Information Letter for Volunteers

Study Title: Prospective AI Enabled Acute Ischemic Stroke Infarct Volume Estimation and Intracranial Emergent Large Vessel Occlusion Quantification

User Friendly Title:A Software to estimate the damage caused to brain tissue and blood vessels in stroke patients having blood clot

Dear sir/madam,

This information letter is intended to help you decide about your participation in this clinical study. It describes the study, what you may expect if you decide to take part, and important information to help you make your decision.

* Participating in this study is voluntary – it is your choice;
* If you join this study, you can change your mind and withdraw at any time;
* It is important you understand why and how this study will be conducted so please go through this document carefully;
* You must ask the research staff if you have any questions.
* Your decision not to participate in the study will not affect your future treatment.

Please take time to read this information, and if you like, discuss it with friends or family to the extent necessary to decide about your participation. Contact the Principal Investigator. If you do not understand something or if you need more information. The names and contact details can be found under “Contact Information” below in this document.

Only participate in this study if your questions have been answered sufficiently, and you voluntarily decide that you want to be part of this study.

Thank you for reading this information and for considering your participation.

## What is the purpose of this study?

You are being asked to participate in this study because you had acute stroke. As a stroke patient your doctor might make a MR or CT scan for your treatment. This is an observational study. Only the MRI and CT data with clinical report data generated during the workflow will be collected and used to make software that can help doctors diagnose stroke patients better. This would speed up the process for future patients and help in improving patient outcomes.

## Where will the study be conducted?

KMC Manipal

## Who can take part ?

Patients with clinical diagnosis of acute ischemic stroke who presented to KMC, Manipal will be included.

## Duration of your participation in the study

The duration of the study is until your discharge from the hospital. Additionally, optionally we collect more data at 30 or 90 days from your follow-up visits, if you will have any.

## Who organized and paid for the study?

This study is organized and paid for by Philips India Limited.

## What will happen to you during the study?

No modification to your treatment workflow. Only the MRI and CT data with clinical report data generated during the workflow will be collected.

## What are the steps in the study and what is expected from me?

If the doctor made the MR or CT scans for your treatment, we need your permission through this consent form to use it for developing software that can make the lives of future stroke patients better. For the sake of the study no extra scans will be made, We also need permission to use measurements from your clinical report like time related to stroke occurrence, clinical scores provided by the doctor assessing the patient condition. Additionally scores related to the severity of the stroke.

In case, you are unable to sign, this form will be provided to your legally authorized representative for taking consent and after that the data collection will be done by the hospital personnel. Additionally, the data collection forms have been designed so that no private information is collected.

## Which equipment will be used in this study?

There will be no additional equipment used in this study.

## Can I stop my participation?

You can stop your participation in the study at any time without giving any reasons.

The Principal Investigator may end your participation in the study if the study team or representative consider it is no longer in your interest or in the interests of the study. In addition, the entire study may be terminated for reasons not connected to you personally. The decision to stop your participation in the study will have no effect on the treatment you receive.

**What are the potential risks of participating in the study?**

This is an observational study and no major risks are associated with this study.

If any unanticipated harms occur, please do not hesitate to inform the Principal Investigator about these harms.

## What are the potential benefits of participating in the study?

The following potential benefits are identified:

* There is no direct benefit to you for participating in this study
* By participating in this study, you are contributing to improving the development of technology that can help diagnose stroke patients faster in the future.

It is the view of the Medical Ethics Committee/Institutional Review Board and the research team that the benefits outweigh the risks.

## What are the alternative treatments available?

Your treatment workflow at the department of neurology at KMC, Manipal is not modificated. So, there are no alternate treatments.

**Cost of participating in the study**

There are no additional costs associated with this study.

## Insurance

As this is an observational study, no insurance will be needed for the participant. Philips has a general liability insurance in case of any unforeseen circumstances.

**Compensation**

No compensation will be provided for participation in this study.

## Will there be any additional health care, if necessary, as a result of my participation?

No, this study only observes the routine health care in the hospital.

## Are there any anticipated expenses for participation?

No, this study only observes the routine health care in the hospital.

## Confidentiality

Philips is committed to respect your privacy rights. For further information from a privacy point of view, please consult the privacy notice(s) belonging to this study.

