Form for participants who are not able to give written informed consent – Best Interest

Lay title:	A pilot study of the MAnagement of Systolic blood pressure during Thrombectomy by Endovascular Route for acute ischaemic STROKE (MASTERSTROKE Trial		
Short title	MASTERSTROKE		
Locality:	**Auckland City Hospital**	Ethics committee ref.:	**18NTB55**
		Local Project number:	**ADHB 7773**
Lead investigator:	**Dr Douglas Campbell**	Contact phone number:	**3757095**

PARTICIPANT INFORMATION - Investigator to complete	
Name of participant	
Participant **Number (if applicable)**	
What is the nature of the participant's **inability** to give own written informed consent?	The participant has suffered an acute ischaemic stroke and will be undergoing endovascular thrombectomy. These patients may be confused and disoriented in time and space and thus not competent to make an informed choice and give informed consent.
Note that as far as possible the wishes of the participant should still be taken into account in making the decision to be as to whether enroll them in this study	

1. ***BEST INTEREST***		
Due to the patients inability to provide own consent at this point in time and in accordance with NZ law and code of right 7 (4), the participant may be treated without signed consent, provided that the treatment is clearly in their best medical interests. Progress to Step 2	**YES** ☐	**NO** ☐

2. ***PROCEDURE FOR TREATMENT WITHOUT CONSENT***		
Is there a family member(s) to consult regarding what the participant would have wanted done in this situation (or, if there is no suitable family member, a friend of the participant, or other person such as their GP who is familiar with their medical wishes)? Whenever possible provide family with a brief overview of what is happening.	**YES** ☐	**NO** ☐

If YES, fill in the three lines immediately below before completing the remainder of this form and then progress to Step 3.

Name of family member of friend consulted ………

Views of family/friend consulted: ……

……

(please also document this in the patient clinical notes)

Date and time of discussion ……
If NO, the participant may be treated without signed consent, provided that the treatment is clearly in their best medical interests. In that case progress to Step 3.

3. ***INDEPENDENT CLINICIAN CONFIRMATION***	
A second opinion from another clinician (who is not directly involved in the study) should confirm that it is in the participant's best interests to be enrolled in the study. **Please insert below the name and signature of the independent clinician affirming study participation is in the participant's best interest and then proceed to Step 4.**	
Name of independent clinician (please print)	
Signature	Date
If it is not possible to obtain a second opinion please state why before proceeding to Step 4.	

4. ***INVESTIGATOR ASSESSMENT***	**YES**	**NO**
I believe that the inclusion of the participant in the research project would be in the best interests of the participant.	☐	☐
In forming this view in relation to the best interests of the participant, I have taken into account:		
a) the **wishes of the participant**, so as far as they can be ascertained	☐	☐
b) the nature and degree of any **significant benefits, discomforts and risks** to the participant in participating in the research project	☐	☐
c) **any other consequences** to the participant if they do or don't participate in the research	☐	☐
I have no reason to believe that including the participant in the research project would be against their wishes.	☐	☐
As a study investigator I will *ensure that families members are kept up to date with what is happening in regard to the trial and when the patient has become stable that both the patient and family are given the opportunity to ask questions and offer ongoing agreement to continue in the study.* as soon as reasonably practicable of:		
a) the participant's inclusion in the research project; and	☐	☐
b) the option to refuse consent for participation to be continued and withdraw the participant without compromising the participant's ability to receive any available alternative treatment or care.		

Name and signature of the investigator who is confirming participant eligibility

Name of Trial Investigator (please print)

Signature _____ Date _____

The investigator must also ensure that a copy of this document forms part of the participant's clinical records

5. ***PATIENT REGAINS CAPACITY TO CONSENT***
If/when the participant subsequently regains the capacity to give written informed consent (e.g. post-treatment), they should do so using the ***Provision for follow-up****.*