**Participant Information Sheet/Consent Form**

**Interventional Study**

Department of Medical Imaging, Royal Hobart Hospital, 40 Liverpool St, Hobart, Tasmania 7000.

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| **Title** | In adults referred for positron emission tomography/computed tomography (PET/CT) does the addition of a 20 second breath hold PET/CT improve the characterization of suspected liver metastases: a prospective pilot study. |
| **Short Title** | Can a breath hold PET/CT improve the detection and assessment of metastatic liver lesions? |
| **Protocol Number** | RHHNM2024\_01 |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr T Bose, Dr D Brauchli |
| **Associate Investigator(s)** | Dr O Pointon |
| **Location** | Department of Medical Imaging, Royal Hobart Hospital |

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

**1 Introduction**

You are invited to take part in this research project. This is because you have been referred for a whole-body PET/CT scan*.* The research project is testing a new way to find tumour spread (metastases) to the liver.

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 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 doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

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 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.

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

This study is trying to work out if we can find small tumours that have spread to the liver. Because these tumours are small, and the liver moves with each breath they are not always easily seen. By holding your breath for twenty seconds, we think we will be able to see these small tumours in better detail. Some studies have shown that a breath hold for 2 minutes, and up to 30 seconds can produce helpful images.

This study is important as even small tumours that have spread to the liver from another part of the body change the way you are treated.

The scanner used to generate images of your body for this research is the PET/CT scanner you will undergo your normal PET/CT today. The machine is approved in Australia and across the world for finding and staging cancer. No experimental device or medication is being used.

The results of this research will be used by the study doctor Dr Tony Boseas a required part of Radiology specialty medical training by the Royal Australian and New Zealand College of Radiologists (RANZCR).

This research has been initiated by the study doctor, Dr Damien Brauchli.

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

If you agree to participate in this research, you will be asked to sign this consent form. You will be given a copy to keep. The signed consent forms will be scanned and stored securely electronically.

There are some eligibility requirements for participation. These include being over 50 years of age, not actively pregnant or breastfeeding, able to give consent, and able to breath-hold for 20 seconds. You will be asked to demonstrate holding your breath for 20 seconds before you sign the consent form.

This research is being conducted as a crossover study. This means you will undergo the control test, the whole body PET/CT, and then the intervention, which is the additional breath hold PET/CT. All participants will undergo both the control and intervention in the same order.

After your scan, a radiology nurse will assess you and measure your vital signs. You can eat if you would like.

There is no blinding, which means everyone in the study is aware of each step.

Your involvement in this study is designed to be as minimal as possible. You be asked at the end of your PET/CT to take several deep breaths and then a single deep breath and to hold your breath for 20 seconds. A CT scan over your liver will be performed. You will be told to breath again, and 30 seconds later you will be asked to hold your breath for another 20 seconds. During this breath hold, the PET scan will be performed.

This concludes your involvement in the study. There is no follow up.

The research project will take approximately 12 months from start to finish; we will be enrolling participants for approximately 6 months.

Bias

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Additional costs

There are no costs associated with participating in this research project, nor will you be paid. All tests and medical care required as part of the research project will be provided to you free of charge.

**4 What do I have to do?**

Your involvement in this study is only while you are having your PET scan. The additional CT and PET scan will take approximately 2 – 3 minutes. There are no instructions for you in participating in this research after the PET/CT scan you will have today.

There are no lifestyle or dietary restrictions. Do not change your regular medications.

**5 Other relevant information about the research project**

A total of 26 people will participate in this study. This is the only site where this research is being conducted, and this project is standalone and not part of a larger project or group of projects.

**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 stage.

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 affect your routine treatment, your relationship with those treating you or your relationship with the hospital or your treating doctors. Regardless of your participation, you will continue to receive the best medical care.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Participation is entirely voluntary.

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

We cannot guarantee or promise that you will receive any benefits from this research. If we can prove that small liver tumours near the top of the liver can be seen during a breath hold, this may help patients in the future.

There will be no clear benefit to you from your participation in this research.

**9 What are the possible risks and disadvantages of taking part?**

This research involves the use of radiation (X-rays). The purpose of the X-rays is to provide anatomic detail about your liver, so the PET scan can be overlapped and give very accurate results. There is no way to avoid this dose of radiation, though we routinely make sure the dose is as low as possible.

