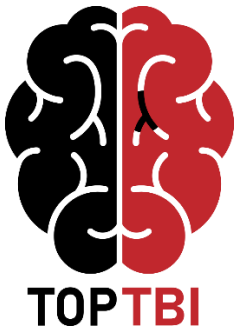
PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

CCTU/TPL002V11 Approved 03/10 /2022 Reviewed 03/10 /2022



Timing Of venous thromboembolism Prophylaxis for adult patients with Traumatic Brain Injury (TOP-TBI): a pragmatic, randomised trial

You are reading this because a member of our team has identified you as someone who has had a traumatic brain injury, or someone you care about has had a traumatic brain injury. We are a group of researchers who are inviting adults who have suffered a head injury, to join this research study that compares early initiation of blood thinning medications (within 72 hours from injury) to late initiation (deferred by a minimum of 120 hours from injury).

This information sheet gives you a detailed information about the study including the aims, risks and benefits of taking part.

In this information sheet, we use the words “I” and “you” referring to the trial participant. Some people in this trial may be unable to read this document themselves or complete the consent form. In that case, a relative/friend can complete the form on their behalf, however the words “I” and “you” still refer to the trial participant and not the person completing the form.

Please let us know who will complete this consent form:

☐ The participant

☐ A relative or friend (Personal Legal Representative)

☐ An independent healthcare professional

You are being invited to take part in a research trial. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the trial if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 tells you the purpose of this trial and what will happen to you if you take part.
Section 2 gives you more detailed information about the conduct of the trial.

Section 1: Purpose of the trial and what will happen

1. What is the purpose of the trial?

A traumatic brain injury (TBI) is a brain injury that occurs when an external force causes damage to the head. These injuries are common and are usually caused by falls, assaults, road traffic accidents and mishaps at home etc. Suffering a TBI increases your chance of developing blood clots in your veins (VTEs). These VTEs complicate recovery from TBI, lead to long-term reductions in quality of life, and can occasionally be fatal. Doctors typically start blood thinning medication to reduce the chances of blood clots forming in patients who have suffered a TBI, as evidence suggests that it can improve patients' long-term function outlook and quality of life.

National UK guidelines recommend starting blood thinning medication within 14 hours of hospital admission, and this has significantly reduced the number of deaths due to VTE during the hospital stay and up to 90 days from discharge. However, some doctors worry that blood thinning medication could increase the risk of further bleeding in the brain, especially soon after injury. This leads to some doctors withholding blood thinning medications from TBI patients for a prolonged period of time (e.g., 5 days). However, studies following TBI patients over a period of time found that those who had received blood thinning medication within 72 hours did not have an increased risk of further bleeding compared to those who received it later. This leads to other doctors starting blood thinning medication for TBI patients within 72 hours of injury.

This study is designed to compare the timing of blood thinning medication and to guide the best practices in the future for initiating blood thinning medication to reduce the rate of blood clots, without introducing complications from further bleeding. In this trial, we will be

testing the early initiation of blood thinning medications (within 72 hours from injury) to late initiation (deferred by a minimum of 120 hours from injury).

If you agree to take part in the trial, you will be allocated into one of the two study groups. The “early” group will commence blood thinning medication within 72 hours from injury, while the “late” group will have their blood thinning medication deferred by at least 120 hours from injury or not administered as per clinical decision. Allocation to either “early” or “late” group will be done in a random way by a computer and not by a member of your clinical care team so the chance of being in either group is 50%.

The rest of the medical treatment and care of patients will not change from usual clinical practice. It is important to understand that the doctor has no influence on whether you are randomised to the “early” group or the “late” group and if you agree to participate it means that you accept the decision to be allocated in either group in a random way. Randomisation is important because it makes sure that every person has an equal chance of being in any of the two groups, and makes the results fair.

You are then followed up with regular assessments and you will be seen by the hospital/ doctor/ care team regularly to have some tests and to see how you are feeling.

