**PARTICIPANT INFORMATION and consent form (PICF)**

**Mercy Hospital for Women**

**Participant Information and Consent Form
Mercy Hospital for Women**

Version 1 30/04/2020

**Full Project Title:**

**Microdox versus normal saline bladder rinse for chronic UTI.**

**Principal Researcher**: Dr Frida Carswell Urogynaecology Fellow

**Associate Researchers**: Dr Alison Desouza, Consultant Urogynecologist

Dr Lore Schierlitz, Consultant Urogynecologist

**1. Introduction**

You are invited to take part in this research project.

This is because you have had a number of urinary tract infections that have been difficult to treat and prevent. We are currently trying to find safe and effective non antibiotic treatments that reduce the risk of developing recurrent urinary tract infections.

This Participant Information and Consent Form tells you about the research project. It explains what is involved to help you decide if you would like 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 wish to talk about the study with a relative, friend or your local GP.

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 section. 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.

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

This project aims to find an effective treatment for recurrent urinary tract infections. The current “gold standard” treatment is long-term low dose antibiotics, which can lead to side effects such as altering your gut and vaginal flora, thrush and antibiotic resistance. There are currently no other products that have proven to be as effective in treating your condition, which is why this research is very important.

This project aims to look at how effective the bladder rinse treatment is in preventing urinary tract infections. It is important for your treating team to observe whether your urinary symptoms and sings of infection improve.

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

1. Patients in the study will attend the Urogynacology department for a bladder rinse solution weekly for 1 month, then fortnightly for 1 month and then monthly for 2 months. The total treatment course is 4 months with 8 bladder rinse treatments. If you live far away from the hospital we can teach you how to administer the bladder rinse yourself or have your GP or the local clinic practice nurse do this for you.
2. If you develop a UTI during the treatment period, antibiotics can be used as needed.
3. Questionnaries about your urinary symptoms and your satisfaction with the of the bladder rinse treatment are to be completed at the start of treatment, the end of treatment and at 3 months following this.
4. We will test your urine for infection throughout the study on a regular basis.

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

The possible benefits of treatment are a reduction or cure in your recurrent urinary tract infections. This would lead to improved bladder health and a decreased need for antibiotic therapy.

The results of this research will help to better care for all women in your situation with recurrent urinary infections. We may also be able to reduce antibiotic resistance if this treatment proves to be successful.

There is no reimbursement or pay for your participation in this research study. We can assist with the cost of hospital parking when you attend for your treatments or follow up.

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

There is minimal risk to patients involved in this study.

* Slight discomfort may be experienced with the instillation of the bladder rinse.
* There is a low risk of introducing a urine infection at the time of bladder rinse treatment.
* There may be some blood in your urine following the treatment.

There are no other known side effects from this treatment.

**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 any time.

Your decision whether to enrol or not, or to later withdraw from the study, will not affect your relationship with the researchers or the Mercy Hospital for Women. It will not alter any decision to continue with any further treatment or surgery you may require.

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

A plain language summary will be provided to participants at the end of the project. We anticipate that the results will be available within two years of commencement of the project.

**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 this research project. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to publish the data in a reputable scientific journal**.** In any publication or presentation, information will be de identified.

All information collected will be stored in a secure, locked office in the Urogynaecology Department at the Mercy Hospital for Women. All information stored on computer will be password protected, accessible only by the researchers.

In accordance with the NHMRC National Statement, the Research Ethics Committee is required to conduct audits of research projects from time to time. It may therefore be possible that the Research Ethics Committee which has approved this research, will seek to view a copy of your signed consent form, or to contact you, to ensure that the research is being conducted according to the ethical standards required by the National Statement.

**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.

In accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years after which it will be destroyed.

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

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the Mercy Hospital for Women.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (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?**

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the principal researcher;

Name: Dr Frida Carswell

Role: Principal Researcher

phone: 03 8458 4890 (Urogynaecology Office)

email: fcarswell@mercy.com.au

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Human Research Ethics Committee, Mercy Health

Telephone: 03 8458 4808

Email: ethics@mercy.com.au

**Consent Form**

**Version Dated 30/04/20
Site: Mercy Hospital for Women**

Full project title:

**Microdox versus normal saline bladder rinse for chronic UTI.**

I have read, or have had this document read to me in a language that I understand, and I understand the purposes, procedures and risks of this research project as described within it*.*

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project, as described.

I understand that I will be given a signed copy of this document to keep.

I consent to the Mercy Health Human Research Ethics Committee which approved this study to access my information, or to contact me to ask about my research experience, in order to ensure that the project is being run in accordance with government standards.

Participant’s name (printed) ……………………………………………………

Signature Date

Declaration by researcher\*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher’s name (printed) ……………………………………………………

Signature Date

Witness’s name (printed)………………………………………………………….

Signature Date

*Note: All parties signing the consent section must date their own signature.*

**Revocation of Consent Form**

**Version Dated 30/04/2020
Site: Mercy Hospital for Women**

Full Project Title:

**Microdox versus normal saline bladder rinse for chronic UTI.**

I hereby wish to WITHDRAW my consent to participate in the research proposal named above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with Mercy Hospital for Women

Participant’s Name (printed) …………………………………………………….

Signature Date