Informed Consent Form

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CardioMEMSTM HF System Post Market Study
Study Document No: CL1004587
Version C
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Sponsor

St. Jude Medical
23 Fourth Avenue
Burlington, MA 01803
United States of America

Informed Consent Form

STUDY TITLE AND NUMBER	CardioMEMS™ HF System Post Market Study CIP-10147
SPONSOR	St. Jude Medical, Inc.
PRINCIPAL INVESTIGATOR	*(Name, title)* *(Address)* *(City, State zip)* *(City, State zip)*
SITE NAME	*(Name)* *(Address)*

INTRODUCTION

You are being invited by your doctor to take part in this research study evaluating the CardioMEMS™ HF system because your doctor has determined that this CardioMEMS™ HF system could be beneficial to you in treating your heart failure (HF).

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 800 subjects at up to 85 sites in Europe and Australia.

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.

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 Post Market Study is to demonstrate that data collected related to the use of the CardioMEMS™ HF system in a commercial setting are comparable with data collected in a controlled clinical trial. The study procedures are not experimental, data collection is the only unique element to study participation.

This is a prospective, open-label clinical trial to be conducted at up to 85 clinical sites outside of the United States (US). There will be up to 800 patients enrolled in the study.

DESCRIPTION OF CardioMEMS™ HF System

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You have been diagnosed with heart failure. Heart failure (HF) is a disorder resulting from damage to the heart. Hypertension (high blood pressure) or coronary artery disease (narrowed or blocked blood vessels to the heart) are the most common causes of heart failure. This damage makes it difficult for the heart to pump enough blood to meet the demands of the body. Heart failure is a progressive disease that often gets worse over time.

Physicians treating heart failure patients rely on signs and symptoms, physical exams, and lab values to manage your therapy. In addition, special procedures are needed to evaluate the condition and performance of the heart. One of these procedures is a right heart catheterization. During this procedure, pressures in the heart and the blood vessels close to the heart are measured using a pulmonary artery catheter (a thin, flexible tube). A heart catheterization offers valuable information to the physician; however, it is limited to a one-time "snap-shot" of the pulmonary artery pressures related to heart function.

The CardioMEMS™ HF system provides a method to measure pulmonary artery (PA) pressures daily by using a small wireless sensor (about the size of a paperclip) implanted into the pulmonary artery (a vessel close to your heart). Once implanted, the sensor communicates through radio frequency to an antenna contained in a pillow connected to an electronic unit and then transmits this valuable information to a secure website for your doctor to review. You will be able to take these PA pressure measurements yourself at home. In addition to these home readings, your PA pressures can also be obtained in the physician's office, clinic, or hospital. Your doctor can access the secure website to view your measurements allowing him/her to make earlier treatment changes (usually changes in medications) to manage your heart failure remotely.

Figure 1. CardioMEMS HF Sensor

The CardioMEMS™ HF system was evaluated during a recent clinical study, CHAMPION, conducted at 64 study sites in the U.S. and enrolled 550 patients with NYHA Class III heart failure who had been hospitalized for heart failure in the previous year. CHAMPION met its primary endpoint of reduction in the rate of heart failure hospitalizations with Treatment patients having 28% fewer heart failure hospitalizations compared to Control patients at 6 months; the benefit was sustained with a 37% reduction over the entire study time period which averaged 15 months. Treatment patients also experienced an improvement in their quality of life compared to Control patients.

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

This research study includes a screening/qualification phase to determine if you are a good candidate for the study. Your doctor or other study personnel will ask you medically related questions. Additional tests will be conducted to determine if you qualify for the study, listed below in "screening visit" section. Once all tests have been completed, your doctor will decide if you qualify to take part in the CardioMEMS™ HF system Post Market Study. If you do not qualify for the study, your participation will end.

If your doctor determines that you qualify, and you decide to take part in this research study, your involvement will last approximately two years. You will be asked to return to the clinic 4 times after you receive a CardioMEMS™ sensor. Each visit will take approximately 45 minutes. You are expected to complete all required follow-up visits.
If you agree to take part in the observational study, your involvement is expected to last up to a maximum of 24 months.

