SUBJECT INFORMATION AND INFORMED CONSENT FORM

It is a medical study; The following information is very important to you, so please read carefully and ask questions, if any information is unclear.	
Subject ID: l___l___l___l___l___l___l___l___l	
Subject Initials: l___l___l___l	**Date:** _____/_____/_____
Principal Investigator Name & Hospital Address	**Dr. Srinivas Mantha,** Consultant Anesthesiologist & Pain Indo-US Superspeciality Hospital, H.No. 7-1-57/B&C, Shyam Karan Road, Anand Bagh, Hyderabad-500 016, Telangana, India.

INTRODUCTION

You are being invited to take part in a research study self-funded by **Dr. Srinivas Mantha**

The title of this study is **Determinants of Common Carotid Intima-Media Thickness (CCIMT) Measured by Ultrasound Echo-tracking Method in Asymptomatic Individuals**

INTRODUCTION

You are being asked to participate as a volunteer for a clinical research study that has been designed to obtain information about **thickness of inner wall of carotid artery by ultrasound**. Before agreeing to participate in this study, you need to read this form. This form, called a consent form, describes the purpose, procedures, benefits, financial payment, risks and discomforts involved in the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No promises or guarantees can be made about the results of the research study. Please ask as many questions as possible in order to decide whether or not to participate in the study.

You are invited to participate as a volunteer in a clinical research study which is approved by the Ethics Committee. This Informed Consent Document is intended to give you some general background about this clinical research study, as well as to explain what is involved.
If you decide to take part in this study, you will be asked to sign the Informed Consent Form to confirm that you understand the nature of the study and what it involves. Before you decide to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your family Doctor, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part in this research study.

For any trial related queries and in event of any discomfort, you are free to contact the doctors **Dr. Srinivas Mantha** (Ph: 9848011291, email: **smantha@srinivasmantha.com**) or **Dr. Sudha Lakshmi** (Ph: 9849522261, email: **drsudha65@yahoo.co.in**)

Your participation in this research study is entirely voluntary and you may withdraw from the study at any time. If you are not completely truthful with the investigator and study staff regarding your health history, your participation in this study may cause harm to you. You can contact IEC with questions about subject rights. The job of IEC is to review and research to ensure you are safe.

This information sheet is available in English, Hindi, Telugu and Urdu. Please feel free to ask any of the above said language version. This will help you to understand the content better. If any of the method or content in this form is not clear, please ask your doctor.
The participation is voluntary and that they are free withdraw from the study for any reason at any time, without penalty or loss of benefits to which they are otherwise entitled.
By signing this document, you acknowledge having received from the investigator or a qualified clinical staff member of Hospital, information regarding this clinical research study.

PURPOSE OF STUDY

This study is being done obtain information about **thickness of inner wall of carotid artery by ultrasound** which will help in determining risk of developing cardiovascular events (heart attack/stroke, kidney failure etc) in the future and getting help in medical advise to prevent or limit the events by the way of medicines or life-style management.

DURATION OF THE STUDY AND HOW MANY SUBJECTS WILL PARTICIPATE

This study will involve measurement of thickness of inner wall (intima-media) of carotid arteries by placing an ultra-sound probe in the neck on either side approximately. The study is planned to be undertaken in 200 male individuals of either gender aged between 20 to 60 years who are otherwise healthy. The study will consist of one visit and will involve a total period of about one hour.

TO BE IN THE STUDY

You cannot participate in this study if you are currently participating in any other clinical research study of any type. You cannot be in the study if you have history of cardiovascular problems (stroke, heart attack, angina) or if you have taking/taken treatment for vitamin D deficiency or if you currently taking lipid (fat) lowering medicines.

WHAT WILL HAPPEN DURING THE STUDY

Screening and Study Visit: The study will be explained in detail to you and you will be given opportunity to ask any questions. You will then be asked to sign an Informed Consent Form/Document. If you qualify through paperwork and initial screening, you will be enrolled in the study. Once enrolled, the study involves the following steps:

1. Taking medical history related to cardiovascular (heart), cerebrovascular (brain) and kidney and medications that you are currently taking or that you have taken before.

2. You will have anthropometric measurements taken for height, weight, waist etc. along with blood pressure measurement. Skinfold thickness will also be taken at 3 sites of your body.

3. You will have ultrasound examination of neck blood vessels on either side

4. About 5 ml blood will be drawn for blood tests done for lipid profile, glycosylated hemoglobin, serum creatinine, vitamin D etc. An electrocardiogram (ECG) will be taken. The evaluation interpretations and data will be documented in the source documents and case-report form (CRF).

