RESTART tICrH

<Trust/Site address 1>
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<Trust/Site address 3>
<postcode>
Tel: <telephone number>

Professional Legal Representative Information Sheet for

RESTART tICrH: A Randomised Trial of Timing to Restart Direct Oral Anticoagulants after Traumatic Intracranial Haemorrhage (tICrH)

- You have been given this information sheet as you have been asked to act as Professional Legal Representative for a patient who might be eligible to take part in this research study.
- Please take time to read the following information carefully. **Part 1** tells you the purpose of the study and what will happen to the patient if you agree for them to take part. **Part 2** provides more detailed information about the conduct of the study.
- If required, you can ask members of the clinical team if there is anything that is not clear, or if you would like more information.
- In this study we want to see what the best time is to start or restart a medication called a direct oral anticoagulant (medicine that makes your blood less likely to clot) after a bleed in the head caused by a head injury (known as a 'traumatic intracranial haemorrhage').
- We will be asking participants to start or restart direct oral anticoagulant (DOAC) after 1 week or 4 weeks.
- Patients that might be able to take part will have had a traumatic intracranial haemorrhage and be aged 18 years or above.
- The study will recruit 1084 participants from around 20 trauma networks and hospitals across the United Kingdom (UK) over a 4 year period.
- In normal clinical care patients will start/restart a DOAC between 1 and 4 weeks after head injury, so this study will not put you at any additional risk. As with any medicine there are risks of side effects. There are more details in this information sheet.
- Patients will be contacted at 6, 12 and 26 weeks after their injury to complete some questionnaires to assess your recovery. This can be over the telephone or online.

How to contact the study team:

If you have any questions about this study, please talk to your research team:

- Principal Investigator <<Name and Telephone number>>
- Research Nurse <<Name and Telephone number>>

Contents:

PART 1: Purpose of the study and what will happen if your patient takes part

Invitation to be a Professional Legal Representative

- We are inviting you to take on the role of Professional Legal Representative for a patient.
- A Professional Legal Representative is a staff member or other professional who consents on a patient's behalf for them to participate in a research study when that person has been assessed to lack capacity to make an informed decision themselves. A Professional Legal Representative must be independent of the research study and team and will only be appointed where the patient does not have a relative or close friend who is able or willing to act as a Personal Legal Representative.
- As the patient is unable to tell us if they are willing to participate in this research study and cannot give consent themselves, we are asking you to consent on their behalf to participate in this study
- Based on your knowledge of the patient, you should consider what you think their past and present wishes and feelings are, and whether you think they would wish to participate if they were able to make their own decisions.
- Your decision is completely voluntary. If you do not want to decide, or if you determine that the patient should not take part in this study, you do not need to give a reason and the patient's standard of care will be the same.
- Before you make your decision, please read the rest of this information sheet carefully and discuss it with others if you like. Please ask if anything is unclear or if you would like more information.
- Take time to decide. You do not have to make a decision on behalf of the patient if you do not wish to.

What will I have to do if I take on this role?

A member of the research team will talk to you first in more detail and you will be able to ask them any questions that you may have. If you have had all of your questions answered and are willing to decide on behalf of the patient then you will be asked to sign a consent form. You will be given a copy of the form and the information sheet to keep.

Why are we doing the RESTART tICrH study?

The aim of this study is to see what the best time is to start/restart a direct oral anticoagulant (DOAC) after a traumatic intracranial haemorrhage. A traumatic intracranial haemorrhage is bleeding within the head due to trauma.

Older people falling from standing height is the most common cause of head injury resulting in admission to hospital. However, there are a range of injuries at all ages that can lead to a bleed on the brain. Up to 1 in 3 patients admitted are taking a tablet medication to reduce the risk of blood clots, known as an oral anticoagulant (OAC). An OAC can increase the likelihood of bleeding in the brain. Most patients take an OAC due to an irregular heartbeat called atrial fibrillation (which increases the risk of stroke) or because of a previous stroke or blood clot. When a scan confirms bleeding in the head OACs are nearly always stopped, but this leaves the question of when it is safe to restart them. The risk of worsening bleeding in the head must be balanced against the risk of stroke or blood clots.

