Participant Information Sheet and Informed Consent Form

Participant Information Sheet Version.1.1	
Study Title	**A Small scale, Prospective, Multicenter, Single arm, Investigator-Initiated Feasibility Clinical Study to Evaluate the Efficacy and Safety of Angioplasty catheter, balloon dilatation, coronary, perfusing, 'GENOSS® DCB(Drug-Coated Balloon)' in Patients with De novo lesion of coronary artery**
Principal Investigator	**Professor Jung Rae Cho, Department of Cardiology, Hallym University Kangnam Sacred Heart Hospital**

1. Overview

This study is designed to evaluate the efficacy and safety of the Genoss® DCB, a balloon catheter used for percutaneous coronary intervention (PCI), in patients with de novo coronary lesions. You are being invited to participate in this study because you meet the eligibility criteria for study subjects. The principal investigator of this study, Professor Jung-Rae Cho, Department of Cardiology, Hallym University Kangnam Sacred Heart Hospital (Tel: 02-829-5109), or the study coordinator, Nurse Eun-Ju Park (Tel: 02-829-5526), will explain the study procedures to you. Participation in this study is entirely voluntary. Before deciding whether to participate, it is important that you understand why this study is being conducted, how your personal information will be used, what the study involves, and the potential benefits, risks, and inconveniences associated with participation. Please take sufficient time to read the following information carefully, and feel free to discuss it with your primary physician, family, or friends if you wish. If you have any questions, the study staff will be happy to provide detailed explanations.

2. Background and Purpose of the Clinical Study

■ Purpose of the Clinical Study

The investigational medical device used in this clinical study, the Genoss® DCB, is a balloon catheter used for percutaneous coronary intervention and is approved by the Ministry of Food and Drug Safety (MFDS) for the treatment of in-stent restenosis (ISR). This clinical study is designed to evaluate whether the Genoss® DCB can be used for the treatment of de novo coronary artery lesions.

■ Background of the Clinical Study

Percutaneous coronary intervention(PCI), a representative treatment for coronary artery disease—

including angina, myocardial infarction, silent myocardial ischemia, and sudden cardiac death resulting from acute cardiac arrest—has advanced rapidly over the past 30 years. Drug-eluting stents (DES) have become the most widely used treatment modality.

Although DES implantation has been shown to reduce restenosis and the need for repeat revascularization, complications such as stent thrombosis and adverse effects related to long-term antiplatelet therapy have been reported due to the permanent implant remaining in the body.

As an alternative therapeutic approach for coronary artery disease, drug-coated balloons (DCBs) were developed. When the balloon coated with an antiproliferative drug is inflated at the target lesion, the drug is transferred directly into the vessel wall. DCBs allow effective drug delivery with a short contact time between the balloon surface and the vessel wall, and they offer the advantage of leaving no permanent implant in the body.

Drug-coated balloons have been widely used and have demonstrated both safety and efficacy in the treatment of in-stent restenosis (ISR) and de novo small-vessel coronary disease. Recently, various studies have explored their use in larger vessels as well. Although sample sizes in these studies have been limited, many have reported that DCBs are effective in treating coronary artery disease, including contributing to vessel dilation.

Based on this background, Genoss Co., Ltd. developed the balloon dilation catheter Genoss® DCB. In this clinical study, the effectiveness and safety of the device will be evaluated in patients with de novo coronary artery lesions.

3. Study Population

Participants in this clinical study will include patients like you who have de novo coronary artery lesions requiring or scheduled for percutaneous coronary intervention. A total of 20 subjects will be enrolled across two domestic sites, with at least 10 subjects expected to be enrolled at this institution.

Subjects who meet any of the following exclusion criteria will be excluded from the study.

Exclusion Criteria

1. Patients with ST-segment elevation myocardial infarction (STEMI).

2. Patients with known hypersensitivity or contraindications to any of the following drugs or substances:

- Aspirin
- Clopidogrel
- Heparin
- Contrast media (e.g., iopromide)
  Note: Subjects with contrast media hypersensitivity may be enrolled if the reaction can be controlled with steroids and pheniramine; however, those with known anaphylaxis must be excluded.
- Prasugrel
- Ticagrelor
- Paclitaxel

3. Patients with an increased risk of bleeding—such as gastrointestinal ulcer—or those with platelet

dysfunction that limits antiplatelet or anticoagulation therapy.