2. What is the drug being tested?

A number of different blood thinning agents may be used in this study and the choice you receive will be determined by clinical suitability (as determined by the doctor managing your care) and local availability. All the agents used will be approved in the UK and by the local hospital treating you. As with all medications, there are risks and potential side effects. Please see section 9 below.

3. Why have I been invited?

You are being invited to participate in this study because you have suffered a TBI, and blood thinning medications are a suitable treatment to reduce your risk of developing a VTE. We plan to include 1,512 participants who have had a TBI in 25 UK National Health Service (NHS) hospitals designated as trauma-receiving hospitals (Major Trauma Centres in England).

4. Do I have to take part?

Participating in this trial is completely voluntary. If you decide to participate you will be asked to sign an Informed Consent Form, however you are still free to change your mind and leave the trial at any time without giving a reason. However, it can be helpful to understand why because it can help the trial to reach conclusions that are more reliable when the team analyse the data at the end of the trial or may inform the design of future trials. If you chose not to participate or to leave the trial, your future medical treatment and normal standard of care will not be affected in any way.

What will happen if we lose contact with you*?*

If the trial team is unable to reach you after 8 weeks to complete the follow up questionnaires they may contact your GP to check on your health and to find out if you still wish to continue with the trial follow up assessments.

If you choose to take part in the trial but later choose to withdraw, we would still like to collect information about your treatment (e.g. hospital admissions, occurrence of blood clots) as this will be invaluable to our research. This information can be collected from your GP or from other national health care records (NHS England, or the Scottish, Welsh, or Northern Irish equivalents). If you have any objection to this, please let your doctor know. Data already collected prior to withdrawal will be kept and analysed.

5. What do I need to know before I take part in this research?

You will be approached to take part in this trial as part of a “screening visit” within the first 3 days of your injury. During this visit, your doctor will first check your eligibility by checking your medical records and asking relevant questions. Once your doctor has confirmed that you are potentially eligible for the trial, you will be invited to participate, and you will be provided with a copy of this information sheet and will be given the opportunity to discuss the study with a member of your local clinical team. You will be given time to decide whether you wish to participate in the trial. During this time, you may want to discuss this with your friends or family.

If you decide to take part you will be asked to sign a consent form and you will be given a copy to keep. After all your trial investigations have been received and your eligibility for the trial has been confirmed, you will be randomly allocated to either the “early” group or the “late” group and will be allocated a trial number.

If you were not able to give informed consent when you arrived in hospital, we may have invited a personal legal representative to consent on your behalf, until you were able to do so. This person would have been either:

• A relative or friend

• A court appointed deputy who has a personal relationship with you

• An Independent Healthcare Professional nominated by the researcher, in the absence of one of the above, and who is suitably independent of the research trial

6. What will happen to me if I take part?

Your trial treatment will start in the hospital and will continue until hospital discharge. You will receive the medication via an injection into your skin or orally in a tablet form. The dose will be decided by your doctor in line with normal prescribing practices and NICE guidelines (clinical guidance recommendations used in the NHS). It is important that the medicine is taken correctly and must not be stopped or changed, without consulting your doctor or the study team first. If you experience any complications during the trial, you will receive the standard care for your condition. Your doctor may decide that it is in your best interest to change your treatment, including changing your medication, at any time. You will also be asked to complete questionnaires on day 30/discharge and at 6 and 12 months – these may be completed by post, email or via telephone.

There will be no additional hospital visits required as a result of trial participation other than the standard of care hospital visits related to your injury.

Your trial participation, including follow-up assessments, will take 1 year from start to finish.

Assessments

To assess your recovery, the study team will contact you after you leave the neurosurgical unit and they will ask you to fill in a short questionnaire pack which will be sent by post to your home address (or with your permission they will email them to you if preferred). You will be asked to complete these questionnaires at 30 days (or discharge if your inpatient stay exceeds 30 days), 6 months and 12 months after your initial injury asking about your current state of health. You may complete the questionnaires either by yourself or with the assistance of a relative/friend. You may bring the completed questionnaire with you when you attend routine clinical outpatient appointments, or you may send it to the local study team by post. You may also be able to complete the questionnaires electronically via email

or using online formats such as Qualtrics. If we do not receive a completed questionnaire, we may telephone you or your relative, to complete them over the phone.