There is very little evidence on the safest time to restart OACs, but most neurosurgeons advise restarting them 1 to 4 weeks after injury.

While your patients OAC is stopped, there is a higher chance of having a blood clot which could cause a stroke, heart attack or clot in your patients legs or lungs. There is

some evidence that this clotting risk doubles between 1 and 4 weeks, which is why we want to restart the OAC as soon as is safely possible. It may be that the bleeding risk is higher earlier (1 week) than later (4 weeks) but there is no evidence around this, which is what this study aims to answer.

Every individual has different risk factors for blood clots or bleeding and these can be discussed with your patients clinician. It may be considered better starting your patient's medication earlier (1 week) or later (4 weeks) depending on these risk factors. However, it is likely they will not have a clear answer for you, which is why we are inviting your patient to take part in the study.

The type of OAC that people normally take has changed in recent years from warfarin to newer medications called Direct Oral Anti-Coagulants (DOACs). DOACs can be easier to use compared to OACs and people taking them may not need to be monitored as closely. Only people that have previously been taking a DOAC or if their doctor decides they should be restarted on a DOAC will be able to take part in this study. This study aims to compare starting/restarting DOACs at 1 week and at 4 weeks after injury.

This study will recruit 1084 patients from across 20 trauma networks and hospitals in the UK. Participants will be involved in the study for a maximum of 6 months.

The results from this study will be used to help us improve the care of patients taking a DOAC after a head injury.

Why has this patient been chosen?

Your patient has been chosen to participate because they have had a head injury resulting in bleeding in the head and their doctor has recommended starting or restarting DOAC in the next 1 to 4 weeks.

Does the patient have to take part?

No, taking part is voluntary. It is up to you to decide whether or not your patient should take part.

If you decide that they should not take part then they will still receive the usual treatment their hospital offers. Their doctor can provide you with more information on this.

If you decide that they will take part you can also change your mind at any time without giving a reason.

The decision you make on whether your patient should take part or not will not affect the standard of care they receive now or in the future.

What will happen to the patient if they take part?

If you agree the patient can take part, you will be asked to sign a consent form. You will be provided with a copy of the consent form and the information sheet to retain.

Once you have signed the consent form, the research team will also check and confirm that this study is suitable for the patient. The patient will then follow the study plan (see study timeline).

The patient will have to:

- Be involved in the study for a maximum of 6 months.
- Start/restart their DOAC when they are asked to do so by the study team.
- Be contacted at 6, 12 and 26 weeks after their injury to complete some questionnaires to assess recovery. This can be over the telephone, video call or in person.
- Take part in an optional interview to ask about their experiences of being in the study.
- Share head scans to help us understand what type of injury they had and build a library of scans for future research.
- Report any serious medical problems (such as blood clots or bleeding) or any readmissions to hospital, to the research team as soon as they can.

What is the optional interview?

We will interview a selection of participants, either over the telephone, videocall or in person to ask about their experience of being in the study. The interviews may be in a group with other participants or individually (your patient can decide). The individual interview will last 30-60 minutes and the group discussion up to 2 hours and will be recorded. This interview will take place within the first 60 days of your patient taking part in the study. The

interview is entirely optional, and you will be asked about it when you complete the consent form.

