Insert Header with institution's name or institution's letterhead

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

[Insert site name]

Title	**Prospective, Multicentre trial evaluating FET-PET in Glioblastoma (FET-PET in Glioblastoma)**
Short Title	**FIG STUDY**
Project Sponsor	TROG Cancer Research
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Location	*[Location]*

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this clinical study. This is because you have recently been diagnosed with Glioblastoma (GBM). This document tells you about the study and describes what will happen if you decide to take part.

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. You may also take this form away with you. Ask questions about anything that you do not 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 GP.

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

If you decide you want to take part in this study, you will be asked to sign the consent form in 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 the tests and research 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?

Glioblastoma (GBM) is the most common primary brain cancer in adults representing over half of all primary malignant (cancerous) brain tumours. Standard treatment for GBM involves surgery followed by combined chemo-radiotherapy and then further post-operative chemotherapy with a tablet called temozolomide.

It is important to understand that the treatment you have and will be receiving is as per usual, i.e. best practice (standard of care). Your treating team will talk with you about what treatment is recommended, the timing of each treatment and the expected side effects. Imaging plays a key role in diagnosis, radiotherapy planning, and monitoring of treatment response inpatients with GBM. The current standard of care imaging is Magnetic Resonance Imaging (MRI) which tells the doctor what the shape and size of the tumour is. A newer form of imaging has been developed using Positron Emission Tomography (PET), where a radiotracer called FET, a chemical compound, is used to detect whether tumour cells are active or not.

It is thought that using FET-PET will help to;

1. More accurately define the tumour and treatment area for radiotherapy planning compared to standard MRI
2. More accurately assess tumour changes versus treatment-related changes which can be hard to interpret with standard MRI scans. This is particularly important in the first 3-4 months after radiotherapy where changes on MRI can be hard to interpret.
3. Help predict the future tumour status and outcome of Glioblastoma after therapy

It is hoped that this new imaging approach, with FET-PET scans, will lead to more accurate assessment, and improve both treatment decisions and outcomes for patients with GBM. Currently FET-PET scans are not part of the routine care for patients diagnosed with GBM.

3. What does participation in this research involve?

To be eligible for this study you must have been recently diagnosed with Glioblastoma (GBM).

If you choose to participate, you will be participating in an interventional single arm study comparing the imaging technique FET-PET to the standard imaging (MRI). Sometimes we do not know which imaging method is best and to find out we need to compare the different imaging methods. The results will be compared to the standard imaging that is MRI to see if one is better.

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

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

If you decide to participate in this research project, the study doctor will inform your GP.

The main steps involved in the study are:

I. **Agreeing to participate in the study (consenting)**
II. **Registration in to the study**
III. **Undergoing the study scans**
IV. **Follow-Up**

You are welcome to bring a family member or friend to all appointments.

I. **Agreeing to participate in the study (consenting):** Your study doctor will talk to you about the study and if you agree to take part, they will ask you to sign the study consent forms. You will be given a copy of these forms to keep. Any trial specific procedures will only take place after you have signed the consent form.

II. **Registration into the study:** After you have given your consent, your study doctor will arrange for some procedures to be conducted. These procedures will include;

Procedure	Details
Clinical assessment	Your study doctor will ask you about your health, any medications you are taking and the symptoms you are experiencing. You will be asked for a blood test to be collected to check the function of your organs, your blood chemistry and your blood cell count. The study team will record your date of birth, postcode, and other relevant details.
Pregnancy test	If you are a woman of childbearing potential, you will be asked to take a urine pregnancy test.
Health and Quality of Life Questionnaire	You will be asked to complete a questionnaire related to any symptoms you may have and their impact on your day-to-day life. This will take approximately 15 minutes to complete.

You will be allocated to join one of the two groups in the study, which is dependent on what stage you are at in your standard treatment at the time of registration;

- **Group 1 participants** will start the study after their initial surgery for GBM and prior to commencing post-operative chemo-radiation treatment (CRT). It is expected that most study participants will be in this group.
- **Group 2 participants** will start the study after chemo-radiation treatment is completed but before they start their monthly cycles of chemotherapy with temozolomide (TMZ) tablets.

Your study doctor will let you know what group you will be in.

III. **Undergoing study scans:**

FET-PET Scans: These scans will be performed in addition to your usual care. You will be required to have 2 or 3 of these scans, depending on when you joined the study (please see please see Figure 1: FIG flow diagram on page 6).