Study Visits:

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Screening Visit
In order to participate in this study the following tests, examinations and reviews will need to be completed and the results must meet the study requirements:

- Physical examination including vital signs (temperature, heart rate, blood pressure), weight, height, Body Mass Index calculation
- Medical and surgical history
- Demographics information (age, race, date of birth)
- New York Heart Association Classification for heart failure (a classification your doctor uses to describe your heart failure)
- Quality of Life (QoL) Questionnaire completion
- Laboratory tests (if necessary)
- Heart failure medication review

Your doctor will determine if you can participate in the study after your examination and lab tests have been reviewed. Once your study eligibility is confirmed, your physician or representative will discuss participation in the study with you. If you agree to take part in the study, your doctor will schedule the Sensor implant visit. You may be instructed to stop blood thinning medications 1-2 days before the implant procedure, however this is up to your doctor.

Implant Procedure (Baseline) (Standard of Care for this type of device)
During the sensor implant visit, the following procedures will be performed:

- Physical examination including vital signs (temperature, heart rate, blood pressure) and weight
- New York Heart Association Classification for heart failure
- Lab tests: Prothrombin Time (PT) with International Normalized Ratio (INR) if you have been prescribed warfarin
- Heart failure medication review
- Right heart catheterization and sensor implant procedure
- Review of adverse events that occurred (if any) since the baseline visit

The Sensor will be implanted during the heart catheterization procedure. The Sensor is placed inside your pulmonary artery (one of the vessels close to the heart) with a special delivery catheter. You may receive a mild sedative before and/or during the procedure but you will be awake so you can follow instructions. An area on your groin will be cleansed with sterile soap and a local anesthetic (numbing) medicine will be injected at that site.

There are two parts to the procedure, the right heart catheterization (RHC) and the Sensor implant. The heart catheterization is performed first. A pulmonary artery catheter is inserted in your groin and then carefully threaded into your heart using an x-ray machine to produce pictures (fluoroscopy). Your heart rate and rhythm will be constantly monitored by an electrocardiogram (ECG). Once the catheter is in the pulmonary artery, a small amount of contrast material (dye) is injected and pictures are taken to make sure the catheter is in the right position and to make sure the branch of the pulmonary artery is the appropriate size. This procedure is called angiography.

Next, a delivery catheter with the Sensor attached is carefully threaded to your pulmonary artery over a guide wire (a very small wire used to guide catheters). The Sensor is then positioned in the pulmonary artery and released from the delivery catheter. The delivery catheter will be removed and the pulmonary artery catheter positioned next to the Sensor. Once the Sensor is confirmed by x-ray to be in the correct position, it will stay inside the pulmonary artery permanently. The doctor will hold a monitor (called an antenna) to your back, chest or side to obtain the Sensor's signal. Pulmonary artery pressure readings will be recorded from both the

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Sensor and the pulmonary artery catheter. The heart catheter is removed and the Sensor will remain in your pulmonary artery.

If the doctor is unable to safely pass the catheter into the pulmonary artery or if the pulmonary artery branch is not the appropriate size, you will not be able to receive the Sensor. Your doctor will follow your progress for 30 days, after this time you will no longer participate in the study.

The procedure (RHC and Sensor implant) may last up to one hour. After the procedure is completed, you may be asked to lay flat on your back for a few hours, to prevent any bleeding from the catheter insertion site. At your doctor's discretion, you may be discharged the day of the procedure or you may be required to stay in the hospital overnight so that your condition may be observed and evaluated.

After the procedure, your doctor or nurse will instruct you how to set-up and take PA pressure readings from your home using the patient electronics system (home readings typically take less than one minute to complete). It is important that you are comfortable with setting up your patient electronics system and that you understand how to take a reading. Should you need assistance with the System when you get home, you may call the Sponsor helpline at [Insert Toll Free Number].

