Assessment of neuroinflammation in boxers (ANIB)

Participant Information Sheet & Consent Form for MS Patients

Neuroinflammation in Boxing: Quantification of translocator protein (TSPO) expression using the tracer, [18F]-PBR111 in a PET/MRI setting.

RBWH HREC reference: HREC/18/QRBW/105
QUT administrative reference: 1700001179

SPONSOR

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Dr. Omkar Patkar
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LOCATION

Herston Imaging Research Facility
RBWH
QIMR Berghofer Medical Research Institute

PART 1: WHAT DOES MY PARTICIPATION INVOLVE?

INTRODUCTION

You are invited to take part in this study because you are a

1. A Relapsing Remitting Multiple Sclerosis (RRMS) patient.

Inflammation in the brain (neuroinflammation) has been seen as a starting point in many brain disorders like dementia, Alzheimer's disease (AD) and multiple sclerosis (MS). The main purpose of this research is to see if involvement in combat sports like boxing which involves repeated blows to the head causes inflammation in the brain and how much brain injury could be tolerated in boxers before having long-term consequences.

This Participant Information Sheet/Consent Form tells you about the study. It explains the tests and interventions involved. Knowing what is involved will help you decide if you want to take part in the study.

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. If you do decide to take part in the study, you will be asked to sign the consent section. By signing this form 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 signed Consent Form to keep.

WHAT IS GENETIC RESEARCH?

Genes are made of DNA – the chemical structure carrying your genetic information that determines many human characteristics such as the colour of your eyes or hair.

Researchers study genes in order to understand why some people have certain conditions, such as where a protein is expressed differently in different people. Understanding a person's genes also may be able to explain why some people respond to a treatment, while others do not, or why some people experience a side effect and others do not.

WHAT IS THE PURPOSE OF THIS RESEARCH?

Brain inflammation occurs after an injury to the brain resulting from combat sport injuries or in several brain disorders like Alzheimer's disease, Parkinson's disease and Multiple Sclerosis (MS). Early detection of brain inflammation can guide the timely use of appropriate therapy and help control/cure the progression of disease symptoms. Currently, brain imaging techniques like Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET) offer the best measurement of brain inflammation, and have been widely used to detect disease behavior in several brain disorders.

MRI reveals the details of brain structure without requiring any radiation exposure. PET makes use of a small amount of a radioactive drug, called a PET tracer that highlights areas of inflammation in the brain which can be seen on a PET image.

The main purpose of this study is to use PET/MRI methods to determine if:

1. Measuring the amount of a particular protein in the brain; translocator protein (TSPO) can be used to estimate inflammation in the brain.
2. Participation in combat sports like boxing causes inflammation in the brain
3. Extent of brain inflammation is related to the extent of boxing exposure in the ring
4. How much brain injury could be tolerated before having serious long-term consequences?

Having this kind of advanced brain imaging available in Brisbane could become very important for monitoring the brain health not just of boxers, but also players in many other contact sports like rugby union or rugby league. Most importantly, this research may serve as a strong background in future PET studies of brain inflammation in cases of AD, MS and other brain disorders.

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.

This research has been initiated by the principal investigator, Professor Paul Cumming. This

research has been funded by the Wesley Medical Research Institute and sponsored by Queensland University of Technology (QUT).

WHAT DOES PARTICIPATION IN THIS RESEARCH INVOLVE?

Before you begin, it is very important that you tell study staff about all medications (including over the counter or herbal medications) that you are taking at the start of the study, as some medicines may affect binding to the TSPO. It is also important that you let the research and clinical staff know if you have a history of kidney or liver impairment for example liver cirrhosis, autoimmune conditions affecting the liver or chronic kidney failure, as these conditions may place you at higher risk of complications with metabolism and removal of the PET tracer from your body.

