Participant Information Sheet

Competitor Assessment at Baseline; Ocular, Neuroscientific

(**CArBON**)

We'd like to invite you to take part in our research study. We plan to investigate how brain function in racing drivers changes following an event that might have led to concussion, in a study called CARS. To help us do this, first we would like to record the normal function of the racing driver's brain, in a study called CArBON. This information sheet is for the CArBON study.

Joining the study is entirely up to you; before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 30 minutes.

Please feel free to talk to others about the study if you wish. If you are aged less than 18 years, this must include your Parent or Legal Representative. Do ask if anything is unclear.

*The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part (**pages 2-4**).*

*Then we give you more detailed information about the conduct of the study (**pages 5-11**)*

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If you have any questions about this study, please talk to the doctors that organise it:

Professor Peter Hutchinson
or **Dr Naomi Deakin** (see **page 11**).

Part 1

1. Why are we doing this study?

Concussion is an important health issue in sport and this is also true for motorsport. The symptoms of concussion include headaches, feeling sick (nausea) or tired (fatigue), as well as problems with memory and concentration. To help manage drivers after concussion, the MotorSport UK (MS UK) published the first Concussion Guidelines in 2016. These guidelines advise avoiding racing for 2-3 weeks after a driver is diagnosed with concussion or is involved in a potentially concussive event during motorsport.

The symptoms of concussion can also be caused by other medical conditions and so concussion is difficult to diagnose. We do not understand how the symptoms of concussion change over time, especially after racing incidents. The **CArBON** study will investigate brain performance (for example memory and problem solving) and brain function in motorsport competitors before they are involved in a potentially concussive event. The information we collect will establish a standard against which we can compare drivers following an incident.

The **CArBON** study will be based in Cambridge, UK and will last for two years (2018 – 2020).

2. What do I need to know about the assessments used in this study?

There is no perfect test for concussion, so the **CArBON** study will investigate a number of different assessment tools which may be useful in motorsport. This will include tests of memory (using software called **CANTAB**), biomarker levels in saliva, and specialised imaging of the head (magnetic resonance imaging including functional sequences, **fMRI**). **CArBON** will also investigate the use of a medical device called **I-PAS** which has proven useful for concussion assessment in other groups of patients. **I-PAS** is currently used for concussion assessment in the American IndyCar series, but does not yet have approval for use in the UK.

3. Why am I being asked to take part?

All competitors in the British Touring Car Championship (BTCC) and its associated series* (see **page 4**), as well as competitors contracted with Aston Martin Racing (AMR) have been invited to participate in the study. We hope that as many drivers as possible will participate.

Do I have to take part?

No. It is up to you to decide. We will describe the study in detail and go through this information sheet with you. If you would like to participate in this study, we will ask you to sign a consent form to show that you have agreed to take part.

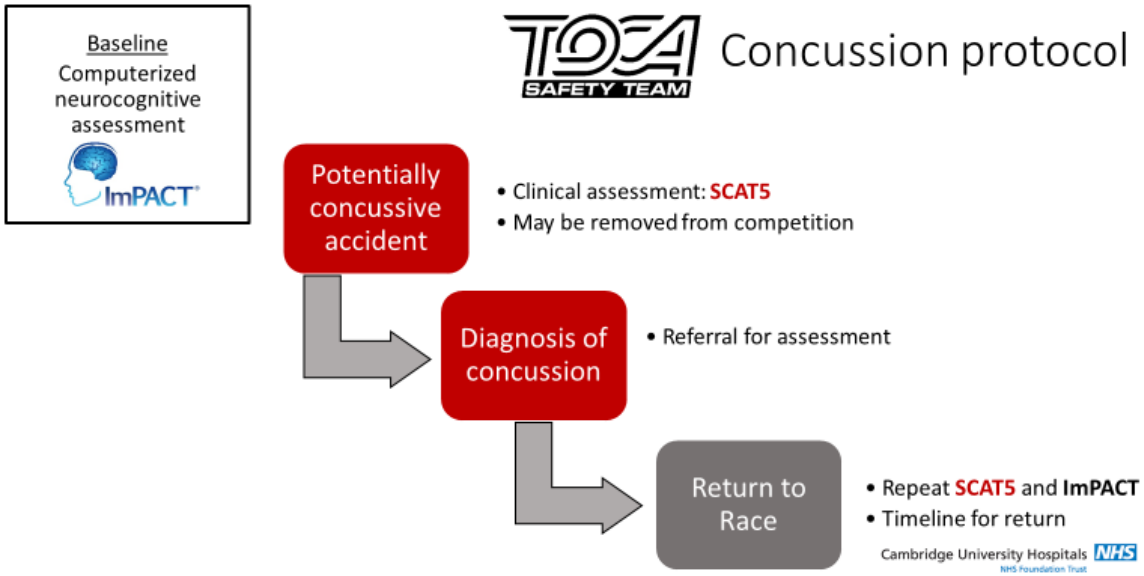
You are free to withdraw your consent at any time, without giving a reason. This will not affect the medical care you receive, or your participation in motorsport.

