Participant Information Sheet/Consent Form

*Adult providing own consent.*

|  |  |
| --- | --- |
| **Title** | Applicability of Positron Emission Tomography using Gallium-68 labelled Fibroblast Activating Protein Inhibitor for the diagnosis, staging and treatment of pancreatic cancer. |
| **Short Title** | A pilot study to evaluate the use of FAPI-PET in pancreatic cancer. |
| **HREC Number** | HREC/2021/QRBW/75096 |
| **Protocol Number** | Version 4 |
| **Coordinating Principal Investigator/** | A/Prof Paul Thomas, Department of Nuclear Medicine, Royal Brisbane and Women’s Hospital  |
| **Location** | Royal Brisbane and Women’s Hospital and Princess Alexandra Hospital |

# Part 1 What does my participation involve?

1. **Introduction**

Positron emission tomography (PET) is a type of scan that is performed after injecting a tracer into the blood stream. Tracers are a special class of molecule that are absorbed by certain types of tissue, and whose location in the body can be tracked with PET scan. PET tracers that are absorbed by cancerous tissue help to determine where cancer may be growing.

Fibroblast activating protein inhibitor (FAPI) is a new PET tracer that accumulates in the abnormal tissue that surrounds cancer. Because there is no absorption by healthy tissue, FAPI-PET tracers may be more effective than existing PET tracers in detecting small deposits of pancreatic cancer.

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

This study will be the first of its kind to perform FAPI-PET for a group of patients with pancreatic cancer or a suspicious pancreatic mass. We will determine its ability to detect small deposits of pancreatic cancer, and its ability to distinguish non-cancerous lumps from cancer tissue. We believe FAPI-PET will be better than existing methods at diagnosing and determining the extent of pancreatic cancer.

It has recently become possible to treat certain cancers by using special variations of PET tracers that deliver a strong dose of radiation directly to the cancer cells. This emerging area of medicine is called “theranostics” (therapy + diagnostics). This study will not utilise FAPI-PET tracers that are designed for this purpose, however we will use the information collected to guide later studies which do. We hope this will pave the way for new treatments that are more effective and have fewer side effects than those currently available.

1. **What does participation in this research involve?**

You will attend the Herston Imaging Research Facility (HIRF) on the RBWH campus to undergo FAPI-PET scan with a low dose computed tomography (CT) scan. The procedure requires insertion of an intravenous (IV) line for injection of the tracer.

You will have three separate PET/CT scans on the same day following just one injection of the FAPI PET tracer:

1. 10 minutes following injection of tracer: Scan over pancreas only (about 15 minutes lying on the scanner bed).
2. 60 minutes following injection of tracer: Scan of head to upper thighs. (about 30 minutes lying on the scanner bed).
3. 180 minutes following injection of tracer: Scan over pancreas only. (about 15 minutes lying on the scanner bed).

The time commitment for taking part in this study is 4 hours.

FAPI-PET scan will take place within 14 days of enrolment in the study, and preferably within 7 days.

If you doctor is investigating a lump in your pancreas to determine what it is, the PET scan will occur before a biopsy is performed.

The results of the research PET scan will only be relayed to your doctor if it is possible that there could be a change to your treatment as a result. In this instance your doctor (a surgeon or oncologist) will discuss the results of the scan directly with you.

You will be followed up as usual by your treating doctors according to usual protocols. The researchers will collect information obtained by your specialists at your follow up visits to compare with the results of the PET scan.

If you undergo surgery or biopsy as part of the management for your pancreatic lump, the pathologist at your treating hospital will perform all the testing that is usually performed to guide your treatment. After this has finished, they will send a maximum of 5 very thin sections of your diagnostic tissue to the Translational Research Institute (TRI) in Brisbane. This will not interfere with your treating team’s ability to diagnose and/or treat your condition. These sections will then undergo further analysis to provide more information about how FAPI-PET can aid diagnosis and treatment of pancreatic cancer. These sections from your tissue sample may also be used in future research to determine if FAPI or certain other PET tracers can be used to diagnose or treat pancreatic cancer. Results of this additional testing will only be relayed to you if it is relevant to your medical care.

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

Upon agreeing to take part in the study your details will be passed on to scheduling staff at HIRF. An appointment will be made for you to undergo the FAPI PET scan within two weeks of you agreeing to participate in this study. You will be required to attend HIRF on the specified date and time. You do not need to fast prior to the PET scan. The scan will be performed at no cost to you. We will arrange re-imbursement for any costs associated with parking to attend your scanning session.

