Number：□□□□□ACS□□□□□
V2.0 March,4,2025

Informed consent form

Study name：Multicenter Comparative Study on the Diagnostic Efficacy of "Ultra-high Sensitivity" Cardiomagnetic Detection and Myocardial Nucleoradiology Scanning for Early Diagnosis of Myocardial Ischemia.

Name：_____ Gender：□Male □Female

Telehone：□□□□□□□□□□□

Contact person (relative) phone number：□□□□□□□□□□□

Address：_____

You will be invited to participate in a clinical study. This informed consent form provides you with some information to help you decide whether to participate in this clinical study. Please read it carefully and ask if you have any questions to the study doctor in charge of the study.

(1) Research content and research purpose:

This research uses my country's independently developed magnetic detection device, which is expected to detect human magnetic function information with ultra-high sensitivity and non-invasively, reflect the corresponding electrophysiological activities of the heart, and provide clinical diagnosis and evaluation of cardiovascular diseases. New means are provided. Magnetocardiographic detection needs to be completed in a magnetic shielding device. In an environment close to zero magnetic field, an atomic spin magnetometer is used to measure and record the magnetic field generated by the electrical activity of the heart. Magnetocardiographic imaging scanning does not require injection of contrast agent and is expected to become a non-invasive, non-contact, fast and convenient detection method.

The study recruited patients with symptoms of myocardial ischemia and considered to be diagnosed with CHD or CMVD in this center. All enrolled patients underwent magnetic electrocardiogram examination and clinical information was collected.

(2)Who can participate in this study:

- Age ≥18 years
- Presence of myocardial ischemia-related symptoms (e.g., angina pectoris) with suspected CHD or CMVD, scheduled for ECT examination
- Signed informed consent form

(3)Study design:

This was a prospective, multicenter clinical study that recruited patients with suspected CHD or CMVD. If you agree to participate in this study, the study doctor will help you assess whether you meet the inclusion criteria first.

Please truthfully inform the study doctor about your basic situation, past medical history and other information. If you participate in this study, you will undergo a magnetocardiographic examination.

Before magnetic cardiology, please carefully read the following precautions, risks and discomforts in this informed consent form. Please remove the metal and items with magnetic strips you carry on your body before inspection, and remove clothes with metal zippers, buttons and steel rings; remove plaster, metal ornaments, bras, etc. within the scanning range as required before inspection. Critically and critically ill patients should be accompanied by family members or clinicians.

This study will collect your baseline demographic information, medical history,clinical data (e.g.laboratory tests,imaging results). Electrocardiograms (ECG), cardiac magnetography images, emission computed tomography (ECT), and coronary angiography data will be used for subsequent analysis.ECT is a routine diagnostic test for patients with suspected coronary heart disease (CHD) or coronary microvascular disease (CMVD). The cost of ECT will be borne by the patient.

(4)Risks and discomforts：

This study involves a number of inspection items, and the risks and discomforts that may arise include:

1.Magnetocardiography is a non-invasive, non-contact, fast and convenient testing method. However, a small number of patients may have unpredictable risks and complications due to their specific physiques or reasons that are difficult to detect by various modern medical methods.

2.This study does not recommend magnetic electrocardiogram examination for claustrophobia, unstable asthma, pregnancy, etc. Please promptly and fully inform the medical staff of the relevant medical history or condition, and cooperate with the medical staff to conduct risk assessment.

3.Most metals will affect the accuracy of magnetocardiographic examination results, while non-magnetic metals of special materials have little impact on magnetocardiographic examination results. Please take the initiative to inform the medical staff whether you have a history of internal implants, including but not limited to pacemakers, artificial heart valves, insulin pumps, cochlear implants, drug pumps, intracavitary stents, catheters, dentures, artificial eyes, etc., and cooperate with the medical staff. Provide relevant materials or instructions.

4.Emergency and critical patients usually have a higher risk for examination, such as aortic dissecting aneurysm, pulmonary embolism, severe cardiac, liver and kidney dysfunction, pulmonary hypertension, etc. Please inform the medical staff of the medical history in advance.

5.Patients with acute myocardial infarction and unstable angina pectoris will have certain risks when going out for examination. The patient's condition is often complex and may be at risk of worsening during transportation. Family members should accompany the examination. If necessary, you can inform the study doctor to arrange for relevant personnel to accompany you for the examination.

(5)Cost of participating in the research：

You will receive free magnetic electrocardiogram and electrocardiogram examinations. If you have coronary CTA or coronary angiography imaging materials, this study will also provide free computer-simulated coronary fractional flow reserve examination.

(6)Benefit：

This study may allow you to have a clearer understanding of your coronary blood flow, which will help your doctor have a more comprehensive understanding of your condition, provide corresponding health guidance, and adjust your diagnosis and treatment plan in a timely manner. The results of this research will be applied to the "ultra-high-sensitive" magnetocardiographic examination device to accurately identify myocardial ischemia early, which will benefit you and other patients with similar conditions.

(7)Your rights and responsibilities：

You have the following rights:

Privacy protection: If you decide to participate in this study, your personal data about your participation in and during the study will be confidential. Your information will be identified by the study number rather than your name. Identifiable information will not be disclosed to anyone other than study members unless you have your permission. All study members are required to keep your identity confidential. Your files will be kept in a locked filing cabinet for review only by researchers. The Ethics Committee and relevant management authorities may directly access your original medical records to verify the procedures and data of the clinical trial, within the scope permitted by applicable laws and regulations, and without infringing on the privacy of the subjects. Our research results will be published in public scientific journals, but personal information such as your address and name will not appear.

You can choose not to participate in this study, or notify the study doctor at any time to withdraw from the study, and any of your medical benefits and rights will not be affected.

You have the following responsibilities

1.Provide your own basic information, medical history, diagnosis and treatment status, etc. to help the research.

2. During the clinical study, cooperate with the study doctor and complete relevant examinations, and cooperate with follow-up.

3. Read carefully and clearly understand the precautions for the inspection, possible risks, accidents and unforeseen circumstances. 4. It is agreed that the doctor will adjust the inspection implementation plan according to specific circumstances during the inspection. Once risks and accidents occur, I authorize the medical staff to deal with them in accordance with medical routines.

(8) Injury compensation

The investigator will make every effort to prevent and treat possible harm caused by this study. If an adverse event occurs in a clinical trial, it will be identified whether it is related to the study. The investigator will provide treatment and corresponding compensation for trial-related damages in accordance with relevant laws of our country.

(9)If you have questions about this study, please contact the study doctor through the following methods:

Doctor name：_____Telephone number：_____

If you have any questions about your rights, please contact the hospital ethics committee through the following methods.

Ethics Committee contact number：_____

If there is any important new information during the study that may affect your willingness to continue participating in the study, the doctor will inform you in a timely manner.

I have accurately informed the subject/legal representative of this document and he/she has accurately read the informed consent form and certified that the subject has the opportunity to ask questions. I certify that he/she consented voluntarily. Investigator signature：_____ Signature date：_____
I have carefully reviewed the above information, and my questions about the clinical research plan have also been explained in detail by the study doctor to understand the status of the entire study. After full consideration, I agree to become a subject in the clinical study. I know that I can withdraw from this study at any time and without any reason. I was told that I would receive a copy of this informed consent form, with my signature and that of the investigator. Subject signature：_____ Telehone：_____ Signature date：_____ Guardian's signature：_____ Relationship with patient：_____ Telehone： Signature date：_____