4. Patients with left ventricular ejection fraction (LVEF) < 30% on echocardiography.

5. Patients with current or past severe renal insufficiency (eGFR < 30 mL/min) rendering them unsuitable for coronary angiography.

6. Patients in cardiogenic shock.

7. Pregnant or breastfeeding women.

8. Patients with comorbidities resulting in an expected life expectancy of less than one year.

9. Patients with current or past significant psychiatric disorders or other medical conditions that may meaningfully affect participation in the study.

10. Patients deemed by the investigator to be unsuitable for the study or at increased risk due to study participation.

11. Patients currently participating in another clinical trial or who have participated in another clinical trial within 90 days prior to the screening date.

12. Any other condition that the investigator considers ethically or scientifically inappropriate for participation, or that could affect study outcomes.

Angiographic Exclusion Criteria

13. Graft vessel lesions.

14. Left main coronary artery lesions.

15. Cases in which pre-dilation cannot be performed or has failed, making application of the investigational device impossible.

16. After pre-dilation of the target lesion, if any of the following conditions are present:

① In large vessels (diameter ≥ 3.0 mm), FFR ≤ 0.80 (FFR measurement may be omitted at the investigator's discretion)

② Flow-limiting coronary dissection requiring stent implantation

③ Residual stenosis > 30%

④ TIMI flow < 3

4. Investigational Medical Device

You will undergo percutaneous coronary intervention (PCI) according to the standard procedures of this institution, and the investigational medical device used in this study is described below.

■ Investigational Device: Genoss® DCB

The Genoss® DCB is a balloon dilation catheter for percutaneous coronary angioplasty. It consists of a balloon, shaft, guidewire tube, and hub. When the balloon is inflated at the target lesion, the vessel is dilated and the drug coated on the balloon surface is transferred into the vessel wall, thereby reducing and preventing stenosis.

The device is used to treat coronary artery diseases by delivering the drug to the affected lesion (see

Figure 1).

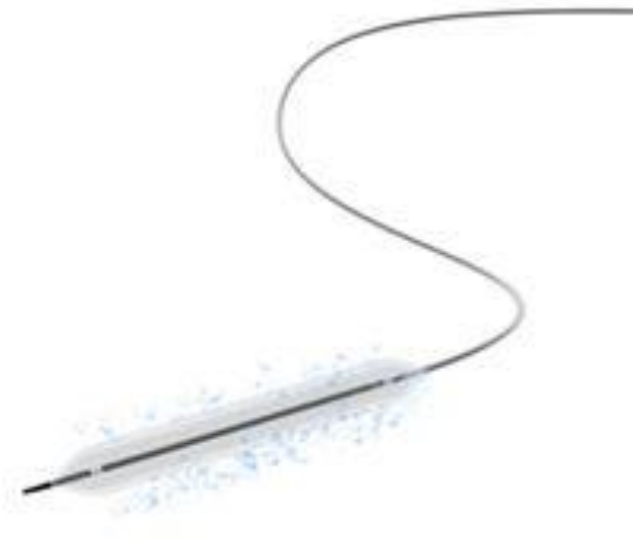

Figure 1. Genoss® DCB

5. Study Procedures

■Screening (Visit 1, 4 weeks before procedure to Day 0; outpatient/inpatient)

You are being considered for participation in this clinical study because you have a de novo coronary artery lesion requiring or scheduled for percutaneous coronary intervention. After receiving sufficient explanation about the study from the investigator and voluntarily signing the informed consent form, screening procedures (eligibility assessments and related tests) will be performed to determine whether you are eligible to participate.

During the screening visit, you will undergo the following assessments in addition to evaluation of the inclusion/exclusion criteria:

- Demographic information
  Date of birth, sex, height, weight, alcohol use, and smoking history.
- Medical history / surgical and procedural history
- Concomitant medications
- Vital signs
  Body temperature, blood pressure (systolic/diastolic), and pulse rate.
- Pregnancy test (blood or urine)
  Performed only for women of childbearing potential
  (Defined as all women with reproductive potential except those who are premenarchal, surgically sterile—such as hysterectomy—or postmenopausal for ≥12 months.)

- Physical examination
  Performed by inspection, inquiry, and palpation.
- Laboratory tests
  Complete blood count, serum biochemistry, cardiac enzymes, coagulation tests, HbA1c, and urinalysis.
  Tests performed within 4 weeks prior to screening may be accepted if available and in accordance with institutional standards.
  Cardiac enzyme testing is mandatory.
- Electrocardiogram (ECG)
- Echocardiography
  May be omitted if results from within the previous 6 months are available.