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 study 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 Royal Brisbane and Women’s or Princess Alexandra Hospitals.

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

The alternative to participation is to continue with your management plan as determined by the clinicians involved in your care.

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

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include:

* Detection of cancer deposits that were not otherwise able to be detected. Knowing the extent of cancer spread will help your treating clinician determine the best treatment for you.
1. **What are the possible risks and disadvantages of taking part?**

Generic risks:

The only additional procedure involved in this research is that of the FAPI-PET scan.

Side effects of the scan which occur commonly include:

* Minor pain, discomfort and bruising due to insertion of an intravenous cannula (IV line).
* Physical discomfort due to lying for extended periods of time (you will have to lie on the scanning bed for up to half an hour at a time).

Adverse reactions from the scan which occur less commonly include:

* Infection from the intravenous cannula site. This may require treatment with antibiotics.
* An allergy to injected tracer. This may require further treatment.

Death because of this procedure has not been reported and is expected to be extremely rare.

Risks associated with radiation exposure:

Undergoing PET scan for this procedure exposes you to a small amount of radiation. The effective dose of radiation from this study is about 12 millisieverts (mSv).

As part of everyday living, everyone is exposed to naturally occurring background radiation. The average Australian receives a dose of 2 mSv of naturally occurring radiation each year. Some other useful examples of radiation exposure include;

• One return flight from Melbourne to London a year produces a dose of 0.11 mSv;

• One computed tomography (CT) scan to the chest produces a dose of 5 mSv;

• The legal annual exposure limit for radiation workers in Australia is 50 mSv.

The dose from this study (12mSv) is comparable to the dose received from many other diagnostic medical x‐rays and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure.

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

In the unlikely event that new information arises relating to harmful effects of FAPI-PET scan during this study, then enrolment will be halted pending re-review of relevant risks and perceived benefit of the study. Irrespective of whether you have already undergone the PET scan, all relevant information in this instance will be relayed to you. We are obliged to take every possible step to reduce harm that may be associated with unanticipated adverse effects from this scan.

1. **Can I have other treatments during this research project?**

All treatments that would usually be given in your specific circumstances will still go ahead.

FAPI-PET scan will occur prior to commencing chemotherapy or radiotherapy, and prior to direct biopsy of the pancreatic tumour if that is to take place. It is important that we arrange for you to undergo the PET scan within a short timeframe to avoid undue delay to commencement of other treatments.

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

You have the right to withdraw from the study at any time. In addition, the investigators may withdraw you from the study at any time if it is considered necessary for any reason.

You can be withdrawn from the study for any of the following reasons:

* You withdraw consent.
* You are not able to comply with the procedures of the study.
* The investigators decide that it is in your best interest to be withdrawn.

If you withdraw from the study you have the right to request that your information in association with the study, be destroyed, and not contribute to the published findings of this study. Similarly, you may request that any tissue samples provided by you and being held for the purpose of the study be destroyed or returned to your treating hospital’s pathology department.

You may indicate your intent to withdraw verbally, in writing or by email. There is a withdrawal of consent form included with this document. To initiate this process, you may contact the study co-ordinator by phone or email:

* Phone: [Hospital Phone Number] and ask to be paged to Dr William McGahan
* Email: William.McGahan@health.qld.gov.au
1. **Could this research project be stopped unexpectedly?**

For a variety of reasons this project may be stopped unexpectedly. You will be notified if this occurs.

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

This study only involves one PET scan. Once this has been completed then you will not be required to partake in any further activities specific to the study. Follow up will continue with your treating clinician as per usual protocols.

# Part 2

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

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

To maintain privacy, data collected by your doctor and hospital staff is only provided to the researchers with a code number and first and last initials. The data will be kept on a file in a computer which is password protected. The computer is secured in a locked facility. Only the researcher/ investigator responsible for data collection will have unlimited access to this information.

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. This information may be obtained from you through your participation in this study, or it may be obtained from your health records held at this and other health services if relevant to the study. 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. Personal details i.e. name, date of birth will not be published. Your information will only be used for the purposes of this research project and it will only be disclosed with your permission, except as required by law.

Information about your participation in this research project may be recorded in your health records.

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.

The data derived from the study will be retained for 15 years according to the regulatory requirement for clinical trial.

Unless specified otherwise by you, the information obtained about you may be used in subsequent studies which test FAPI-PET on a larger scale. If in the future there are trials which test FAPI as a treatment for your cancer, we may use information collected in this study to determine if you are eligible, and may contact you if this is the case.

1. **Complaints and compensation**

Involvement with this study will be at no cost to you. You are entitled to re-imbursement for the following costs which may be incurred by attending for your scanning session:

* Travel costs: To the value of $50
* Food purchase within RBWH campus: To the value of $30 per patient and accompanying person/s.

Parking at Herston Imaging Research Facility is free of charge.

Proof of purchase in the form of receipts and travel tickets are required where applicable.

If due to physical disability you require a carer to attend with you, or travel costs are greater than $50, please make contact with study coordinator and we will endeavour to ensure these occur at no cost to you.

If at any time you feel it necessary to make a complaint relating to your involvement in this study, you are encouraged to do so via the research governance office, the details for which are listed below.

In the unlikely event that you come to harm because of this study you are entitled to seek compensation in accordance with the laws that govern medical liability in Australia.

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

This research project is conducted by the Queensland Pancreatic Cancer Theranostic Collaborative and funded by Metro North Hospital and Health Service. We are actively seeking funding from additional sources so that even more patients may be involved with this study.

You will not benefit financially from your involvement in this research project.

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 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 Royal Brisbane and Women’s Hospital.

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.

1. **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 via main switch (07) 3646 8111 or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | William McGahan |
| Position | Academic Registrar  |
| Telephone | [Hospital number] and ask to be paged |
| Email | William.McGahan@health.qld.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**

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:

|  |  |
| --- | --- |
| Position | Research Governance Officer  |
| Telephone |  |
| Email |  |

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

|  |  |
| --- | --- |
| Reviewing HREC name | Metro North Health HREC A (EC00172) |
| HREC Executive Officer | HREC Coordinator |
| Telephone | (07) 3646 5280 |
| Email | MetroNorthResearch-Ethics@health.qld.gov.au |

**Withdrawal of Consent Form**

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| **Title** Applicability of Positron Emission Tomography using Gallium-68 labelled Fibroblast Activating Protein Inhibitor for the diagnosis, staging and treatment of pancreatic cancer. |
| **Short Title** A pilot study to evaluate the use of FAPI-PET in pancreatic cancer. |
| **Coordinating / Principal Investigator** A/Prof Paul Thomas, Department of Nuclear Medicine, Royal Brisbane and Women’s Hospital * Phone: [Hospital Specific Phone No.] and ask to be paged
* Email: Paul.Thomas@health.qld.gov.au
 |

**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 the Royal Brisbane and Women’s Hospital or Princess Alexandra Hospital.

Data already collected about me may be retained and used for the purposes of this study:

 Yes [ ]

 No [ ]

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

*Reason for withdrawal (optional):*

**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.

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

|  |  |
| --- | --- |
| **Title** | Applicability of Positron Emission Tomography using Gallium-68 labelled Fibroblast Activating Protein Inhibitor for the diagnosis, staging and treatment of pancreatic cancer. |
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| **HREC Number** | HREC/2021/QRBW/75096 |
| **Protocol Number** | Version 4 |
| **Coordinating Principal Investigator/** | A/Prof Paul Thomas, Department of Nuclear Medicine, Royal Brisbane and Women’s Hospital * Phone: [Hospital Specific Phone No.] and ask to be paged
* Email: Paul.Thomas@health.qld.gov.au
 |
| **Location** | Royal Brisbane and Women’s Hospital and Princess Alexandra 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 have had an opportunity to ask questions and I am satisfied with the answers I have received. The nature, purpose and risks of the research project have been explained to me. I understand them and agree to take part.

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 thin sections taken from tissue specimens collected as part of my usual care will undergo additional processing to be analysed for this and future related studies.

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

I understand the statement about reimbursement and costs contained in the Information Sheet. I understand that authorised representatives of the Sponsor, regulatory authorities and ethics committee representatives will be granted direct access to my medical records.

Name of Participant (please print)

Signature Date

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

I have given a verbal explanation of the research project, its procedures and risks, and 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)

 I have provided information over the phone [ ]

 I have provided information in person [ ]

Signature Date

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

**Declaration by Interpreter**

Does the patient speak fluent English?

 Yes [ ]  (declaration by interpreter not required)

 No [ ]  (declaration by interpreter† is required).

I have provided a translation of all written and verbal information provided regarding this study in a language that the patient understands fluently, and I believe that the participant has understood that translation.

Name of Interpreter† (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Interpreter code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_

Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 I have provided translation over the phone [ ]

 I have provided translation in person [ ]

Signature Date

† The interpreter must be appointed by Queensland Health to translate in a language that the patient understands fluently.

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