Informed Consent Form

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Sponsor	Abbott - Heart Failure 168 Middlesex Turnpike Burlington, MA 01803 USA

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STUDY TITLE AND NUMBER	**Post Market Surveillance of the HeartMate 3 Left Ventricular Assist System in Hong Kong and Taiwan, ABT-CIP-10382**
SPONSOR	**ABBOTT**
PRINCIPAL INVESTIGATOR	***Name of principal investigator*** ***Address***
SITE NAME	***Institution/Site Name*** ***Address***

INTRODUCTION

You are being invited by your doctor to take part in this research study evaluating HeartMate 3 because your doctor has determined that this device could be beneficial to you in treating your heart failure.

Signing this Study consent form does not mean that you will take part in the Study. You will have to meet certain requirements. If you do not meet the requirements, you will be told.

This form explains why this research study is being done and what your role will be if you decide to participate. This form also talks about the possible risks that may happen if you take part in this study.

The Study will enroll approximately 30 subjects at approximately up to 4 sites in Hong Kong and Taiwan.

Please read this form, and ask your study doctor any questions you may have about the research study so that your questions may be answered before you decide if you want to take part in the study. Please take your time and talk about this information with your family, friends, or family doctor.

This consent form may contain some words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not understand. It is important that you understand what is in this form.

Taking part in this research study is entirely voluntary. If you don't wish to take part, you don't have to. You will receive standard care if you do not wish to take part in the study. Refusing participation will not involve any penalty or loss of benefit regarding your further medical care.

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If you decide you want to take part in the research study, you will be asked to sign, date and put your name on the consent section before any study-related activities are performed. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research study
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to collect information on how helpful the HeartMate 3 device is in improving the symptoms of heart failure. This is an observational study, which means that information regarding the effectiveness of this device in addressing your heart condition will be collected and nothing new or different will be done with your care.

DESCRIPTION OF THE HEARTMATE 3

The HeartMate 3 pumps your blood when your heart cannot pump enough blood. It consists of a pump, driveline cable, controller, and power source. The pump will be implanted inside your chest. The pump is connected to the controller, which is external to your body, by the driveline. The controller delivers power to the pump. It will also be used by your doctor to adjust the settings of the pump to optimally support your heart.

The HeartMate 3 has been approved by the for commercial use. It is therefore not an investigational device. Even though your device had been approved, this study will allow Abbott to continue to monitor its safety and effectiveness for a period of up to 2 years.

The HeartMate 3 has been approved by the Hong Kong and Taiwanese regulatory agencies and is currently in commercial use. It is therefore not an investigational device. Even though your device had been approved by the FDA, this study will allow Abbott to continue to monitor it for a period of up to 2 years.

WHAT WILL BE REQUESTED FROM YOU IF YOU TAKE PART IN THIS STUDY?

In order to determine if you qualify to participate in this study, your doctor or other study personnel will ask you medically related questions. In addition to this, data contained in your medical records will be reviewed by your doctor. This visit will occur prior to being implanted with the HeartMate 3 device.

If your doctor determines that you qualify, and you decide to take part in this research study, your involvement will last approximately until you have performed a 24 months post-implant visit or you have experienced an outcome, whichever comes first. You will be asked to return to the clinic up to 5 times. The duration of these visits may vary depending on the standard clinical practice of your center. You are expected to complete all required follow-up visits.

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The study visits will be scheduled to match the clinic visits you would normally have for follow-up care, if you were not participating in this study. You will be asked to return to the clinic at 1, 3, 6, 12 and 24 months post-the HeartMate 3 device implant for study follow-up. At each of these visits, data from some of the tests that will be performed as a standard part of the follow-up care for patients with heart failure will be gathered for this study. Representatives of the Sponsor may attend your follow up visits.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are risks, discomforts, and inconveniences to you, associated with any research study (or to an embryo, unborn child or nursing infant if you become pregnant). These risks deserve careful thought. The risks and adverse effects of each are listed but they will vary from person to person. You should talk with the study doctor if you have any questions.

The assessments required for the study would be performed as a routine part of your care for heart failure, even if you were not participating in this study. You should talk with the study doctor if you have any questions regarding theses assessments and any risks associated with them

Other than the risks normally associated with major surgery, including general anesthesia, adverse events that may be associated with the use of the HeartMate 3 are listed below. Adverse events are listed in anticipated decreasing order of frequency, except for death, which appears first due to severity:

- Death
- Bleeding
- Abnormal Heart Beat
- Localized Infection
- Device Malfunctions
- Right Heart Failure
- Respiratory Failure
- Driveline Infection
- Blood Infection
- Kidney Dysfunction
- Stroke
- High Blood Pressure
- Venous Blood Clot
- Liver Dysfunction
- Arterial Non-Brain Clot
- Fluid Collection around the Heart
- Infection associated with the HeartMate 3 pump
- Heart Attack

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- Damage to Red Blood Cells
- Pump Clotting

There may be other risks or discomforts to you (or to an embryo, unborn child or nursing infant if you become pregnant) that are not known at this time. If important information is learned during the course of this research study, your doctor will be notified by the Sponsor. Your doctor will discuss with you important new information that is learned during the course of this study that may affect your condition or willingness to continue to take part in this research study.