Your physician will have access to your hemodynamic information (PA pressure readings and heart rate) through the CardioMEMS™ HF system. He/she will evaluate your pulmonary artery pressures daily or weekly as required and use the information to better manage your heart failure. Therefore, it is very important that you take pressure readings as directed by your doctor.

You will be contacted by your doctor or his/her staff periodically during the study when adjustments in your medications are necessary. You should feel free to contact your physician or his/her staff as you would normally. It is important that you notify your study doctor immediately if you have any worsening symptoms of heart failure.

As a participant in the Post Market Study, it is very important that you follow all the instructions from your doctor, including taking PA pressure readings and going to all of the scheduled follow-up visits.

Follow-Up Visits

You will return to see your doctor for follow up study visits at 1 month following your implant procedure and 4 more times over the next 2 years (6 months, 12 months, 18 months, and 24 months). These visits are part of you routine clinical Follow Up after Sensor Implant. During the study visits, the following procedures will be performed:

- Updated medical and surgical history
- Assessment of adverse events if any occurred since your last visit
- Physical examination including vital signs (temperature, heart rate, blood pressure), and weight
- Assessment of your NYHA functional class
- Completion of the QoL Questionnaire (at 6, 12, 18, and 24 month visits)
- Review of your heart failure medications
- Your doctor may obtain PA pressure measurements during the visit
- You will be reminded to take your PA pressure readings and will be provided counseling regarding the AHA or the ESC guidelines for sodium and fluid restrictions in your diet.

MEDICATIONS BEFORE, DURING AND AFTER THE STUDY PROCEDURE

Following the implant procedure, your doctor will give you instructions on taking a blood thinning medication. If you are currently on warfarin therapy or other similar medication, you will be asked by your doctor to restart this medication. If you are not currently on warfarin therapy, you will be

placed on blood thinner medication daily for 1 month and aspirin daily. If necessary, laboratory tests on your blood will be done periodically so your doctor can make certain you are receiving the proper blood thinning medication during the trial. Your study Doctor will discuss these medicines with you.

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. While in the study, you will have the tests and procedures described in the "What will be requested from you if you take part in this study?" section listed above. 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.

To date, the CardioMEMS HF System has been safely tested in 567 patients in the United States. During the CHAMPION trial, there were no failures of the device (sensor) and no other unanticipated complications. We do not know all of the risks. Some of the possible risks are also complications of the right heart catheterization and/or drugs associated with the procedure and blood thinning medications. Some of these risks include:

- Air embolism (air bubble in the bloodstream)
- Allergic reaction
- Abnormal heart rate or rhythm
- Bleeding
- Bruising
- Chest pain
- Myocardial infarction
- Nausea
- Stroke
- Infection
- Sepsis
- Delayed wound healing
- Thrombus formation (blood clots)
- Hematoma (collection of blood internally)
- Venous trauma (injury to your veins)
- Valve damage
- Hemoptysis
- Sensor not releasing from delivery system
- Pulmonary infarct (damage to the lung)
- Pulmonary embolism (blood clot to the lung)
- Death
- Atrial dysrhythmia

Some of the side effects that you may experience will go away shortly after the procedure, but in other cases side effects can be serious, long lasting, and/or permanent.

Resetting of the sensor baseline may also be performed as deemed necessary by Sponsor or your physician. Baseline resetting may require an echocardiogram or a RHC procedure and would include the risks associated with those procedures. 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.

If you are pregnant or plan to become pregnant in the next 24months, 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?

The results of the CHAMPION trial showed that through the use of the information obtained from the CardioMEMS™ HF System, physicians were able to adjust medications that allowed for a significant reduction in hospitalizations for heart failure. To experience the most benefit from the CardioMEMS™ HF System, it is important that you take readings daily or as instructed by you physician. Your participation in the Post Approval Study will also help your doctor, the sponsor, and the regulatory authorities evaluate the public health benefit for patients in the future.

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

An alternative is not to participate in this study and continue with your current care. If you choose not to be in the study and the CardioMEMS sensor is implanted, your doctor will still have access to the PA pressure data provided from the CardioMEMS™ HF System and use that information in addition to traditional standard of care methods to follow and treat your heart failure.

