SUBJECT INFORMATION AND CONSENT FORM

Better Contraceptive Choices: Immediate vs. Interval Insertion of IUC after Second Trimester Abortion

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PURPOSE:

You are being invited to take part in this research study because you are having an abortion; you are currently at least 12 weeks pregnant and have decided you would like intrauterine contraception (IUC), either a Copper Intrauterine Device (IUD) or a Mirena IUS (Levonorgestrel-Releasing Intrauterine System), after the abortion.

Women can become pregnant almost immediately following an abortion. Intrauterine contraception (IUC) is one of the best Birth Control methods. Studies have shown it is best to insert the IUC immediately after an abortion for a pregnancy less than 12 weeks. For pregnancies over 12 weeks (called "second trimester") there isn't evidence to suggest whether it is best to put in the IUC right away, or to wait 4 weeks. This study will find out which time is best to put in IUC after a second trimester abortion. Pregnancy rate at one through five years will be compared for the two groups. The investigators will not receive any personal payment for any aspect of the study.

STUDY PROCEDURES:

If you decide to join this study, **you will have your abortion and follow up for the abortion in the normal way**, including your follow up for any problems or complications related to your abortion. We will use an independent computer system to randomly decide if you will have your IUC put in immediately after your abortion, or four weeks later (with an acceptable range between 3-5 weeks). You will have an equal chance to be assigned to either group.

You will be asked to give consent for us to use your Personal health Number (PHN) to learn if you have any new pregnancy conceived during the next five years. **We want to link your Medical Services Plan (MSP) Personal Health Number (PHN) and date of birth to the databases of Ministry of Health Services, Population Data BC and PharmaNet to collect data within:** Medical Services Plan Registration and Premium Billing, PharmaCare, PharmaNet, Vitals Statistics, , Therapeutic Abortion Database and hospital utilization and Discharge Abstract Databases and chart records of BC abortion clinics.. We will collect data about any health care visits, or prescriptions, and associated costs for immediate infections or complications and for any abortion, miscarriage, contraception and

outcomes for any pregnancy conceived in the five years following this abortion. This data will be retained for twenty five years, as required by Health Canada policy, and then destroyed.
We will ask you to have follow-up examinations at 3, 6, and 12 months following the abortion. In addition you are welcome to return at any time to your study site for any concern you may have or for removal of your IUC if you should so wish. At each visit a pelvic examination and ultrasound will be performed to confirm the presence of the IUC and detect any complications or recurrent pregnancy. Follow-up examinations for out of town women may also be performed by a health care worker chosen by the participant. We will also ask you to complete short questionnaires today, and at 3 and 6 months and again each year after your abortion to five years. It should take 10 – 15 minutes to complete the questionnaire.

WHAT DOES THIS STUDY INVOLVE?

This study is taking place at several clinics in BC where UBC Faculty of Medicine physicians perform abortions. We will enroll a total of 716 women (350 choosing Mirena and 366 choosing Copper IUD), approximately half of each IUC group will be randomized to get an immediate insertion and the other half will be randomized to get an interval (4 week) insertion. This study will be started in April 2010 with approximately a 14 month recruitment period. All follow up will be finished by 2016. This study will not be started prior to approval from the appropriate Research Ethics Boards (REB).

WHO CAN PARTICIPATE IN THIS STUDY?

Participation in this research study is offered to women who
(1) are residents of British Columbia, registered with the MSP health care system;
(2) have given consent to have an abortion for a pregnancy of 12 weeks or more; and
(3) have decided to use IUC after the abortion.

WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

Participation in this study is not suitable for only a few women who: - plan to move out of BC within the next year; - plan to become pregnant within the next year; - have current untreated infection of the female uterus, fallopian tubes, and/or ovaries, chlamydia or gonorrhea; - have large (over 5cm) uterine fibroids or anomalies such as bicornuate or heart shaped uterus; - have an allergy to copper or polyethylene or have Wilson's Disease (if choosing CuT380-IUC); - have undiagnosed abnormal uterine bleeding; - known cancer of the uterus or cervix; - known or suspected progestin-dependent cancer, including breast cancer; or active liver disease; or actual benign or malignant liver tumors; or hypersensitivity to levonorgestrel (if using Mirena); bacterial endocarditis; established immunodeficiency (like active AIDs); currently active cancer affecting blood; recent molar pregnancy; or currently enrolled in another investigational study.

Women who choose to participate but have the very rare (less than 1 in 1000) complication of uterine perforation at the time of abortion, or the rare (less than 1 in 500) complication of excessive bleeding, will not be eligible to have an IUC at the time of their abortion, and so won't be included in further aspects of the study.

WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY?

Women having their IUC placed at the time of their abortion may have a slightly higher chance that the IUC will be expelled, or pushed out of the body, within the first few weeks. You are likely to know if you expel the device, and if so, it will be up to you to decide what method of contraception you would like to then use, or if you would like to buy an IUC to insert. All possible care will be taken to preserve the privacy and confidentiality of women during the process of the follow up contact. We do not think this contact will bring any harm to you.

Please also see below the possible side effects of using Mirena (at a rate of more than 1% after 3 months) **These side effects are not expected to be any different as a result of the insertion time you will be given**: Change in menstrual bleeding patterns (irregular menstrual bleeding, heavier or lighter periods, shorter or longer periods, or lack of a menstrual period, or painful periods) (29.4%), abdominal pain (11.0%), nausea (2.2%), depression (2.1%), headache (5.8%), breast pain (3.2%), back pain (3.5)%, genital discharge (1.3%), acne (2.8%). Infections and infestations (2.3%). There is a small chance (1/1000) the IUC may perforate (go through) the wall of the uterus at time of insertion.

Mild post-insertion cramps or discomfort may occur in rare cases of using CuT380-IUC. Increased menstrual bleeding or spotting may occur, mainly during the first 1- 2 cycles after insertion.

WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else. Refer to UBC CREB Guidance Note #12, at http://rise.ubc.ca/helpCenter/GN/CREB_Guidance_Notes.html#Policy12

WHAT ARE THE BENEFITS TO PARTICIPATING IN THIS STUDY?

There may or may not be direct benefits to you for taking part in this study. If you choose to participate you will be contributing to better understanding of the contraceptive choices for women in the future, as well as helping other women know exactly when it is best to put the IUC in after an abortion. If you take part, **you will receive a free IUC of your choice and a $20 gift card**.

You may access the results of this study which will be posted on our web site: www.bcc4me.ca when available in approximately 2018.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. No information that discloses your identity will be released or published. Research records and medical records identifying you may be inspected in the presence of the Investigator or her designate by representatives of Health Canada, the BC Ministry of Health Services, the UBC Research Ethics Boards and (for Mirena participants) Bayer Incorporated, or by the "IUC study Data and Safety Monitoring Board", for the purpose of monitoring the research. No records which identify you by name or initials will be allowed to leave the Investigators' offices.

LEGAL RIGHT: Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else involved in the study.

WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions, or desire further information about this study before or during participation, **you can contact Dr. Wendy V. Norman at (604) 761-7767**. *If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the* **Research Subject Information Line** *in the University of British Columbia Office of Research Services* **by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598.**

SUBJECT CONSENT TO PARTICIPATE:

Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected. All data collected about you during your enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

Please take your time in reviewing this document. We encourage you to discuss any concerns you may have with us. Your signature indicates that you have received a copy of this consent form for your own records.

SIGNATURE:

My signature signifies that I understand the meaning of participation in this study and have had all my questions answered and that I consent to participate.

Printed name of subject	**Signature**	**Date**
Printed name of translator (if applicable)	**Signature**	**Date**
Dr. W. V. Norman **Principal Investigator**	**Signature**	**Date**