

PARTICIPANT INFORMATION form

*Sexual Health Unit,  
School of Population Health  
The University of Melbourne*

Project Title

Woman on Woman's Health  
(WOW)

## **PARTICIPANT INFORMATION FORM**

***Sexual Health Unit, School of Population Health, University of Melbourne***

### **Full Project Title: Woman on Woman's Health (WOW)**

Principal Researcher: Dr Catriona Bradshaw

Student Researcher: Dr Katherine Fethers

Associate Researchers: Professor Christopher Fairley, Dr Jane Hocking, Dr Marcus Chen, Associate Professor Sepehr Tabrizi and Professor Suzanne Garland

Project Coordinator: Dr Sandra Walker

### **1. Introduction**

You are invited to take part in this research project. The research project aims to understand whether a common genital infection called bacterial vaginosis (BV) is transmitted to women and how it may be related to different types of sexual activities. We hope this research will lead to improvements in understanding and treatment for BV.

This Participant Information Form tells you about the research project. It explains what is involved to help you decide if you want to take part. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide you want to take part in the research project, you will be asked to sign the consent form. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to be involved in the procedures described;
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Form and the Consent Form to keep.

### **2. What is the purpose of this research?**

The aim of this study is to see how commonly BV occurs in women with female sexual partners and how it may be related to sexual activity. In BV a woman's usual healthy vaginal bacteria (in particular lactobacillus bacteria) are replaced by an overgrowth of mixed bacteria. BV is a common condition, and studies have shown it affects 10-30% of women in countries such as the United Kingdom and United States. BV may cause symptoms of an abnormal vaginal discharge or odour (smell). However, more than half the women with BV do not have any symptoms so are often unaware of the infection. In most women BV has no complications, but it can cause miscarriage, premature birth and pelvic infections, and can increase a woman's risk of getting sexually transmitted infections. The current recommended treatment for BV is with antibiotics, either 7 days of metronidazole tablets by mouth or 7 days of a vaginal cream, clindamycin. Studies have shown that these treatments cure 70-80% of women within a month, however,

up to half experience another case of BV within 6 months of treatment. Importantly, we don't know why this happens. Several studies have demonstrated that women who have female sexual partners are at higher risk of BV than other women but it is not clear why this is so. Some studies suggest BV may be sexually transmitted, however this remains unproven. Our research aims to understand how common BV is in women with female sexual partners, and how it may be related to sexual activity, in order to then develop more effective treatments and to prevent the complications associated with BV for women. We aim to have 500 women participating in this study for up to two years and the study will be open to eligible women nation wide. The results of this research will be used by the researcher Dr Katherine Fethers to obtain a PhD in medicine.

### **3. What does participation in this research involve?**

Participation in this project will involve completing a questionnaire on-line that will be coded and does not have your name on it. You will only be able to access this questionnaire with a username and password we will provide. We will be asking you personal questions so that we can understand how BV develops and if it is spread between people. The questionnaire takes 5 to 10 minutes to complete. Your answers will be stored on a database that is password protected and access restricted in locked premises that are only accessible with a security key tag. It is important that you understand that your answers are not stored on the website and cannot be viewed once they have been entered, by you or anyone else using your computer after you. We will also ask you to collect a vaginal swab once a week for two weeks (3 times) at the beginning of the study. Studies have shown that women find self-collecting swabs easy and acceptable, and often prefer it to a doctor taking a swab. We will give you clear written instructions on how to collect a swab. The vaginal swabs will be tested for BV and then stored, this is discussed on page 9. If you have BV you can access antibiotic treatment either through our clinical service, Melbourne Sexual Health Centre (MSHC) or through your GP if you prefer. We will give you a free study number to phone us to discuss any concerns about sexual health, including BV and sexually transmitted infections (STIs). In recognition of the time and commitment to the study we will be giving women a \$20 Coles-Myer voucher at the beginning of the study.