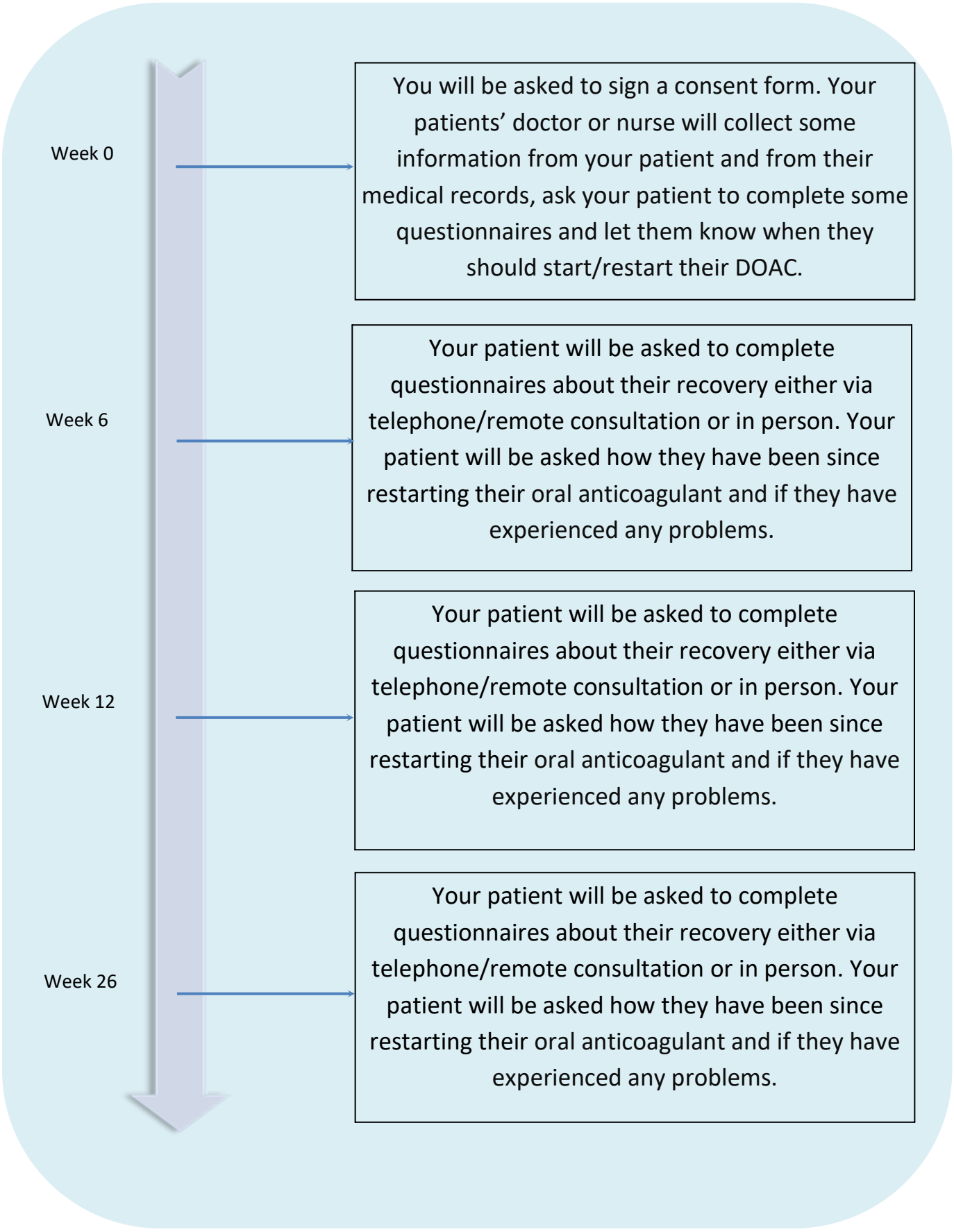
What is the Computed Tomography (CT) scan library?

As part of standard clinical care, all patients who experience a traumatic intracranial haemorrhage will have a CT scan of their head on admission to hospital and sometimes further follow-up scans as decided by the doctors making decisions about their care. In this study we want to collect these scans by linking them electronically and securely sending them to the University of Plymouth so that we can build a library of images. This will enable us to understand more about the patterns of head injury seen in patients who take part in this study and can be very helpful for future research.

Standard clinical care scans will be collected only; no additional scans will be completed as part of the study. We will use CT scans that your patient has already had for their normal clinical care to confirm eligibility and inform study outcomes. These CT scans will also be stored securely and anonymously at the University of Plymouth so that we can look at these scans in more detail and they can be used in the future in further research.

