Informed Consent Form: A Clinical Study on *Tanhuo* Decoction in the Treatment of Acute Coronary Syndrome Combined with Cerebral Atherosclerosis in the Elderly

Part I: Information for Research Participants

Dear Research Participant:

We plan to conduct a clinical study titled "Clinical Study on Tanhuo Decoction in the Treatment of Elderly Patients with Acute Coronary Syndrome Complicated with Cerebral Atherosclerosis." As your condition may meet the inclusion criteria for this study, we sincerely invite you to participate. This Informed Consent Form aims to elaborate on the purpose, procedures, potential benefits, risks, and possible inconveniences or discomforts of the study. Please read it carefully and make a prudent decision as to whether to participate based on your personal circumstances. If you have any questions or uncertainties while the research staff explains the content of this form, please feel free to ask at any time, and we will answer them patiently. You may discuss this with your family, friends, and your doctor before making a decision.If you are currently participating in any other clinical research, please inform the research staff.The Principal Investigator (PI) for this study is Xia Jinggang, Chief Physician of the Cardiology Department at Xuanwu Hospital, Capital Medical University. The sponsor of this study is Xuanwu Hospital, Capital Medical University, and it is funded by the National Administration of Traditional Chinese Medicine.

1. **Why is this study being conducted?**

Inflammatory mechanisms are involved in the development and progression of cardiovascular and cerebrovascular atherosclerosis. Currently, Western medical anti-inflammatory treatments show limited efficacy. This project employs Tanhuo Decoction, an in-hospital preparation of Xuanwu Hospital, to treat cardiovascular and

cerebrovascular atherosclerotic comorbidities and to verify its effectiveness in controlling inflammation as well as its drug safety.

2. **Who is invited to participate?**

Individuals meeting the following criteria may be invited to participate: (1) Hemodynamically stable within 24 hours of treatment for Acute Coronary Syndrome (ACS); (2) A previous clear diagnosis of ischemic cerebrovascular disease, or carotid/cerebrovascular ultrasound after admission confirming intracranial or extracranial arterial stenosis ≥50%; (3) Presentation of "Phlegm-Heat Syndrome" (Tan-Re) based on a weighted TCM assessment (including tongue body, tongue coating, stool, facial expression, eyes, respiration, fever, pulse, mouth sensation, and urine), with a total score ≥7; (4) Age ≥60 years; (5) Male or female; (6) Signed Informed Consent Form.

Exclusion Criteria: (1) Patients whose hemodynamics remain unstable after 24 hours or with ACS-related hypotension (BP <90/60 mmHg), or those requiring Coronary Artery Bypass Grafting (CABG) based on coronary lesion status; (2) Previous chronic heart failure of various causes; (3) History of ischemic stroke, peptic ulcer, active bleeding, or major surgery within the last 3 months; (4) Hepatic or renal insufficiency (ALT or AST >5 times the upper limit of normal; Creatinine Clearance <30 mL/min/1.73m2); (5) Previous history of bronchial asthma; (6) Platelet count <80x10^9/L; anemia (Hemoglobin ≤100g/L); (7) Contraindications or allergies to Aspirin, Clopidogrel, Ticagrelor, or Statins; (8) Previous neoplastic diseases (cancer); (9) Allergy to Traditional Chinese Medicine (TCM) components.

3. **How many people will participate?**

This is a multi-center clinical study. We plan to recruit 480 research participants in the Department of Cardiology at Xuanwu Hospital, Capital Medical University.

4. **What does the study involve?**

Participants meeting the inclusion/exclusion criteria will be randomly assigned to either the Tanhuo Decoction treatment group or the control group. The Tanhuo Decoction group will take Tanhuo Decoction for 7 days. Both groups will undergo laboratory tests at baseline and after 7 days, including complete blood count (CBC), biochemistry, high-sensitivity C-reactive protein (hs-CRP), and Interleukin-6 (IL-6). Telephone follow-ups for Major Adverse Cardiovascular and Cerebrovascular Events (MACCE) will be conducted during hospitalization and at 1, 3, 6, and 12 months after discharge.

Both the treatment and control groups will receive standard Western medical diagnosis and treatment for ACS. Only the treatment group will take Tanhuo Decoction for 7 days.

5. **How long will the study last?**

The study will last for 1 year. You may choose to withdraw at any time without losing any benefits you would otherwise be entitled to. However, if you decide to withdraw midway, a relevant medical examination may be conducted after withdrawal for your safety.

6. **Impact on daily life?**

The study will not affect your daily life; the Tanhuo Decoction is only taken during your hospital stay. To ensure your safety and the validity of the results, we kindly ask that you do not participate in any other clinical research involving drugs or medical devices during the study period.

7. **Risks and adverse reactions?**

Tanhuo Decoction is a mature in-hospital preparation that has been used for many years, confirming its high safety profile with no recorded adverse reactions. Should any adverse reaction occur, participants must inform the research staff immediately so that medical measures can be taken.

8. **Potential benefits?**

Enrolling in the Tanhuo Decoction group may lower inflammatory markers associated with Acute Coronary Syndrome.

9. **Alternative treatments?**

You may choose not to participate in this study; this will not have any adverse effect on your routine care. Current conventional treatments for your specific health condition include interventional therapy and Western pharmacotherapy.

