 **October 2015**

##  IRAS ID: 307899

## Strapline

## PARTICIPANT INFORMATION SHEET FOR NON-PARTICIPANTS

**Study Title:**  **Is the naturally occurring prebiotic Lactoferrin an acceptable alternative to antibiotic/antifungal tablets for women with bacterial vaginosis or thrush?** The **LISA** (**L**actoferrin **I**n**S**tead of **A**ntibiotics/antifungals) randomised feasibility study.

**Chief Investigator: Dr Pippa Oakeshott**

Invitation to participate in a telephone interview for a research study on women’s health

You are being invited to take part in a telephone interview to explore your reasons for not taking part in the LISA study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and ask if there is anything that is not clear to you. *Thank you for reading this.*

What is the purpose of the study?

We want to find out about your reasons, views, and opinions which contributed to you deciding not to take part in the study.

This will aid development of a future study to find out whether naturally occurring prebiotic Lactoferrin vaginal pessaries (made from cows’ milk) are acceptable, effective and cost-effective as an alternative to antibiotic tablets for women with bacterial vaginosis or vaginal thrush/candida.

Why have I been chosen?

We are asking women who have declined participation in the study if they are happy to help us further and be interviewed on their reasons for not taking part.

Do I have to take part?

It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason, and this will not affect your medical care.

What will happen to me if I take part?

 You would be interviewed over the phone by one of the research team. The time required for the telephone interview would be approximately 10 minutes. The phone interviews will be recorded from speakerphone using a handheld digital voice recorder which can only be connected to using a lead (i.e. not wifi or bluetooth). Phone interviews will not be recorded on or saved on a telephone.  At the earliest opportunity the audio recording will be safely transferred to a secure server and deleted from the handheld digital recorder. The interview will later be listened to and written down in full (transcribed). Transcription will be undertaken by a professional transcriber who is approved by St George’s, University of London and who has signed a confidentiality agreement. The audio recording will be destroyed once transcription is completed. We will write a final report about the research and articles for academic journals. It is possible that we will directly quote something you have said in an interview. However, all information or anything you have said will be anonymised so that it is not possible to identify you.

**What are the risks of taking part?**

We do not think there is anything in this component of the study that could be harmful to you. If you feel that a question seems sensitive or personal, you would not have to answer any question that you do not want to.

If you do have any further questions or concerns regarding your involvement, please contact the research team (contact details listed below).

**What are the possible benefits of taking part?**

You would not directly benefit from participation in this part of the study. But you will be helping us in the development of a future study to find out whether naturally occurring Lactoferrin vaginal pessaries (made from cows’ milk) are acceptable, effective and cost-effective as an alternative to antibiotic tablets for women with bacterial vaginosis or vaginal thrush/candida. The findings from the interviews will allow us to improve our understanding of the acceptability and perception of the treatments.

As a *thank you* to you for taking part in the telephone interview, you will receive a £10 note.

**What if there is a problem?**

If you have a problem related to the study, please contact us as soon as possible (contact details listed below). If we cannot help you, you will be directed to the Patient Advice and Liaison Service (PALS) at Guys and St Thomas’ NHS Trust 020 71887188 pals@gstt.nhs.uk. Women recruited at the Curran practice should contact the practice manager on 020 74116866.

**Will my taking part be kept confidential?**

Your confidentiality would be respected. You would be assigned a unique study number as a participant in this study. Only this number would be used on any research-related information collected about you during this study so that your identity as a participant in this study would be kept confidential.

A written and verbal consent will be gained by the research assistant before a telephone audio-recorded interview begins. Before audio-recorded interviews, the participants would be reminded not to give identifying information. The recorded interviews will be anonymised and all participants will be allocated a letter and number code e.g. P6, P8. Any stories you choose to share that have the potential to be easily identified would be altered to protect any possible third-party identification.

All data with identifying information would be kept as a hard copy in locked cabinet in a locked room with the Site Principal Investigator. Certain identifiable information will need to be shared with SGUL for the purpose of your participation. This will be securely stored and managed.

**What will happen to the results of the research study?**

We aim to publish the results of the study in a scientific journal. If this is completed, a copy of the published results will be available from Dr Oakeshott (contact details listed below).

**Who is organising and funding the research?**

The study is being organised by St George’s, University of London, and funded by the National Institute for Health Research.

**Who has reviewed the study?**

This study has been reviewed and given a favorable opinion by a national Research Ethics Committee and the Health Research Authority (HRA)

**What if I want to complain about the way data is handled?**

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner’s Office (ICO) (<https://ico.org.uk/>).

**Data Protection Privacy Notice**

St George`s, University of London, conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.sgul.ac.uk/about/our-professional-services/information-services/information-governance/data-protection/data-protection-policy>).

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent, unless St George’s, University of London, is required by law to disclose it.

For the purposes of data protection law, the university is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you for 5 years after the study has finished after which time, any link between you and your information will be removed.

**Contact for further information**

If you have any questions, the research team will be happy to answer them. Please feel free to contact Dr Pippa Oakeshott at the Population Health Research Institute, St George’s, University of London, SW17 0RE on 07772 846496 or oakeshot@sgul.ac.uk.

**Thank you for reading this information sheet and for considering taking part in this research.**