CT Head imaging is part of your patient's routine care. If your patient takes part in this study they will not undergo any additional x-ray imaging procedures. These procedures use ionising radiation to form images of your patient's body and/or provide treatment and/or provide your patient's doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to your patient are the same whether they take part in this study or not.

Study Timeline



Procedure	Description	Research Treatment or Standard of care
Starting/restarting DOAC	Once randomised onto the study your patient will be told at which timepoint they should restart their DOAC. Your patient will be reminded when it's time to start/restart.	***Research Treatment***
Completing study questionnaires – Modified Rankin Scale	The modified Rankin Scale (mRS) is a commonly used scale for measuring the degree of disability or dependence in the daily activities. This will be completed at baseline, 12 weeks and 26 weeks from joining the study, this may be completed earlier if your patient no longer wishes to take part in the study.	***Research Treatment***
Completing study questionnaires – Barthel Index	The Barthel index is a scale that measures someone's ability to complete activities of daily living. This will be completed at baseline, 12 weeks and 26 weeks from joining the study, this may be completed earlier if your patient no longer wishes to take part in the study.	***Research Treatment***
Completing study questionnaires - Extended Glasgow Outcome Scale	The Glasgow Outcome Scale measures functional outcome. This will be completed at baseline, 12 weeks and 26 weeks from joining the study, this may be completed earlier if your patient no longer wishes to take part in the study.	***Research Treatment***
Completing study questionnaires - Rockwood Frailty Score	The Rockwood Frailty Score measures the level of frailty. This will be completed at baseline, 12 weeks and 26 weeks from joining the study, this may be completed earlier if your patient no longer wishes to take part in the study.	***Research Treatment***
Health Economics Questionnaires – EQ-5D-5L and resources use questionnaires	The EQ-5D-5L and resources use questionnaire will be used to collect information on health and whether your patient has been to any health services whilst taking part in the study. This will be completed at baseline, 6 week, 12 weeks and 26 weeks from joining the study and may be completed earlier if your patient no longer wishes to take part in the study.	***Research Treatment***
CT Scan	As part of standard clinical care all patients who experience traumatic intracranial haemorrhage will have a CT scan and sometimes several follow-up CT scans, in order to guide management of the head injury. We want to collect images from these standard clinical care scans at baseline and up to 12 weeks for our CT repository. We will also review any standard care clinical scans that your friend/relative may have up to 26 weeks to check eligibility and inform the study outcomes	**Standard of Care**

What is this study testing?

We want to test the timepoint after head injury at which DOAC should be started/restarted. The study is comparing starting/restarting at 1 week or 4 weeks after head injury.

How will I know which treatment the patient is going to have?

In research studies we often split participants up into groups to look at how different treatments work. In the RESTART tICrH study participants will be split into two groups at random:

· One group will start/restart at 1 week

· The other group will start/restart at 4 weeks

It is really important that each group in the RESTART tICrH study has a similar mix of participants in it, so we know that if one group of participants does better than the other it is very likely to be because of the timing of starting/restarting the DOAC and not because there are differences in the types of participants in each group.

We use a computer programme that puts participants into groups 'at random' – you might hear this described as 'randomisation' or 'random allocation', but they all mean the same thing.

In the RESTART trICH study your patient is equally likely to be in the group starting/restarting a DOAC at 1 week as they are to be in the group starting/restarting a DOAC at 4 weeks.

Your patient's healthcare team will let you know which group they are in.

It is recognised that anticoagulants known as DOACS are now preferable to vitamin K antagonists (eg Warfarin) as they are safer. If your patient is taking warfarin they may be asked to start a DOAC (apixaban, dabigatran, rivaroxaban or edoxaban) rather than warfarin if you decide for them to take part in the study.

What are the alternatives for treatment?

If you choose for your patient not to take part in this study then the doctor looking after them will choose the best treatment for your patient.

