

And Associated Lok Nayak, G. B. Pant Hospital & Guru Nanak Eye Centre, 2-B.S.Z. Marg, New Delhi-02

You are being invited to participate in a research study.

Before you take part in this research study, we wish to explain the study to you and give you the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form.

Protocol Title:

Principal Investigator(s):

(insert the details given below in the information sheet)

PURPOSE OF THE RESEARCH STUDY (state what is being studied, what the study is designed to discover or establish, *explain why patient is being selected*, state recruitment and/or study period, state number of subjects recruited in this study)

STUDY PROCEDURES AND VISIT SCHEDULE (insert brief explanation of study procedures, the study medication / study device, number of times study intervention will be performed, how many blood specimens are required and the amount of sample required, state number of times follow-up visits to be made)

WITHDRAWAL FROM STUDY (*Add anticipated consequences, if any, of discontinuing the study drug or device, Clearly state the protocol-specific termination procedures*).

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

POTENTIAL BENEFITS

SUBJECT'S RIGHTS

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

COSTS OF PARTICIPATION (insert that there would be no cost for participation in this study)

RESEARCH RELATED INJURY AND COMPENSATION (insert if there are any provisions to compensate trial subjects for research related injury. If not just state, you would be treated for any trial related adverse event t or injury at no additional costs at this hospital)

WHO TO CONTACT IF YOU HAVE QUESTIONS (Insert Name and contact Details including place and phone numbers here).