INSTITUT JANTUNG NEGARA
National Heart Institute

PATIENT'S INFORMATION
(Please Stick Label)

PROCESS OF OBTAINING INFORMED CONSENT FORM FROM RESEARCH PARTICIPANT (USE OF IMPARTIAL WITNESS)

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

A. Use of Impartial witness (subject Illiterate and cannot read consent)

The study was explained to the subject by me with the following information and information in the PIS and ICF as well. As the subject was unable to read, impartial witness is present.

The consent process, purpose, risks, benefits, subject's responsibility, right to withdraw at any time point, right to the confidentiality and also explain to subject he/she do not have to participate in this study to get access to the treatment and services for the disease or condition. Impartial witness confirmed that the subject was accurately explained, understood and voluntarily agreed to participate. The subject was given an ample time to consider prior to the participation.

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)

A. 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:

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