What are the benefits and risks for the patient of taking part?

There is no clear evidence for the best time to start/restart a DOAC after a head injury. There is the potential for all participants in the study to benefit from taking part, because regardless of which group your patient is allocated to, all participants will be taking a DOAC by 4 weeks. Although there may be no direct benefit to your patient by taking part, we hope that the results from the study will help doctors and patients in the future when making decisions about treatment.

Both time-points for starting/restarting the DOAC have been shown to improve symptoms but we do not know which time is best. In normal clinical care patients will start/restart a DOAC between 1 and 4 weeks after head injury, so this study will not put your patient at any additional risk.

There are four types of DOACs that are usually prescribed, your patient will be prescribed one that patients would usually get in their hospital. With all anticoagulants it is important to look out for signs of bleeding when taking them, your patient should contact their Doctor at their Hospital or their General Practitioner (GP) if they notice any signs of bleeding. There are certain medications that should not be taken with a DOAC, your patient's Doctor or Nurse will discuss this with them. Each type comes with adverse reactions (side effects) as with any medication and these are listed below:

Eliquis (Apixaban)

Common adverse reactions seen in other patients include haemorrhage (bleeding), contusion (bruising), epistaxis (nose bleed), and haematoma (collection of blood under the skin), anaemia (low number of red blood cells), thrombocytopenia (low platelet count), eye haemorrhage (bleeding in the eye), hypotension (low blood pressure), nausea, gastrointestinal (GI) haemorrhage (bleeding in the digestive system), haemorrhoidal haemorrhage (rectal bleeding), mouth haemorrhage (bleeding in the mouth), rectal haemorrhage (bleeding from the bottom), gingival bleeding (bleeding gums) gamma-glutamyltransferase (GGT) increased (increase in GGT which is an enzyme found throughout the body), alanine aminotransferase

(ALT) increased (increase in ALT which is an enzyme found throughout the body), skin rash, haematuria (blood in urine) and abnormal vaginal haemorrhage, urogenital haemorrhage (bleeding from female reproductive system).

Pradaxa (Dabigatran)

The most common adverse reactions seen in other patients include anaemia (low number of red blood cells), epistaxis (nose bleed), GI haemorrhage (bleeding in the digestive system), abdominal pain, diarrhoea, dyspepsia (indigestion), nausea, rectal haemorrhage (bleeding from the bottom), skin haemorrhage (bleeding into the skin) and genitourological haemorrhage, including haematuria (bleeding from female reproductive system and blood in urine).

Lixiana (Edoxaban)

The most common adverse reactions seen in other patients include epistaxis (nose bleed), haematuria (blood in urine) and anaemia (low number of red blood cells), dizziness, headaches, abdominal pain, Lower GI haemorrhage, upper GI haemorrhage (bleeding in the digestive system), oral/pharyngeal haemorrhage (bleeding from mouth and throat), nausea, blood bilirubin increased, gamma-glutamyltransferase (GGT) increased (increase in GGT which is an enzyme found throughout the body), cutaneous soft tissue haemorrhage (bleeding into the skin), rash, pruritus (itching of the skin), macroscopic haematuria/urethral haemorrhage (blood in urine), vaginal haemorrhage, puncture site haemorrhage and abnormal Liver function tests.

Xarelto (Rivaroxaban)

The most common adverse reactions seen in other patients include epistaxis (nose bleed) and GI tract haemorrhage (bleeding in the digestive system), anaemia (low number of red blood cells), dizziness, headaches, eye haemorrhage (bleeding in the eye), hypotension (low blood pressure), haematoma (bleeding under the skin), haemoptysis (coughing blood), gingival bleeding (bleeding gums), abdominal pains, dyspepsia (pain in the upper abdomen), nausea, constipation, diarrhoea, vomiting, Increase in transaminases, pruritus (itching of the skin), rash, ecchymosis (bruise), cutaneous haemorrhage subcutaneous haemorrhage (bleeding into the skin), pain in extremity, urogenital tract haemorrhage (bleeding in urinary tract), renal impairment, fever, peripheral oedema (accumulation of fluid in legs, ankles, arms or hands), decreased general strength and energy and postprocedural haemorrhage.