If you do not have BV on any of the 3 vaginal swabs, we would like you to participate in a two year study where you collect a vaginal swab once every 3 months for up to 2 years. In this study we will not need to see you in person, everything will be posted to you and can be completed at home and returned to us by post. Every three months we will send you a pack containing a swab, a slide, a reply-paid envelope and clear instructions. We will provide a prepaid envelope to post the swab and slide back to us. We will contact you if we detect BV on the swab, and can arrange for you to have treatment. We will also ask you to fill out the sexual behaviour questionnaire on-line every 3 months, it is coded and does not have your name on it and is very similar to the one you do at the beginning of the study.

**If you develop an abnormal vaginal discharge or odour** that may be BV at any stage in between the 3 monthly samples, we ask you to contact study investigators, free call 1800 082 820, collect a vaginal swab to return in the post and complete a brief online questionnaire. This aspect of the study is important in order to understand if BV has occurred. We will then contact you with your result and arrange treatment where appropriate.

**If you start any new sexual relationships** during the study period, we also ask you to collect a vaginal swab within one week of having sex and another swab two weeks later (so two swabs within the first three weeks of first sexual contact in this new relationship). We also ask you to complete a brief online questionnaire. You can contact us at any stage to clarify the timing of these two samples relative to your new

relationship. This aspect of the study is very important in order to understand if BV develops around the time of new sexual relationships.

We will send you a regular text message or email to notify you when the next study kit will arrive in the post. We would like where possible to obtain a sample from any new female or male sexual partners. While we recognize this may be difficult for you, if you are happy to we ask you to give them the study card in your 'new sexual partners' kit and they can contact us. It is important that you understand that your personal information will not be revealed to any partners. By giving your partner the study card you agree that they may mention your name so that your data may be code linked, for the purpose of the final analysis. It is important that you understand that no information is given out about specific individuals to other participants, including partners, at any stage during or after this study.

So in summary this two year study requires you to:

- collect a vaginal swab and slide once a week (three times) and complete an online survey at the beginning of the study
- If you do not have BV on these first three samples, then:
- collect a vaginal swab and slide and complete an online survey every 3 months (we will send a reminder for this)
- collect a vaginal swab and slide and complete a brief online survey if you develop vaginal symptoms of BV in between follow up points during the study
- collect a vaginal swab and slide within one week of having sex and another swab two weeks later and complete a brief online survey
- give any new sexual partners during the study, that you feel comfortable with, a study card to see if they would participate on one occasion only

We will give you a free study number to phone us to discuss any concerns about sexual health, including BV and sexually transmitted infections. We can arrange for a review at MSHC, a confidential health service, that provides STI and HIV testing and medication for free if required. In recognition of the time and commitment to the study we will be giving you a Coles-Myer voucher for \$20 every 3 months you are involved in the study plus \$40 for completing the study. If you develop BV during the study then there is no need to continue in the study, but we will instead arrange for review and treatment if appropriate. This will mean that some women will not continue in the study for the whole two year period. If you do not develop BV during the study we ask you to remain in the study where possible for two years.

We will also ask you on the consent form whether you agree to storage of vaginal swabs and slides collected during this study. These samples will be stored in a laboratory freezer for future testing for known or possible causes of BV and other infections relevant to research on bacterial vaginosis and sexually transmitted infections. We do not understand the cause of BV, and if research in the future shows it may be a newly discovered micro-organism (eg bacteria or virus), then we would like to be able to test stored vaginal samples from this study. Your samples will be stored in a secure laboratory freezer and your name is not on the sample. Samples are stored labelled only with a study code and date of birth. Study investigators will be the only people with access to your samples and study information, to maintain your privacy and confidentiality. Research collaborators will only have access to your stored samples with our permission but will not have access to your personal information. If you do not wish us to do this you will be able to tell us on the consent form and still participate in the study. The results of future research on stored samples will be made available to

participants if they are relevant to your health and you have indicated you would like to receive such results on the consent form.

