**Patient information sheet**

**NeuroHSI**
**A prospective observational study to evaluate the use of an intraoperative hyperspectral imaging system in neurosurgery**

**PART 1**
We would like to invite you to take part in our research study.
Joining the study is entirely up to you. However, 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 you would like to take part and answer any questions you may have. This should take about 40 minutes.
Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and the process if you take part.

The second part will give you more detailed information about the conduct of the study. Please ask if anything is unclear.

**What is the purpose of the study?**
The purpose of this study is to obtain images during brain surgery using a new type of surgical non-contact camera system. The study will obtain video images at the various stages of the operation. This will not alter the operation performed. The data obtained will also be used to develop the system's key computer-processing features. This will enable real-time information to be given to the surgeon whilst they are performing the procedure and has the potential to make neurosurgery safer and more precise.

**Why have I been invited?**
You have been invited to take part in the study because you have a lesion in the brain and have been advised that you need an operation.
Patients from King's College Hospital will be invited to take part. We expect approximately 81 patients will take part.

**Do I have to take part?**
No. The decision to take part is entirely up to you. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking part. You are free to discuss the information with anyone you

wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

**What will happen to me if I take part?**

If you agree to take part in this study, we will obtain written informed consent from you. Participating in this study will not affect the treatment you receive and will not alter the surgical operation performed.

The study involves taking additional video images during your operation which will extend the operation by up to 15 minutes.

Your operation will be completed in the usual manner and your surgeon will not use any of the acquired intraoperative data to guide surgical management.

Following your surgery, you will have follow-up imaging as part of your routine clinical care. Information from these investigations will be used in the study.

Your involvement in the study will stop after you have your post-operative imaging.

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**What are the possible benefits of taking part?**

We cannot promise the study will help you but the information we get from this study will help improve the future treatment of people needing brain surgery.

**What are the possible disadvantages and risks of taking part?**

The risk of this research causing you any harm is extremely low.

There should be no increased risk to the operation as a result of using the imaging system. Furthermore, any imaging acquired during the procedure will not be used by the surgical team.

**Who is organising and funding this study?**

The doctor in charge of this study is: Mr Jonathan Shapey. The study is funded by NIHR and is being sponsored by King's College London and King's College Hospital NHS Foundation Trust.

Your doctor is not being paid for their role in the study.

Jonathan Shapey (Chief Investigator) is an employee of King's College London (King's) and co-founder of the recently formed King's spinout Hypervision Surgical Ltd (HVS). Jonathan Shapey and King's College London are shareholders and have an equity interest in the company.

**How have patients and the public been involved in this study?**
Service users helped develop the research topic and what research questions should be asked and one of them is a co-applicant who will continue to be involved in the study. Potential participants were involved in reviewing the Participant Information Sheet.
In designing this study, we have taken into account patient opinions on the frequency of participant visits and the tests that we will carry out.

**Who has reviewed this study?**
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by _____Research Ethics Committee. It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the study can go ahead.

**Expenses and Payments**
There are no funds available for payments to those participating in this study.

**What happens when the research study stops?**
Your participation in the research study will stop after you have had your routine post-operative MRI scan after surgery. However, as a patient, your treating Consultant will continue to see you in the out-patient clinic until they feel it appropriate to discharge you from further follow up.

**This completes Part 1 of the Information Sheet.**

If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

**PART 2**

**What if new information becomes available?**
Sometimes we get new information about the treatment being studied. If this happens, your study doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study he/she may ask you to sign an agreement outlining the discussion.
This new information that becomes available might specifically affect you and your health. If this happens, your study doctor might consider that you should withdraw from the study. He/she will explain the reasons for withdrawing from the study and arrange for your care to continue.

If the study is stopped for any other reason, we will tell you and arrange for your continuing care.

**What will happen if I don't want to carry on with the study?**
You are free to withdraw from the study at any time; and if you would like to do so; please speak to your study nurse or doctor.