Following your discharge from hospital, we will contact you at three months, 6 months and 12 months to ask you about your current health and any potential side effects of the trial drug. We may also contact your GP, local hospital, or rehabilitation centre for information regarding your recovery. If you would prefer to answer the questionnaire over the phone or require the questionnaire in another format (e.g., different language, large print), please let us know. The questionnaire pack should take 20 minutes to complete each time. **We ask you to report any clots you experience over the next 12 months to your GP and a member of our research team. This is the only commitment between assessments.**

7. What will I have to do?

You will not be asked to undertake any interventions in addition to the standard care you would normally receive from your doctor. You will need to take the study medication as directed by your doctor until hospital discharge or a clinical decision to stop. It is important that you fill in the questionnaires when these are sent to you.

You should tell the trial team if you feel unwell or different in any way. If you have any major concerns or are feeling very unwell, please contact your trial doctor immediately using the contact numbers at the end of this information sheet.

You should discuss your participation in this trial with any insurance provider you have (e.g., travel insurance, protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate your cover.

8. What are the potential benefits?

There is no guarantee that you will benefit from taking part in this trial. The timing of initiating the blood thinning medication following TBI may prevent you from developing a clot without introducing complications from further bleeding. As a consequence of your participation in the trial you may be seen more often and/or feel more supported. Information gained from this trial may help improve treatment for adults with TBI in the future.

9. What are the possible risks?

As with any intervention, there are risks and complications, but there are no additional disadvantages or risks involved in taking part in this trial. Both of the timings used to initiate blood thinning medications are used by doctors to prevent clots following TBI already.

The medication to be used in the trial and the timings of giving the medication are routinely used by doctors to prevent blood clots following TBI. Thus, being part of the trial does not subject you to any additional risks that you are not already subject to as part of routine clinical care. The main risk when starting this blood thinning medication (for all patients even if they are not involved in the trial) is potentially causing the brain bleed to get worse. This can happen to patients in the early group and in the late group. However, the evidence from studies so far has shown that starting these medications does not increase the risk of further brain bleeding. None of the timings are experimental, but at present there is not enough information to determine which timing of initiation is most suitable and provides the highest level of health benefits to an individual.

Possible side effects:

The most frequently reported side effects associated with blood thinning medication are:

- Injection site reactions such as redness, irritation, and bruising
- Heparin-induced thrombocytopenia (low platelet count)
- Bleeding

Other possible side effects associated with blood thinning medication are:

- Headache
- Dizziness
- Sleep problems
- High blood pressure
- High potassium
- Mood changes
- Decreased bone mineral density
- Liver problems
- Nausea, vomiting

More information about the specific treatment you will receive can be provided by the medical team treating you

In the unlikely event of you experiencing any serious unforeseen reactions, or if any concerns arise, the drug will be stopped immediately. Your doctor will carefully monitor all of your medicines to check for any possible interactions. If something goes wrong while you are taking part in this Trial, your local clinical team will do everything they can to look after you and will make sure you are closely supervised while taking part in the trial.

If you withdraw from the trial due to side effects of the trial medication, your doctor will decide which alternative treatment is best for you. You will still be able to continue with the follow-up questionnaires if you wish to and / or agree for the research team to continue collecting data relating to your health (such as hospital admissions) from NHS England, which would not require any involvement from you, if you agreed

10. What are the alternatives for treatment?

The alternatives for treatment are routine standard care at this hospital. A variety of mechanical compression methods exist to reduce the risk of clots for trauma patients: graduated compression stockings, pneumatic compression devices, foot pumps, and neuromuscular electrical stimulators. You will also be able to benefit from these mechanical methods if you participate in the trial as they can be used as part of the standard care for your condition.

11. What happens when the trial stops?

Once treatment with the study drug has finished, you will continue to be treated and managed as per the routine standard of care at your hospital.