What happens if I am aged less than 18 years at the time of the study?

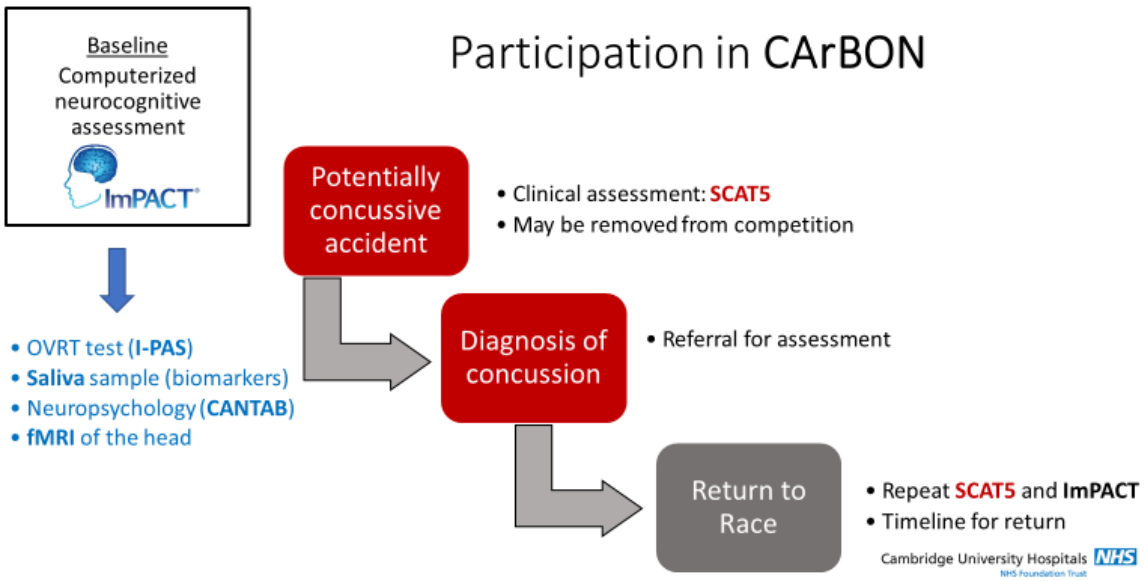
We ask that you bring a Parent/Legal Representative to all assessments. We ask that they also read this sheet and consent to participation with you if you wish to proceed.

4. What will I need to do if I take part?

You may be familiar with the Concussion protocol (see below), which includes baseline neurocognitive testing with the Immediate Post-Concussion Assessment and cognitive Test (**ImPACT**). You must complete this assessment to be eligible to participate in your championship; for more information please contact the **Race Medical Director** (page **11**) or **Team Principle**.



If you decide to take part in the **CArBON** study, you will still follow the Concussion protocol, but will complete four extra assessments at baseline, highlighted in blue:



Wherever possible, we will organise these assessments at a time and location convenient to you, however it is necessary to travel to Addenbrooke's Hospital in Cambridge for the brain scan (MRI). You are welcome to bring someone with you to the assessments (such as a partner, relative, friend or team member).

In line with motorsport policy, if you are aged less than 18 years you must be accompanied by a *Parent or Legal Representative* to all assessments.

If you are involved in a potentially concussive event during race activity you will be invited to participate in the **Concussion Assessment and Return to Sport** (**CARS**) study. We can discuss this with you now and arrange to contact you after such an event, if you would like to know more. There is no obligation to take part in the **CARS** study.

5. Possible side effects

There is a small risk that the use of the head-mounted **I-PAS** device may make you feel dizzy or sick (nauseous). We will use short and slow tests to check how you respond. If you feel unwell, we will stop the testing.

We also ask that you do not participate in any driving activity until one hour after the I-PAS assessment is complete.

This completes Part 1 of the Participant Information Sheet.

