***Participant Information and Consent Form***

*The Townsville Hospital*

**Full Project Title: *A Prospective Randomized Trial Comparing the Bard Inlay Optima Stent with the Cook Universa Soft Ureteral Stents Using The Validated Ureteric Stent Symptom Questionnaire***

**Principal Investigator: *Doctor Alexander Ngoo***

This Participant Information and Consent Form is **9** pages long. Please make sure you have all the pages.

**Part 1 What does my participation involve?**

1. Introduction

You are invited to participate in this research project because:

1. You are undergoing a procedure to have a ureteral stent inserted
2. Your doctor believes you would benefit from the insertion of a ureteral stent

The research project is testing the types two types of stents – the Bard Inlay Optima and the Cook Universa Soft Ureteral Stent. Both stents are approved prosthetics by Queensland Health and are considered standard treatments for the condition you have.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read the following information carefully. Feel free to ask questions about any information in the document. Once you understand what the project is about and if you agree to take part in it, 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 have the tests and treatments that are described;

• consent to the use of your personal and health information as described

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

1. **What is the purpose of this research?**

Ureteral Stenting is a common procedure for urology patients. Ureteral stenting involves the insertion of a thin tube (a stent) into your kidney’s ureters to prevent or treat an obstruction of urine flow from the kidney. Currently there are many different brands and designs of stents available to urologists to be inserted however there ultimately is quite limited evidence to suggest any particular stent brand or design is superior to others in terms of post-operative discomfort or other symptoms. This study is aimed at trying to determine if there is any difference in post-operative discomfort for patients between the Bard Inlay Optima and Cook Universa Soft Ureteral stents. Medications, drugs and devices must be approved for use by the Australian Federal Government. Both stents listed above are approved prosthetics to treat kidney stones before or after lithotripsy (stone destruction). Neither have any evidence to suggest superiority to one another.

If this study demonstrates that one stent design appears better in terms of post-operative discomfort than others, there will be significant benefits to the community. First, it will allow for urologists to select better stents for future patients requiring ureteral stenting procedures such as the one you are about to undergo. Second, these findings may help guide future stent designs and ensure that future urology patients have less post-operative stent discomfort.

This research has been initiated by study doctor, Doctor Alexander Ngoo and being conducted under the guidance of Doctor Phillipe Wolanski, consultant urologist of the Townsville Hospital.

Therefore, this project aims to address the following questions:

1. How do the Cook Universa Soft and Bard Inlay Optima Stent compare to one another in relation to post-operative stent related symptoms at 1 and 3 weeks post insertion?
2. To what extent to post-operative stent symptoms, as defined by a validated questionnaire known as the Ureteral Stent Symptom Questionnaire (USSQ) correlate with bladder irritation symptoms as defined by the International Prostate Symptom Score (IPSS).
3. **What does participation in this research project involve?**

You have been selected as you are a patient who is over 18 years of age and having a ureteral stent placed in unilaterally (on one side of their body).

If you choose to consent, you be participating in a randomised controlled double blinded research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). The study is also double-blinded. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving

Therefore, if you choose to consent, you will first be randomized to have either a Bard Inlay Optima or a Cook Universa Soft Stent inserted for your condition. As mentioned above, neither you nor the primary investigator will be aware of whether a Bard Inlay Optima or Cook Universa Soft. This is designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Following this, you will be called at 1 week and 3 weeks post-op by an investigator associated with the study. The investigator will talk through the Ureteral Stent Symptoms Questionnaire (USSQ) and International Prostate Symptoms Score Questionnaire (IPSS) with you and record your answers. This should take approximately 30 minutes each time. A copy of the relevant questionnaires are attached to the back of this patient consent form for your viewing. Moreover, we would ask that you hold onto this consent form post-operatively as the attached questionnaires will help both you and the investigator talk through the relevant questions with greater ease.

We would make clear that post-operatively you will then be managed as you would have had you not participated in the study. You will be provided with all normal medications, review by medical staff and follow up as appropriate. Your care will in no way be affected whether you participate in this study or not.