12. Expenses and payment?

You will be monitored whilst in the hospital as per normal clinical practice. Thereafter, we will contact you by post, email, telephone or at a routine outpatient visit. If we ask you to complete a postal questionnaire, we will send a pre-stamped addressed envelope for the reply. You will not receive any payment for participating in this study and we do not anticipate you will incur any expenses by participating in this study.

Section 2: Trial Conduct

13. What if new information becomes available?

Sometimes the research team will receive new information about the treatment being studied. If this happens, your trial doctor will inform you and discuss with you whether you should continue in the trial. If you decide not to carry on, your trial doctor will make arrangements for your normal care to continue. If you decide to continue in the trial, he/she may ask you to sign an updated consent form. It is possible that your trial doctor might suggest you withdraw from the trial. He/she will explain the reasons and arrange for your care to continue. If the trial is stopped for any other reason, your local clinical team will inform you and arrange your continued care. **What if I decide I no longer wish to participate in the trial?**

You are free to withdraw from this trial at any time without giving a reason and without affecting your future standard of care or medical treatment. If you decide not to participate any further, you will only need to inform your doctor and he/she will withdraw you from the trial. If you do not wish to carry on with the trial, you will be offered the local NHS standard of care and followed by NHS follow up visits. Any data already collected or results from tests already performed on you will continue to be used in the trial analysis. This data is recorded 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.

We would still like to collect information about your health and treatment you may receive, including from NHS England data, as this will be valuable to our research. If you have any objection to this please let your doctor know when you decide to withdraw from the trial.

The trial doctor may also choose to withdraw you from the trial if they feel it is in your best interests or if you have been unable to comply with the requirements of the trial.
Reasons for trial withdrawal could include:

- You have experienced a serious side effect
- You are unable to complete the visits, medication or trial documentation as required

If you have experienced any serious side effects during the course of the trial which require you to withdraw from the trial, your trial doctor will follow-up with you regarding your progress until the side effect has stabilised or resolved.

14. What if there is a problem?

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this

trial, you should ask to speak with the trial doctor who will do their best to answer your questions (see contact number at end of form).

If you remain unhappy and wish to complain or have any concerns about any aspect of the way you have been approached or treated during this trial, you can also do this through the NHS complaints procedure. You can do this through your hospital's Patient Advice and Liaison Services (PALS). Details can be obtained through your local clinical team.

In the event that something does go wrong and you are harmed by taking part in the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust or the University of Cambridge. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). The University has also obtained insurance which provides no-fault compensation i.e., for non-negligent harm, you may be entitled to make a claim for this.

15. How will we use the information about you?

Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge are the Sponsors for this clinical trial based in the United Kingdom. We will be using information from you, your medical records, and your GP in order to undertake this trial. This information will include:

- Your name
- Initials
- Gender
- Date of birth
- NHS number (if you have one or obtain it while participating to the trial)
- Contact details (full address, telephone, email) to send you follow up questionnaires and to contact you by telephone
- Hospital admissions and imaging

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

The trial team would like to l collect additional healthcare information, such as admission to a hospital, from other national organisations as described below. In order to identify and obtain information about you from these organisations we will need to collect and send

personal identifiers (name, sex, date of birth, postcode and your NHS/CHI number) to them. All data collected in this way will be stored on secure and encrypted servers held within the University of Cambridge and will be accessible only to the small team of researchers directly involved with the study. We will need to retain this data for the duration of the study and then archive it for up to 5 years or in accordance with the relevant clinical study regulations and legislation in force at the current time. The data will then be destroyed.

Data will be collected from these registries:

1. NHS England – this is a national provider of information on healthcare in the UK and links this information to the databases below:

- Hospital Episode Statistics (HES) - The NHS in England collects information on all hospital admissions, including when, why and for how long they happen. By collecting information from HES, it means that we can use the information the NHS already holds rather than having to ask patients to attend hospital for extra study visits. This information will be used in the study to help provide some of the results for this trial.
- Civil Registration of Death - In the unfortunate event that a person dies, this information is obtained from civil registration mortality data by the NHS England. Because it is important for us to know what happens to patients in the study, NHS England will provide the study team with any information they might have on participants in the study.

