Initial Questionnaire

Principal Investigator: Dr Michel Shamy

OHSN-REB Number: 20230286-01H

Dear Participant,

We are conducting a research survey to explore the willingness of patients at risk of stroke to participate in a trial using *advance consent,* where we ask for patient permission to take part in a study before they're eligible. We would greatly appreciate if you took 5 minutes to answer the following 8 questions.

Researchers usually try to ask for a patient's permission or consent before including them in a clinical trial. But, because a stroke typically stops a patient from being able to give consent before they are included in a trial, we are looking at methods to get patient consent before their stroke ever happens. Advance consent is one of these methods. It means that a person who could be eligible to participate in a clinical trial in the future if they ever were to have a stroke, could give consent before they have had their stroke, when they are feeling well and have had time to think it over and ask questions.

For example, a physician has identified that their patient is at risk of a stroke. She tells the patient about this risk, but she also informs the patient that there is an ongoing clinical trial testing a new treatment that could potentially be beneficial to the patient if, for whatever reason, they do have a stroke within the next year. The doctor discusses the details of the clinical trial with the patient; the patient is then asked if they would be interested in enrolling for this clinical trial if they did suffer a stroke in the future and become eligible.

Before we begin, we would like to know about your experiences with clinical trials so far. A clinical trial is one of the ways doctors determine if a new treatment is safe and effective.

_Participant ID: ____

1. Have you ever been approached to participate in a clinical trial?
    a. Yes
    b. No
2. If so, how many times?
    a. _____

Version Date: 1st June 2023

3. How much do you agree with this statement: 'I believe it is appropriate to invite people at risk of stroke to provide or decline consent for participation in a clinical research trial in case they have a stroke.'
    a. Strongly agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly disagree
4. How much do you agree with each of the following statements?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I would give advance consent for participation in a specific acute stroke trial where I knew all the details					
I would give advance consent for participation in acute stroke trials generally, without knowing the specifics of any given trial					

5. [if participants answers 'strongly agree, agree, or neither agree nor disagree' to both questions in Q4, proceed to this question. If disagree or strongly disagree, skip to Q7]

    You were invited to take this survey because you have been identified as being at risk of a stroke.

    Would you be open to the idea of providing advance consent to one of the studies currently ongoing at this hospital?

    a. Yes
    b. No

    Please note that this would function just like an ordinary consent to participate in research. You give your permission to participate in both the treatment as well as any follow-up activities, and research staff may access your health files to gain information to complete the study. However, you would only be included in this study if you become eligible (i.e., have a stroke). If you don't have a stroke, then nothing would happen. Please note that you can withdraw your consent at any time.

Version Date: 1st June 2023

6. You answered Yes to the previous question. Can you tell me what influenced your decision?
   Or
   You answered No to the previous question. Can you tell me what influenced your decision?
7. To which gender do you most identify?
   a. Male
   b. Female
   c. Non-Binary/Third gender
   d. Prefer not to Say
8. What is your age?
   a. 18-29
   b. 30-39
   c. 40-49
   d. 50-59
   e. 60-69
   f. 70-79
   g. 80+

Version Date: 1st June 2023