[Privacy notice template - studies (en)](https://share-intra.philips.com/:w:/r/sites/STS20131115093003/_layouts/15/Doc.aspx?sourcedoc=%7BFDA59315-41D0-40D9-AF01-EC8AA6543B85%7D&file=Privacy%20Notice.docx&action=edit&mobileredirect=true).

Information from the study records including your name, address, medical records, results of tests, study results will be kept confidential and will be reviewed only by authorized personnel from the sponsor or their representative, Ethics Committee or regulatory bodies. The data will not be made available to another individual unless you specifically give permission in writing. Information and results from this study may be presented at meetings or published in journals without including your name and personal identifications. No reference will be made in oral or written reports which could link you to the study.

A description of this clinical study will be available on http://ctri.nic.in as recommended by the Clinical Trials Registry India. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## What happens if relevant information about my health status is found during the study?

It is possible that during the study some information is discovered about your medical condition that you were not aware of. If any new information is found during the study relating to your health, then by consenting to the study, you agree to this new information being shared with you. If you do not want to be informed and hence do not agree, you cannot participate as a volunteer in the study.

**Confidentiality of Philips’ confidential information**

During the study you might come across confidential information of Philips. The information brochures, study descriptions, equipment, user manuals, instructions, together with information generated by you during the study, e.g. measurement results, user feedback, is confidential information belonging to Philips. You agree to keep the secrecy and confidentiality of such information and use it only for the purpose of your participation in the study.

**Thank you very much for reading this information letter and for considering participating in this medical study. If you decide to participate you will get a copy of this information letter and a copy of the signed informed consent.**

## Contact Information

If you have any questions about the informed consent process or your rights as a participant, you may contact the Member Secretary of the Kasturba Medical College and Kasturba Hospital - Institutional Ethics Committee at Room 22, Ground floor, KMC Faculty Rooms, adjacent to KMC Administrative Block, Kasturba Medical College, Manipal - 576104. Phone: 0820 29 33522. Timings: 9:00 AM to 5:00 PM.

If you have any questions regarding this study including requests for additional information about the study, please contact the Principal Investigator. In the unlikely event of an injury, please contact the Principal Investigator [prakashini.k@manipal.edu](mailto:prakashini.k@manipal.edu).

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**INFORMED CONSENT for** Prospective AI Enabled Acute Ischemic Stroke Infarct Volume Estimation and Intracranial Emergent Large Vessel Occlusion Quantification

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* I have read and understood the information letter about this study and all my questions have been answered by the Principal Investigator.
* I had sufficient time to consider my participation in this study and I am fully aware that my participation in the study is voluntary.
* I agree to participate in this study and follow the Principal Investigator’s instructions.
* I know that I can decide not to participate or stop my participation at any time without giving any reason for this decision. If I do so, this will not influence any treatment that I am receiving. I understand that there are no consequences if I decide to withdraw.
* I agree to the use of my relevant personal data and research data for the purposes described in the information letter;
* I agree that my personal physician/doctor will be informed about my participation in this study
* I agree that the sponsor's representatives, regulatory authorities and Ethics Committee representatives will be granted direct access to my medical records.
* I understand that any and all information related to the study, including anything in writing and verbally communicated to me is confidential information belonging to Philips. I hereby agree to keep the aforesaid information confidential and use it exclusively for the purpose of deciding on my participation in the study
* I agree to take part in the above study. I confirm that I have received a copy of the Participant Information Sheet along with this signed and dated informed consent form.
* I agree to being informed about new findings/information related to my health and future medical care that are detected during the study.
* I agree that the data from this study may be used in the future for research and development purposes related to Neurology, Radiology projects and diagnose stroke patients faster in future.

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Name (Participant) Signature Date

**Principal Investigator or authorized designee**

I have answered all questions about the study and discussed the meaning and scope of this informed consent and signed it in the presence of the participant.

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Name Signature Date

**Subject's legally authorized representative**

I have been informed about the subject's inclusion in the study, and about all aspects of the study. I agree with the participation of the subject, for whom I’m legal representative, in this study.

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Name Relationship with subject Signature Date

**External Reader**

I have read the informed consent out to the participant in his/her native language (in the presence of an independent witness whose details are set out below) and have answered all questions about the study and discussed the meaning and scope of this informed consent and signed it in his/her presence.

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Name Signature Date

**Independent Witness**

I was present during the reading of the informed consent to the participant in his/her native language and am satisfied that the information was accurately explained and that the informed consent was freely given by the participant.

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Name Signature Date