

PATIENT'S INFORMATION  
(Please Stick Label)

## PROCESS OF OBTAINING INFORMED CONSENT FORM FROM RESEARCH PARTICIPANT

Study Title	
Study Protocol Number	
Sponsor	
Patient Information Sheet and Informed Consent Form Version (PIS and ICF)	
Principal Investigator	
<b>A. Obtain Consent From Research Participant</b> <p>The study was explained to the subject 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 subject he/she do not have to participate in this study to get access to the treatment and services for the disease or condition.</p> <p>The subject was given an ample time to consider prior to the participation. The subject understood the PIS and ICF and voluntarily agreed to participate in the research program.</p>	
<b>B. Consenting</b> <p>Language used to explain: _____</p> <p>Any question: <input type="checkbox"/> All question answered. <input type="checkbox"/> No question raised</p> <p>Discussion with the family member prior to participation: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Other family member available during the explanation: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Relationship: _____</p> <p><input type="checkbox"/> Consented</p> <p><input type="checkbox"/> 1 Copy of PIS and ICF given to patient</p> <p><input type="checkbox"/> 1 Copy filed in PMR</p> <p><input type="checkbox"/> 1 copy in the Investigator Site File (ISF)</p>	
<b>C. Recruitment</b> <p><input type="checkbox"/> Register and assigned subject with the study identification: _____</p> <p>Investigation/Procedure: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Next appointment date: _____</p> <p><input type="checkbox"/> Contact number to call if experience any adverse event: _____</p> <p><input type="checkbox"/> Institut Jantung Negara Research Ethics Committee Number: _____</p>	
Name and Signature of Investigator Obtaining Informed Consent	Date: _____ Time: _____
Name and Signature of Study Coordinator	Date: _____ Time: _____