PARTICIPANT INFORMATION SHEET

Differentiating Renal Oncocytoma from Renal Cell Carcinoma Using Sestamibi Imaging

[DRORCCSI Trial]

Dear Potential Participant

You are invited to participate in a research study into specialised imaging for diagnosis of undiagnosed kidney masses.

The study is being conducted by Envision Medical Imaging and Uropath

1. Ronald Cohen – Uropath Director and Research Supervisor
2. Ronny Low – Envision Radiologist
3. Thomas England – Principle Investigator
4. Jian Li – Statistical Analytics

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of this study?

The purpose is to investigate the possible role of specialised imaging called Sestamibi SPEC/CT in the diagnosis of renal masses. If proven to be effective this imaging technique could be more frequently used in the standard investigation of renal masses awaiting diagnosis. In doing so the number of invasive renal biopsies may decline.

Why have I been invited to participate in this study?

You are eligible to participate in this study if you are an adult with a renal mass and are scheduled to undergo a biopsy of your kidney, arranged by urologist, in the near future.

What does this study involve?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form amended to the end of this document.

Participation in this study is entirely voluntarily and will require approximately 2.5 hours of your time (not including travel). There is no cost to participants as the cost of the imaging will be covered by the research team.

Before coming to the imaging center, you will need to fast for 4 hours (i.e. you must NOT eat or drink, except water, for 4 hours prior to the imaging).

After arriving, you will be required to fill out a small questionnaire and answer some questions regarding your medical history and your current health status.

Following this, a nuclear medicine technologist will insert a small needle into your arm to inject the contrast material. You will need to wait for approximately 1 hour for the material to reach your kidneys. After this time has passed you will lie down, underneath a camera, for about 45 minutes.

Once complete, you will be free to drive home. It is recommended that you avoid coming into close proximity with pregnant women and small children.

How is this study being paid for?

The study is being funded by the Western Australian Urological Research Organisation (WAURO).

Will I benefit from the study?

Whilst participating in this study may not directly benefit you, your Urologist will have access to the results of the imaging and may use the findings as they see appropriate. This study aims to further medical knowledge and may improve future management of individuals with incidentally found renal masses.

What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect your relationship with any participating organisation. You may wish to withdraw even after you have provided consent.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

Please refer to the final page of this document for withdrawal details.

Are there risks to me in taking part in this study?

Following the scan, you will feel fine, there are no expected residual after effects. You will be able to drive home.

You may experience a metallic taste in your mouth (lasting no lo her than a few minutes) when the radioactive material is injected.

Rarely, you may have feelings of tingling, flushing, nausea, headache, or rash/swelling at the injection site. Whilst these outcomes are unlikely, we would like you to make yourself known to the health staff at the imaging center so we can take any necessary precautions.

Tell your doctor or a nurse immediately if you notice any of the following; chest pain, swelling in the face or throat, difficulty breathing, changes to your heart rate, vomiting, fever, feelings of light-headedness.

Do not be alarmed by the list of side effects, you may not experience any of them.

Exposure to radiation, albeit a relatively small amount, is not without risk. In this study you will be exposed to a small amount of radiation called "ionizing radiation" Studies have shown that receiving a lot of radiation at one time or getting many small doses over time may cause cancer, however, the risk of getting cancer from this study is very small.

Please let us know if you have been exposed to any radiation through your work or participation in other research projects.

What happens with the results and how will my confidentiality be secured?

With your permission, outlined in the consent form amended, the specialised imaging will be interpreted by a single radiographer. Following the results of your upcoming renal biopsy, the interpretation of these images will be compared to the findings of your kidney tissue sample.

All your imaging and biopsy results will be de-identified, such that the individual radiographer who will interpret the imaging and the researcher comparing the tissue sample diagnosis with the scanning report will be unaware of your identity. Your images and biopsy results will be tagged with a number e.g. participant 164 rather than any information that could lead to your identification.

With all the information gathered from participants such as yourself we plan to publish the results in either an international or national urological/imaging journal and present the findings at urological conferences. You will not be able to be identified.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

What should I do if I want to discuss this study further?

When you have read this information, the researcher, Thomas England, will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him via

Mobile – 0425883022

Email – tbjengland@gmail.com

Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the St John of God Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the St John of God Hospital via (08) 9382 6111

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.

PARTICIPANT CONSENT FORM

Differentiating Renal Oncocytoma from Renal Cell Carcinoma Using Sestamibi Imaging

[Using Specialised Imaging to Differentiate Common Renal Masses]

1. I, ...

   agree to participate in the study described in the participant information statement set out above ***(or: attached to this form).***

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship with the ***Envision Medical Imaging Centre and Uropath Urological Pathology Specialists.***

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact the Principal Investigator, Thomas England via mobile or email.

7. I give permission for the research team to obtain the results of my upcoming renal biopsy

8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Please turn over to complete consent…

Signature of Participant	Name (Printed)	Date

Signature of Witness	Name (Printed)	Date

Signature of Investigator	Name (Printed)	Date

PARTICIPANT REVOCATION OF CONSENT FORM

Differentiating Renal Oncocytoma from Renal Cell Carcinoma Using Sestamibi Imaging

[Using Specialised Imaging to Differentiate Common Renal Masses]

REVOCATION OF CONSENT

I hereby wish to WITHDRAW my consent to participate in the study described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the Envision Medical Imaging Centre and Uropath Urological Pathology Specialists

Signature of Participant	**Name (Printed)**	**Date**
_____	_____	_____

The section for Revocation of Consent should be forwarded to Thomas England

Email – tbjengland@gmail.com