There are no other approved therapies similar to the CardioMEMS™ HF System. Currently, patients' weights are monitored by simple or sophisticated scales and medications are adjusted accordingly. There are also telephone or internet systems used for the monitoring of worsening heart failure symptoms. Your study doctor will discuss other options available to you.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

No payment will be made to you for taking part in this study.

WHO IS ORGANIZING AND FUNDING THE RESEARCH STUDY?

This research study is being sponsored and funded in *[insert country]* by Abbott. Abbott may benefit financially from this research study if, for example, the project assists Abbott to obtain approval for a new device. In addition, if knowledge acquired through this research study leads to discoveries that are of commercial value to Abbott, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

[Name of institution] will be compensated by Abbott for undertaking this research study. No member of the research study team will receive a personal financial benefit from your involvement in this research study (other than their ordinary wages).

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

Any tests or examinations that are not part of your routine care and that are required as a consequence of your participation in this study will be free of charge. There will be no cost associated with the use of the patient unit at your home.

[Any country specific additional requirements should be added here.]

WHAT IF YOU ARE INJURED BECAUSE OF THIS STUDY?

If, during your participation in this study, you are injured as a direct result of the study treatment, Abbott agrees to pay reasonable medical expenses necessary to treat the injury; provided you have followed the directions of the study doctor and to the extent you are not otherwise reimbursed by medical insurance. The study doctor and sponsor will determine whether any

illness or injury is a direct result of the study treatment or procedures performed for the purposes of the study. If you desire, you may arrange to have treatment performed by a licensed doctor selected by you, or, upon your request, the sponsor will arrange to have treatment provided by the study doctor or another licensed doctor.

Please be aware that your healthcare payer/insurer might not cover the costs of study-related injuries or illnesses. You will not lose any of your legal rights or release the sponsor, the study doctor, the study staff, or study site from liability for mistakes or misconduct by signing this consent document. If you are injured during this study, the study doctor will discuss with you the available medical treatment options. The sponsor will comply with all applicable laws and regulations as they apply to patient injuries and treatment.

In the event of an emergency, seek immediate medical attention.

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.
[Statement above may be modified to comply with local laws]

Your study doctor or designee will discuss with you what follow-up is required if you decide to withdraw, or 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.

ROLE OF THE SPONSOR REPRESENTATIVE

The role of the sponsor representative in this study is to provide training and technical support. A representative of the sponsor may be present during the sensor implant procedure. The sponsor's representative may assist your doctor to make sure your CardioMEMS™ HF System is working as expected. The representative will work under the direction of your doctor and may be aware of your medical history but will in no way compromise your confidentiality.

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 European and local law. However, information from the study may be exported to countries where different data protection laws apply.

If you decide to participate in the study, the study Sponsor and others who work with the study, such as the study staff *and Ethics Committee (EC) will see health information about you. The EC* is a group of people who perform independent review of the study as required by laws governing this type of study. Regulatory agencies, EC and Sponsor's representatives may inspect your medical records.

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

- To analyze and make conclusions about the results of the study

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- For reporting undesirable events to the FDA and other government health agencies

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

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 subject 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 key-coded personal data may be transferred outside of the European Economic Area, including to the U.S., for purposes that include, without limitation, processing, monitoring, auditing and control of the study or the conduct of inspections by the relevant authorities, medical product development, additional scientific analysis of the study data and obtaining approval to use and market medical products resulting from, or related to the study. Your coded study data may be transferred to other countries, including the U.S., where data protection laws may not be as strict as in your own country. However, Sponsor has taken security measures to ensure your identity will not be disclosed.

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

[*Any country specific additional requirements regarding personal data protection should be added here.]*

A description of this clinical study will be available on https://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.

You have a right to access your personal data and to have any justifiable corrections made. If you wish to do so, you should request this to your study doctor.

If you reside in the European Economic Area, please see the supplementary information set out in the Annex 1 attached to this form.