WHAT ARE THE RISKS FOR WOMEN OF CHILDBEARING AGE?

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk . Subjects who become pregnant while taking part in the study should contact the study doctor right away.

If you are pregnant or plan to become pregnant in the next 24 months, you should discuss your participation with your study doctor. Subjects who become pregnant while taking part in the study should contact the study doctor right away.

WHAT ARE THE POTENTIAL BENEFITS TO YOU OR OTHERS?

Participation in this clinical study does not have any additional benefits or risks for you beyond what a patient may otherwise experience with the approved HeartMate 3 device. However, this study will allow the collection of country specific data to incorporate within the continuing research and development activities of the manufacturer of the HeartMate 3 device.

IF YOU DO NOT WANT TO TAKE PART IN THIS RESEARCH STUDY, WHAT OTHER OPTIONS ARE AVAILABLE TO YOU?

You may choose not to participate in this study. If you choose not to participate, your study doctor will discuss other options available to you.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not be paid to take part in the study. You or your insurance company will be billed in the usual manner for the hospital's standard procedures.

IF YOU CHOOSE TO TAKE PART IN THIS STUDY, WHAT ARE THE COSTS?

You and your insurance company are responsible for the costs of all tests, procedures, and devices that are considered standard of care. There is no guarantee that your insurance company will cover 100% of these costs. You should check with your insurance company to verify coverage or payments of these procedures.

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WHAT IF YOU ARE INJURED BECAUSE OF THIS STUDY?

If you suffer any injuries, illnesses, or complications as a direct result of participation in this study, medical treatment will be available to you. You or your insurance company will be responsible for all costs resulting from such treatment. No other arrangement has been made for other compensation (such as lost wages, lost time or discomfort) with respect to such injuries. However, signing this consent form in no way limits your legal rights against the Sponsor, investigators, or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

During the study, if you experience any injuries, illnesses, or complications from taking part in this study, please contact Dr. _____ at ___-___-_____.

WHAT ARE YOUR RIGHTS IF YOU DECIDE TO TAKE PART IN THIS RESEARCH STUDY?

Your signature on this consent form means that you have received information about this research study and that you agree to be a part of the research study.

You may stop taking part in the research study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to stop taking part in this research study for any reason, you should contact Dr. _____ at ___-___-_____.

If you do withdraw your consent during the study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research study project can be measured and properly analyzed. You should be aware that data collected by the sponsor up to the time you withdraw will be part of the study results.

Your study doctor or designee will discuss with you what follow-up is required if you decide to withdraw, or you are withdrawn from the research study before the study is finished.
Your doctor may stop your participation in the research study at any time, without your consent, for any reason. Additionally, the sponsor may stop the study at any time.

HOW WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?

If you decide to take part in this study, your medical records and personal information will be kept confidential to the extent allowed by Federal, State, and local law. Personal data is defined as any information that identifies you or information from which you could be identified, and may include information such as your name, identification numbers, medical insurance numbers, your health information, and other information that may individually identify you.

Information from the study may be exported to countries where different data protection laws apply. The data protection laws in other countries may be less strict then those of your country.

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If you decide to participate in the study, the study Sponsor and others who work with the study, such as the study staff and Institutional Review Board (IRB) will see health information about you. The IRB is a group of people who perform independent review of the study as required by laws governing this type of study. Regulatory agencies, IRB/EC and Sponsor's representatives may inspect your medical records. Trained Sponsor representatives may assist doctors during the implant of the study device and help with technical support during the follow up study visits.

The Sponsor may use the information in any of the following ways:

- To analyze and make conclusions about the results of the study
- For reporting undesirable events to the FDA (choose agency) and other government health agencies
- For processing, monitoring, auditing and control of the study or the conduct of inspections by the relevant authorities
- To conduct new medical research study, to reanalyze the study results in the future or to combine your information with information from other studies
- To develop new medical products and procedures, and other product-development related activities.
- To assist with submitting insurance claims and processing reimbursements requests
- For regulatory submissions for product approvals to government regulatory agencies (including those in other countries)

While using the information in the above mentioned ways, the Sponsor may give study data to its affiliated companies in the U.S. or other countries. The Sponsor may also share the information with its research or business partners or companies it hires to provide study-related services. Information received during the study will not be used for any mailing lists or sold to anyone for marketing purposes.

