

## **Informed Consent Form**

### **Survey on the Reproductive and Child-Rearing Situations of Patients with Severe Mental Disorders**

Participant Name: \_\_\_\_\_

Participant ID: \_\_\_\_\_

You are being invited to participate in a clinical research study. Before deciding whether to participate, it is important that you understand why this research is being conducted and what it will involve. Please take time to read the following information carefully. You may ask the research team any questions you have at any time—now, during, or after the study. You may also wish to discuss your participation with family or friends. Your decision to participate is entirely voluntary, and you will have ample time to consider it.

If you are currently participating in other research studies, please inform your study physician or researcher.

#### **1. Study Purpose**

We are recruiting participants aged 18–59 diagnosed with one of the following six severe mental disorders: Schizophrenia, Bipolar disorder, Delusional disorder, Schizoaffective disorder, Mental disorders due to epilepsy, Intellectual disability with associated mental disorders. All participants must be enrolled in the National Community Management and Treatment Program for Severe Mental Disorders.

Currently, China lacks precise data on the reproductive and child-rearing circumstances of individuals with mental disorders. This epidemiological survey aims to clarify these

patterns among patients with severe mental disorders to inform national mental health policy development.

## **2. Participant Enrollment**

Approximately 100,000–200,000 eligible participants receiving community-based mental health services across 10 selected cities/regions in China will be surveyed.

## **3. Study Procedures**

Your participation involves completing a structured questionnaire, which will take approximately 20 minutes after providing informed consent.

## **4. Potential Risks**

We anticipate minimal risk of discomfort during questionnaire completion. Should you experience psychological distress:

Contact the research team immediately for support.

If clinically significant symptoms are identified, we will refer you to specialized care while continuing to provide services.

## **5. Potential Benefits**

While no direct benefits are guaranteed, the collected data will contribute to evidence-based mental health policy formulation.

## **6. Confidentiality**

All personal data will be de-identified using coded identifiers.

Research records will be securely stored at Peking University Sixth Hospital.

Only authorized personnel (ethics committees, researchers, and sponsors) may access identifiable information.

Published results will never disclose individual identities.

## **7. Costs**

There are no costs associated with participation.

## **8. Compensation**

Not applicable.

## **9. Voluntary Participation**

Participation is entirely voluntary.


You may withdraw at any time without penalty.

Data collected prior to withdrawal will remain part of the study.

## **10. Contact Information**

For study-related questions or emergencies:


Chen Weiran (Researcher)


 188-4262-8078 (Work hours)

 Peking University Sixth Hospital, 51 Huayuan North Road, Haidian District, Beijing

For rights/concerns/complaints:

Institutional Review Board, Peking University Sixth Hospital

 010-82077885

 ethics\_pku6@sohu.com

### **Statement of Informed Consent**

The researcher has thoroughly explained to me (and my legal guardian) the purpose, procedures, risks, and benefits of this "National Survey on Reproductive and Child-Rearing Circumstances Among Patients with Severe Mental Disorders."

I confirm that I understand the consent form and have had sufficient time to ask questions.

I am aware of whom to contact for study-related concerns or emergencies.

I understand that my participation is voluntary and that I may withdraw anytime without consequence.

I consent to the confidential use of my data for legitimate research purposes.

I will receive a signed copy of this consent form.

Participant (Printed Name): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: // \_\_\_\_

Legal Guardian (Printed Name): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: // \_\_\_\_

Relationship to Participant: \_\_\_\_\_

\*(Guardianship hierarchy for minors: 1) Non-affected parent; 2) Grandparents; 3) Adult siblings; 4) Other relatives/friends approved by local authorities.)\*

Investigator (Printed Name): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: // \_\_\_\_\_