NON-IUD GROUP INFORMATION AND CONSENT FORM
Contraception satisfaction and effectiveness post abortion:
A randomized controlled trial

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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 less than 12 weeks pregnant and have decided you do not want to use an 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. We want to better understand how to offer the most effective contraception after a pregnancy like yours. We are studying different types of contraception and want to know how effective these are, and how satisfied women are with using them to prevent pregnancy after abortion. Pregnancy rates at one through five years for women choosing to use an IUD will be compared to women like you who prefer not to have an IUD. 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 difference if you decide to take part in this survey will be that you will be asked to fill out initial and follow-up questionnaires.

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, PharmaNet, Vital Statistics, Provincial Laboratory Information System, 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). You will have your abortion and follow up care in the normal way. We will follow up with you at 3 and 6 months and 1 year after your abortion to ask you to complete a contraception satisfaction questionnaire. 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. This survey should take between 10-15 minutes to fill out and you will be able to choose how you participate (i.e. via mail, phone or internet survey). The rest of the time we will follow up using the database information alone. All follow up will be finished by 2018. 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 of less than 12 weeks and at the time of the abortion have chosen not to use intrauterine contraception.

WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

Participation in this study is not suitable for women who plan to move out of BC within the next year; or who plan to become pregnant within the next year.

WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY?

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.

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. If you take part, **you will receive a $10 gift card** each time you fill out a survey. You will have an opportunity to access the results of the study from our web site www.bcc4me.ca as soon as they are 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 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 and they will be destroyed after twenty five years following publication of the research.

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 1-877-9CART90 or 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 1-877-822-8598).**

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, 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 copy of this signed and dated consent form for your own records.

SIGNATURES

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