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: ( ) _____

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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:

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 voluntarily 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 representatives from the Sponsor, Ethics Committee 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.

_____
Initials

Name of Participant (please print): _____
Signature: _____ Date: _____ Time: _____

Name of Person Obtaining Consent (please print): _____
Signature: _____ Date: _____

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I have read and understood the subject information of above mentioned research study and all my questions have been answered. I agree that above mentioned subject agrees to participate in this study.

Participant's Legal Representative (please print): _____
Signature:_____ Date: _____ Time: _____

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Annex 1 - Supplementary Information for persons located in the EEA

The EU General Data Protection Regulation ("GDPR") is in force from 25 May 2018. The GDPR amends and updates the rights you have in relation to your personal data, and what companies that process your personal data are permitted and required to do. This Annex provides you with further information of how Abbott and its affiliates ("Abbott" or "we" or "us") processes your personal data, in addition to that which is set out in the consent form.

What is Personal Data?

"**Personal data**" is any information that identifies you or from which you could be identified, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or one or more factors specific to the physical, psychological, genetic, mental, economic or social identity. Personal data includes subsets of special categories of information that reveal information about your health, among other things.

Further information you need to know

- **On what basis does Abbott process your personal data?** – We process your personal data for the following reasons: (i) where there is a public interest to do so, such as for scientific research purposes; or (ii) where it is necessary to protect one's vital interests, such as in relation to the provision of medical care.

- **International transfers** – We transfer your personal data outside of the European Economic Area ("EEA") to third countries which do not offer the same level of protection as required by the EEA. In order to safeguard your personal data, we will only make such transfers on the basis of (i) a decision of the European Commission that permits this, or (ii) subject to approved Standard Contractual Clauses. Please note, Abbott has entered into data transfer agreements based on EU Standard Contractual Clauses to transfer your personal data from the EU to third countries, such as the United States. To receive a copy of the EU Standard Contractual Clauses which we use to export your personal data from the EEA, please contact our EU Data Protection Officer (details below).

- **Storage** – Your personal data will be stored for as long as it is needed: (i) to complete the study; (ii) to seek approval from regulatory authorities to market the studied CardioMEMS™ HF System; (iii) for study reports or scientific presentations; or (iv) for future research.

- **What rights do you have in relation to your personal data?** – The GDPR introduces new and extended rights in relation to your personal data beyond those already highlighted to you. However, as your personal data is being processed by Abbott for scientific research purposes in the public interest, some of these rights will be suspended or restricted (including the rights to access and rectify your personal data). Accordingly, the following rights may be available to you in relation to Abbott's processing of your personal data:
    i. the right to erase any personal data that Abbott holds about you, unless this is likely to render impossible or seriously impair the achievement of the objectives of that processing (for example, the purposes for which Abbott is

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Annex 1 - Supplementary Information for persons located in the EEA

processing your personal data, as described further in the consent form and this Annex);

ii. the right to lodge a complaint with your national data protection supervisory authority or to receive compensation for any damage you suffer; and

iii. the right not to be subjected to automated decision-making intended to evaluate certain personal aspects relating to you, such as analytics based on conduct.

iv. Please note, however, that Abbott does not use automated decision making technology in conjunction with your personal data so (iii) above will not apply in this case.

- **What happens if you don't provide us with your personal data?** – As explained in the consent form, we need your personal data for clinical research, to seek regulatory approval, for study reports or scientific presentations, or for future research. Any failure to provide such personal data will mean that you are unable to participate in the study, or any future research.

- **Data Protection Officer ("DPO")** – If you have any queries in relation to the processing of your personal data please contact our EU DPO by email at eu.dpo@abbott.com or by post by heading your correspondence "EU DPO" and posting it to the following addresses:

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

or

Abbott Labs Ltd
c/o Abbott House
Vanwall Business Park
Maidenhead
SL6 4XE
U.K.

or

Abbott AG
Neuhofstrassee 23
P.O. Box CH-6341 Baar
Switzerland