

# Informed Consent Form

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**Study Title:**

FREEZing-of-Gait Etiology–Phenotype–Outcome Pathway Cohort  
(FREEZE-Path Cohort)

**ClinicalTrials.gov Identifier:** Not yet assigned

**Protocol Version:** V1.0

**Document Date:** October 20, 2025

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## Invitation to Participate

You are invited to participate in a research study entitled “**FREEZing-of-Gait Etiology–Phenotype–Outcome Pathway Cohort (FREEZE-Path Cohort)**”.

This study is conducted by the research team at **Tianjin Huanhu Hospital** and has been reviewed and approved by the Ethics Committee of Tianjin Huanhu Hospital. The study will be conducted in accordance with the **Declaration of Helsinki** and applicable laws and regulations.

Before deciding whether to participate, please read the following information carefully. This document explains the purpose of the study, study procedures, potential risks and benefits, your rights and responsibilities, and your right to withdraw at any time. You may discuss this study with your family members, friends, or your study doctor.

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## 1. Study Procedures

To participate in this study, you must meet all of the following conditions:

- (1) Age between **30 and 85 years**
- (2) Presence of **freezing of gait** or **non-freezing gait** or **balance impairment**
- (3) Diagnosis of **Parkinson’s disease or related parkinsonian syndromes** according to Movement Disorder Society (MDS) diagnostic criteria
- (4) Ability to complete gait and balance assessment tasks independently or with assistance
- (5) Willingness to participate and provide informed consent

This study is a **prospective, observational, multicenter longitudinal cohort study**. Its purpose is to describe the etiology, clinical phenotypes, treatment exposure, and outcomes of freezing of gait across different neurological conditions, including Parkinson's disease, atypical parkinsonian syndromes, vascular parkinsonism, idiopathic normal pressure hydrocephalus, and related disorders.

Approximately **700 participants** will be enrolled. The total study duration is approximately **60 months**.

If you agree to participate, you will be assigned a unique study identification number. Follow-up assessments will be conducted at: Baseline, 3, 6, 12, 18, 24, 30, and 36 months.

Additional visits may be conducted after major events such as first freezing of gait episode, falls, surgery, or stroke.

During the study, information collected as part of routine clinical care may include:

- (1) Standardized gait-provoking tasks (7-meter walk, Timed Up and Go test, 360-degree turning, narrow doorway passing) with synchronized video recording
  - (2) Balance testing and gait parameter assessment
  - (3) Clinical scales and questionnaires (e.g., NFOG-Q, MDS-UPDRS II/III, Hoehn and Yahr stage, MMSE, MoCA, HAMD, HAMA, PDQ-39, constipation scale, PDSS sleep scale, olfactory testing)
  - (4) Speech tasks using a standardized protocol
  - (5) Structural brain MRI (3.0T), and in some centers functional MRI, EEG, or fNIRS
  - (6) Results of routine laboratory tests and other examinations obtained during standard medical care
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## 2. Potential Risks

This study does **not involve any experimental treatment or additional medical intervention**. It only involves collection of information generated during routine clinical care. Therefore, no additional risks beyond standard medical care are expected.

If you experience any discomfort during routine care, please contact your doctor promptly.

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## 3. Potential Benefits

You may not receive any direct medical benefit from participating in this study. However, your participation may help researchers better understand freezing of gait and improve future diagnosis, treatment, and rehabilitation strategies for patients with similar conditions.

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## 4. Voluntary Participation and Withdrawal

Your participation in this study is **completely voluntary**. You may choose not to participate or withdraw from the study at any time without penalty. Your medical care and legal rights will not be affected.

The study doctor may discontinue your participation if continued participation is not considered appropriate or if safety concerns arise.

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## 5. Confidentiality

All information collected in this study will be kept confidential. Your identity will be protected using a unique study identification number. Personal identifiers will not appear in publicly posted documents or study reports. Results will be reported only in aggregate form.

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## 6. Contact Information

If you have any questions about this study or wish to learn about study progress, please contact your study doctor:

**Telephone:** +86-135-1220-4476

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## 7. Ethics Committee Contact

If you have questions regarding your rights as a research participant, you may contact the Ethics Committee:

**Telephone:** +86-22-5906-5815

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## Statement Regarding Public Posting

This document is a **public posting version** of the informed consent form prepared for ClinicalTrials.gov. **Participant names, signatures, identification numbers, and handwritten dates are intentionally excluded** from this version.