2. Equivalent national health record organisations exist in Wales (Secure Anonymised Information Linkage, Public Health Wales – SAIL), Scotland (electronic Data Research and Innovation Service, Public Health Scotland – eDRIS) and Belfast Health and Social Care Trust. If you live in these areas, the study team will obtain similar central healthcare records from these sources.

Once the data has been linked and collected, your personal identification details will be removed for analysis.

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 (trial number or screening number). The people who analyse the information will not be able to identify you and will not be able

to find out your name, NHS number or contact details. We will keep all information about you safe and secure

. You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-participants/
- our leaflet available from www.hra.nhs.uk/participantdataandresearch. Alternatively, please visit:
    - for Cambridge University Hospitals NHS Foundation Trust: https://www.cuh.nhs.uk/participant-privacy/
    - For University of Cambridge: https://www.medschl.cam.ac.uk/research/information-governance or email The Information Governance team at: researchgovernance@medschl.cam.ac.uk
- by asking one of the research team refer/to/add contact details
- by sending an email tocuh.gdpr@nhs.net, or
- by ringing us on [**phone number**].

Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge will act as the data controllers for this trial. This means that they are responsible for looking after your information and using it properly. Once we have finished the trial, we will keep some of the data so that 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 trial. Your rights to access, change or move your information are limited, as the Sponsor organisations need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally identifiable information possible.

De-identified information about your health and care relevant to this trial may be made available for other research studies run by CUH and/or the University of Cambridge or other organisations. These organisations may be NHS or other public sector organisations, academic institutions, charities and commercial companies in the UK or abroad. Before your data is shared with other organisations all personal identifiers, such as names, addresses and dates of birth, will be removed. Making information from trials available for further research helps maximise the benefit of conducting trials and allows other researchers to verify results and avoid duplicating research.

All information collected about you because of your participation in the trial will be kept strictly confidential and will only be accessible by authorised personnel. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence. The only individuals from the Sponsors and regulatory organisations who will have access

to information that identifies you will be people who manage the trial or audit the data collection process. It may be necessary to allow authorised personnel from government regulatory agencies (e.g. Medicines and Healthcare products Regulatory Agency (MHRA)) and/or NHS bodies to have access to information about you. This is to ensure that the trial is being conducted to the highest possible standards.

Images will be stored at Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge, and then reviewed by experts in the UK or internationally. All identifiable information will be removed before transfer from the acquiring site. Your images will only be identified via your trial number (or screening number) and the date of acquisition. Expert doctors will have access to your de-identified data to perform their review.

With your permission, your trial doctor will notify your GP that you are participating in the trial. Your GP will be sent a copy of this information sheet and a copy of your signed consent form. This communication is intended to ensure this information goes in your GP medical records. If you are transferred to a local hospital or rehabilitation centre, your doctors may contact the trial team to let us know where you are. The NHS will use your name and contact details to contact you about the research trial/send documents to you, and make sure that relevant information about the trial is recorded for your care, and oversee the quality of the trial. Under no circumstances will you be identified in any way in any report, presentation or publication arising from the data collected. Only anonymous trial data, without any personal information, will be published at the end of the trial. We will write out reports in a way that nobody can work out that you took part in the trial.

16. How will the results of the trial be published?

The results of the trial will be anonymised and presented in a way that individual participants cannot be identified. When the results of this trial are available, they may be published in peer reviewed medical journals and used for medical presentations and conferences. They will also be published in an approved, publically accessible online Clinical Trials Register. The results of the trial will be anonymised and you will not be able to be identified from any of the data published The research team will also write a summary of the results to charities to disseminate study results to the members of the public.

Anonymous datasets from the trial may also be made available to other researchers in line with national and international data transparency initiatives. Should you wish to discuss the results of the trial, you should contact your trial Doctor; you will have the opportunity if you wish to be informed of the results of the trial once fully analysed. If you would like to obtain a copy of the published results please contact your trial doctor directly who will be able to arrange this for you.

17. Who has reviewed this trial?

This is a non-commercial clinical trial funded by the National Institute for Health Research (grant number: NIHR152722). Potential participants were involved in reviewing the Participant Information Sheet. In designing this trial, we have taken into account patient opinions on the frequency of participant visits and the tests that will be carried out.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This trial has been reviewed and given favourable opinion by the (give name of the REC). The Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK have also reviewed this trial. While the trial is ongoing, the results will be reviewed by a Trial Steering Committee (TSC) to ensure that it is appropriate to continue with the trial.

18. Further information and contact details

If you have any questions or concerns about your disease or this clinical trial, please discuss them with your doctor or nurse. You can get in touch with the doctors and nurses to discuss any doubts or worries you may have about the trial. Contact details are shown below:

Trial Doctor: Dr (xxxxxxx) Tel: (xxxxxxx)

In the event of an emergency please contact:

Research Nurse(s) (insert name) Tel: (insert number)

Hospital Details (insert name and address of hospital)

INFORMED CONSENT FORM – TOP-TBI

ADULT PATIENT

Trial Title: Timing Of venous thromboembolism Prophylaxis for adult patients with Traumatic Brain Injury: a pragmatic, randomised trial **(TOP-TBI)**

Principal Investigator: [Printed name to be inserted]

Participant Number: _____

	If you agree with each sentence below, please initial the box	**INITIALS**
1	I have read and understood the Participant Information Sheet version 1.1, dated 27/11/2024 for the above trial and I confirm that the TOP-TBI trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected, and that any data already collected or tests already performed will continue to be used in the trial as described in this information sheet	
3	I understand that personal information about me will be collected during the trial and from my medical records, GP and NHS England and used in accordance with this information sheet. This information will be kept in the strictest confidence and I will not be identifiable in any results published.	
4	I understand that research personnel, responsible individuals from the sponsor and regulatory authorities, may look at sections of my medical notes or information related directly to my participation in this trial where it is relevant to my taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
5	I understand that de-identified information collected about me may be used to support other research in the future, including research conducted by both commercial and non-commercial organisations in the UK and abroad.	
6	I understand that my name, gender, date of birth, postcode, and NHS/CHI number will be used to access my central healthcare data that are held and maintained by the national health record organisations described in section 6 (Assessments) to provide information about my health status as part of this trial. I understand	

	that, if I live in Wales, Scotland, or Northern Ireland, this information will be obtained from the equivalent sources described.	
7	I understand that my personal data might be transferred between the trial team at different trial sites in relation to my participation in this trial. I understand that any personal data will be sent using secure/encrypted mail servers etc.	
8	I understand that my GP will be informed of my participation in this trial and sent details of the TOP-TBI trial.	
9	I have read and understood the compensation arrangements for this trial as specified in the Participant Information Sheet	
10	I understand that the doctors in charge of this trial may close the trial, or stop my participation in it at any time without my consent.	
11	I understand that if the trial team loses contact with me, they will try to contact me or my next of kin by telephone, and they may also contact my GP, local hospital, or rehabilitation centre to find out about me	

I agree to participate in this trial

_____	_____	_____
Name of patient	Signature	Date

For trial team use only:

_____	_____	_____
Name of person taking consent	Signature Date	Date

Time of Consent (24 hour clock): _____:_____

1 copy for the patient, 1 copy for the trial team, 1 copy to be retained in the hospital notes, 1 copy emailed to **cuh.top-tbi@nhs.net**

INFORMED CONSENT FORM – TOP-TBI

Personal Legal Representative

ADULT RELATIVE/FRIEND

Trial Title: Timing Of venous thromboembolism Prophylaxis for adult patients with Traumatic Brain Injury: a pragmatic, randomised trial **(TOP-TBI)**

Principal Investigator: [Printed name to be inserted]