*****(The BTCC is part of the TOCA series, a UK motorsports events package that includes, as of 2020, two adult (Porsche Carrera Cup Great Britain and Michelin Ginetta GT4 Supercup), one mixed age (Mini Challenge) and two adolescent (Simpson Race Products Ginetta Junior Championships and British Formula 4 Championship; certified by Fédération Internationale de l'Automobile, FIA; powered by Ford) racing series.)

6. More information about taking part - Part 2

i. Background to the study and the purpose of the research

We suspect that motorsport competitors have better reaction times and visual capabilities than the general population, but there is little data available to support this. After a diagnosis of concussion, it is usual to compare post-injury assessments to baseline values, however there is very little data available for motorsport specifically. This makes it difficult to accurately assess competitors after concussion and might affect the quality of care that they receive. The **CArBON** study will investigate brain function in motorsport competitors before an accident has occurred and create a database of assessments to which post-injury tests can be compared. The results of the **CArBON** study will form part of **Dr Naomi Deakin's** PhD thesis. We aim to recruit 50 participants and will be recruiting drivers from the BTCC and its associated series.

We would like to invite you to participate, but you are under no obligation to do so. Taking part will have not affect the medical care you will receive. If you decide not to proceed with the **CArBON** study or to leave the study at any point, it will not alter your medical care then, or in the future.

Who is organising and funding the research?

The study is joint sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge, organised by a research group from the Academic Division of Neurosurgery, Department of Clinical Neurosciences and the Department of Psychiatry. Funding has been provided by the Global Institute for Motor Sport Safety/the Federation Internationale de l'Automobile (FIA).

Who has looked at and approved the study?

All research in the NHS is looked at by an independent group of people called the Research Ethics Committee. The Committee is created to review each project carefully and to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the relevant Ethics Committee, as well as the motorsport-specific FIA Scientific Advisory Committee (SAC).

ii. What does taking part involve?

Competitors participating in the BTCC and its associated series or contracted to AMR are managed according to a Concussion protocol (**page 3**). It is usual practice for you to complete a baseline **ImPACT** assessment before competing in your championship. If you are involved in a potentially concussive event during the racing season, you repeat the ImPACT assessment and complete a **SCAT5**.

If you choose to participate in **CArBON** you will be invited to complete some additional assessments. We would like to assess your:

- Biomarker levels in saliva (5min)
- Eye and inner ear function, plus reaction times, using a 3D head-mounted display (**I-PAS**; 10min)
- Thinking and memory, using the computerised **CANTAB** battery (40min)
- Brain structure and function, including assessment of blood oxygen levels (90min)

We will try to complete these assessments at a location convenient to you; either at the Medical Centre of race circuits participating in BTCC, venues for AMR competition in England or at Addenbrooke's Hospital, Cambridge. We expect that all the assessments will take 3-4 hours to complete.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time without giving a reason, but we would like to know if this is your decision. Information that was already collected about you may still be used, unless you ask us not to use it. Your withdrawal will not affect your medical care in any way.

What will happen if I miss a study appointment?
If you are unable to attend an appointment, please contact the **Study Co-Ordinator** as soon as possible. If we do not hear from you, we will contact you (or your Parent/Legal Representative, if applicable) a maximum of three times to re-arrange the appointment. If we are unable to contact you on the third attempt, we will withdraw you from the study and pass your details to either the **Race Medical Director**, **Team Principle** or **Chief Investigator**, so that they may ensure that you are safe and well.

iii. What are the possible benefits of taking part?

What are the possible benefits of taking part?
There will be no direct benefit to participants because of participation in the **CArBON** study. However, if you wish, participants in the **CArBON** study may have access to a jpeg (or similar) of their brain MRI, shared by email, after the usual report has been completed. We also hope the results will improve the future medical management of drivers after concussion and that the results will help update the MS UK concussion guidelines and Concussion protocol.

iv. Possible risks and disadvantages

What is the risk of physical harm?
Provision of a saliva sample, MRI of the head and computerised assessment of thinking and memory are not associated with significant risks of physical harm.

The **I-PAS** device, which will be used to assess eye, inner ear and reaction time function, has been identified as a non-significant risk device by the Food and Drug Administration, FDA. The device will also be reviewed by the Medicines & Healthcare products Regulatory Agency, MHRA, prior to use in this study. It is not expected that testing with the **I-PAS** system will be associated with any risk of physical harm.