10. **Is participation mandatory?**

Your participation is entirely voluntary. You may refuse to join without any negative impact on your current or future medical care. Even if you have agreed to participate, you may change your decision at any time and notify the researchers of your withdrawal without facing discrimination or retaliation. If you decide to stop participating, please notify the research staff so they can provide recommendations and guidance based on your health status.

The sponsor or regulatory authorities may also decide to terminate the study during the research period. If the study is terminated early, we will notify you immediately and your researcher will plan your follow-up treatment based on your health condition.

For participants who withdraw midway, we have a final follow-up plan for safety reasons, which you have the right to refuse. If new information relevant to your health and rights is discovered after your withdrawal, we may contact you again.

Once you decide to withdraw, we will stop collecting new data related to the study and will promptly destroy already collected data. However, in rare cases (e.g., to maintain scientific integrity, ensure data safety, or for government regulatory oversight), limited information may still be used or disclosed anonymously.

11. **Costs?**

Research-related examinations and treatments specified in the protocol are free of charge after signing the Informed Consent Form. If the research doctor suggests non-research-related procedures based on your condition, or if you decide on your own to undergo such procedures, this study will not cover those costs.

12. **Treatment of research-related injury?**

If your health is harmed during participation, please notify the research staff (Xia Jinggang, 13621041267). We will take necessary medical measures. According to national regulations, we will bear the medical expenses and provide economic compensation for research-related injuries.

13. **What do I need to do?**

(1) Provide accurate medical history and current health status. (2) Report any health problems occurring during the study. (3) Inform researchers of any new drugs, vitamins, or herbs taken. (4) Do not use any unauthorized medication or treatments. (5) Take the research medication as prescribed and attend visits as required. (6) Return unused medication and empty packaging at each visit. (7) Maintain a log card and carry it to each visit. (8) Store the research medication in a refrigerator, out of reach of children, and do not transfer it to others. (9) Do not participate in other medical research. (10) Use appropriate contraception during the specified period. (11) Follow the researcher's instructions. (12) Ask questions at any time if anything is unclear.

14. **Confidentiality?**

If you decide to participate, your personal information will remain confidential. Blood samples will be labeled with a code rather than your name. Identifiable information will not be disclosed outside the research team without permission. Study results will be published without disclosing personal data.

15. **Handling of biological samples?**

This study primarily collects blood samples. Sample processing will follow the standard medical routines of Xuanwu Hospital, Capital Medical University

16. **Potential Use of Research Data and Biological Samples for Future Research**

If the data and biological samples from this study are to be used for other future research, a new application will be submitted to the Ethics Committee for approval before such research can be conducted. Samples intended for future research will be stored in the Laboratory of the Department of Cardiology, where standardized storage and utilization procedures will be implemented. Your diagnosis and treatment records at our hospital will be preserved concurrently. Should any significant health issues concerning you be discovered in future research, the researchers will inform you in an appropriate manner, in accordance with and following relevant national procedural requirements.

☐I agree to the use of my data/samples by this research group for future studies related to atherosclerosis

☐I agree to share my data/samples with other research teams within China for studies related to atherosclerosis.

☐I agree to share my data/samples with international researchers for studies related to atherosclerosis.

☐ I do not agree to the sharing or secondary use of my data/samples.

17. **New Information Related to the Study**

During the course of the study, if any new information regarding the treatment becomes available, we will inform you in a timely manner. We will ensure that your right to be informed and your right to self-determination are respected, allowing you to decide whether to continue participating in the study or to withdraw.

18. **Arrangements After the Conclusion of the Study**

Upon completion of the study, the provision of the research medication will cease. Your doctor will discuss subsequent treatment plans and follow-up care with you.

19. **Whom to Contact in Case of Questions or Difficulties?**

If you have any questions related to this study, please contact Xia Jinggang at 13621041267. Note: This contact number should be available 24 hours a day.

If you have any questions regarding your rights as a research participant, you may contact the Ethics Committee of Xuanwu Hospital, Capital Medical University at 010-83199270.

Part II: Signature Page for Informed Consent

Statement of Informed Consent by the Research Participant

I have been informed of the background, purpose, procedures, risks, and potential benefits of the project titled "Clinical Study on Tanhuo Decoction in the Treatment of Elderly Patients with Acute Coronary Syndrome Complicated with Cerebral Atherosclerosis." I have had sufficient time and opportunity to ask questions, and the answers provided have been to my satisfaction. I have also been informed of whom to contact should I have further questions or require additional information. I have read this Informed Consent Form and agree to participate in this study. I understand that I may withdraw from the study at any time during the research period for any reason without penalty. I have been informed that I will receive a copy of this Informed Consent Form, which includes both my signature and that of the researcher.

Participant Signature: _____ Date: _____

Statement of Information by the Researcher

I have elaborated in detail to the research participant on the background, purpose, procedures, potential risks, and possible benefits of the "Clinical Study on Tanhuo Decoction in the Treatment of Elderly Patients with Acute Coronary Syndrome Complicated with Cerebral Atherosclerosis." I have ensured that they had sufficient time to read the Informed Consent Form and discuss it with others, and I have patiently answered all study-related questions they raised. I have provided the participant with contact information for questions and have informed them that he/she may withdraw from the study at any time during the research period without providing any reason.

Researcher Signature: _____ Date: _____