If you meet all inclusion and exclusion criteria—except those requiring confirmation on the day of the procedure (e.g., angiographic findings and pre-dilation success)—your admission and procedure dates will be scheduled. You will be admitted on the planned date and receive pre-procedure management and medications (aspirin and a P2Y12 inhibitor).

■Procedure Day (Visit 2; inpatient/outpatient)

Before the PCI procedure, you will undergo the following evaluations:

- Physical examination
- Vital signs

Your physician will review the coronary angiography performed prior to PCI to confirm whether you meet all criteria that could not be assessed during screening. If you satisfy all eligibility criteria, you will be enrolled in the study. If not, you will be withdrawn from the study, and alternative treatment will be provided according to institutional standards.

The investigator will perform the PCI procedure using the investigational device in accordance with institutional protocols. The procedure is expected to take approximately 2 hours, though the exact duration may vary.

After the procedure, you will undergo the following assessments:

- Physical examination
- Vital signs
- Electrocardiogram (ECG)
- Laboratory tests (cardiac enzymes)
  Cardiac enzymes will be measured twice: once between 6–12 hours post-procedure and once between 18–24 hours post-procedure.
  If cardiac enzymes were not assessed before the procedure, an additional test will be conducted immediately after PCI (total of three measurements).

Additional follow-up tests may be performed per institutional standard procedures if elevated levels are observed.

- Adverse events / Serious adverse events
- Concomitant therapies

You will remain hospitalized for observation, and discharge timing will be determined by the investigator according to institutional standards.

■Follow-up Period (Visits 3–4)

Visit 3 (1 month ± 1 week after the procedure; outpatient)

At the 1-month follow-up visit, the following assessments will be performed:

- Vital signs
- Physical examination
- Laboratory tests: CBC, serum chemistry
  (Performed according to institutional standard procedures)
- ECG
- Adverse events / Serious adverse events
- Concomitant therapies

Visit 4 (6 months ± 2 weeks after the procedure; outpatient)

At the 6-month follow-up visit, the following assessments will be performed:

- Vital signs
- Physical examination
- Laboratory tests: CBC, serum chemistry, HbA1c
  (Performed according to institutional standard procedures)
- ECG
- Coronary angiography
  Performed to evaluate device effectiveness.
- Adverse events / Serious adverse events
- Concomitant therapies

The clinical study will conclude after all follow-up assessments are completed and all adverse events, if any, have resolved or no longer require follow-up. If adverse events persist but the investigator determines that further follow-up is unnecessary, the study may also be terminated at Visit 4. Any adverse events or residual symptoms that persist after study completion will be managed according to institutional medical procedures.

■ Unscheduled Visit

If, during the follow-up period, you experience ≥50% stenosis at the target lesion and symptoms suggestive of angina or myocardial ischemia, you will undergo repeat revascularization (ischemia-

driven target lesion revascularization or target vessel revascularization).

If repeat revascularization occurs before the scheduled 6-month follow-up, you will undergo all assessments planned for the unscheduled visit and will then be withdrawn from the study.

During an unscheduled visit, the following assessments will be performed:

- Demographic information
- Physical examination
- Vital signs
- Pregnancy test
- Laboratory tests: CBC, serum chemistry, HbA1c
  (Performed according to institutional standards)
- ECG
- Coronary angiography (prior to repeat revascularization)
- Adverse events / Serious adverse events
- Concomitant therapies

■ Concomitant Therapies

You must inform the study physician of all medications you are taking and any treatments you may receive during the study period. All baseline medications will be recorded during screening, and any new or changed medications will be documented thereafter.

Because of the nature of this study, dual antiplatelet therapy (DAPT) may be prescribed after the procedure. These medications may influence the assessment of safety and effectiveness and will be selected based on your clinical condition.

During the study period (from enrollment to study completion), any treatment—including medications or non-pharmacologic therapies—that may affect the assessment of safety or effectiveness is prohibited.

If such treatments are used, you will be withdrawn from the study.

However, if a prohibited medication is required as a one-time treatment unrelated to the study, and the investigator judges that it will not affect the study outcome, its use may be allowed, and the details will be recorded in the case report form (CRF).