What happens if I change my mind?

If at any point you decide that the patient should stop taking part in the study, they will still receive treatment and the follow up usually offered by their hospital.

If you do decide they should stop taking part we will ask you if you would like them to:

· continue to complete follow up visits for the study **or**

· stop taking part with no more study visits.

Information on how we will handle yours and the patient's information in the event of them withdrawing is detailed in Part 2 of this Information Sheet.

What if new information becomes available?

Sometimes during the course of a research project, important new information becomes available about the treatment/drug that is being studied. If this happens, the patient's doctor will tell you about it and discuss with you whether you want the patient to continue in the study. If you decide to withdraw the patient their doctor will make arrangements for their care to continue. If you decide they should continue in the study you will be asked to sign an updated consent form.

On receiving new information, the doctor might consider it to be in the patient's best interests to withdraw them from the study. He/she will explain the reasons and arrange for their care to continue.

If the study is stopped for any other reason, you will be told why and the patient's continuing care will be arranged.

What happens when the study stops?

At the end of the study your patient will continue to be treated by their clinical team.

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research results have shown. They may also be used to apply to the regulatory authorities to make the drug widely available and/or for research related to the development of pharmaceutical products, diagnostics or medical aids.

Confidentiality will be ensured at all times and neither you nor your patient will be identified in any publication.

Any information derived directly or indirectly from this research, as well as any patents, diagnostic tests, drugs, or biological products developed directly or indirectly as a result of this research may be used for commercial purposes. Neither you nor your patient have any right to this property or to any share of the profits that may be earned directly or indirectly as a result of this research. However, in signing this form and donating tissue and/or blood samples for this research, your patient does not give up any rights that they would otherwise have as a participant in research.

What if there is a problem?

Any complaint about the way you or the patient have been dealt with during the study or any possible harm they might suffer will be addressed. Detailed information is given in Part 2 of this information sheet.

Will taking part in the study be kept confidential?

Yes. All information about the patient's participation in this study will be kept confidential. Detailed information on this is given in Part 2.

PART 2: Detailed Information about the conduct of the study

Who is running the study?

The Walton Centre National Health Service (NHS) Foundation Trust is the Sponsor of this study and is responsible for managing it. They are based in Liverpool in the United Kingdom. They have asked that the day to day running of the study is carried out by a team based at the Liverpool Clinical Trials Centre (LCTC, part of the University of Liverpool), researchers from the University of Plymouth (part of the central study team) and health economics researchers from Bangor University (part of the central study team).

The study has been reviewed by the Health Research Authority the National Research Ethics Service Committee and the Medicines and Healthcare products Regulatory Agency (MHRA) to make sure that the study is scientifically and ethically acceptable.

This study is funded by National Institute for Health and Care Research (NIHR) Health Technology Assessment programme.

Your patient's doctor will not receive any personal payment for including them in this study. The hospital may receive additional funding to help with any extra costs that supporting this study might incur.

How will my, and the patient's information be collected and handled?

Walton Centre NHS Foundation Trust, University of Liverpool, University of Plymouth and Bangor University are the joint Data Controllers for this study and will need to use information from your patient's medical records for this research project.

This information will include your patient's NHS number/ Postcode for health economic research and initials/ name/ date of birth as part of consent. Your patients contact details will be collected if you agree for your patient to be contacted for the optional interview or future research.

Individuals from Walton Centre NHS Foundation Trust, the LCTC, Plymouth University and Bangor University, NHS organisations and regulatory organisations may look at your patient's medical and research records to check the accuracy of the research study and that it is being done properly.

People who do not need to know who your patient is will not be able to see their name or contact details. Their data will have a code number (study ID) instead.