Participant Number: _____

	If you agree with each sentence below, please initial the box	**INITIALS**
1	I have read and understood the Participant Information Sheet version 1.1,27/11/2024 for the above trial and I confirm that the trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my relative/friend's participation in this trial is voluntary and that they are free to withdraw/ be withdrawn at any time, without giving a reason and without their medical care or legal rights being affected. Any data already collected or tests already performed will continue to be used in the trial as described in this information sheet.	
3	I understand that personal information about my friend/relative will be collected during the trial and from their medical records, GP and NHS England and used in accordance with this information sheet. This information will be kept in the strictest confidence and none of their personal data will be published.	
4	I understand that sections of my friend/relative's medical notes or information related directly to their participation in this trial may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to their taking part in research and that they will keep their personal information confidential. I give permission for these individuals to have access to their records	
5	I understand that de-identified information collected about my friend/relative may be used to support other research in the future, including research conducted by both commercial and non-commercial organisations in the UK and abroad	
6	I understand that my friend/relative's/ name, gender, date of birth,	

	postcode, and NHS/CHI number will be used to access their central healthcare data that are held and maintained by the national health record organisations described in point 6 (Assessments) to provide information about their health status as part of this trial. I understand that, if they live in Wales, Scotland, or Northern Ireland, this information will be obtained from the equivalent sources described.	
7	I understand that my friend/relative's personal data might be transferred between the trial team at different trial sites in relation to their participation in this trial. I understand that any personal data will be sent using (secure/encrypted mail servers etc).	
8	I understand that my relative's/friend's GP will be informed of their participation in this trial and sent details of the TOP-TBI trial.	
9	I have read and understood the compensation arrangements for this trial as specified in the Participant Information Sheet.	
10	I understand that the doctors in charge of this trial may close the trial, or stop my relative's/representee's participation in it at any time without my consent.	
11	I understand that if the trial team loses contact with my friend/relative, they will try to contact me /my relative by telephone, and they may also contact my relative's GP, local hospital, or rehabilitation centre to find out about them	

I agree to my relative/friend participating in this trial:

Name of relative/friend	Signature	Date

Name of patient	Relationship to patient

For trial team use only:

Name of person taking consent	Signature	Date

Time of Consent (24 hour clock): _____:_____

1 copy for relative/representee, 1 copy for the trial team, 1 copy to be retained in the hospital notes, 1 copy emailed to **cuh.top-tbi@nhs.net**

INFORMED CONSENT FORM – TOP-TBI

Independent Healthcare Provider (IHP)

Enrolment form – TOP-TBI

Trial Title: Timing Of venous thromboembolism Prophylaxis for adult patients with Traumatic Brain Injury: a pragmatic, randomised trial **(TOP-TBI)**

Principal Investigator: [Printed name to be inserted]

Participant Number: _____

ALL 5 Questions must be initialled (and the 4 ticks marked) and the form signed to authorise enrolment		Initial Box
1) I confirm that the participant's next of kin is not available for discussion		
2) I confirm that I am independent, defined for this trial as: **A person who is NOT connected with the conduct of the trial**, specifically:	Also tick boxes	
a) NOT the sponsor of the trial;	❑	
b) NOT a person who undertakes activities connected with the management of the trial;	❑	
c) NOT an investigator of the trial, or;	❑	
d) NOT a health care professional who is a member of the investigators team for the purposes of the trial (Not on delegation log)	❑	
3) I confirm that I have been fully informed of the name trial, its objectives and trial procedures and that enrolment of the participant mentioned above in the name trial is appropriate according to my professional medical judgment.		
4) As far as I am aware, the participant would not object to being involved in this trial.		
5) I understand that a member of the research team will provide the next of kin, and the participant (if they regain capacity), with information about the trial as soon as possible and I understand that their agreement will be sought in order to continue.		

Name of researcher	Signature	Date

Name of IHP	Signature	Date

Time of authorisation (24hr clock) _____:_____

1 copy for the IHP, 1 copy for the trial team, 1 copy to be retained in the hospital notes, 1 copy emailed to **cuh.top-tbi@nhs.net**