Permitted Concomitant Medications

① Before the procedure

The administration and dosage of aspirin, clopidogrel, ticagrelor, and prasugrel are determined by the investigator. If the patient has an allergy or adverse reaction to clopidogrel, or if clopidogrel is unavailable, ticlopidine may be administered. Additionally, antiplatelet agents such as cilostazol may be added at the investigator's discretion.

② During the procedure

The administration and dosage of heparin are determined by the investigator, and antiplatelet agents such as glycoprotein IIb/IIIa inhibitors or anti-thrombin IIb/IIIa may also be administered at the operator's discretion.

③ After the procedure

After the procedure, aspirin, clopidogrel, ticagrelor, and prasugrel are administered according to the investigator's decision regarding dosage and administration. If the patient is hypersensitive to clopidogrel, ticlopidine may be used. Generally, dual antiplatelet therapy (DAPT) is performed for up to six months after the procedure, but the duration may be adjusted based on the patient's condition.

Medications Requiring Caution

- Caution should be exercised when using substrates of CYP3A4 and/or CYP2C8, including terfenadine, cyclosporine, lovastatin, midazolam, and ondansetron, or drugs with high plasma protein binding (especially sulfonylureas, coumarin-type anticoagulants, salicylates, sulfonamides, and digoxin).
- Potential interactions between paclitaxel and additional drugs (e.g., anticancer agents) should be reviewed according to the relevant prescribing information.

6. Standard Treatment Methods (Other Treatments Outside the Clinical Trial)

You are not required to participate in this clinical trial to treat new lesions in the coronary arteries. If the clinical trial investigator determines that you are not suitable for this trial, other treatment options will be provided. The alternative treatments available if you do not participate in this clinical trial include the following:

■ Receiving the following treatments without participating in the clinical trial:

- Balloon angioplasty
  This procedure involves widening the narrowed area with a balloon catheter and then removing it. Compared to surgery, it causes less scarring and stress and allows faster recovery. However, there is a risk of vessel tearing or restenosis (re-narrowing) after the procedure.
- Percutaneous coronary intervention using conventional/drug-eluting stents or stent grafts
  This procedure involves inserting a conventional stent, drug-eluting stent, or stent graft (covered stent) into the narrowed area. Compared to surgery, it causes less scarring and stress and allows faster recovery. It is effective in expanding and maintaining the narrowed area, but over time, there is an increased risk of restenosis due to neointimal growth inside the stent, or the stent/stent graft may migrate from its original position.
- Surgical removal of the narrowed area
  This involves surgically excising the stenotic portion of the vessel lumen. It is advantageous

because it can treat stenosis even in vessels with severe curves, but the recovery period is longer, and there is a higher risk of blood flow-related infections.

7. Potential Benefits of Participation

■ Expected Benefits from Participating in the Clinical Trial

Participation in this clinical trial cannot be guaranteed to provide you with direct personal benefit. However, by evaluating whether the investigational medical device, Genoss® DCB, can be used to treat new lesions in the coronary arteries, your participation may help improve treatment options for future patients.

8. Potential Risks, Side Effects, and Discomforts from Participation

During participation in this clinical trial, you may experience known or unforeseen adverse events related to the investigational medical device. Additionally, any procedures or interventions performed as part of the trial may carry unexpected risks. However, routine risks or discomforts associated with coronary angiography and interventional procedures for the treatment of coronary artery disease can occur even if you do not participate in this study. Your clinical trial investigator will discuss these risks with you.

Adverse events can vary from person to person. You may experience some, all, or none of the listed events. If any discomfort or adverse events occur, immediate treatment and monitoring will be provided, and thorough investigation of the cause will be conducted.

Expected Adverse Events

(Related to coronary intervention procedures)

- Acute myocardial infarction
- Allergic reactions
- Aneurysm or pseudoaneurysm
- Coronary artery rupture
- Arrhythmias including ventricular fibrillation and ventricular tachycardia
- Cardiac tamponade or pericardial effusion
- Cardiogenic shock / pulmonary edema
- Coronary artery spasm
- Death
- Fever
- Heart failure
- Hematoma
- Bleeding / bleeding requiring transfusion
- Hypotension / hypertension
- Localized or systemic infection

- Inflammation
- Vascular occlusion
- Pain or tenderness at the access site
- Renal failure
- Stroke, cerebrovascular events / transient ischemic attack
- Systemic embolism
- Thrombosis

(Related to the drug, paclitaxel)