What are the possible disadvantages?
The assessments and MRI scan take a few hours to complete. The MRI must be completed in Cambridge, which might not be close to where you live. This might be inconvenient to you.

The MRI scan involves the use of a large magnet. If you have any metal implants in your body, or have worked with metal previously (such as welding), we must discuss this further prior to starting the scan. It is possible, but unlikely, that the MRI scan may find an anomaly that you

are not aware of. If this happens the study team will refer you to a specialist at Addenbrooke's, or a hospital local to where you live. For any MRI-specific queries, please contact the Wolfson Brain Imaging Centre-appointed independent adviser, Superintendent Radiographer Vicky Lupson (vcl21@wbic.cam.ac.uk).

What are the risks to confidentiality?
Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge (UoC) are the sponsors for this study and both are based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge will keep identifiable information about you until the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information or by emailing the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk.

Further information can also be found at: https://www.medschl.cam.ac.uk/research/information-governance/ or alternatively you may email the Information Governance team at: researchgovernance@medschl.cam.ac.uk.

Who else will have access to my data?
It is important that you understand who will be able to access data collected in the **CArBON** study, and what relevant legislation will apply.

Cambridge University Hospitals NHS Foundation Trust will collect information from you and/or your medical records for this research study in accordance with our instructions. Cambridge University Hospitals NHS Foundation Trust will use your name, date of birth, NHS and/or hospital number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Individuals from Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Cambridge University Hospitals will pass these details to the Sponsors along with the information collected from you and/or your medical records. The only people in the sponsor organisation who will have access to information that identifies you will be people who need to contact you to for study visits or to audit the data collection process. Other people who analyse the information will not be able to identify you and will not be able to find out your name, date of birth, NHS and/or hospital number or contact details.

Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you from this study until the study has finished.

Special considerations for **RESCUE-RACER**

The **CArBON** study is funded by the Federation Internationale de l'Automobile (**FIA**) who are based in France and Switzerland. The study team will send an annual report to the Funder (**FIA**), which will summarise the progress of the **CArBON** study. This will include anonymised information, such as the number of participants and the assessments that have been completed.

The **CArBON** study uses a device (**I-PAS**) which is provided free of charge for research purposes by the manufacturer, Neurolign Technologies Incorporated (**Neurolign**), who are based in the United States of America and Canada. The study team plan to share anonymised **I-PAS** data with the device manufacturer (**Neurolign**) who have offices located in Pittsburgh, USA and Toronto, Canada. This will include your age at the time of testing, and scores from the eye, inner ear and reaction time tests (**I-PAS**). The sharing of this data will be subject to a Data Transfer Agreement, approved by CUH, in accordance with Human Research Authority (**HRA**) guidance '*Sharing of Anonymous Data Collected for Research Purposes'*. Neurolign employees who analyse the **I-PAS** data will not be able to identify you and will not be able to access your personal information. The study team may also be required to send **I-PAS** data to regulatory authorities, if requested, which will be subject to the appropriate approvals.

No identifiable information will be shared with **FIA** or **Neurolign**, therefore it is unlikely that identifiable information will be accidentally disclosed. The annual report and I-PAS data to be transferred will be approved locally prior to sharing.

What if there is a problem?

Please contact the **Study Coordinator's** if there is any problem with your involvement in the study (**page 11**).

What if I am unhappy with things or something goes wrong?

If you have concerns about any aspect of this study, you are encouraged to contact the **Study Co-Ordinator** who will do their best to answer your questions (contact details **page 11**). If you remain unhappy and wish to discuss the matter with an independent service or to formally complain, you can do this through the NHS Complaints Procedure. Details can be obtained from the Addenbrooke's Patient Advice and Liaison Service (contact details **page 11**).

Are there compensation arrangements if something goes wrong?

In the unlikely event of anything untoward happening, all patients registered with Cambridge University Hospitals NHS Foundation Trust are covered by the Trust's indemnity. In addition, clinical staff carry their own personal insurance. In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Cambridge, who will provide insurance cover for negligent and nonnegligent harm to research subjects in the UK under the University's Clinical Trials and/or Human Volunteer Studies policy, subject to ethical approval of the study.

v. Eligibility

The study protocol outlines some exclusion and inclusion criteria for participation in **CArBON**. For example, you must not have been diagnosed with concussion in the last 6 months. If you choose to participate, a member of the study team will discuss the criteria with you. If you are not eligible, your medical care will not be affected in any way and you will be managed as per the usual Concussion Protocol.

vi. Involving your GP and the TOCA Safety Team/AMR team members

Will my GP be informed?