- Group 1 participants will have a FET-PET1 scan prior to the start of chemo-radiation treatment.
- Both Group 1 and then Group 2 participants will have a FET-PET2 scan performed 4 weeks after completion of chemo-radiation treatment (and before the start of ongoing chemotherapy cycles with Temozolomide tablet).
- Both Group 1 and Group 2 participants will have a FET-PET3 scan. This will be done when your MRI scans shows that the tumour might be becoming active. The exact timing of this scan will likely be different for each participant and will be decided by your treating medical team.

You will need to fast for 4 hours prior to having each FET-PET scan and each scan will take approximately 1 hour. The FET dose is 200MBq +/- 10%.

It is important to understand that the results of both the early, initial FET-PET1 scan (before chemo-radiation) and the FET-PET2 scan (4 weeks after chemo-radiation) will not be immediately shared with your treating specialist team, as they are performed as research scans and will be reviewed by a different panel of specialists. Your standard radiotherapy treatment will not be altered as a result of the FET-PET1 scan.

This study aims to work out which is the best way to interpret these early FET-PET scans and so the results will not be used to immediately change your treatment.

In contrast, as the FET-PET3 scan is done at the time that the tumour might be becoming active, based on the MRI scan appearances at the time, the results of the final FET-PET3 scan will indeed be shared with you and your treating specialist team.

MRI Scans: These scans will be performed as at the same time points during your treatment as you would normally be ordered by your treating specialist team for your standard care. Each MRI will take approximately 40-60 minutes and will be performed with intravenous contrast each time. Your study doctor will discuss the results with you after each MRI scan is done.

FDG-PET scan: This study asks that you undergo a standard FDG PET (using the radiochemical FDG) to provide some additional information to help guide your treatment, if there is concern the brain cancer is becoming active based on your MRI scans. Although it is important that this FDG-PET scan is done as part of the study overall, it is not considered mandatory or essential, so your treating medical team will discuss this with you. This scan will take approximately 2 hours, including the time for the FDG tracer injection and scan.

Biomarker research: The researchers conducting this study are interested in looking for biomarkers (biological molecules found in blood and tissue) to see if there are any relationships between the biomarkers, with the way the GBM tumour responds to the various treatments and the FET-PET and MRI scans that you will undergo. Finding biomarkers can help in the development of future treatments or predict how well a patient with GBM may respond to specific treatments.

For all participants enrolled into this study, tissue and blood samples will be required at certain time points.

- Tumour tissue from your initial surgery will be requested from the original specimen which was removed.
    - Your tumour will be analysed to see if it contains changes to a protein, called MGMT, which may indicate response to the Temozolomide chemotherapy. This test may be conducted at your local institution or, if not available, will be conducted at the *Olivia Newton-John Cancer Research Institute (*ONJCRI) in Victoria. Results of this test will be shared with your treating medical team.
    - Your tumour will also be analysed for other changes within the Ribonucleic acid (RNA) and deoxyribonucleic acid (DNA) (mutations) and other proteins. See section 10 for more details.
- Blood sample:
    - Approximately 50mls of blood be taken at the time of study enrolment and also on the day of some FET-PET scans for analysis of research tumour biomarkers. See section 11 on page 8 for more details for more details.

The biomarker research, apart from the MGMT results, is experimental and will not be suitable for guiding decisions about your treatment. Accordingly, we do not plan to make your individual results from these studies available to your treating medical team.

IV. Follow up:

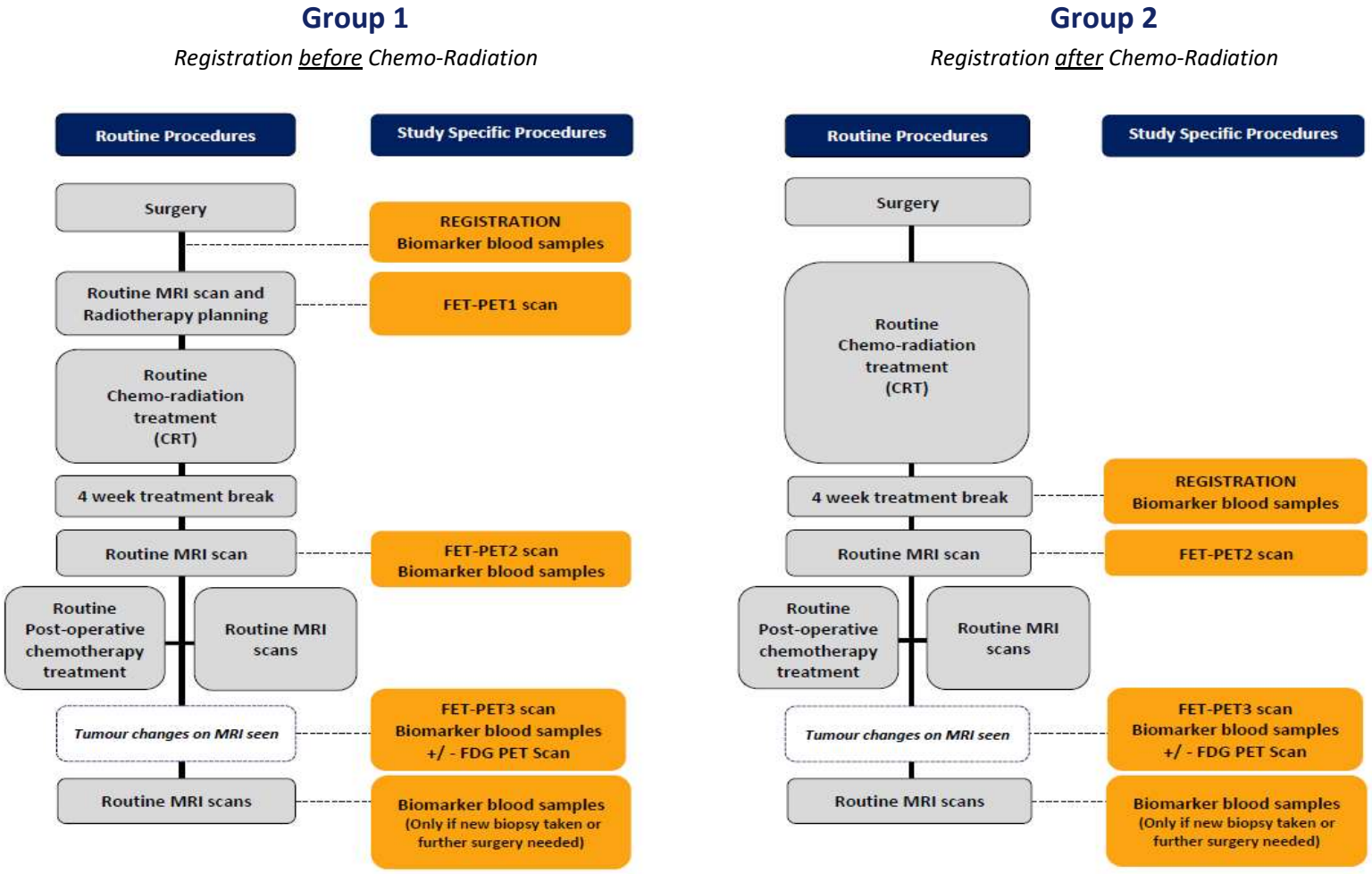
If it is confirmed that your brain cancer has become active again in the future, we would still like to collect information to check on your health status. In the event that you are no longer able to attend clinic appointments, the study team may still collect information about your health via your medical records.

If a further neurosurgical procedure is needed in future, we will request a sample of this tumour tissue and ask you to have another blood sample taken for biomarker analysis at that time if at all possible.

Other assessments:

- **Clinic Assessments:** At 4 weeks, 3 months, 6 months and 12 months after completion of chemo-radiation and at the time that the FET-PET3 scan is done, your study doctor/s will ask you about your health, any medications you are taking and any symptoms you may be experiencing. Your study doctor will also order routine blood tests to check your health. These assessments are part of your standard of care treatment for GBM.
    - **Health and Quality of Life Questionnaire:** During the clinical assessment visits and once in the last week of chemo-radiation (Group 1 participants only) you will be asked to complete a questionnaire related to any symptoms from your brain tumour and their impact on your day to day life. This will take approximately 15 minutes to complete.

Figure 1: FIG flow diagram



4. Medicare and Pharmaceutical data

One of the aims of this study is to look at the resource use and cost effectiveness of FET-PET scans amongst your treatment overall. To do this, at the end of the study, the study doctors would like to assess your data held at the Department of Human Services regarding what medical and pharmaceutical benefits you have accessed 6 months prior to and during your time on the study. This will include such information as health consultations, procedures and tests, the schedule fee for each of these items (e.g. an appointment with your GP or blood tests to monitor your cholesterol level) and the medications you have received.