- Allergic / immune reactions
- Hair loss
- Anemia
- Blood transfusion
- Gastrointestinal symptoms
- Hematologic abnormalities (leukopenia, neutropenia, thrombocytopenia)
- Liver enzyme abnormalities
- Vascular wall tissue changes including infection, cell injury, or necrosis
- Muscle or joint pain
- Peripheral neuropathy
- Cardiac conduction abnormalities
- Pseudomembranous colitis

9. Compensation and Costs Related to Participation

■Costs associated with participation:

During this clinical trial, tests and treatments performed according to institutional standard procedures—such as pregnancy tests, physical examinations, vital signs assessment, laboratory tests, electrocardiograms, echocardiography, and coronary angiography—are considered standard care for your condition. These procedures would be performed even if you did not participate in the trial. Therefore, the costs of these tests and treatments are generally your responsibility.

However, for post-procedure visits [Visit 3 (1 month after the procedure) and Visit 4 (6 months after the procedure), total 2 visits], the consultation fees (follow-up visit fees) will be covered by the investigator, so you will not incur costs for these visits.

Additionally, coronary angiography performed during the 6-month post-procedure follow-up is conducted specifically to evaluate the investigational medical device's outcomes. The costs of these tests will be covered by the investigator, and you will not need to pay for them. After the completion of the trial, if further follow-up is required according to the institution's standard procedures, any associated costs will be your responsibility.

The investigational medical device used in this trial is provided by the sponsor; therefore, you will

not bear any cost for the device.

■Monetary compensation for participation:

There is no direct monetary payment for participating in this clinical trial.

However, to compensate for your time and travel, transportation expenses of 100,000 KRW will be provided for each post-procedure visit [Visit 3 (1 month) and Visit 4 (6 months), total 2 visits]. In addition, if an unscheduled visit is required due to revascularization of the target lesion before the end of the study, a transportation fee will also be provided for that visit.

Transportation expenses may be adjusted based on the extent and duration of your participation. For example, if you choose to withdraw from the trial or if the investigator determines that continued participation is not appropriate, transportation expenses will be provided only for the visits completed.

10. Handling and Disposal of Human-Derived Specimens

During this clinical trial, blood and urine samples will be collected at each visit (Visit 1–5), for a total of 5 times. Up to 12 mL of blood and up to 20 mL of urine will be collected per visit. The collected blood and urine samples will be used for laboratory tests and pregnancy tests.

After analysis, any remaining blood will be disposed of in accordance with the Waste Management Act.

If the investigator intends to use, store, or provide the collected human-derived specimens for purposes other than this clinical trial, or to a third party, separate additional consent will be requested from you.

If you withdraw your consent to participate in this clinical trial, no further specimens will be collected, and any remaining human-derived specimens will be disposed of.

11. Withdrawal from the Clinical Trial

During the course of this clinical trial, if you experience any of the situations or events listed below, or even if situations not listed occur, the investigator may request that you discontinue participation in the trial:

- You or your representative request to withdraw from the clinical trial.
- Continuation of the trial is difficult due to adverse events.
- Target lesion revascularization occurs before the 6-month post-procedure point (before the primary efficacy assessment).
- Surgery, medication, or medical devices that may affect safety or efficacy evaluations, other than target lesion revascularization, are used concurrently.
- You fail to comply with instructions for participating in the clinical trial.
- It is determined that you do not meet the requirements of the clinical trial.

- Follow-up observation of you is not possible.
- You become pregnant.
- The clinical trial is suspended or canceled.

If any of these reasons apply, the investigator will discuss the matter with you. Even if the application of the investigational device has already begun, you may be requested to discontinue participation at any time. Furthermore, if new information arises that may affect your willingness to continue participation, you or your representative will be informed promptly.

If you are withdrawn from the clinical trial, appropriate alternative treatments will be provided, and the investigator will perform any necessary tests and procedures to ensure your safety.

12. Continuous Provision of New Trial-Related Information

During the course of this clinical trial, any new significant information that may affect your decision to continue participation will be promptly communicated to you or your representative as soon as it becomes available.

13. Compensation Measures for Trial Subjects in Case of Harm (Medical Treatment/Compensation)

If any adverse events related to the investigational medical device occur, you will receive treatment according to the hospital's standard procedures for each symptom. Even if your participation in the clinical trial is terminated early due to an adverse event, any residual symptoms caused by the event will be treated with appropriate medical care according to the hospital's standard procedures until recovery.