Your decision to withdraw from the study will not affect the care you receive.

If you withdraw your consent; information collected about you may continue to be used if you are happy with this. However, you can withdraw consent for all information collected to be destroyed where this is possible.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to your study doctor who will do their best to answer your questions (Mr Jonathan Shapey, 020 3299 9000). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital or looking on the NHS choices website.
http://www.nhs.uk/pages/home.aspx

Every care will be taken during the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

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 legal action for compensation against King's College London and King's College Hospital NHS Foundation Trust but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal National Health Service complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this.

**Will my taking part be kept confidential?**
If you consent to take part in the research, any of the information collected about you may be inspected by the sponsor (including representatives of the sponsor). These inspections are

solely for the purposes of the research and analysing the results. Your records may also be looked at by regulatory authorities to check that the study is being carried out correctly.

The organisations listed above will keep information about you confidential and secure. Your name will not be used in any reports about the study and all data is stored in accordance with the principle of the Data Protection Act 2018. However, your hospital doctor may tell your GP about your participation if you agree to enter the study.

**Involvement of the General Practitioner/Family Doctor (GP)**
With your consent, your GP will be informed of your involvement in the trial.

**What will happen to any samples that I give?**
The tissue samples taken during surgery will be analysed by the neuropathologists at King's College Hospital as part of your normal clinical care and will then be stored with all the other tumour tissue obtained during your operation.

**What will happen to the results of the research study?**
Results from this study will be used as part of an educational project (e.g. PhD – you can find the names of the PhD fellows affiliated with this study at the end of this form).
Results from this research study will be made publicly available through the study website (www.neurohsi.uk) and through publication of open-access research papers, presentation of results at scientific meetings, patient events, and online via King's College London and relevant charity websites/social media.
All identifiable personal data used for research will be anonymised before publication of the results.

**How we will use your data**
We will need to use information from you and your medical records for this research project.

This information will include your:
- Name
- Hospital number
- Date of birth
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are my choices about how your information is used?**
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Where can I find out more about how my information is used?**
You can find out more about how we use your information:

- on the Health Research Authority website www.hra.nhs.uk/information-about-patients/
- in a leaflet called: HowWeWillUseYourData KCH V1 (21-11-19) – available from the study team
- at our website https://www.kch.nhs.uk/about/corporate/data-protection
- by emailing our Data Protection Officer on kch-tr.dpo@nhs.net

## Thank you

Thank you for considering taking part and taking the time to read this information sheet.
If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

### Further information and contact details

INVOLVE, Alpha House, University of Southampton Science Park, Chilworth, Southampton, SO16 7NS
Telephone: 023 8059 5628  Email: involve@nihr.ac.uk

If you, your relatives, or friends have any questions about participating in this study, please contact the Principal Investigator – Mr Jonathan Shapey (Consultant Neurosurgeon).
Mr Jonathan Shapey
Department of Neurosurgery
King's College Hospital, Denmark Hill, London SE5 9RS
Email: Jonathan.shapey@kcl.ac.uk
Tel: +44 (0)20 3299 6331

TBA
Research study nurse
King's College Hospital, Denmark Hill, London SE5 9RS
Email: TBA
Tel: TBA

**PhD fellows affiliated with this study**

Mr Li Peichao
School of Biomedical Engineering and Imaging Sciences
9th floor, Beckett House
1 Lambeth Palace Road
SE1 7EU

Miss Anisha Bahl
School of Biomedical Engineering and Imaging Sciences
9th Floor, Beckett House
1 Lambeth Palace Road
SE1 7EU

Mr Oscar Maccormac
School of Biomedical Engineering and Imaging Sciences
9th Floor, Beckett House
1 Lambeth Palace Road
SE1 7EU

**Study Website**

www.neurohsi.uk

Your doctor ..... Tel: .....

Your nurse/study coordinator..... Tel: .....