**A drawing of a brain

Description automatically generated with medium confidenceGraphical user interface, application

Description automatically generatedPROFESSIONAL LEGAL REPRESENTATIVE**

**SHORT INFORMATION SHEET AND CONSENT**

**(Final Version 1.0: 03/11/2021)**

**Title of Study:** TICH-3

**IRAS Project ID:** 297457  **CTA ref:** 03057/0074/001-0001

**Name of Researcher**:

**Name of Participant:**

I confirm that I have been given a copy of the Short Professional Legal Representative Information Sheet (Version 1.0 dated 3/11/2021) and I agree as professional Legal Representative on behalf of this stroke patient

* The patient will take part in the TICH-3 study and be given the study medication
* For their medical records to be accessed
* To be followed up at 6 months
* For their GP to be informed
* For their contact details to be collected and used for the purpose of the study
* For their anonymised research data to be used in further research analysis about ICH.

I understand that they are free to withdraw from the study at any point without giving a reason.

For participants who are enrolled following agreement by a professional legal representative as soon as relatives are available or when the patient regains capacity, a detailed information sheet will be provided, and written consent sought for continuation in the trial.

**Professional nominee consent - to be completed if participant does not have capacity to consent**

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Name of Person giving Date Signature

nominee consent

Relationship to patient (please tick): Healthcare Professional

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# Name of Person taking consent Date Signature

**Telemedicine used** (please tick if Yes)

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Name of Witness if consent taken Date Signature

over the telephone

Does not contain

medicine

Contains medicine

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

You have been asked to act as a professional legal representative to consider if you think that the patient named above should take part in the TICH-3 study.

TICH-3 aims to assess whether the drug tranexamic acid reduces the risk of death and/or improves disability 6 months after stroke due to intracerebral haemorrhage (ICH).

Because intracerebral haemorrhage is an emergency and the potential benefits of the study treatment (tranexamic acid) are likely to be related to how soon after stroke the treatment is given, every minute counts. We need to decide about giving the treatment as quickly as possible. As the patient is not well enough to decide, and no relatives are immediately available you have been asked to decide on their behalf. You are able to make this decision in accordance with emergency consent procedures.

The patient has been identified because they have had a stroke caused by intracerebral haemorrhage - and they fit the requirements for this research project. At present they are not able to tell us whether to take part, so we are asking your opinion. If you do decide they would take part you will be given this information sheet to keep and be asked to sign a consent form. We are inviting approximately 5500 participants with intracerebral haemorrhage to take part from around the UK and worldwide.

Tranexamic acid is approved for use in emergency patients with bleeding after trauma, labour or surgery. The side effects from tranexamic acid are generally mild and can include diarrhoea, low blood pressure and dizziness. Importantly, because the treatment works by stopping bleeding there is a chance it can cause a deep vein thrombosis (DVT) or Pulmonary embolism (PE). However, in previous studies in stroke patients, and in people with emergency bleeding due to trauma, involving many thousands of patients, tranexamic acid at the dose used in this study (2g) was safe and did not increase blood clots.

In this study the treatment (either tranexamic acid or saline) is administered as intravenous infusion through a venous cannula with a loading dose infusion over 10 minutes followed by an infusion over 8 hours.

During the next 7 days members of the clinical and research team will monitor the potential participants condition and record relevant information from their medical notes.

For participants who are enrolled following agreement by a professional legal representative as soon as relatives are available or when the patient regains capacity, a detailed information sheet will be provided, and written consent sought for continuation in the trial.

The participants’ decision to withdraw would overrule the decision of either a professional or relative acting as the legal representative.