In the event that any injury occurs as a result of this clinical trial, the clinical trial investigator will take the best possible measures to treat the injury. The costs incurred for such treatment will be covered in accordance with the insurance policy and compensation regulations applicable to this clinical trial.

14. Protection of Personal Information and Confidentiality

By agreeing to participate in this clinical trial, **you are consenting to the collection and use of your personal information, including sensitive information, to the extent necessary for the clinical trial.** The personal and sensitive information collected from you during this trial includes:

- Personal Information: initials, sex, date of birth, height, weight
- Sensitive Information: information regarding physical or mental health or condition, health information in your medical records, etc.

This information is collected solely for the purposes of conducting, analyzing, and reporting the results of this clinical trial and will not be used for any other purpose or disclosed to third parties.

If you withdraw your consent to participate in this clinical trial, your participation will be terminated, and the clinical trial investigator and staff will not contact you for trial-related matters or collect

additional information. However, information already collected may continue to be used for the purposes of the clinical trial.

Records containing your identifiable information collected during the trial will be managed in accordance with the Personal Information Protection Act (e.g., using coded numbers) to ensure confidentiality. Even if the results of this trial are compiled into reports, published, or presented, your identity will remain confidential.

However, during and/or after the trial, monitors, auditors, the Institutional Review Board (IRB), and the Ministry of Food and Drug Safety may review your medical records directly within the scope necessary to verify the trial procedures and data reliability, while maintaining confidentiality. Signing this consent form signifies your permission for such direct review.

All trial-related documents will be stored in a locked facility for three years from the date of product approval and will be appropriately disposed of thereafter.

15. Voluntary Participation and Right to Withdrawal/Cessation

As previously explained, your participation in this clinical trial is entirely voluntary; you may choose to participate or not. You may also withdraw from the trial at any time for any reason. You are not required to provide a reason for withdrawal, and there will be no penalties or disadvantages as a result.

Choosing not to participate or deciding to withdraw from the trial will not result in any loss of benefits to which you are otherwise entitled. If you wish to withdraw from the trial, please inform your clinical trial investigator either verbally or in writing.

16. Responsible Personnel and Contact Information for the Clinical Trial

During the clinical trial, you may request additional information from the trial personnel listed below at any time if you have questions or concerns about this clinical trial. You may also contact them in case of any potential risks, discomforts, or any harm related to the clinical trial.

Contact for issues, concerns, or questions arising from human research:

Hallym University Kangnam Sacred Heart Hospital

- Principal Investigator / Clinical Trial Physician: Professor Jo Jung-rae ☎ 02-829-5109
- Clinical Trial Research Nurse (or Research Coordinator): Nurse Park Eun-joo ☎ 02-829-5526

If you have questions about your rights as a participant, concerns about the clinical trial, or wish to speak with someone not directly involved with the trial, please contact:

Contact for participant rights and concerns:

Hallym University Kangnam Sacred Heart Hospital

- Institutional Review Board (IRB): ☎ 02-829-5527

Informed Consent Form Version.1.1

Study Title	**A Small scale, Prospective, Multicenter, Single arm, Investigator-Initiated Feasibility Clinical Study to Evaluate the Efficacy and Safety of Angioplasty catheter, balloon dilatation, coronary, perfusing, 'GENOSS® DCB(Drug-Coated Balloon)' in Patients with De novo lesion of coronary artery**
Principal Investigator	**Professor Jung Rae Cho, Department of Cardiology, Hallym University Kangnam Sacred Heart Hospital**

1. I have received a verbal explanation about this clinical study, have read the above Subject Information Sheet, and have discussed it with the responsible investigator.
2. I have been informed of the risks and benefits and have received satisfactory answers to my questions.
3. I voluntarily agree to participate in this study.
4. I understand that I may refuse to participate or withdraw from the study at any time without affecting my future medical care, and that such a decision will not cause me any harm.
5. By signing this information sheet and consent form, I agree that my personal information may be collected and processed by the researchers for medical research purposes within the limits allowed by applicable laws and regulations.
6. I understand that I will receive a copy of this consent form.

Participant	Name:	Sign:	Date:
Legal Representative	Name:	Sign:	Date:
(If applicable)	Relationship to participant		
Witness (if applicable)	Name:	Sign:	Date:
Person obtaining consent	Name:	Sign:	Date: