

PATIENT'S INFORMATION
(Please Stick Label)

RE-CONSENT PROCESS FOR RESEARCH PARTICIPANT

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

A. Re-consent From Research Participant

The new additional information explained to the subject by me with the following information 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 subject he/she do not have to continue participate in this study to get access to the treatment and services for the disease or condition.

The subject was given an ample time to consider to continue or not in participating in this research program. The subject understood the new additional information and voluntarily agreed to continue participation in this 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

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: _____