Data will be sent from your patient's hospital or neurosurgical unit to the LCTC.

The LCTC will send data securely to Bangor University for health economics analysis. The LCTC will also send personal data (NHS Number, Name, Date of Birth and Postcode) securely to NHS England to request that information about any visits your patient has had to health care services or hospital admissions for the purposes of health economics analysis are provided to Bangor University (England only). The data provided by the LCTC and NHS England to Bangor University will be linked to your patient's study ID. Bangor University will not receive any of your patient's personal data. If you do not want us to collect this information from NHS England then please let us know.

Your patient's hospital or neurosurgical unit will send standard care brain scan images to The University of Plymouth. These images will be sent securely using a system called the Image Exchange Portal (IEP) provided by Sectra. This service is used by almost every hospital in the UK. When the images are sent through the IEP they will contain your patient's name, NHS number and date of birth. So that the team in The University of Plymouth can link their images to their study participant number the LCTC will need to send a copy of their consent to The University of Plymouth securely. The images will be linked to study participant number by an administrator at the University of Plymouth who is independent of the study. Once the images have been linked to your patient, they will be added to the University of Plymouth research portal at which time they will only contain their study participant number. This means that the people who will then look at your patient's images will not be able to identify them. Researchers at the University of Plymouth will look at your patient's images together

with some data that we collect in this study so that we can report the characteristics of participants in the study. The LCTC will send data to The University of Plymouth. The University of Plymouth will store your patient's images anonymously for future research.

We will notify your patient's GP that they will be taking part in the study for their information.

We will keep all information about your patient and you safe and secure.

Once we have finished the study, we will keep the data for 25 years, so we can check the results (if needed). We will write our reports in a way that no-one can work out that your patient took part in the study.

What are my choices about how my and the patient's information is used?

Your patient can stop being part of the study at any time, without giving a reason, but we will keep information about them that we have already collected. If your patient chooses to stop taking part in the study, we would like to continue collecting information about their health from their hospital. If you do not want this to happen, tell us and we will stop.
In some cases, however, we may need to continue to collect limited information about any side-effects of the study treatment your patient may experience. We will only do this where we are required to do so by law.

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

Information sharing for other research

When you agree for the patient to take part in a research study, the information about their health and care may be beneficial 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. The patient's 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, or equivalent standards**.**

If you agree for the patient to take part in this study, you will also have the option to agree for them to take part in future research using their data saved from this study.

Where can I find out more about how my and the patient's information is used?

You can find out more about how we use yours and your patient's information:

- at the LCTC website: https://lctc.org.uk/
- at www.hra.nhs.uk/information-about-patients .
- by asking one of the research team
- by sending an email to **<site email>**, or
- by ringing us on **<site phone number>**
- in the Health Research Authority leaflet available from www.hra.nhs.uk/patientdataandresearch
- by contacting the University of Liverpool Data Protection Officer on LegalServices@liverpool.ac.uk
- by contacting the Walton Centre NHS Foundation Trust Data Protection Officer on wcft.dpo@nhs.net
- by contacting the University of Plymouth Data Protection Officer on dpo@plymouth.ac.uk
- by contacting the Bangor University Data Protection Officer on sarah.riley@bangor.ac.uk
- In the LCTC's "Privacy Notice" available from: https://www.lctc.org.uk/privacy
- In the Walton Centre NHS Foundation Trust "Privacy Notice" available from: https://www.thewaltoncentre.nhs.uk/your-information-your-rights.htm
- In the University of Plymouth "Privacy Notice" available from: https://www.plymouth.ac.uk/research/governance/research-participant-privacy-notice
- In the Bangor University "Privacy Notice" available from: https://cheme.bangor.ac.uk/data-protection.php.en

If you are not happy with the way your information is being handled, or with the response received from us, you have the right to lodge a complaint with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, SK9 5AF (www.ico.org.uk).

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of the local research team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting local NHS Patient Advice and Liaison Service (PALS) or equivalent. Members of the local hospital team should be able to provide this information to you.