To allow the study doctors' access to this information, you will be asked to sign an additional consent form when you register into this study and to provide your Medicare number and other details (such as your name and address) needed by the Department of Human Services to make sure the correct information is given to the study doctors. This consent form (or a certified copy) will be sent to the Australian Government Department of Human Services to show that you have consented to the study doctors accessing this information

5. What do I have to do?

If you agree to participate in this study, you agree to be responsible for attending all trial-specific appointments according to our instructions. You also agree to comply with the other conditions in this document. If you cannot, or do not wish to accept this responsibility, then we cannot accept you as a participant in the study. Either way you choose, you will still receive the best possible care whether or not you take part in this study

Your doctor will ask you about procedure or medicines you may be taking. Including any over the counter medications. Please let us know about any changes to these while you are participating in this clinical study.

6. Other relevant information about the research project

This study aims to recruit up to 210 Australian patients with newly diagnosed GBM and will take place among 10 different hospital sites across Australia.

7. Do I have to take part in this research project?

Participation in any research 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 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 then withdraw will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

8. What are the alternatives to participation?

You do not have to take part in this study to receive the standard of care treatment for treatment of your GBM at this hospital. This study offers extra imaging to compare the standard MRI imaging with FET-PETs. Standard of care treatment and standard MRIs will still be undertaken if you do not wish to take part in this study. Your study doctor will discuss these options with you before you decide whether to take part in this study. You can also discuss the options with your local GP.

9. What are the possible benefits of taking part?

This research will not potentially provide you with any personal benefit, but the information we collect may reveal important information that may benefit future patients with GBM.

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

The focus of this study is to understand the benefits of using FET-PET scans in GBM, in addition to routine imaging using MRI scans. To date, no significant side effects have been reported with the use of the FET radiotracer injection (for the FET-PET scans), therefore it is highly unlikely that any significant side effects will occur. The chance of a reaction to the tracer injection is very low. If a possible reaction does occur, this will be managed by a member of the study team. It is unlikely that an 'allergic' reaction would occur after the FET radiotracer injection, and any reaction, even if it does occur, is more likely to be local discomfort at injection site. There may be side effects that the researchers do not expect or do not know about. Please tell your study doctor immediately about any new or unusual symptoms that you may experience, especially in the first two days after the FET radiotracer injection.

This study 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 overall dose from this research project is [insert site mSV] mSv. The dose from this research project is comparable to that received from many diagnostic medical X-rays and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated]

The radiological imaging associated with this study is the same as you would normally receive for your care at this hospital.

Having an imaging tracer injected or blood and tissue sample taken may cause discomfort, bruising, minor infecting or bleeding. If this happens, it can be easily treated.

11. What will happen to my test samples?

At your routine blood tests, about 20 mls (1 tablespoon) of blood will be collect to examine your full blood count and biochemistry. These tests will be used to determine your general health status and to screen for a variety of disorders, such as anaemia and infection, as well as nutritional status. These samples are a part of your routine care for your cancer. All blood samples taken for this purpose will be stored and destroyed in line with the Hospital/Pathology lab's policy.

Blood and tissue collected for biomarker research will be stored at the hospital until they are shipped to the central laboratory located at the Olivia Newton John Cancer Research Institute in Victoria. All samples will be coded with your unique study number before being sent. In addition, some samples may also be sent for analysis at other laboratories in Australia and/or the USA, such as Vanderbilt University Nashville Tennessee and Duke University Durham North Carolina. The researchers will not be able to link your samples to your personal information.

Due to rapid advances in technology, it is not possible to predict which exact tests will be available at the time the biomarker research is conducted. The biomarker research may look at mutations in genes involved in the growth of cancer, or in the way that genes affect how your body responds to the treatment. It may also include studying the features of the tumour and the surrounding cells and structures such as blood vessels, immune cells and cells in the connective tissue.

The biomarker research to be undertaken in this study, with the exception of the protein MGMT test results, will not benefit you directly but may help people in the future who have the same kind of cancer as you have. This research is experimental and will not be suitable for guiding decisions about your treatment. Accordingly, we do not plan to make your individual results from these studies available to your doctor.