1. STEP 1: CONSENT AND QUESTIONNAIRES

If you wish to take part after you have read this information booklet, a member of the study team will contact you to set a time for appointment/s. A PET/MRI appointment at HIRF will be organized at a convenient time for you. We will provide you with a map to assist you with getting there. The study doctor will take assess your weight, height and vital signs (heart rate, blood pressure, temperature, respiratory rate) before you proceed with the PET/MRI appointment

You will only need to come in for 1 visit. A member of the research team will discuss the study with you and answer any questions you may have. If you give your consent to take part, we'll ask you about your medical history and all treatments and/or medications that you are taking including anticoagulants [(for example heparin, warfarin (Coumadin), rivaroxaban (Xarelto), dabigatran (Pradaxa), apixaban (Eliquis), edoxaban (Savaysa), enoxaparin (Lovenox) or fondaparinux (Arixtra)] or herbal remedies, supplements and vitamins. This is because certain medications like benzodiazepines taken within one week of scanning which include but not limited to diazepam (Valium, Ducene, Antenex), oxazepam (Serepax, Murelax, Alepam), nitrazepam (Mogadon, Alodorm), temazepam (Euhypnos, Normison, Temaze), lorazepam (Ativan), flunitrazepam (Rohypnol, Hypnodorm), bromazepam (Lexotan) or clonazepam (Rivotril) can affect the results of the brain scan. We also need to know if you have any history of alcohol dependence since you may be at a risk of alcohol intoxication as the PET tracer is made up in 10 % alcohol. If you have taken any benzodiazepine medication within one week prior to your scanning appointment or have a history of alcohol dependence, you will be excluded from participating in the study.

We will ask you to complete a simple 10-min questionnaire to assess your brain function and mood followed by the PET/MRI scan.

2. STEP 2: PET/MRI

Before the PET/MRI scan, it is very important that you tell the study staff if there are any metals/metallic impacts/metal piercings in your body by completing a standard Metals Safety Questionnaire. This is because the powerful magnetic field inside the PET/MRI instrument can detect certain kinds of metals which may put you at a very high risk of complications in MRI/PET procedure. A team member will review your answers and give you clearance before proceeding with the rest of the appointment. Also if you experience symptoms of severe claustrophobia from lying in a confined space (for example anxiety whist travelling in a lift), it is likely that you my not be able to tolerate the scanning procedure as it requires to lie down in the PET/MRI scanner for more than an hour.

HCG Urine Test

(Please skip this information box if pregnancy test does not apply to you)

For female participants during the screening stage of this study we will ask you questions regarding pregnancy. If you indicate that you have not undergone menopause or have had any surgical procedures like removal of uterus, we will ask you to complete a pregnancy test on the scanning day (before the PET tracer [18F]-PBR111 is administered). This test requires a urine sample. If you indicate that you do not wish to take the pregnancy test, you will not be allowed to participate in the study. While PET/MRI scanning is considered safe for pregnant women, we must avoid any exposure to radiation with the PET tracer if you should fall pregnant around the time of scanning. Therefore, any positive pregnancy test will require that you defer from the study. We will use a hospital grade Human chorionic gonadotropin (HCG) urine pregnancy screen test. This test requires you to provide a urine sample. These results of the pregnancy test may take a few minutes to appear. Once the doctor has confirmed a negative pregnancy result, you may proceed with the rest of the PET/MRI appointment.

In the unlikely event a positive result is returned from the HCG urine test, we will let you know of the positive pregnancy result in a private room. We will be required to cancel your PET/MRI appointment. We recommend that you seek advice from your preferred health care professional if a positive result is returned.

You will have a needle inserted into a vein of both arms. A cannula (a small, flexible tube) will be placed inside both veins. The PET tracer [18F]-PBR111 will be injected through the left arm cannula and into your blood stream. 10 minutes after the PET tracer has been injected, we will collect a small blood sample from you via the right arm cannula. We will collect approximately two tablespoons of blood. This blood will be used for biochemical testing to see how well your body metabolizes the PET tracer.

In addition to this blood sample, another small blood sample of approximately two tablespoons will be collected to identify the type of TSPO you have. These blood tests will not reveal any specific health information about you, and will only be used for the abovementioned purposes. Your blood samples will be disposed of after the testing.

We will then acquire images of your brain using the PET/MRI scanner. The PET/MRI scan will take approximately 120 minutes after injection of the tracer.