There are no additional costs associated with participating in this research project, nor will you be paid. You will however have to pay for some medicines according to hospital policy.

1. **What do I have to do?**

The only thing you will need to do to participate in this study is to give up approximately 1 hour of your time in total to receive two 30-minute phone calls from the study investigators at 1 week and 3 weeks post operatively. As mentioned above, your post-operative management and course will not be changed in any way. You will still be allowed and encouraged to take your regular medications as per normal, you may still donate blood. You will not have any additional lifestyle or dietary restrictions separate from the procedure and advice of your treating medical team as per normal.

1. **Other relevant information about the research project.**

The planned sample size is 140 patients who will be recruited through the Townsville and Toowoomba Hospital Urology Department. These hospitals are the only sites where this research is being conducted.

1. **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 stage. However, we would note that any data collected will be retained for completeness and in compliance with law. .

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not in any way affect your routine treatment, your relationship with those treating you and/or with the *Townsville or Toowoomba Hospital.*

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

1. **What are alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these including not participating in this study. If you do not, you will go ahead with your previously discussed management with your treating doctor in which you will have a stent inserted as per the choice of the surgeon operating on you. This is opposed to the process stated above where you would instead be randomized to a stent group. In essence, management of your health would not be different whether you participated in this study or not.

Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

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

There will be no clear benefit to you from your participation in this research. However, there are possible future benefits to the wider community. If there is evidence that one stent design is superior to another, there are clear benefits. First, it will allow for urologists to select better stents for future patients requiring ureteral stenting procedures such as the one you are about to undergo. Second, these findings may help guide future stent designs and ensure that future urology patients have less post-operative stent discomfort.

1. **What are the possible risks and disadvantages for taking part?**

You are being asked to participate in this study because you are already receiving a stent as part of your normal care. As mentioned above, all stents being used in this study are already approved for use by the Australian government and are used in the *Townsville or Toowoomba Hospital* currently for ureteral stenting. Neither stent carries evidence that one is better than the other in terms of post-operative discomfort. Also, as stated earlier, your clinical care will not be affected in any way by your participation in this study. You will receive the same medical management and follow up as you would have had you never participated in this study.

Therefore, by participating in this study you are not taking on any additional medical risk, discomfort or side effects that you have not already been made aware of for the procedure itself by your treating doctor.

There are two main disadvantages for taking part. First, you will be called at 1 week and 3 weeks post operatively for approximately 30 minutes at a time to answer the questionnaires. This is personal time that you will have to provide. Secondly, there is a risk, small though it may be, of a breach of privacy if some of your questionnaire data was inadvertently reidentified to you. However, all steps will be taken to preserve your privacy by ensuring that all data taken will be against your assigned study ID number as opposed to any identifying details. Moreover, all information will be stored on secured and password protected computers and files within the *Queensland Health* computer system.

The information taken from the phone questionnaires will be stored on Queensland Health computers in a de-identified form. Your data will be assigned your study number to allow them to be re-identified and matched later against which stent you had inserted. Assigning your data a study number will ensure that your privacy is best maintained.

If you become upset or distressed because of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

1. **What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

1. **What if I withdraw from this research project?**

If you decide to withdraw, please notify a member of the research team via the contact details at the end of this form. The decision will not affect your routine treatment, your relationship with those treating you or your relationship with the site.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results.

1. **Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• Unacceptable side effects

• The drug/treatment/device being shown not to be effective

• The drug/treatment/device being shown to work and not need further testing

• Decisions made by local regulatory/health authorities

1. **What happens when this research project ends?**

The results of the project are intended to be published in scientific and medical journals. In any publication, information will be provided in such a way that participants cannot be identified. A copy of the eventual publication will be provided on request to the participant if desired.