After this biomarker research has been conducted, we would also like to store any leftover samples for use in any ethically approved future research studies that may or may not be related to this study. This means that your samples would be stored indefinitely or until they are used up. In the future, other doctors and scientists may use your samples to learn about many different diseases and conditions. Their goal is to improve health outcomes and develop new treatments. You will retain the right to have your samples destroyed at any time by contacting your study doctor. If you decide to have your samples destroyed, any data or analyses that were done before the request cannot be removed. However, all of your remaining samples will be destroyed. The researchers will not sell your tissue or blood. You will not benefit financially if this research leads to the development of a new treatment and/or medical test.

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

Sometimes during the course of a trial, new information becomes available about the treatment that Is being studied. If we find something new about an intervention while this study is underway, your study doctor will discuss with you what it means and also discuss whether you want to continue in the study. 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, they will explain the reasons and arrange for your regular health care to continue.

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

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved.

14. 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. 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 by the sponsor 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 group.

15. Could this research project be stopped unexpectedly?

Yes, if this study is stopped earlier than planned, the study doctor will let you know and explain the reason behind the decision.

16. What happens when the research project ends?

Once the study has finished, it is likely your doctors will still ask you to attend follow up visits to confirm your health status as part of your ongoing care.

Part 2 How is the research project being conducted?

17. What will happen to information about me?

A copy of your signed consent forms will be sent to the TROG Cancer Research central office in Newcastle (NSW), which coordinates the FIG study, for audit purposes. For consent to the main study, all identifying information will be removed, but for the consent to access Medicare and pharmaceutical information, all identifying information will visible, as this is required by the Australian Government, Department of Human Services. By signing the consent form, you are agreeing to this.

Information about your participation in this study will be recorded in your health records and this and other relevant information may be obtained from these records held at this or other health services (such as your GP) for the purpose of this research.

Australian and [insert the name of a state or territory] privacy law gives you the right to request access to your information that the researchers have collected and stored. The law also gives you the right to request corrections to any information about you that you disagree with. Please contact the study team (see section [insert the number of the section containing the study-team contact] of this document) if you would like to access your information.

We will not disclose your information without your permission, except in compliance with the law. Information about you may be obtained from your health records held at this institution and may be obtained from other health services for the purposes of research. Should you wish to cease treatment we would like the option to maintain follow-up. If you sign the consent form, you agree to the study team accessing health records if they are relevant to your participation in this study.

Information concerning your participation in the study will be sent to the TROG Cancer Research central office by the study doctor or their designate. This may include copies of sections of your medical records, medical reports, your radiotherapy treatment plan and imaging scans. This information will only be identified by your initials, date of birth and/or a unique study number. In no instance will the study centre identify you by name on these documents. They have policies of strict confidentiality and will not release any information concerning you, except to other researchers in this study. You will not be identifiable as an individual in any publication resulting from this study.

The re-identifiable/coded (it is possible to use the code to re-identify you) information held by the sponsor however, will not be destroyed. Only the study team at [insert site name] will be able to re-identify you from the code.

It is anticipated that the results of this study 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 personally identified.

18. Data sharing

Information collected during the study, which can include any imaging, will be stored indefinitely as it may be utilised in future research by the study investigators, study sponsor and collaborating researchers to advance our knowledge about cancer and its treatments. This may involve combining the data collected from multiple related trials in Australia and from around the world. If this happens, anonymised information about you may be passed to these researchers, they would not be able to identify you from the information provided.

MBS and PBS data collected during this study will not be used for future research.

19. 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.

20. Who is organising and funding the research?

This research study is being sponsored by the Trans Tasman Radiation Oncology Group (t/a TROG Cancer Research), a not-for-profit research group involving many cancer researchers in Australia, as well as internationally. This study has been awarded funding by the Medical Research Future Fund, Cure Brain Cancer Foundation and the Australian Brain Cancer Mission / Cancer Australia.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to TROG Cancer Research, the study doctors or their institutions, there will be no financial benefit to you or your families from these discoveries.

No member of the research team will receive a personal benefit from your involvement in this study (other than their ordinary wages).

21. 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 study has been approved by the HREC of Austin Health.

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 interest of people who agree to participate in human research studies.