For this, we will ask you to lie on a table inside the PET/MRI scanner. The scanner will record information about your brain. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so that you can keep still.

The PET/MRI scanner is noisy and we can give you some earphones to reduce the noise. We will supply you with an emergency buzzer. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you. If you become upset or distressed please discuss with your study doctor.

3. We will provide you with vouchers for parking or taxi fares up to $50 per study visit, as required. In appreciation of your participation we will reimburse you with a $100 Coles/Myer voucher. This will be paid after completion of the PET/MRI scan. **STEP 3: FOLLOW UP PHONE CALL**

You will receive a follow up phone call 7 days after the completion of the PET/MRI exam at a time convenient to you. At this time we will ask you for some feedback, including if you feel different in any way since your PET/MRI scan.

OTHER RELEVANT INFORMATION ABOUT THE RESEARCH PROJECT

The study will involve approximately 40-50 participants who will be scanned using the PET

tracer [18F]-PBR111, which is one of the only three PET tracers for TSPO available in Australia.

DO I HAVE TO TAKE PART IN THIS RESEARCH PROJECT?

Participation in this research project is ***voluntary***. If you do not wish to take part, you have no obligation. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage and do not need to provide any reason. If you do decide to take part to the study, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether or not to participate, or any decision to withdraw, ***will not*** affect your routine treatment, your relationship with those treating you, or your relationship with QIMR Berghofer Medical Research Institute or RBWH.

WHAT ARE THE ALTERNATIVES TO PARTICIPATION?

You do not have to take part in this research project to receive treatment at RBWH .You can discuss your options to participate in the study with your preferred MS specialist or your local doctor.

WHAT IF AN ABNORMALITY IS FOUND ON MY SCAN?

In the unlikely event that medically significant findings not related to this study are detected, HIRF has a standard procedure to provide you and your nominated doctor with copies of the MRI scan so that you can make an informed decision of what to do next.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

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

WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Risks related to Pregnancy:

The effects of PET/MRI imaging and [18F]-PBR111 on the unborn child are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female who has not undergone menopause or has had any surgical procedures like removal of uterus, we will ask you to complete a pregnancy test on the scanning day (before the PET tracer [18F]-PBR111 is administered).

Both male and female participants are strongly advised to use effective contraception during the course of the research before the scanning session and for 24 hours post scan to be eligible to participate. You should discuss methods of effective contraception with your study doctor.

For Female participants, if there is any chance that you may be pregnant, such as missed contraception or uncertain HCG test whilst participating in the research project, your scan will be deferred. If you do become pregnant while participating in the study, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

If you are male, you should not father a child or donate sperm for at least 24 hours after the scan.

Risks related to MRI:

Magnetic attraction for some metal objects in/on your body can pose a safety risk, so it is important that metal objects are not taken into the scanner room. You will need to complete a metals safety questionnaire upon arriving at the scanning appointment. You will be screened for metal before each scan, but **it is very important that you tell us if you have any metal on or inside your body such as a pacemaker or metal pins before you enter the scanner**.

The scans we are taking are for research purposes only. They are not intended to be used

like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your PET/MRI scans for features relevant to the research project.

In the rare case that something unusual is found on your PET/MRI image that may pose any risk to your health in the future, we will contact you to discuss about the findings. For MS patients, we will also inform the referring doctor. Since the scans are for this research study only, there is a high chance that we will **not find** any unusual features with your scan.

Risks related to PET [18F]-PBR111

Adverse reactions for the tracer previously observed include injection site reddening, injection site irritation, and injection site pain, nausea, wrist pain, ear pain, and a runny nose. Minor discomfort, bruising, minor infection or bleeding can be easily treated.