Every care will be taken in the course of this clinical study. However, in the unlikely event that the patient is harmed by taking part in this research project, there are no special compensation arrangements. If the patient is harmed and this is due to someone's negligence, then they may have grounds for a legal action for compensation against the NHS Trust where they are being treated but they may have to pay for their legal costs. The normal National Health Service complaints procedures should be available to them.

Thank you for taking the time to read and consider this information sheet. Should you decide that the patient can take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.

RESTART tICrH

<Trust/Site address 1>
<Trust/Site address 2>
<Trust/Site address 3>
<postcode>
Tel: <telephone number>

FOR SITE USE ONLY:

Site Name:																			
Participant Study Number																			
Participant Initials:				Participant DOB:			/			/									

Professional Legal Representative Consent Form

To be completed by the professional legal representative:

Once you have read and understood each statement please enter your initials in each box.	Initial
1. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.	
2. I understand that participation is voluntary and that I am free to withdraw my patient from the study at any time, without giving a reason, and without their care or legal rights being affected. However, the study team may need to collect some limited information for safety reasons.	
3. I agree for my patient to take part in the above study.	
4. I give permission for a copy of this fully completed consent form to be sent to the LCTC (where it will be kept in a secure location) to allow confirmation that my consent was given.	
5. I understand that relevant sections of my patient's medical notes and any data collected during the study may be looked at by authorised individuals from the central study team and representatives of the Sponsor, regulatory authorities and the local NHS Trust. I give permission for these individuals to have access to my patient's records and data.	
6. I agree to my patient's GP being informed of their participation in the study.	
7. I agree for my patient's routine care CT scans (which will contain name, NHS number and date of birth), study data and a copy of this consent form to be transferred to the University of Plymouth and for The University of Plymouth to store CT scan images anonymously to be looked at in future research studies	
8. I agree for the relevant data on my patient's NHS hospital admissions and treatment to be collected for the purposes of this study and understand this will include accessing electronic NHS health care records from NHS England for the financial years commencing 6 months before the start of the study and covering the duration of the study, for health economic analysis **(for England only)**.	
9. I agree for my patient's personal data (including name, postcode, date of birth, NHS number) and a copy of this consent form to be shared with NHS England so they can provide Health Economic researchers working on the study with information regarding my patient's medical data and hospital attendances **(for England only)**.	
10. I understand that my patient's data will be kept by the Data Controllers and all others archiving data and at my patient's hospital in a confidential manner for 25 years from the end of the study.	
The statements below are **optional** (your patient can still take part in the study even if you do not wish to agree to these):	
11. I agree to allow information and data or results arising from this study to be used in future healthcare and/or medical research providing my patient's confidentiality is maintained.	
12. I agree that my patient may be contacted to take part in the optional interviews to ask about their experiences of being in the study should they regain capacity. (if you agree to this statement provide your patient's details below):	

NHS number:												
Postcode												

Telephone number:													
Email address:													

RESTART tICrH

<Trust/Site address 1>
<Trust/Site address 2>
<Trust/Site address 3>
<postcode>
Tel: <telephone number>

FOR SITE USE ONLY:

Site Name:																				
Participant Study Number																				
Participant Initials:				Participant DOB:			/			/										

13. I agree that my patient may be contacted in the future in relation to this or other related studies.
(if you agree to this statement provide your patient's details below):

Telephone number:												
Email address:												

To be completed by the Professional Legal Representative

Your patient's full name (please print)			
Your full name (please print):			
Your signature:		Date:	

To be completed by the Researcher (after professional legal representative has completed the form):

Researcher full name (please print):			
Researcher signature:		Date:	

Please file the original wet-ink copy in the RESTART tICrH Investigator Site File, and make three copies: one for the participant, one for the medical notes and one to be sent to the LCTC.

To be completed by the Impartial Witness (only if the legal representative is unable to sign the consent form):

Witness full name (please print):			
Witness signature:		Date:	
Participant's full name (please print):			