Study Title: Biomarkers for RAtional Investigation for Neurological Decision Support in traumatic brain injury: a prospective cohort study with embedded RCT BRaINS-TBI

Chief Investigator: Dr Virginia Newcombe

Principal Investigator: *<Insert local PI name here>*

SUMMARY INFORMATION SHEET FOR PARTICIPANTS

We would like to invite you to take part in a research study. It is important that you understand why the project is being carried out and what will be involved.

1. **What is the purpose of the study?**

This study is trying to learn more about mild traumatic brain injury (mTBI).

2. **Why have I been invited to participate?**

You are currently being treated in this hospital for a head injury.

3. **Do I have to take part?**

No. It is up to you to decide whether or not to take part. Your decision about whether to take part will not affect your treatment.

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

We will collect clinical information about you, including:

- We will take a blood and saliva sample as soon as possible after you arrive at the ED and again about 2 hours later. The total blood taken will be no

more than 66ml (30-36ml each time), in addition to any blood collected as part of your regular medical care. We'll try to combine these blood draws with your regular medical care. In addition, we may ask you to provide small capillary blood samples. We would also like to ask you to consent to samples being taken for optional genetic testing.

- A member of our research team will interview you to get some background information, including your medical history. You'll also fill out some short questionnaires and do some study-specific tests.
- We'll follow up on your recovery at several times in the future (2 to 4 weeks, 3 months, and 6 months after your injury). These check-ups can be done over the phone, by mail, or online. They will include questionnaires and computer-based cognitive tests). Some participants may be invited to attend a face-to-face visit, if this is relevant we'll cover your travel costs. All participants will also receive a £20 voucher at the end of the 6 months follow-up.
- We would like to collect all routine clinical information which is recorded on equipment used to treat you. This information will be collected by the research team and be kept confidential. Further information about the type of data we collect can be found on this website www.hrs.nhs.uk/patientdataandresearch.

Some participants will also be invited to take part in a randomised controlled trial (RCT) as part of this study. If you are eligible and invited to the RCT part of the study, you will be randomly allocated by computer to one of two groups. The intervention group will use tests based on the blood samples we collect from you to determine whether you need a CT scan. In the control group the decision to have a CT scan will be based on existing clinical guidelines. All usual care options will be available to your treating doctor regardless of which group you are in.

5. What will happen to any samples and study data collected?

In this research study we will use information from you, your medical records, and your GP. We will only use information that we need for the research study. We will

let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some data in case we need to check it or use it for future research.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

6. **What will I have to do?**

Please read this summary sheet and ask any questions that you may have. A more detailed information sheet will be given to you by a member of the research team.

7. **Who is the Sponsor for this study?**

This study is sponsored jointly by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge.

8. **How has this study been reviewed?**

All research conducted in the NHS in the UK is looked at by an independent group of people called a Research Ethics Committee to ensure your relative's/friend's safety, rights, wellbeing and dignity are protected. This study has been reviewed and given a favourable opinion by the East of England Essex Research Ethics Committee.

9. **Where can I find further information?**

For further information about the BRaINS-TBI study, please go to https://norwichctu.uea.ac.uk/brains-tbi/ or email the team on:

brains-tbi@medschl.cam.ac.uk.