This research study involves that you be exposed to a small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation, which amount to about 2 millisieverts (mSv) each year. The effective dose from participation in this study is about 4.2 mSv, which is the amount you would naturally receive in three years. The radiation dose is similar to many diagnostic medical X-ray and nuclear medicine procedures. **No harmful effects of this dose of radiation have been demonstrated, as any effect is too small to measure.**

There is a slight risk of pain, bleeding, discomfort, and/or bruising at the injection/cannulation puncture sites. There is a rare chance of infection at the puncture sites and also a rare chance of fainting due to the injection. If any of these events happen, medical help will be available. The doctor will ask you for any negative reactions after administering the PET tracer and upon completion of the scan. It is important to let us know if, at any time, you are feeling any discomfort or sensations during the imaging appointment. It is important to let us know if you experience any negative reactions in the week after completion of the PET imaging exam. Therefore, we will telephone you approximately one week after each session to confirm that you have had no reactions. If you do experience a negative reaction after completion of the scanning session, you must contact us, and we strongly encourage you to seek medical advice from your preferred health care professional (please phone 000 or present to a hospital if urgent medical attention is required). If you would like to report any negative reactions please contact the Principal Investigator on the contact details listed at the end of this information sheet.

WHAT WILL HAPPEN TO MY TEST SAMPLES?

Your blood will be labelled with your participant ID number, transported and processed at laboratories at QIMR Berghofer. The laboratories will analyze your blood sample immediately or in small batches with a genetic test only to identify your TSPO type and a routine laboratory test to see how your body metabolizes the tracer.

Your blood sample will not be used for any additional genetic or non-genetic analysis.

Knowing what type of TSPO you have or how your body metabolizes the tracer will not reveal any future health risk to you or having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the project.

Your blood samples will be used for the purposes of this research project only. Your blood samples will be destroyed at the end of the research project

The information arising from the analysis of your blood sample will be used for this research project or for other future related or unrelated research projects. Any future projects will be reviewed by an HREC at that time and your information will be anonymized.

WHAT IS THE POTENTIAL IMPACT ON MY FAMILY IF I TAKE PART?

The research study will only use your blood sample to identify the type of TSPO you have and how your body metabolizes the tracer and **will not have any potential impact in your family.**

WILL I BE GIVEN THE RESULTS OF THE RESEARCH PROJECT?

The individual information about the type of TSPO or how your body metabolizes the tracer will not be revealed to you.

At the end of the study, a summary of the group findings (not individual) may be made available to those participants who request to know the outcome of the research.

WHAT IF NEW INFORMATION ARISES DURING THIS RESEARCH PROJECT?

Sometimes during the course of a research project, new information becomes available about the procedure or disease that is being studied. If this happens, the Principal Investigator will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the Principal Investigator will inform your referring physician . If you subsequently decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, the Principal Investigators 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 inform you and/or your referring physician .

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 a week before the start and after the completion of the studyThe referring physician will be consulted to ensure safety before participation. 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 in the research project.

WHAT IF I WITHDRAW FROM THIS RESEARCH PROJECT?

If you decide to withdraw from the project before the scanning session, please notify a member of the research team before you withdraw. This notice will allow that person or the Principal Investigator to discuss any health risks or special requirements linked to withdrawing. If you do withdraw your consent during the research project, the research team 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 the 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 retain your data, you must tell them before you join the research project.

COULD THIS RESEARCH PROJECT BE STOPPED UNEXPECTEDLY?

It is not expected that the clinical trial will finish prematurely. However, Circumstances that may warrant termination of clinical trial include, but are not limited to:

1. Unacceptable side effects
2. The investigational product being shown not to be effective
3. Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

In any case, the data will be stored for a minimum of 15 years as required by the Therapeutics Goods Association (TGA).

WHAT HAPPENS WHEN THE RESEARCH PROJECT ENDS?

This PET/MRI study is designed for research purposes only and you will not be given feedback on your individual results. At the end of the study, a summary of the group findings will be made available to those participants who request to know the outcome of the research.

PART 2: HOW IS THE RESEARCH PROJECT BEING CONDUCTED?