POSSIBLE SIDE EFFECTS AND RISKS OF THE STUDY

There are no side effects related to the study and if anything found will be followed to resolution. If you experience any adverse event, contact the Investigator and in case of a real medical emergency, contact your medical professional.

All of the side effects of the test procedures may not be known. There may be rare and unknown side effects, including reactions that may be life threatening.

If you are not completely truthful with the investigator and study staff regarding any side effects, you participation in this study may prove harmful to you.

PAYMENT FOR INJURY RELATED TO THE STUDY

No research-related injury is anticipated from this study, but if at all any such injury occurs, the costs of any necessary medical care will be borne by the primary investigator. Financial compensation will not be available for lost wages, disability, or discomfort due to this study. All adverse events will be followed to resolution.

POSSIBLE BENEFITS OF THE STUDY

You may or may not receive benefits from this study. Any abnormal test results will be conveyed to the individuals participating in the study for further management.

RELEASE OF YOUR MEDICAL RECORDS AND PRIVACY (CONFIDENTIALITY)

I understand that all records of my participation in this study will be kept confidential, except under certain circumstances (as required by law) such as when members of the regulatory may review the study data. However, the investigator, the Sponsor and/or its representative will look at and copy information that is collected during the study. The IRB may also view the confidential data.

The following will be given a copy of this information:

- The regulatory authorities
- Other government offices

By signing this consent form, you authorize the investigator to release your study-related medical records to the Investigator and/or his representatives. If the study results are presented at meetings or printed in publications, your name will not be used.

The Institutional Ethics Committee may be contacted for any further information concerning subjects' rights questions.

LEGAL RIGHTS

You will not lose any of your legal rights as a research subject by signing this consent form.

WHOM TO CONTACT

For answers to questions about this research or to report a research related injury or adverse event, contact the Investigator at **040-66252848** during office hours, +91-**9848011291** as a 24 hour contact number. All adverse events will be followed to resolution.

This study has been reviewed and approved to be conducted at this center by

Name of the Ethics Committee: Institutional Ethics Committee, Indo-US Superspeciality Hospital.

Chairman: Hon'ble Mr. Justice K. Ramaswamy

Address:
H.No. 7-1-57/B&C,
Shyam Karan Road,
Anand Bagh,
Hyderabad-500 016
Telangana, India.
Phone: 040 – 23782378
Fax: 040-23782376.

PAYMENT FOR BEING IN THE STUDY

You will not be paid for taking part in the study. There will be no charges for any of the investigations which will be performed on you during the study. You will be reimbursed for you transportation and for the time incurred to complete the study procedures.

YOUR PARTICIPATION IN THE STUDY

Your participation in this study is entirely voluntary, and there will not be any kind of force. You may not want to be in this study or you may leave the study at any time without punishment or loss of benefits to which you are otherwise entitled and without affecting your future medical care. The investigator, or the regulatory may take you out of the study without your permission at any time for the following reasons:

- If you do not follow the instructions of the investigator
- If it is discovered that you do not meet the study requirements
- If the study is cancelled
- If it appears to be medically harmful to you

If you leave the study or if you are taken out of the study for any reason, you may be asked to return to the investigator's office for a final visit. This is to make sure that you are in good health.

CONFIDENTIALITY

Since the products and ideas discussed in these interviews may not be available to the general public, I agree not to disclose any information relating to this study to any third party, and not to use this information and knowledge for any purpose other than for the performance of this study.

NEW FINDINGS

You will be told about any significant new findings, if identified during the study.

INFORMED CONSENT DECLARATION FORM

Study Title: Determinants of Common Carotid Intima-Media Thickness (CCIMT) Measured by Ultrasound Echo-tracking Method in Asymptomatic Individuals

Study No: _____ **Subject's Name:_____**

Subject's Initials: 1___1___1___1 **Date of Birth/Age of the subject:_____**

		Subject initial
1	I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.	[ ]
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
3	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
4	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[ ]
5	I agree to take part in the above study.	[ ]

I _____ have received a copy of this form. The details have been explained to me by the study staff organization and I have understood the same. I hereby willingly affix my signature in confirmation of my participation in this study.

Subject's Signature:/Thumb impression _____ Date: _____/_____/_____

Name of Legally Acceptable Representative (LAR): _____

Signature of LAR: _____ Date: _____/_____/_____

Signature of the Investigator: _____ Date: _____/_____/_____

Study Investigator's Name: _____