The dose of radiation involved is very small. It is approximately 10% of the CT dose you would normally receive for a PET/CT scan. It is also equivalent to the amount of background radiation we all receive in 1 year from the environment around us. This amount of radiation is so low that no adverse effect has ever been demonstrated.

There are theoretical detrimental effects of X-ray radiationon the unborn child and on the newborn baby. For this reason, it is important that that research project participants are not pregnant or breast-feeding. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

Psychologic distress

If you become upset or distressed as a result 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.

Data collection

This research project involves the collection of information about your PET scan. This information will be stored in a re-identifiable (or coded) format. Any published data will not be identifiable.

Radiation

This research project involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this research project is about 2mSv. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. This risk is believed to be very low.

**10 What will happen to my test samples?**

We will not be collecting any fluid, tissue or blood samples from your in this research.

**11 What if new information arises during this research project?**

Sometimes during a research project, new information becomes available about the test 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.

**12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you will be able to take all of the medications or treatments you have been taking for your condition or for other reasons.

**13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any special requirements linked to withdrawing.

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 up to the time you withdraw will form part of the research project results.

If you do not want them to do this, you must tell them before you join the research project.

**14 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 test being shown not to be effective

• The test being shown to work and not need further testing

It is extremely unlikely the research project will be stopped unexpectedly.

**15 What happens when the research project ends?**

Your involvement in this research is solely today, the day of your PET/CT scan. We will not contact you for any follow up. You may provide an email address and we can notify when the results of this research have been published. This is voluntary.

**Part 2 How is the research project being conducted?**

**16 What will happen to 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.

You will be assigned a study number at the start, this will be on the form we use to collect the data about your PET/CT scans. The data that links your name and your study number will be kept secure and confidential. Only the three study doctors will have access to it.

Your information will only be used for the purpose of 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 the purpose of 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 the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the institution relevant to this Participant Information Sheet, Royal Hobart Hospital, 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.

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. All published data is collated and anonymized. Occasionally scan images are also published, if this is the case we will make sure they are non-identifiable and do not contain any unique features that could be used to identify a single person.

In accordance with relevant Australian and Tasmanian 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.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**17 Complaints and compensation**

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 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.

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

This research project is being conducted by Dr Tony Bose. There is no private or institutional sponsorship. There is no intended or perceived financial gain from this research.

The study doctors have no financial disclosures.

**19 Who has reviewed the research 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 University of Tasmania.

This trial is also registered with the Australia and New Zealand Clinical Trials Registry (ANZCTR).

The study has been reviewed and approved by the Department of Health and Human Services Tasmania Research Governance Office.

The study has been reviewed and approved by the Royal Australian and New Zealand College of Radiologists (RANZCR).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 6166 8308or any of the following people:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr Tony Bose |
| Position | Radiology registrar |
| Telephone | 61668308 |
| Email | tony.bose@ths.tas.gov.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Dr Tony Bose |
| Position | Radiology registrar |
| Telephone | 61668308 |
| Email | Tony.bose@ths.tas.gov.au  |

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:

|  |  |
| --- | --- |
| Reviewing HREC name | UTAS HREC |
| HREC Executive Officer |  |
| Telephone | [ HREC Executive Officer Phone number] |
| Email | [ HREC Executive Officer Email address] |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email | research.governance@health.tas.gov.au |

**Consent Form -** *Adult providing own consent*

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| **Title** | In adults referred for positron emission tomography/computed tomography (PET/CT) does the addition of a 20 second breath hold PET/CT improve the characterization of suspected liver metastases: a prospective pilot study. |
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| **Associate Investigator(s)** | Dr O Pointon |
| **Location** | Department of Medical Imaging, Royal Hobart Hospital |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Royal Hobart Hospital concerning my disease and treatment for the purposes 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 and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

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| --- |
|  |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior 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.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

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

**Form for Withdrawal of Participation**

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| --- | --- |
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| **Associate Investigator(s)** | Dr O Pointon |
| **Location** | Department of Medical Imaging, Royal Hobart Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Royal Hobart Hospital.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

Description of circumstances:

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**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.

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|  |
|  | 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.