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

By signing the consent form you consent to the Principal Investigator 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. Your contact details will be filed securely and only study research staff will have access to your personal details. Electronic files will be password protected and stored on secure servers. 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 for the purpose of this research. By signing the consent form you agree to the study team accessing your 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 authorized representatives of the Sponsor (QUT), the institutions relevant to this Participant Information Sheet, HIRF and Royal Brisbane and Women's Hospital or as required by law. By signing the Consent Form, you authorize release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

The results of this trial will be made available to the supplier of [18F] PBR111, The Australian Nuclear Science and Technology Organization (ANSTO), for research and marketing purposes of ANSTO products. 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.**

Information that is medically relevant 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 Principal Investigator 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 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.

Some scientific journals are now asking to provide anonymized data for future use by scientists around the world. Anonymized data is data that does not include any information that could identify you (i.e. name or initials). Sociodemographic (e.g., age, gender, handedness), neurocognitive (e.g., IQ, severity of symptoms), physiological (e.g., heart rate, type of TSPO) and scanning data may be coded and uploaded to secure servers. Please indicate on the consent form whether you are happy for your anonymous data to be stored on secure servers and used in future research collaborations.

COMPLAINTS AND COMPENSATION FOR INJURY

If you suffer any injuries or complications as a direct result of this Clinical Trial, 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. If you suffer any distress or psychological injury as a result of this research project, you should contact the study team as soon as possible. They will assist you in arranging appropriate treatment and support.

Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the study doctor). You will be compensated by the sponsor of the study, QUT.

WHO IS ORGANIZING AND FUNDING THE RESEARCH?

This research study is being conducted by the QUT Principal Investigator (PI) Professor Paul Cumming from the School of Psychology and Counselling. This study is being conducted and sponsored in Australia by QUT. The study is funded by a grant awarded to Professor Cumming by the Wesley Medical Research Institute.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). If knowledge acquired through this research leads to discoveries that are of commercial value to QUT, the research team or their institutions, there will be no financial benefit to you or your family from these discoveries.

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 RBWH HREC and administratively approved by QUT and should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact QUT Research Ethics Advisory Team on telephone (07) 31385123, email: humanethics@qut.edu.au and/or the Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women's Hospital, Herston, QLD, 4029 on telephone (07) 3646 5490, email: RBWH-Ethics@health.qld.gov.au. QUT will be responsible for supervising the standard of care where the research will be carried out. 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.

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 Clinical Trial 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 **Lead Principal Investigator, Professor Paul Cumming @ 07 3138 4757 or by Email paul.cumming@qut.edu.au** or any of the following people:

Clinical Contact Person:

Name	Dr. Bjorn Burger
Position	Qualified Physician (RBWH) and Systems Neuroscience) group member, QIMR Berghofer)

Telephone	+ 61 0 423452760
Email	bjorn.burgher@qimrberghofer.edu.au

QUT HREC details:

Position	QUT Research Ethics Advisory Team
Telephone	(07) 31385123
Email	humanethics@qut.edu.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 at QUT:

Reviewing HREC name	QUT Research Ethics Advisory Team
Telephone	(07) 31385123
Email	humanethics@qut.edu.au

Complaints contact person for Royal Brisbane and Women's HREC (HIRF):

Reviewing HREC name	Royal Brisbane and Women's Hospital HREC (EC00172)
HREC Executive Officer	HREC Coordinator
Telephone	(07) 3646 5490
Email	RBWH-Ethics@health.qld.gov.au

Consent Form

Title: Assessment of neuroinflammation in boxers (ANIB)

Neuroinflammation in Boxing: Quantification of translocator protein (TSPO) expression using the tracer [18F]-PBR111 in a PET/MRI setting.

RBWH HREC reference: HREC/18/QRBW/105
QUT administrative reference: 1700001179

SPONSOR	Queensland University of Technology (QUT) 2, George Street, Brisbane, QLD 4122 Phone: 07 3138 5354 Email: ocsclinicaltrials@qut.edu.au
COORDINATING PRINCIPAL INVESTIGATOR	Professor Paul Cumming
CLINICAL SITE INVESTIGATOR	Professor Michael Pender
IMAGING SITE INVESTIGATOR (HIRF)	Associate Professor Paul Thomas
PRINCIPAL CO-INVESTIGATOR	Professor Karen Sullivan
ASSOCIATE INVESTIGATOR	Dr. Omkar Patkar, Dr. Bjorn Burgher, , Ms. Nanette Douglas, Ms. Louise Campbell, Dr. Fatima Nasrallah
LOCATION	Herston Imaging Research Facility (HIRF), RBWH and QIMR Berghofer Medical Research Institute,

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Declaration by Participant

I have read and/or understoodthe Participant Information Sheet.

