# Informed Consent Form • Information Sheet

**Dear Sir/Madam,**

You are invited to participate in a clinical study titled “Establishment of Disease and Symptom Characteristics and Traditional Chinese Medicine Prognostic Risk Model After Coronary Revascularization Based on a Large-Sample Database”.

Before you decide whether to participate, please read the following information carefully. It will help you understand the purpose of the study, why it is being conducted, and the potential benefits, risks and inconveniences. This study has been reviewed and approved by the Medical Ethics Committee of The Third Affiliated Hospital of Zhejiang Chinese Medical University and follows Chinese regulations and the ethical principles of the Declaration of Helsinki for the protection of research participants.

## Study Introduction

### 1. Study Background

Coronary revascularization (PCI/CABG) is the core technique for improving the prognosis of patients with severe coronary artery disease (CAD), and the number of PCI procedures in China is continuously increasing. However, revascularization does not fully solve the long-term prognosis problem: 20%–30% of patients still experience recurrent angina, and 10%–15% develop a major adverse cardiovascular event (MACE) within one year after surgery. The causes involve multiple mechanisms such as in-stent restenosis, microvascular dysfunction, and incomplete revascularization, which seriously affect long-term survival and quality of life, making postoperative management difficult.

Facing these heterogeneous, multifactorial clinical problems, existing single-domain assessment tools (e.g., GRACE, SYNTAX-II) cannot cover the systemic, functional and psychological dimensions, nor can they reflect the patient’s overall status. The holistic view and syndrome differentiation system of Traditional Chinese Medicine (TCM) provide a complementary

theoretical framework, but TCM syndrome differentiation still lacks uniform objective criteria. The integration of artificial intelligence (AI) and multi-omics technologies makes it possible to construct a multidimensional identification and prediction system that links “macro-symptoms and micro-indicators”, aiming to objectify TCM syndromes, explore molecular basis, and build a comprehensive prognostic model integrating modern indicators and TCM syndrome information.

Our team, based on previous clinical resources and data analyses, has already built a preliminary model framework. This study is designed to systematically complete the construction and validation of this integrated system, substantially improving risk management after revascularization and providing a modern tool for the principle of “preventing disease progression”.

## 2. Study Objectives

(1) Based on literature research, develop the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”.

(2) Conduct a longitudinal study after coronary revascularization, construct a multi-source clinical research database integrating macro- and micro-indicators, screen out at least three sensitive and specific biomarkers for typical TCM patterns, and clarify their molecular biological characteristics.

(3) Based on the multi-source clinical research database and using AI, build one prognostic risk model for post-revascularization outcomes and clinically validate it in at least three medical institutions, achieving a predictive accuracy >85%.

## 3. What will I need to do if I take part?

If you meet the inclusion criteria and agree to participate, you will be enrolled in this observational study. This study does not involve randomization and will not change your current routine treatment (including medications, rehabilitation, etc.). Your cooperation will include the following:

1) Baseline assessment and biospecimen collection (on the day of enrollment)

(1) Information recording:

- Demographic data: age, sex, marital status, height, weight, ethnicity.

- General clinical data: vital signs, past medical history, concomitant medications, allergy history.

(2) Clinical assessment: measure basic vital signs (respiration, heart rate, temperature, blood pressure after 5 minutes of rest); perform TCM four-examination (inspection, listening/smelling, inquiry, palpation); record TCM-Western medicine diagnoses and TCM syndrome; complete the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”.

(3) Procedure information: from your medical records, record detailed characteristics of the current revascularization procedure, including access route (radial/femoral/brachial), target vessel information (number, location), and stent data (number, length, diameter).

(4) Biospecimen collection:

- Peripheral venous blood (about 15 mL) will be drawn for routine blood tests, blood lipids (total cholesterol, LDL, triglycerides, HDL), blood glucose (fasting glucose, HbA1c), cardiac enzymes (CK-MB), liver and kidney function, and also for proteomics and metabolomics analysis.

- A sterile swab will be used to gently scrape your tongue coating for microbiomics analysis.

(5) Echocardiography and 24-hour ambulatory electrocardiography (ECG).

2) Regular follow-up visits (at week 12, 24, 36, and 48 after enrollment)**

(1) At each follow-up, we will record:

- Whether any cardiovascular adverse events have occurred (e.g., new myocardial infarction, repeat revascularization, hospitalization for heart failure, etc.).

- Complete the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization” to assess symptom changes.

**4. What are the inclusion and exclusion criteria?**

(1) Inclusion criteria:

① Meet the diagnostic criteria for post-coronary revascularization;

② Age ⩾18 years;

③ Sign the informed consent form.

(2) Exclusion criteria:

① Patients with malignant arrhythmias, severe heart failure, myocardial diseases, structural heart disease or other severe cardiovascular diseases;

② Severe pulmonary insufficiency, severe liver or kidney dysfunction, severe electrolyte disturbances;

③ Pregnant or breastfeeding women;

④ Patients with severe psychiatric disorders, tumor-related blood diseases, rheumatic immune diseases or severe infections;

⑤ Other reasons leading to poor cooperation or compliance.

