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TICH-3 Working Practice Document

Consent Process
No. 005

This document is intended to give guidance on informed consent in the TICH-3 trial, including which documents are to be used at each stage of the process. The study protocol states that "the need for urgent treatment, in an attempt to prevent potentially fatal deterioration means that it would be inappropriate to delay treatment until fully informed consent can be obtained from an incapacitated patient". This document provides guidance on the following situations;

- Patient has capacity to provide consent
- Patient has capacity but time prohibits full written consent
- Patient lacks capacity to give consent
    1. Relative present
    2. Relative not present.
- Patients who regain capacity to consent.

Summary for consent with respect to TICH-3:

1. Consent for the TICH-3 study can be taken by any appropriately trained health professional (doctor or nurse, but NOT administrative staff or healthcare support staff), provided that they have received appropriate training in the trial regimen – particularly the inclusion and exclusion criteria and they can answer all questions that may arise from the potential participant or relative.

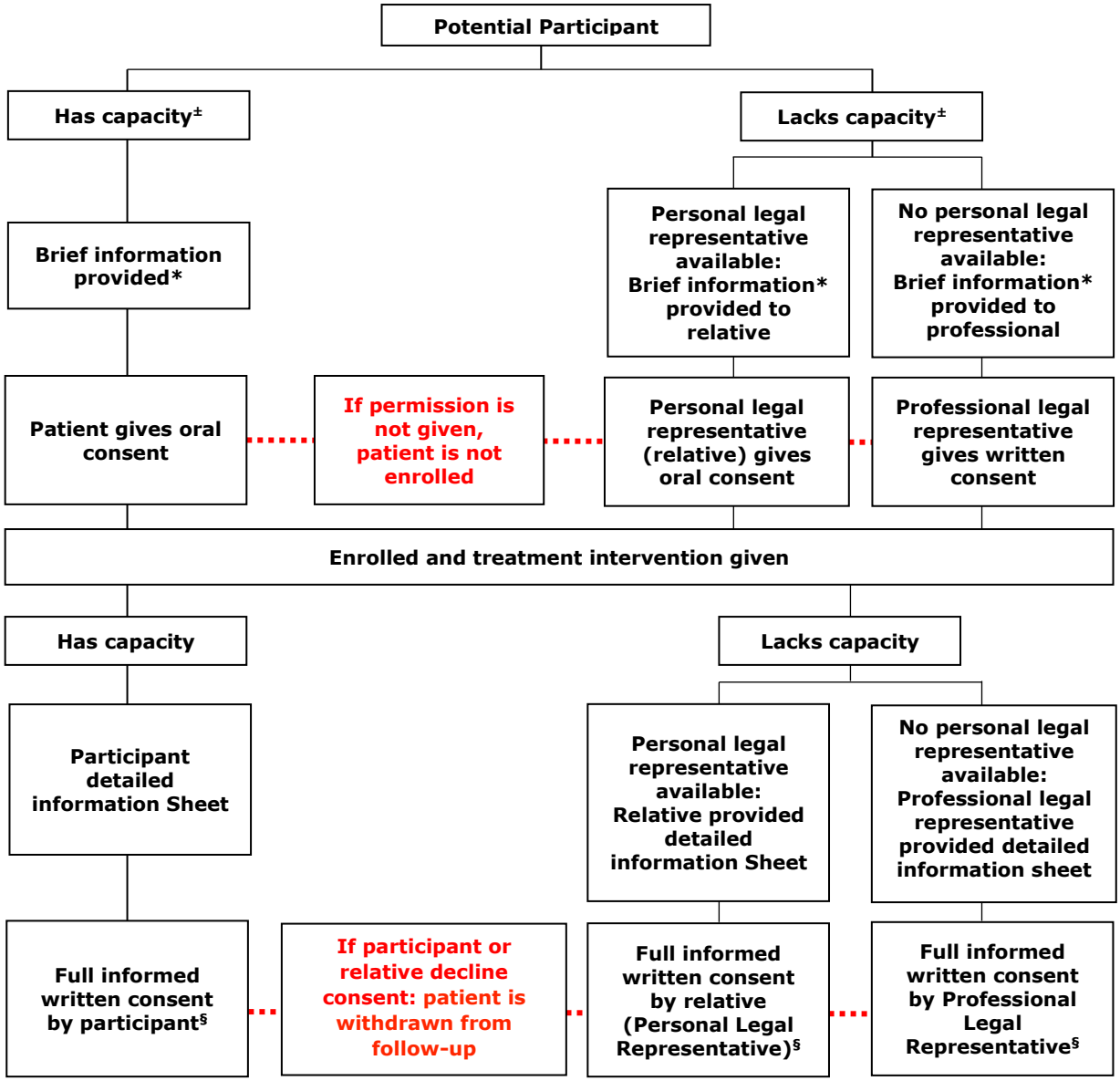
2. All staff that are able to take consent for the trial, must have consent specified on the Site Delegation/Signature Log which needs to be signed/approved by the Principal Investigator. Person taking initial consent must be delegated role J and person taking written consent must be delegated role Z. The PI must decide whether code J should be applied as a delegated role and code Z is assigned to those with relevant investigator roles (not administrators, pharmacists, radiology, etc) and confirmed by the PI.

3. The Principal Investigator (PI), or another appropriately trained researcher who is trained on TICH-3 and is on the site's TICH-3 delegation/signature log, should be available if the patient, relative who is providing proxy consent, or site staff require further information.

4. The PI, or another appropriately trained health professional as defined above should make a comment in the notes on the same or next day that the patient fulfilled the inclusion criteria and that the patient, relative or independent physician, gave consent.

Once it has been decided that the potential participant meets the eligibility criteria, the following consent procedure should be followed, in each situation, using the documents highlighted in bold.

TICH-3 Consent Process



±Assessment of capacity is the responsibility of the treating clinical team.
*Further written information provided if requested or required and questions answered. Independent doctor will sign at this stage.
§If the patient dies before written consent can be obtained, the participant data collected to date is utilised – to exclude this data would introduce bias in the trial.
$If the patient does not regain capacity and has to relatives, the participant data is utilised – to exclude this data would introduce bias in the trial.

Consent flow chart version final 1.0 09.11.21