

Request Ratification of an approval obtained from an external HREC

Application	ID	2022/HE002545	Version	0.02
UQ is the lead institute in the project	Yes			
UQ is the sponsor for the project	Yes			
The project involves UQ students undertaking research for their degree at another institution	No			
UQ is a site for the research	No			
Application type	Ratification			
Project title	Clinical utility of [68Ga] FAPI PET/CT in patients with potentially resectable PDAC.			

Project summary	<p>This project aims to assess the clinical benefit of FAPI-PET/CT in patients with potentially resectable pancreatic cancer.</p> <p>FAPI-PET/CT will be assessed by comparing it to FDG-PET/CT and to histological assessment of FAP expression in the patients' pre- and post-op tissue samples. The study is a single-centre, prospective study and will be conducted at PAH. It aims to recruit 20 patients. Patients will be booked for both a FAPI-PET/CT and FDG-PET/CT prior to starting chemotherapy and again after completion of chemotherapy. The patient's biopsy specimen pre-chemotherapy and resection specimen post-chemotherapy will be stained for FAP expression. We anticipate the following outcomes: FAPI-PET/CT will be superior to FDG-PET/CT in assessing tumour and its response to chemotherapy. Higher FAP expression in the tumour will result in higher FAPI tracer uptake and is associated with a poorer response to chemotherapy. The change in SUVmax on FAPI-PET/CT following chemotherapy will correlate with response to treatment.</p>
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Ethics committee or equivalent review body	Name	Metro South Human Research Ethics Committee	Type	National
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Approved start and end date	Start date	16/12/2022	End date	31/12/2024
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Research involves	Clinical Trial
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Ethics review type	Human Research Ethics Committee
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Participants	People in dependent or unequal relationships and Aboriginal and Torres Strait Islander peoples
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Chief Investigator, or Supervisor in case of student research

Name	Associate Professor Victoria Georgina Atkinson		
School, Institute or Faculty	Princess Alexandra Hospital Southside Clinical Unit	Staff Id #	0058869
Telephone	+61448632604	Email	v.atkinson@uq.edu.au

Additional researchers/co-investigators, including students and non-UQ investigators

Researcher	Title, given name, and family name	School, Centre, Institution	Email
2	Dr Shannon Rose Leftwich	Frazer Institute	s.joseph@uq.edu.au
3	Associate Professor Fiona Simpson-Fraser	Frazer Institute	f.simpson@uq.edu.au

Additional comments**Attachments**

Document title	Document type	File name	File size (bytes)
89855 Ethical clearance letter.pdf	External Ethics Approval Certificate	89855 Ethical clearance letter.pdf	327233
HREA Form.pdf	Application Attachment	HREA Form.pdf	929320
FAPi Research Protocol_Version 5_CLEAN.pdf	Application Attachment	FAPi Research Protocol_Version 5_CLEAN.pdf	505670
PICF_version1_29.08.2022_CLEAN.pdf	Application Attachment	PICF_version1_29.08.2022_CLEAN.pdf	255444
Radiation Dose Risk Report - 68Ga-FAPi.pdf	Application Attachment	Radiation Dose Risk Report - 68Ga-FAPi.pdf	339319
CV C Berman_ Aug 2022.pdf	Application Attachment	CV C Berman_ Aug 2022.pdf	275043
V Atkinson CV_Aug 2022.doc	Application Attachment	V Atkinson CV_Aug 2022.doc	336384
ICH GCP Certificate.pdf	Application Attachment	ICH GCP Certificate.pdf	119563
Ethics Submission Cover Letter.docx	Application Attachment	Ethics Submission Cover Letter.docx	27178
89855 table responses1_HREC_1612202 2.docx	Application Attachment	89855 table responses1_HREC_1612202 2.docx	14006

Declaration by the Chief Investigator

Conditions of Approval for Ratifications/Registrations

- 🕒 On commencement of this research, the researcher provides an undertaking to notify the Research Ethics and Integrity of all complaints or adverse events that may arise from this research.
- 🕒 Modifications made to this project must be approved by the lead external ethics committee
- 🕒 For projects that meet the criteria for ratification (i.e. UQ as the lead institute, sponsor, UQ students undertaking research at another institute for their degree and/or UQ as a research site):
 - Modifications approved by the external ethics committee must be submitted as an amendment for ratification to UQ via MyResearch.
 - An annual report must be submitted via MyResearch in accordance with the National Statement, and a final report submitted on completion of the study (a copy of the report submitted to the external ethics committee meets this requirement).
- 🕒 For clinical trials the UQ Clinical Trials Procedure must be followed, including registering the trial and undertaking an appropriate risk assessment.

Name	Associate Professor Victoria Georgina Atkinson	Date	12/01/2023
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