22. Further information and who to contact

We have included several contacts for you below. Who you contact depends on what information you need:

Treating Hospital contact person

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

If you wish to discuss the study or with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Austin Health Human Resources Ethics Committee
Position	Mrs Lisa Pedro
Telephone	(03) 9496 4035
Email	ethics@austin.org.au

Local Research Office contact

Contact	[Position]
Telephone	[Phone number]
Email	[Email address]

Insert Header with institution's name or institution's letterhead

Consent Form - *Adult providing own consent*

Title	**Prospective, Multicentre trial evaluating FET-PET in Glioblastoma (FET-PET in Glioblastoma)**
Short Title	**FIG Study**
Project Sponsor	TROG Cancer Research
Coordinating Principal Investigator/ Principal Investigator	*[Coordinating Principal Investigator/ Principal Investigator]*
Location	*[Location where the research will be conducted]*

Consent Agreement

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 *[Name of Institution]* concerning my disease, medical history 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 the sponsors of this study may make my data available to other researchers for future research. Any data transferred to a third party for future research will remain coded with my unique number and will not contain my personal information. I give permission for these individuals to have access to my data.

I consent to my treating doctor/s being notified of my participation in this study and any clinically relevant information noted by the study doctor in the conduct of the study.

I consent to the storage and use of blood and tissue samples taken from me as described in the Participant Information Sheet, for any future extended research (this research may include genetic testing).

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

Koh E-S, *et al. BMJ Open* 2023; 13:e071327. doi: 10.1136/bmjopen-2022-071327

Declaration by Participant

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances, a witness* to the informed consent is required *(see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9)*

Name (please print) _____

Signature _____ Date _____

* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

Declaration by Study Doctor/Senior Researcher†

I have given an explanation of the clinical study, its procedures and risks and I believe that the participant has understood that explanation.

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, the research project.

Declaration by Interpreter (if applicable)

I am a qualified interpreter. I have given an explanation of the research project, its procedures and risks and I believe that the patient has understood that explanation.

Name of Interpreter (please print) _____

Signature _____ Date _____

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

Insert Header with institution's name or institution's letterhead

Consent Form – MBS/PBS information

Title	**Prospective, Multicentre trial evaluating FET-PET in Glioblastoma (FET-PET in Glioblastoma)**
Short Title	**FIG Study**
Project Sponsor	TROG Cancer Research
Principal Investigator	[Principal Investigator]
Location	[Insert site name] [Location]

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

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the FIG Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD / MM / YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

Koh E-S, *et al. BMJ Open* 2023; 13:e071327. doi: 10.1136/bmjopen-2022-071327

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

☐ Medicare claims history OR

☐ PBS claims history OR

☐ Medicare & PBS claims history

for the period* DD / MM / YYYY to DD / MM / YYYY to the FIG Study.

**Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), the consent period above may result in multiple extractions.*

DECLARATION

I declare that the information on this form is true and correct.

Signed: _____ (participant's signature)

Dated: DD / MM / YYYY

OR

Signed by _____ (full name)

_____ (signature) on behalf of participant

Dated: DD / MM / YYYY

☐ Legal guardian**

☐ Power of attorney** ☐ Guardianship order**

**Once a young person has turned 14 years old, they must consent to their own information being released*

*** Please attach supporting evidence*

APP 5 – PRIVACY NOTICE

Your personal information is protected by law (including the Privacy Act 1988) and is collected by the Australian Government Department of Human Services for the assessment and administration of payments and services.

Your information may be used by the department, or given to other parties where you have agreed to that, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

You can get more information about the way in which the department will manage your personal information, including our privacy policy at humanservices.gov.au/

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*				Hospital indicator	Item category
	999999A				N	1
999999A	999999A				N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under co-payments can now be provided for data after 1 June 2012

Insert header with your institution's name or institution's letterhead

Withdrawal of Participation

Title	**Prospective, Multicentre trial evaluating FET-PET in Glioblastoma (FET-PET in Glioblastoma)**
Short Title	**FIG Study**
Project Sponsor	TROG Cancer Research
Principal Investigator	[Principal Investigator]
Location	[Insert site name] [Location]

Declaration by Participant

I wish to withdraw my 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 *[Institution]*.

I consent that any further information collected in my routine care be used in the above research study.

Yes ***No***
(please tick)

☐ ☐

Name of participant (please print) _____

Signature _____ Date_____

Declaration by study doctor/senior researcher†

I have given a verbal explanation of the implications of withdrawal from the trial and I believe that the participant has understood that explanation

Signature _____ Date_____

Name of study doctor/ researcher† (please print) _____

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

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