# Informed Consent Form for "A Multicenter Evidence-Based Clinical Study on the Safety and Efficacy of Wenyang Tongbi Formula in the Treatment of Chemotherapy-Induced Polyneuropathy"

**Sponsor:** National Cancer Center / Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College

**Protocol No.:** NCC6157

**Version:** V2.0

**Date:** 2026-04-20

**Introduction:**

You are invited to participate in a clinical research study. Before deciding whether to participate, please read the following information carefully. Discuss it with your family or friends if you wish. If you have no further questions and agree to participate, you will be asked to sign this form.

## 1. Background

**Nature of Study:** This is a multicenter study initiated by the National Cancer Center, involving multiple collaborating hospitals.

**Disease Condition:** Chemotherapy-induced peripheral neurotoxicity (CIPN) causes symmetrical numbness, pain, and sensory abnormalities in the limbs. It is a dose-limiting toxicity with no universally effective treatment. While mecobalamin (Vitamin B12) is widely used to prevent/treat neuropathy, its efficacy varies.

**Investigational Product:** Wenyang Tongbi Formula (Patent No. ZL202310257730.9) is a TCM prescription composed of 7 herbs (*Astragali Radix, Cinnamomi Ramulus, etc.*). It aims to warm Yang, unblock collaterals, and resolve toxins. Preliminary studies suggest it improves CIPN symptoms and functional status. This trial aims to confirm these findings.

## 2. Purpose of the Study

**Primary Objective:** Evaluate the Overall Response Rate (ORR) based on NCI-CTCAE criteria.

**Secondary Objectives:** Assess time to symptom relief, quality of life (EORTC QLQ-CIPN20), neuropathic pain (DN4), TCM syndrome scores, performance status (ECOG), and biomarker changes (NEFL, IL-6, NGF).

**Safety:** Monitor physical exams, lab tests, ECGs, and adverse events.

## 3. Study Design & Procedures

**Participants:** 144 patients with breast or colorectal cancer.

**Randomization:** You will be randomly assigned (1:1) to either the **Treatment Group** or the **Control Group** using a double-blind method.

**Treatment Group:** Active Wenyang Tongbi Granules + Placebo Mecobalamin.

**Control Group:** Placebo Wenyang Tongbi Granules + Active Mecobalamin.

**Duration:** 42 consecutive days.

**Visits & Assessments:**

You will be required to attend 3 visits (Baseline/Day 1, Day 21, Day 42). At each visit:Physical examination and medical history.Blood and urine tests (CBC, Liver/Kidney function).Electrocardiogram (ECG).Questionnaires (NCI-CTCAE neurotoxicity grade, EORTC QLQ-CIPN20, DN4 pain scale, KPS score, TCM syndrome scale).

**Biomarker Collection:**

With your consent, 5ml of blood will be drawn at baseline and Day 42 to analyze biomarkers. This is optional and refusal will not affect your participation.

## 4. Risks and Benefits

**Risks:** As a TCM formula, Wenyang Tongbi has shown minimal side effects in previous use. However, there is a risk of allergic reactions. Mecobalamin may cause mild gastrointestinal discomfort. All AEs will be managed promptly by the research team.

**Benefits:** Your condition may improve, but there is no guarantee. Your participation will contribute to scientific knowledge and potentially help future patients.

## 5. Alternatives

If you choose not to participate or withdraw, you will receive standard care, typically mecobalamin tablets, as recommended by clinical guidelines.

## 6. Voluntary Participation & Withdrawal

Participation is entirely voluntary. You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. The investigator may also terminate your participation if you experience severe AEs, disease progression, or non-compliance.

## 7. Privacy and Confidentiality

Your personal identity will be kept strictly confidential. You will be assigned a unique study ID number. All records linking your name to the ID will be stored securely in a locked cabinet/encrypted database. Only authorized research personnel, the IRB, and regulatory authorities may access your records for monitoring purposes. Results will be published anonymously. Biological samples will be stored in a dedicated, secured freezer.

## 8. Costs and Compensation

The study drugs (active/placebo) and biomarker tests are provided free of charge. You will not be compensated for participating.

## 9. Contact Information

**Study Investigator:** Dr. Yin, Tel: +86 15705360777

**Ethics Committee:** Tel: +86 010-87788495, Email: cancergcp@163.com

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## Signatures Page

**Subject Declaration:**

I have read and understood the information provided about this study. All my questions have been answered satisfactorily. I understand that my participation is voluntary and I can withdraw at any time without affecting my medical care. I consent to the collection and use of my medical data for this research.

I consent to the optional biomarker blood draw: ☐ Yes ☐ No

**Subject Signature:** _____ **Date:** _____

**Legal Representative Signature (if applicable):** _____ **Date:** _____

**Relationship to Subject:** _____

**Investigator Declaration:**

I certify that I have explained the nature, purpose, risks, and benefits of this study to the subject. I have provided sufficient opportunity for questions and believe the subject has given informed consent freely.

**Investigator Signature:** _____ **Date:** _____

**Contact Info:** _____