We won't routinely inform your GP about your participation in **CArBON**, unless you specifically ask us to. We believe that there is no benefit in routinely informing GPs because participation in this study will have no immediate or long-term effects on your health.

However, we will ask for consent to contact your GP to access your medical records for previous history of concussion. You can choose whether we are able to access these records or not.

Will the TOCA Safety Team/AMR be informed?

We won't routinely inform the TOCA Safety Team or team members at AMR about your participation in **CArBON**, unless you specifically ask us to. We believe that there is no benefit in routinely informing these people because participation in this study will have no immediate or long-term effects on your health.

If you decide to take part in the **CArBON** study, we will ask for consent to access your records held by the TOCA Safety Team/AMR (including medical and accident data). This will allow the study team to utilise data already collected about you (such as previous ImPACT assessments, medical reports from accidents and in-car footage). You can choose whether we are able to access these records or not.

vii. Saliva sample

If you decide to participate in **CArBON**, we will ask you to provide a single saliva sample (less than 20ml) using a collection kit. The sample will be collected at the Race Circuit Medical Centre or during your visit to Addenbrooke's Hospital, Cambridge. There are no known risks to saliva donation. We plan to analyse levels of biomarkers associated with concussion (specific consent). We will also ask for your consent to analyse the samples for other markers in the future (generic consent); there is no obligation to agree to this. We do not believe there is any likelihood of discovering any significant health related finding for either analysis. The saliva will be separated and frozen for analysis in the future, which may be conducted at another research centre in the UK.

viii. Expenses and payments

If you decide to participate in the **CArBON** study, you may be eligible to receive a single payment for your time (£50, up to one day) and, when attending Addenbrooke's Hospital for assessment, your travel (up to £40).

ix. Accessing NHS data

If you decide to participate in the **CArBON** study, we will seek consent to access your medical records (collected in hospital, by a Family Doctor/GP or at motorsport events) to confirm your concussion history. You can choose to provide this consent or not. CUH and UoC will use this information to verify your history of conditions that might change the outcome of our research, such as concussion.

x. How will study data be stored?

To make participation in the study as easy as possible, **CArBON** assessments may be completed at race circuits participating in the TOCA series or venues for AMR competition in England. To do this we must use portable computers such as a study laptop or study iPad. The use, security and storage of these devices and their data will be in line with CUH remote working policy. Linked anonymised data will then be transferred to University devices for analysis and storage.

Study data will be kept securely for a minimum of 15 years and possibly indefinitely at the University of Cambridge and Cambridge University Hospitals (CUHT) data archive, in accordance with good research practice.

Anonymised study data shared with **Neurolign** will be stored in line with their Health Insurance Portability and Accountability Act of 1996 policy (**HIPPA**). Study data will be stored securely and only accessed by Neurolign employees who are collaborating on the project.

What will happen to the study results?

It is our aim to share the results of the study with other scientists and healthcare professionals. The results will be published in peer-reviewed scientific journals, internal reports and conference presentations, as well as publication on websites and other forms of scientific dissemination. All disseminated results will be anonymised and unidentifiable.

xi. Related research (generic consent)

How your data may be used in future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

This completes Part 2 of the Participant Information Sheet.

Thank you for considering participation in this study. Our research depends entirely on the goodwill of potential volunteers such as you. If you require any further information, we will be pleased to help you in any way we can.

You may withdraw from the study at any time without explaining why and it will not affect your present or future medical treatment in any way.

This research study has been approved by the **East of England Cambridge Central Research Ethics Committee**.

7. How to contact us

Study Coordinator	**Chief Investigator**
Dr Naomi D Deakin	Prof PJ Hutchinson
Address: Dept of Clinical Neurosciences Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ www.rescueracer.org naomi.deakin1@nhs.net	Address: Box 167, Academic Division of Neurosurgery, Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ

TOCA Safety Team Medical Director	**AMR Team Principle**
Dr Paul Trafford	Paul Howarth
Address: British Touring Car Championship Accessed via: http://www.btcc.net/contact/	Address: Aston Martin Racing Banbury, Oxfordshire

For further independent assistance, please contact:

Patient **A**dvice & **L**iaison **S**ervice (**PALS**)
Box 53, Cambridge University Hospitals NHS Foundation Trust,
Hills Road, Cambridge CB2 0QQ
Tel: 01223 216 756
E-mail: pals@addenbrookes.nhs.uk