#### **4. What are the possible benefits?**

Possible benefits for you personally from involvement in this study include being tested for BV regularly over 2 years and access to expert advice regarding sexual health and BV. The researchers in this study are physicians who have a particular expertise in sexual health. We will provide a free number for you to call to discuss any sexual health concerns you may have. Participation in this study may not give you any personal benefit other than knowing that you are involved in a study that is part of improving current treatment of BV for women.

#### **5. What are the possible risks?**

Self-collection of vaginal swabs is a simple and painless procedure. This method has been used in numerous studies and in situations where women prefer to not to be examined. We will provide clear instructions and diagrams and there is no risk associated with this procedure. Participants will be asked to complete questionnaires on-line during the study that include questions on sexual practices. This information is sensitive, and the sole purpose of these questions is to try and understand how sexual activity may lead to the development of BV. The nature of the questionnaires will be discussed with you at enrolment by a female researcher who recognises the personal and sensitive nature of these questions. Although we ask you to inform new sexual partners of this research study where you feel comfortable doing so, this is clearly optional and may not be something you are comfortable doing. We wish to clarify that if your partners do participate they cannot access any of your personal information at any stage. If you become upset or distressed as a result of your participation in this research, we will be able to arrange for you to have counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team. We have trained counsellors in place at MSHC, but we have also provided contact information for the experienced counsellors at the Centre against Sexual Assault (CASA) below if you have had any unwanted sexual experiences including sexual assault in the past and have not received counselling or medical review and wish to do so. The toll free number for the Centre Against Sexual Assault is 1800 806 292.

Your confidential information will be respected and protected. The information collected by online questionnaires will be stored with a code and date of birth only in a password protected database with access restricted to study personnel. Any information linking the code with your personal identity will be kept in a separate password protected and access restricted database, accessible only to study investigators. Your personal identifying information will only be used to give you your results and you will be asked a series of questions to verify your identity with any phone contact.

#### **6. Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you decide to withdraw, please notify a member of the research team. This notice will allow that person or the research supervisor to inform you if there are any special requirements linked to withdrawing. If you decide to leave the project, the researchers would like to keep the personal and health information about you that has been collected. This is to make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the research project. Your decision whether to take part or

not, or to take part and then withdraw, will not affect your relationship with the researchers or the Melbourne Sexual Health Centre.

**7. How will I be informed of the final results of the project?**

Participants will be told if BV has been detected within a fortnight of each swab being collected. When the study is complete we will look at how frequently BV developed over two years in the study group. We expect the overall results to be available within 6 months of completion of the study. We plan to publish these results in a medical journal, but they will be published in such a way that no person can be identified (eg. 5% of 500 women developed BV over two years). Following completion of the project, a copy of the overall results can be made available to you. Please indicate if you would like this on the Consent Form.

**8. What will happen to information about me?**

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of providing you with your swab result. Your information can only be disclosed with your permission, except as required by law. Your data will only be stored in password protected and access restricted databases in locked premises that are only accessible with a security key tag. Data will be stored indefinitely in accordance with the Alfred Hospital policy on the management of research data and records. We plan to publish the findings of this study in a medical journal and present them at medical conferences, so that other doctors will understand the results. This will be done in a manner that pools all the results – no individual could be identified.

**9. Can I access research information kept about me?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information. Further, in accordance with regulatory guidelines, the information collected in this research project will be kept indefinitely. You must be aware that the information may become de-identified at some point and access to information about you after this point will not be possible.

**10. Is this research project approved?**

The ethical aspects of this research project have been approved by the Human Research Ethics Committees of the Alfred Hospital and The University of Melbourne. This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**11. Who can I contact?**

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

a) If you want any further information concerning this project, or if you have any questions at any stage, you can contact researcher Dr Katherine Fethers on (03) 9341 6243 or Dr Catriona Bradshaw (03) 9341 6253. You can also contact us toll free on 1800 082 820.

b) If you have any complaints about any aspect of the project, the way it is conducted or any general questions about being a research participant, then you may contact Ms Rowan Frew, Ethics manager, Research and Ethics Unit, The Alfred Hospital on (03) 9076 3848.