SUBJECT INFORMATION AND CONSENT FORM
Contraception satisfaction and effectiveness post abortion:
A randomized controlled trial

PRINCIPAL INVESTIGATOR: Dr. Wendy V. Norman, MD, FCFP, DTM&H, MHSc
Clinical Professor, Dept of Family Practice, Faculty of Medicine, UBC
Team Leader: Clinical Abortion Research Team, Women's Health Research Institute, Provincial Health Services Authority
wvnorman@interchange.ubc.ca (604) 761.7767 or 1(877)922.7890

Co- Investigators: Dr. J. Chiles, Resident, Dept of Family Practice, Medicine, UBC
Dr. C. Turner, Resident, Dept of Family Practice, Medicine, UBC

Funding Provided By: **Dr. Sue Harris Women's Health Research Grant**
Society of Family Planning

PURPOSE:

You are being invited to take part in this research study because you are having an abortion; you are currently at less than 12 weeks pregnant and have decided you would like a copper Intrauterine Device (IUD) after the abortion. This consent will explain to you what the study involves and if you wish to participate you will be asked to sign this form.

Women can become pregnant almost immediately following an abortion. Intrauterine contraceptive devices (IUDs) are one of the best birth control methods. Studies have shown it is best to insert the IUD immediately after an abortion for a pregnancy less than 12 weeks. There are a few different types of copper IUDs available in Canada but there is not evidence to show which one works better for women after they have an abortion. This study will find out which IUD women prefer and which is most effective. Pregnancy rates at one through five years will be compared for two IUDs. 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. The only change to standard procedure will be that we will use an independent computer system to randomly decide if you will have a Flexi-T 380 IUD or a Nova-T IUD put in immediately after your abortion. 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) and date of birth 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, Children in Care and Social Assistance databases, Therapeutic Abortion Database and hospital utilization and Discharge Abstract Databases and chart records at BC abortion clinics. It is unusual to include date of birth or initials on research records. Most studies submit information with code numbers or letters only. These additional identifiers are necessary for this study as we want to be able to collect data about any health care visits,

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 after research publication, as required by Health Canada policy, and then destroyed. Linking of these databases takes place in a highly secure research environment with every possible precaution taken to ensure your privacy and confidentiality are respected.

WHAT DOES THIS STUDY INVOLVE?

This study is taking place only at the Women's Services Clinic in Kelowna, BC. We will enroll between 500 and 750 women (250-500 choosing to have a copper IUD inserted and 250 choosing an alternate form of contraception). Of those choosing a copper IUD approximately half will be randomized to get a Flexi-T 380 IUD and the other half will be randomized to get a Nova-T IUD. All follow up will be finished by 2018.

We will ask you to fill in a follow up survey at 3, 6, and 12 months following the abortion. The information on this questionnaire will be stored in a secure database on a server located within Canada, whether the survey is filled out via our BC hosted web page (www.bcc4me.ca) or as a paper form. It should take 10 – 15 minutes to complete the questionnaire and you will be able to choose how you fill it out (i.e. via mail, phone or internet survey).

This study will not be started prior to approval from the appropriate Research Ethics Boards (REB). The results of this study will be used for presentations and be published in medical journals.

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; and (2) have given consent to have an abortion for a pregnancy less than 12 weeks 0 days

WHO SHOULD NOT PARTICIPATE IN THIS STUDY? Participation in this study is not suitable for only a few women who: (1) plan to move out of BC within the next year; (2) plan to become pregnant within the next year, or (3) have an allergy to copper or polyethylene or have Wilson's Disease;
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 IUD 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? There is a possibility that the IUD 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 IUD 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. Mild post-insertion cramps or discomfort may occur in rare cases of using a copper IUD. Increased menstrual bleeding or spotting may occur, mainly during the first 1- 2 cycles after insertion.

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 what IUD is best to put in after an abortion. If you take part, **you will receive a free IUD and** each time you fill out a survey **a $10 gift card**. You will have an opportunity to 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 identifying you may be inspected in the presence of the investigator or her designate by representatives of the UBC or the IH Research Ethics Boards 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 questions or desire further information about this study before or during participation, **you can contact Dr. Wendy V. Norman at 604-761-7767, or Toll Free at 1-877-922-7890 or by email at wvnorman@interchange.ubc.ca** . *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 (Toll Free Number 1-877822-8598) or** *contact the* **Chair of the Interior Health Research Ethics Board through the Research Office at 250-870-4602.**

SUBJECT CONSENT TO PARTICIPATE:

Your participation in this research is entirely voluntary. You may withdraw from this study by contacting the Principal Investigator at the number provided above 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 for five years beyond the date of research publications, however, no further data will be collected.

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 signed and dated 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**