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

I have completed the Safety Screening Questionnaires accurately.

I give permission for my doctors, other health professionals, hospitals or laboratories to release

information to QUT concerning my diagnosis and treatment for the purposes of this project. I understand that such information will remain confidential.

I acknowledge that the possible risks associated with participation in the study have been explained to me to my satisfaction and I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I further acknowledge that the project is for research purposes only.

I freely agree to participate in this Clinical Trial 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, if I decide to discontinue the study treatment, I may be asked to attend follow- up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

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

Name of Participant (please print)_____

Signature _____ Date _____

Declaration by Principal Investigator/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.

Name of Principal Investigator/
Senior Researcher† (please print)_____

Signature _____ Date _____

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

Declaration by Participant for access to de-identified data

By signing this consent section, I acknowledge that anonymous medical and imaging data may be stored in secure servers accessible (on request) by scientists around the world to facilitate further research.

Name of Participant (please print)_____

Signature _____ Date _____

Name of Principal Investigator/ Senior Researcher† (please print)_____

Signature _____ Date _____

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

Consent Form for Blood Genotyping

Title: Assessment of neuroinflammation in boxers (ANIB)

Neuroinflammation in Boxing: Quantification of translocator protein (TSPO) expression using the tracer [18F]-PBR111 in a PET/MRI setting.

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LOCATION	Herston Imaging Research Facility (HIRF), RBWH and QIMR Berghofer Medical Research Institute

Declaration by Participant

I have read or someone has read the Participant Information Sheet to me and I understand the information contained in it.

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

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 project without affecting my future health care.

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to QUT, RBWH and HIRF concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that my genetic samples will only be used for the purposes of this research project to identify the type of TSPO I have.

With respect to the use of the information arising from my TSPO genetic testing, I give permission for the information to be used in this research project or any future closely related or unrelated research projects. Any future projects will be reviewed by an HREC at that time and my information will be anonymized.

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 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.

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

Form for Withdrawal of Participation

Title: Assessment of neuroinflammation in boxers (ANIB)

Neuroinflammation in Boxing: Quantification of translocator protein (TSPO) expression using the tracer [18F]-PBR111 in a PET/MRI setting.

RBWH HREC reference: HREC/18/QRBW/105
QUT administrative reference: 1700001179

SPONSOR	Queensland University of Technology (QUT) 2, George Street, Brisbane, QLD 4122 Phone: 07 3138 5354 Email: ocsclinicaltrials@qut.edu.au
COORDINATING PRINCIPAL INVESTIGATOR	Professor Paul Cumming
CLINICAL SITE INVESTIGATOR	Professor Michael Pender
IMAGING SITE INVESTIGATOR (HIRF)	Associate Professor Paul Thomas
PRINCIPAL CO-INVESTIGATOR	Professor Karen Sullivan
ASSOCIATE INVESTIGATOR	Dr. Omkar Patkar, Dr. Bjorn Burgher, , Ms. Nanette Douglas, Ms. Louise Campbell, Dr. Fatima Nasrallah
LOCATION	Herston Imaging Research Facility (HIRF), RBWH and QIMR Berghofer Medical Research Institute,

Declaration by Participant

I wish to withdraw from participation in the above Clinical Trial and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with QIMR Berghofer Medical Research Institute.

Name of Participant (please print)_____

Signature _____ Date_____

Reasons for withdrawal: _____

_____

After my withdrawal,

1. I give permission for the data that has been generated from my participation in this research study to be kept and used by the research team Yes ☐ No ☐

2. Destroy all data generated from my participation in this research study Yes ☐ No ☐

Declaration by Principal Investigator/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.

Name of Principal Investigator/ 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.**