

## INFORMATION SHEET FOR THE PATIENT - PARTICIPANT

Dear Sir/Madam,

You are invited to participate in a proposed research work entitled, *“To estimate the prevalence of hsCRP in acute ischemic stroke and subtypes”*.

This study will be conducted by the Department of Neurology in collaboration with the Department of Biochemistry at Sir Ganga Ram Hospital (SRGH), New Delhi-110060. This study will involve 150 participants. The details provided in the sheet will apprise you of the research and facilitate your decision-making as to whether you wish to participate in the research study. The study period is expected to be from July 2014 to Dec 2015

### **BACKGROUND:**

A “stroke” happens when blood flow to a part of the brain is interrupted. This blood flow interruption is not uncommon. Usually a blood vessel in the brain gets blocked or it bursts open, leading to consequences like speech difficulty, weakness with inability to move any part of the body, deviation of angle of mouth etc. There are two major types of stroke: ischemic stroke and hemorrhagic stroke. “Ischemic” stroke occurs when a blood vessel that supplies blood to the brain is blocked by a blood clot. “Hemorrhagic” stroke

occurs when a blood vessel wall in part of the brain becomes weak and bursts open, causing blood to leak into the brain. When brain cells die during a stroke, functional ability controlled by that area of the brain is lost. These abilities include speech, movement and memory. How a stroke patient gets affected depends on the site/area where the stroke occurs in the brain and how much the brain is damaged.

CRP is an acute phase reactant synthesized and secreted in the liver after an acute inflammatory stimulus. High levels of hsCRP is a risk factor for, coronary heart diseases (affecting major artery supplying heart muscles), atherosclerosis and 'stroke'. hsCRP contributes to atherosclerosis (fatty substance getting deposited in the inner layer of blood vessel causing narrowing of lumen and blockade) by causing inflammation, increasing plaque size and instability.

#### **NATURE AND PURPOSE OF THE STUDY:**

This is a type of research work which will be carried out on patients with ischemic stroke. hsCRP is an established risk factor for cardiovascular diseases but its studies regarding it's association in patients with stroke are limited especially from India. The study will enable us to get data on Indian population, so that it may help many future stroke patients in India.

**PROCEDURE TO FOLLOW:**

If you allow and wish to participate in this study, you will be examined by a physician, relevant questions asked and a proforma filled. All your test reports will be noted down and stored in a secured manner. A five milliliter blood sample will be collected from you, which will be analyzed for hsCRP level.

**BENEFIT OF PARTICIPATION:**

There is no guarantee that you will '*directly*' benefit from participating in this study. However, *indirectly*, your clinical and investigative evaluation may help your treating doctor to offer more appropriate treatment for you. In addition , your participation in this study may allow the investigators to gain valuable knowledge that may benefit others in the future.

**RISKS OF PARTICIPATION:**

None

**CONFIDENTIALITY AND PRIVACY OF RECORDS:**

The data generated from your participation will be saved and maintained with due confidentiality and privacy by investigators and only authorized persons will have access to it. You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical

examination, investigations and medical history). By signing this document, you will be allowing the research team, investigators, other study personnel, institutional ethics committee and any person or agency required by law to view your data, if required. The information from this study, if published in scientific journals or presented at scientific meeting, will not reveal your identity.

**NUMBER OF PARTICIPANTS:**

The study expects to recruit 150-participants.

**FREEDOM TO PARTICIPATE AND WITHDRAW FROM THE STUDY:**

You shall be required to sign a form for informed consent to participate in the research work, which shall be signed by the treating doctor also. You would be required to sign a copy of information sheet after writing, "*I have been given a copy of information sheet*" which the doctor would keep and another copy will be given to you. You should feel free to ask any questions about research work and treating doctor shall be willing to answer them. If at any moment you decide to withdraw from the study, you shall be free to do so, and by doing so you would not experience any kind of loss in the form of penalty or loss of benefits, which you were otherwise going to receive.

**FOR FURTHER INFORMATION, CONTACT:****1. DR DAVINDER SINGH RANA**

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In situation of any concern/complaint please refer to:

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