Your personal data will be key-coded using a unique patient number before they are processed with the purpose not to permit your identification, except if necessary for the purpose of the study or for regulatory obligations. Your coded study data will be processed manually as well as by computer and analyzed during and after the study.

Your name or identifying information will not be provided for publications in medical journals. Data which has all identifying information removed is called "de-identified data". Your permission for the use, retention, and sharing of your de-identified health information will continue indefinitely.

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WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

To get answers to any questions about this study, or if at any time you feel you have experienced a research-related injury, please contact your study Doctor:

Name of Study Doctor: _____

Phone Number of Study Doctor: ( ) _____

In addition, if you have any concerns, complaints or questions about your rights as a research study subject or an injury that you believe is a study-related, please contact:

Name of person at IRB/EC:
Title of person at IRB/EC:
IRB/EC phone number:
IRB/EC email, if known:

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CONSENT TO PROCESSING OF PERSONAL INFORMATION

The purpose of collecting and using your personal information is to execute this study and may include, among other things, organizing, analyzing and reporting treatment and other results, monitoring of medical devices and studying and developing new applications for medical devices

[Collection and Use of Personal Information]

The following personal information will be collected and used for the purposes listed above.

- Age
- Sex
- Ethnicity
- Country in which clinical trial is held

Unless provided otherwise by applicable laws, your personal information will be maintained and utilized until the above purposes of collection and use are attained.

You may freely decide on whether to give consent to the collection and use of your personal information as set forth above, and you have the right to terminate your participation at any time. While you cannot participate in this study if you refuse the collection and use of personal information, there will be no other disadvantages to you regarding prescriptions or medical treatment.

☐ **I understand the explanation on the collection and use of my personal information and I hereby agree thereto.**

[Collection and Use of Sensitive Information]

The following sensitive information will be collected and used for the purposes listed above.

- Health related information including medical records, current health status, results of medical tests such as laboratory standards, and etc.

Unless provided otherwise by applicable laws, this sensitive information will be maintained and used until the above purposes of collection and use are attained.

You may freely decide on whether to give consent to the collection and use of this sensitive information as set forth above. If you refuse the collection and use of this sensitive information, there will be no disadvantages to you regarding prescriptions or medical treatment.

☐ **I understand the explanation on collection and use of my sensitive information and I hereby agree thereto.**

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[Transfer of Personal Information to a Third Party]

With regard to the above purposes, the items among the personal information and sensitive information listed above will be shared with the third parties listed below with your consent in order to, among other things, organize, analyze, report results of the study, correct prescriptions and dosage of future medications, study and development of safer medications, etc.

- Abbott Medical Hong Kong and Taiwan and its affiliates (list of companies provided at www.abbott.com)
- Abbott research partners
- Government health agencies
- Institutional Review Board
- Hospital

Further, according to applicable laws and regulations, the doctor participating in the research or Abbott Medical Hong Kong and Taiwan and its affiliates receiving your information may provide your personal information and sensitive information in a form that does not identify the individual to relevant government institutions such as but not limited to the government health agencies and the US Food and Drug Administration. These institutions may request access to your information based on applicable laws and regulations. Your information will only be shared and used for the abovementioned purpose and will be strictly protected as personal information according to relevant laws.

Unless provided otherwise by applicable laws, your personal information will be retained and used by third parties until the above purposes of collection and use are attained.

You may consent to share your personal information as set forth above, and you have the right to terminate participation at any time. While you cannot participate in this study if you refuse the collection and use of personal and sensitive information, there will be no other disadvantages to you regarding prescriptions or medical treatment.

☐ **I understand the explanation on the transfer of my personal information to a third party and I hereby agree thereto.**

☐ **I understand the explanation on the transfer of my sensitive information to a third party and I hereby agree thereto.**

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CONSENT SIGNATURE PAGE

Consent and authorization for participation in this research study

Your signature indicates that you have read the information in this form and have decided to take part in the study. You will be given a signed copy of this form to keep.

- I have read all of the above information in this consent and authorization form.
- I have had the opportunity to ask questions and have received answers concerning areas I did not understand.
- I willingly give my consent to participate in this study and to comply with the procedures related to it.
- I confirm that my key-coded study data will be used in the analysis and de-identified or anonymized data may be included in publications.
- I understand that I am free to refuse to participate in the proposed study, without giving any reason and without my medical care or legal rights being affected.
- I understand that I am free to withdraw from the proposed study at any time, without giving any reason, without my medical care or legal rights being affected.
- I give my permission to Sponsor representatives and research partners, IRB and the regulatory authorities to access and use my medical records and personal information as described in this form.
- I give the study team permission to inform my personal physician of my participation in this study.

Name of Participant (please print): _____

Signature: _____ Date: _____ Time: _____

Name of Person Obtaining Consent (please print): _____

Signature: _____ Date: _____