**5. What are the benefits of participating?**

You and the community may benefit from this study. Benefits include early detection of problems and enhanced communication with doctors. Through the internet and telephone, we will provide you with consultation services regarding post-revascularization management, and you will have access to patient education information.

**6. What are the risks of participating?**

This is an observational study of TCM patterns without any additional interventions. There may be a risk of information leakage; we will do our best to protect your information, but absolute security cannot be guaranteed. The study requires some examinations that will take up some of your time and may cause inconvenience.

**7. Will participating in this study increase my medical expenses?**

This study is funded by a provincial applied basic research plan. All study-related assessments and examinations are free of charge, including: one routine blood test, one lipid panel, one blood glucose test, one cardiac enzyme test, one liver and kidney function test, one tongue coating collection, one proteomics analysis, one metabolomics analysis, one microbiomics analysis, one echocardiography, and one ambulatory ECG.

Participating in this study will not generate additional medical expenses. The routine medical expenses necessary for the treatment of your coronary heart disease and related conditions will be covered by your existing insurance or out-of-pocket payments as usual.

**8. What compensation will be provided for participating?**

To thank you for your participation and compensate for your travel expenses during follow-ups, if you complete all four follow-up visits, you will receive 240 RMB as a transportation and nutrition subsidy. If you withdraw early, you will receive a proportional subsidy based on the number of follow-ups you have actually completed.

**9. Compensation for injury**

Doctors will do their utmost to prevent any harm related to this study. If any injury occurs that is related to the study, The Third Affiliated Hospital of Zhejiang Chinese Medical University will bear the corresponding treatment costs and compensation.

**10. Will my personal information be kept confidential?**

Doctors will record laboratory and examination results in your medical records. Your medical records (study case report forms, laboratory reports, etc.) will be kept intact in the hospital. The researchers, the sponsor, and the ethics committee will be allowed to access your medical records.

We will make every effort, within the limits permitted by law, to protect the privacy of your personal medical information. Any public reports of the study results will not disclose your personal identity.

**11. How can I get more information?**

(1) Routine inquiries: You may ask any questions about this study at any time. You can contact your study doctor, Wang Yanfei, at 15869195971.

(2) Information updates: If any important new information arises during the study that might affect your willingness to continue, your doctor will inform you promptly.

(3) Contact for rights and concerns:

If you need further information about the study or your rights, you may

contact the overall principal investigator, Professor Liu Qiang, at 13588121905.

If you have any complaints, suggestions, or wish to independently consult about your rights and welfare, you may contact the Medical Ethics Committee of The Third Affiliated Hospital of Zhejiang Chinese Medical University (Tel: 0571-87238255, Office address: No. 219 Moganshan Road, Xihu District, Hangzhou).

Contact for study-related injury: If you experience any discomfort or believe an injury may be related to the study, please immediately contact your study doctor Wang Yanfei (Tel: 15869195971). She will evaluate your condition and arrange necessary medical diagnosis and treatment.

**12. Must I participate in this study?**

Participation is entirely voluntary. You may refuse to participate or withdraw at any time without being penalized or losing any benefits to which you are otherwise entitled.

**13. Can I withdraw from this study early?**

You have the right to withdraw from this study at any time without discrimination, retaliation, or any effect on your medical care. If you choose to participate, we hope you will complete the entire study process.

**14. What should I do now?**

It is your decision whether to participate. You may discuss it with your family or friends before making a decision. Before deciding, please ask your doctor any questions you have until you fully understand the study.

**15. Medical Ethics Committee**

If you have any dissatisfaction during the study, please contact the Medical Ethics Committee of The Third Affiliated Hospital of Zhejiang Chinese Medical University (Tel: 0571-87238255).

Thank you for reading the above information. If you decide to participate, please tell your doctor, who will arrange all study-related matters for you.

Please keep this information sheet.

# Informed Consent Form • Signature Page

**Consent Statement**

1. 1. I have read this informed consent form. The study personnel have explained the purpose, content, risks and benefits of this study to me in detail.

2. I have discussed and asked questions about this study, and I am satisfied with the answers.

3. I have had sufficient time to make my decision.

4. I voluntarily agree to participate in the clinical study described herein.

5. If my condition changes and I need any other treatment, I will first seek the doctor’s advice or truthfully inform the doctor afterwards.

6. I agree that the drug regulatory authority, ethics committee, or study sponsor’s representatives may access my study records.

7. I will receive a signed and dated copy of this informed consent form.

Finally, I decide to participate in this study and will follow the doctor’s instructions.

Signature of participant: _____ Date: _____ (DD/MM/YYYY)

Participant’s contact telephone:

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I confirm that I have explained the details of this study to the participant, including their rights, potential benefits and risks, and have

provided them with a signed copy of the informed consent form.

Signature of doctor: _____ Date: _____ (DD/MM/YYYY)

Study doctor’s contact telephone:

(This page is an essential part of the informed consent form. Each informed consent form must be signed and dated by the participant or legal representative and the study doctor to be valid.)