Participant Information Sheet/Consent Form

Adult providing own consent

Title	The clinical utility of [^{68}Ga]-labelled fibroblast activation protein inhibitor (FAPI) positron emission tomography and computed tomography (PET/CT) in patients with resectable or borderline resectable pancreatic ductal adenocarcinoma (PDAC) undergoing neoadjuvant chemotherapy.
Short Title	Clinical utility of [^{68}Ga] FAPI PET/CT in patients with potentially resectable PDAC.
Principal Investigator	Dr Catherine Berman Medical Oncology Fellow Division of Cancer Services, Princess Alexandra Hospital, QLD
Co-Investigators	A/Prof Victoria Atkinson Dr Thomas O'Rourke Dr Caroline Cooper Dr Stanley Ngai Dr Shannon Leftwich Dr William Mullally
Location	Princess Alexandra Hospital, Woolloongabba, QLD

Part 1: What does my participation involve?

1. Introduction

You are invited to take part in this research project. This is because you have pancreatic cancer, and this project is testing a different scan believed to be more accurate than conventional scans in determining the extent of pancreatic cancer in the body. It will also evaluate how the cancer responds to the chemotherapy.

This Participant Information Sheet/Consent Form tells you about the research project and explains the tests involved. Knowing what is involved will help you decide if you want to take part in the research. Before deciding whether to take part, you might want to talk about it with a relative, friend or your local doctor. Please ask questions about anything that you do not understand or want to know more about.

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

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 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?

Positron emission tomography (PET) is a type of scan that is performed after injecting a tracer into the blood stream. Tracers (a fluid medium injected into a vein through an intravenous line), 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 of the tracer in healthy tissue, FAPI tracers are believed to be more effective than existing tracers in detecting pancreatic cancer.

This study will be evaluating FAPI-PET/CT in a group of patients with pancreatic cancer who have been assessed by their doctors as requiring chemotherapy, before a surgical operation is performed to remove the cancer. We believe that FAPI-PET/CT will be better than existing imaging methods in assessing the response of the cancer to chemotherapy. We need to prove whether it is more effective.

We will evaluate FAPI-PET/CT by comparing it to:
- FDG-PET/CT (FDG is the conventional tracer used in cancer patients)
- Assessing the tumour response to chemotherapy from your pre- and post-op tissue samples.

3. What does participation in this research involve?

Upon agreeing to take part in the study and signing the consent form, your details will be passed on to the Coordinating Principal Investigator. Appointments for FAPI-PET/CT and FDG-PET/CT scans will be made for you based on your availability.

You will undergo both FDG-PET/CT and FAPI-PET/CT at the Princess Alexandra Hospital. The scans will be scheduled on separate days within approximately 7 days of each other. These scans will be performed before starting your standard chemotherapy. The scans will not delay the start date of your treatment. Both scans will be repeated after completion of 4 cycles of chemotherapy.

The procedure requires insertion of an intravenous (IV) line for injection of the tracer. Should you have a central line inserted prior to your scan, this line can be used.

The results of the research PET scan will be relayed to you only at your request and in discussion with your treating doctor. After completing the second set of scans, you will be followed up as usual by your treating doctors at the Princess Alexandra hospital (PAH) according to standard protocols.

To correlate the results of the scan with your response to chemotherapy, we want to stain a tissue sample from your biopsy, and after your surgery, for Fibroblast Activation Protein (FAP). This requires a separate consent from you allowing us to access and test your tissue specimens.

There are no additional 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. You will be reimbursed for any reasonable travel, parking and other expenses associated with the research project visits up to a maximum of $30 per visit.

4. What do I have to do?

On the day of your scheduled FDG-PET/CT, you will be required to fast for >6 hours. Your blood glucose will be checked before the scan to ensure normal blood glucose levels. The scan will occur 60 minutes after IV injection of FDG tracer. The time commitment for this scan will be approximately 2 hours.

On the day of your scheduled FAPI-PET/CT, you will have the scan 60 minutes after IV injection of FAPI tracer. The time commitment for this scan will also be approximately 2 hours. These scans will be repeated as above after completing 4 cycles of chemotherapy.

The histology specimens for FAP staining will be obtained and tested by the Queensland Pathologists at PAH.

5. 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, or to take part and then withdraw will not affect your relationship with the health care professionals treating you or your relationship with the Princess Alexandra Hospital.

6. What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. The alternative to participation is to continue with your management plan as determined by the clinicians involved in your care.

7. What are the possible benefits of taking part?

We cannot guarantee or promise that you personally will receive any benefits from this research.

A possible benefit may include detection of cancer resistant to chemotherapy, that is not otherwise able to be detected using conventional imaging techniques. Knowing the extent of your cancer response will help your treating clinician determine the best treatment for you.

Future benefits from this study may include the development of new therapy options for patients with 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/CT tracers that are designed for this purpose, however we will use the information collected to guide later studies which do use FAPI tracers for this purpose. We hope this will pave the way for new treatments that are more effective and have fewer side effects than those currently available.

8. What are the possible risks and disadvantages of taking part?

Generic risks:

Side effects of PET/CT scans which occur commonly include:
- Minor pain, discomfort and bruising due to insertion of an 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:

This research study involves exposure to a 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 study is about 13mSv. This dose is comparable to that received from many diagnostic medical x-ray and nuclear medicine procedures.

The annual occupational radiation exposure limit is 50 mSv per year, and even at this level, the increased cancer risk is so low that it cannot be measured against the normal incidence of cancer. It is therefore, anticipated that you will be at no increased risk of harmful effects from the PET scans you receive.

9. What will happen to my test samples?

You will be asked to provide additional consent for the assessment and testing of your biopsy and resection tissue samples. The pathologists from Pathology Queensland at PAH will retrieve your samples, perform the FAP testing and document the results. The samples will then be returned to their usual storage place as per laboratory protocols.

10. What if new information arises during this research project?

In the unlikely event that new information arises relating to harmful effects of FAPI-PET/CT scan during this study, then enrolment will be halted pending 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.

11. Can I have other treatments during this research project?

No treatments or medications need to be stopped or changed for the time you are involved in the research project. All treatments that would usually be given in your specific circumstances will remain the same according to standardized treatment protocols.

12. 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.

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.

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 Coordinating Principal Investigator by phone or email.

13. 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.

14. What happens when the research project ends?

This study involves investigational PET scans and review of pre- and post-op tissue samples. Once these have been completed, you will not be required to partake in any further activities specific to the study. Follow up will continue with your treating doctors as per usual protocols.

Part 2: How is the research project being conducted?

15. What will happen to information about me?

To maintain privacy, data collected by your doctor and hospital staff will be provided to the researchers with a code number and your 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 investigators responsible for data collection will have access to this information.

By signing the consent form, you consent to the study investigators 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 Coordinating Principal Investigator 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 trials.

Unless specified otherwise by you, the information obtained about you may be used in future studies which test FAPI-PET/CT on a larger scale. Subsequent studies based off this study will only be undertaken once appropriate ethics and governance approvals have been sought. 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.

16. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the Coordinating Principal Investigator as soon as possible and you will be assisted with arranging appropriate medical treatment.

Involvement with this study will be at no cost to you. You will be reimbursed for any reasonable travel, parking and other expenses associated with the research project visit, up to a maximum of $30 per visit. 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 $30, please make contact with the Coordinating Principal Investigator 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 HREC coordinator, 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.

17. Who is organising and funding the research?

This research project is being conducted by the medical staff at the PAH. An established research cost centre will be utilized to provide support for the conduct of this study. We are also seeking funding from additional sources so that even more patients may be involved with this research.

You will not benefit financially from your involvement in this research project and no member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18. 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 Metro South Health HREC.

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.

19. Further information and who to contact

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

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 you can contact the Coordinating Principal Investigator

Name	Dr Catherine Berman
Position	Medical Oncology Fellow
Telephone	07 3176 2111
Email	Catherine.Berman@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:

Reviewing HREC	Metro South Health Human Research Ethics Committee
HREC Executive Officer	HREC Coordinator
Telephone	07 3443 8049
Email	MSH-Ethics@health.qld.gov.au

Consent Form

Adult providing own consent

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Co-Investigators	A/Prof Victoria Atkinson Dr Thomas O'Rourke Dr Caroline Cooper Dr Stanley Ngai Dr Shannon Leftwich Dr William Mullally
Location	Princess Alexandra Hospital, Woolloongabba, QLD

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 Princess Alexandra Hospital concerning my disease 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.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Investigator

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Investigator (please print) _____

Signature _____ Date _____

Declaration by Participant

By signing this consent section, I agree to the use of tissue samples obtained from my routine biopsy and from possible future surgical resections for the purposes of this research project.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Investigator

I have given a verbal explanation of the procedures regarding use of the patient's tissue samples and I believe that the participant has understood that explanation.

Name of Study Investigator (please print) _____

Signature _____ Date _____

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

Form for Withdrawal of Participation

Adult providing own consent

Title	The clinical utility of [68Ga]-labelled fibroblast activation protein inhibitor (FAPI) positron emission tomography and computed tomography (PET/CT) in patients with resectable or borderline resectable pancreatic ductal adenocarcinoma (PDAC) undergoing neoadjuvant chemotherapy.
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Principal Investigators	A/Prof Victoria Atkinson Dr Thomas O'Rourke Dr Caroline Cooper Dr Stanley Ngai Dr Shannon Leftwich Dr William Mullally
Location	Princess Alexandra Hospital, Woolloongabba, QLD

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 Princess Alexandra Hospital

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Investigator

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 Investigator (please print) _____

Signature _____ Date _____

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

Form for Withdrawal of Tissue Samples

Adult providing own consent

Title	The clinical utility of [68Ga]-labelled fibroblast activation protein inhibitor (FAPI) positron emission tomography and computed tomography (PET/CT) in patients with resectable or borderline resectable pancreatic ductal adenocarcinoma (PDAC) undergoing neoadjuvant chemotherapy.
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Location	Princess Alexandra Hospital, Woolloongabba, QLD

Declaration by Participant

I wish to withdraw my tissue samples from this research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Princess Alexandra Hospital

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Investigator

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

Name of Study Investigator (please print) _____

Signature _____ Date _____

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