**Part 2 How is the Research Being Conducted?**

1. **What will happen to the information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Any questionnaire information you answer will be stored in a de-identified form. However, these forms will be kept in a way that ensures they can be re-identified to match your questionnaire answers against the stent type that was inserted in you. All personal information obtained throughout the study will only be accessible in its re-identifiable form by the principal and associated investigators. All data will be stored at Queensland Health Hospitals in either electronic or paper format. Records will be stored de-identified with no identifiable information will be used in publication of the results. Following the 15 year period required by the National Health and Medical Research Council (NHMRC) for retention of research data, all information will be deleted and permanently destroyed.

Your information will only be used for this research project and it will only be disclosed with your permission, except as required by law. Information about you may be obtained from your health records held at this and other health services for this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project

Your health records and any information obtained during the research project are subject to inspection (for verifying the procedures and the data) by the relevant authorities, the institutions relevant to this Participant Information Sheet, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above

In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information

1. **Complaints and Compensation**

As this study is not involving any additional medical risk beyond the procedure you were going to undergo, it is important to recognize that any resultant side effects, complications and issues with your medical care that may occur are separate and not a consequence of consenting to this study. Therefore, in this regard, any complaints or requests for compensation are processed and compensated for through the systems already place at Queensland Health.

However, if you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate compensation and or medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

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

This research project is being conducted by Dr Alexander Ngoo of the Townsville Hospital.

Bard or Cook may benefit financially from this research project if, for example, if the project demonstrates that one stent is superior to the other, it may assist Bard or Cook in marketing and obtaining tenders for their stent.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

1. **Who has reviewed this medical project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *The Townsville Hospital.*

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.

1. Further information and who to contact

Should you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, you may contact:

**Position:** HREC Coordinator

**Telephone:** (07) 4433 1440

**Address:** The Townsville Hospital

IMB 52, PO Box 670
Townsville QLD 4810

**Name:** Doctor Michael Kwok

**Position:** Toowoomba Hospital Stent Study Coordinator

**Telephone:** 4616 6000

**Address:** The Toowoomba Hospital

 154 Pechey Street

 Toowoomba QLD 4350

**Name:** Doctor Alexander Ngoo

**Position:** Principal Investigator

**Telephone:** 4433 1111

**Address:** The Townsville Hospital

 100 Angus Smith Drive

 Townsville QLD 4814

**Email:** AlexanderGa-Onn.Ngoo@health.qld.gov.au



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***Participant Information and Consent Form***

*The Toowoomba Hospital*

**Full Project Title: *A Prospective Randomized Trial Comparing the Bard Inlay Optima Stent with the Cook Universa Soft Ureteral Stents Using The Validated Ureteric Stent Symptom Questionnaire***

**Principal Investigator: *Doctor Alexander Ngoo***

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *Toowoomba Hospital* concerning my diagnosis, inpatient hospital management for the purpose of this project. I understand that such information will remain confidential.

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 hereby consent to the following;

|  |  |
| --- | --- |
| * + To be randomized to have either a Bard Inlay Optima or Cook Ultrathane Stent inserted for treatment of my current medical condition
 |  |
| * + To be called at 1 week and 3 weeks post-operatively to complete the Ureteral Stent Symptoms Questionnaire and International Prostate Symptoms Score Questionnaire
 |  |
| * + Storage of all data on Queensland Health computer systemsfor study analysis and use
* . To be contacted again should further questions or similar projects in which I may be interested to participate arise
 | Yes [ ]  No [ ]  |
|  |  |

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:

*Note:* All parties signing the Consent Form must date their own signature.



***Revocation of Consent Form***

*The Toowoomba Hospital*

**Full Project Title: *A Prospective Randomized Trial Comparing the Bard Inlay Optima Stent with the Cook Universa Soft Ureteral Stents Using The Validated Ureteric Stent Symptom Questionnaire***

**Principal Investigator: *Doctor Alexander Ngoo***

I hereby wish to WITHDRAW my consent to participate in the research proposal named above and understand that such withdrawal WILL NOT jeopardize any treatment or my relationship with *The Toowoomba Hospital*

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

Signature Date

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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