you about your medical history, just like the nurse at your doctor's office would.

We will also ask your permission to record the results of your most recent pelvic exam from your medical record. The research portion of this visit (after you have seen your regular doctor) will take about 1.5 hours.

2) Study Visit 1

If you have chosen to participate in the study, we will ask you to answer some more questions after your regularly scheduled IUD "string check" follow up visit with your doctor. Your doctor typically asks you to come in for your "string check" visit about 4-6 weeks after you get your copper IUD. After your visit with your doctor, we will ask you some questions to figure out if you are still eligible to continue in the study. If you have not had certain bleeding changes, then your study participation will end. If you are no longer in the study, we will still keep the information you have given us so far.

If you continue in the study at this point, you will be placed into one of two groups. You will not know which group you are in. The group you are placed in will be chosen randomly, like flipping a coin. One group will receive 440 mg of naproxen sodium (Aleve) in pill form and the other group will receive a placebo pill. You will not know which tablet you are getting. You will take one tablet twice a day (12 hours apart) at the beginning of your monthly period, for no more than **SEVEN** consecutive days. You will receive enough medication for three months. You will also receive an instruction sheet and study contact information in case you have questions. This study visit can take up to one hour.

3) Monthly Bleeding Diaries

We will also ask you to keep a bleeding diary. You will complete both a paper and electronic bleeding diary. The electronic bleeding diary will consist of daily text or email messages about your bleeding for the day.

If you do not respond to the text/email message, a second text/email will be sent the following morning. You have only these two chances to report your bleeding information via text/email for that day, otherwise you will need to use the paper diary.

You will be compensated $1 for each day you provide information about your bleeding.

4) **Monthly Email or Phone Call**

You will receive a monthly phone call or email from the research coordinator for 4 months. They will ask you questions about your IUD and your satisfaction with that method of birth control. They will ask you questions about your monthly period such as date of your period, did you experience pain, and are there changes in your bleeding. They will also review your monthly bleeding diary with you and ask about any other changes in your health. These phone calls or email may take about 15 – 20 minutes of your time.

5) Study Visit 2

This visit will happen about 6 months after you had the Copper IUD inserted. We will ask you to return to the clinic for a study visit. You will be asked to bring back your bottle of study medication (even if it is empty) and we will ask you to complete several questionnaires. This visit will take about 1.5 hours.

The research coordinator will ask the same questions asked in the monthly phone call. We will also ask you to complete questionnaires about:

- Your sexual desire, arousal and satisfaction.
- Your quality of life including your satisfaction with your relationships, work and other areas of life.
- Your history and experience with menstrual cramping and bleeding.
- Your satisfaction with the Copper IUD.

Are there side-effects or health risks from taking this medication?

There are possible side effects associated with taking the study medication, naproxen sodium (Aleve) even though it is a medication you can buy at the drugstore without a doctor's prescription. Millions of women take Aleve, and side effects are very rare. It is possible you may experience the following side effects:

- Heartburn
- Nausea
- Vomiting
- Ringing in Ear
- Bloating
- Diarrhea
- Constipation
- Black Stools
- Severe Abdominal Pain
- Vision changes
- Fluid Retention
- Allergic Reaction to the study medication

If you experience any of the above please be sure to let the research staff know. As with any drug, there may also be other side effects that we don't know about.

Are there other risks involved in this study?

You may feel uncomfortable answering personal and private questions about your period and sex life. Research staff will do everything possible to help you feel more comfortable, but you never have to answer any questions you don't want to.

There is also a risk that someone who is not on the research team could find the private information you give us. We make every effort to keep your personal information secure and private. One way we keep your information is safe is by assigning you a "subject ID number. " This number is used instead of your name on all study documents so no one can figure out which answers are yours. The research coordinator has a list of subject ID numbers that show which ID number was assigned to which person. This is the only document where your name is linked to the study ID number. This document, and all of the information you provide for this study, is kept on a password protected computer at the University of Washington.

What if I decide I don't want a Copper IUD?

Depending on your birth control needs and medical history you may prefer to use another method of birth control. **You do not need to participate in the study to have access to the Copper IUD.**

Will I benefit from being in this study?

You will not directly benefit from participating in this study. Information from this study will help health care professionals establish better care for women who use a copper IUD.

Who is paying for this study?

Teva Pharmaceuticals, the company that makes the Copper IUD, is paying the University of Washington and the research team to conduct this study.

Will my information be private?

The data from this study will be confidential. Your information will be linked to your subject ID number. The research team will have access to the information you provide for this study.

Who besides the research team might see my study information?

Government or university staff sometimes review studies like this one to make sure they are being done safely and legally. Teva Pharmaceuticals, the sponsor of this study may also review the study records to make sure the study was done safely and legally. Teva can review these records any time up to 5 years after the study is finished. If a review of this study takes place, someone from outside the research team may read your study records. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

This study will be registered with ClinicalTrials. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who else will know that I was in this study?

Your healthcare providers at UW Medicine will know you have participated in this study because it will be noted in your health record at UW Medicine. They do not have access to the study information so they will not know your survey answers, only that you participated in the study.

What if I don't want to participate or change my mind?
You may refuse to participate and you are free to withdraw from this study at any time without penalty. This means if you chose not to participate or to leave the study early your care at UW Medicine will not be affected in any way and you will still receive a gift card incentive for each study visit that you completed.

Will I get paid to be in this study?

You will receive a $25.00 gift card for the first study visit and a $40.00 gift card for the second visit. You will receive $1.00 a day for 4 months for responding to the daily texts and/or completing the diary about your bleeding. You will receive a $45.00 gift card for the final visit. If you complete all the study visits you will receive $222.00 in gift cards. We will also pay for parking for subjects who return for the final study visit.

Do these payments get taxes taken out?
The US government requires us to have your name, address, and social security number in order to pay you for your time. That information, your payment amount, and the name of the study will be kept secure and confidential in our department's financial office and the University's financial office. If you are paid a total of $600 or more as a research subject in a calendar year, the University is required to report the payment to the Internal Revenue Service (IRS). The University will send you a form (IRS form 1099) in January documenting the payment total.

Who pays for my doctor's visits in this study?

You or your insurance company will be responsible for the costs of the visits with your clinician to have IUD insertion and the 4-6 week follow-up visit. These visits would occur even if you are not in the research study. The study will reimburse your for parking for the last study visit. Your health insurance will not be charged for this last study visit.

What if I have a serious health emergency while I am in the study?
For a life-threatening problem, call 911 right away or seek help immediately. Contact Dr. Godfrey at 206-598-6190 (UWMC Paging) when the medical emergency is over or as soon as you can. For all other problems: contact Dr. Godfrey at 206-685-4895 right away. She will treat you or refer you for treatment.

What if I get injured because of the study medications or procedures?
If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility.

If you are harmed or injured as a result of your participation in this study, the costs of your medical treatment may be billed to you or your insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP). The researcher may request HSAP

coverage. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. We will bill your health insurance for treating problems that result from your reproductive care or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

I am willing to be contacted in the future about other studies related to female reproductive care.

_____ YES _____ NO

Copies to: Researcher
Subject