INSTITUT JANTUNG NEGARA
National Heart Institute

PATIENT'S INFORMATION
(Please Stick Label)

PROCESS OF OBTAINING INFORMED CONSENT FORM FROM LEGAL AUTHORIZES REPRESENTATIVE

Study Title	
Study Protocol Number	
Sponsor	
Patient Information Sheet and Informed Consent Form Version (PIS and ICF)	
Principal Investigator	

A. Obtain Consent From Legal Authorizes Representative

The study was explained to the legal authorizes representative by me with the following information and information in the above PIS and ICF as well, consent process, purpose, risks, benefits, subject's responsibility, right to withdraw at any time point, right to the confidentiality and also explain to legal authorizes representative that subject under he/she care do not have to participate in this study to get access to the treatment and services for the disease or condition.

The legal authorizes representative was given an ample time to consider prior allowing the subject to participate in this study. The legal authorizes representative understood the PIS and ICF and voluntarily agreed to allow the subject to participate in the research program.

B. Consenting

Language used to explain:_____
Any question: □ All question answered. □ No question raised
Discussion with the family member prior to participation: □ Yes □ No
Other family member available during the explanation : □ Yes □ No

Name: _____

Relationship: _____
□ Consented
□ 1 Copy of PIS and ICF given to patient
□ 1 Copy filed in PMR
□ 1 copy in the Investigator Site File (ISF)

C. Recruitment

□ Register and assigned subject with the study identification: _____
Investigation/Procedure: □ Yes □ No

_____
□ Next appointment date: _____
□ Contact number to call if experience any adverse event: _____
□ Institut Jantung Negara Research Ethics Committee Number: _____

Name and Signature of Investigator Obtaining Informed Consent	Date: Time:
Name and Signature of Study Coordinator	Date: Time:

Institut Jantung Negara Sdn. Bhd. (245794-V) 145, Jalan Tun Razak, 50400 Kuala Lumpur, Malaysia • **Tel** +603 2617 8200 • **Fax** +603 2698 2824 • **Website** www.ijn.com.my