# Informed Consent (PX2023021)

Project name (Project number): Research on the recognition of delirium in neurocritical patients based on facial expression behavior patterns (PX2023021)

Applicant: Beijing Tiantan Hospital, Capital Medical University CRO: Beijing Tiantan Hospital, Capital Medical University

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# informed consent

Dear patients:

We cordially invite you to participate in the research project "Facial Expression-Based Behavioral Pattern Recognition for Dementia Identification in Neurocritical Patients", approved under Beijing Municipal Hospital Research Program. This collaborative study will be conducted at Beijing Tiantan Hospital, Capital Medical University, with an estimated 3,180 participants expected to volunteer. Certain sections of this document comply with regulatory requirements and have been reviewed and approved by the Ethics Committee of Beijing Tiantan Hospital, Capital Medical University, to safeguard the rights of all patients involved.

**1. Why do we need this research?**

Delirium, an acute and reversible neurological disorder, is characterized by fluctuating consciousness levels, inattention, and impaired cognitive function. As a common complication in critically ill patients, its prevalence ranges from 20% to 80% depending on patient demographics, significantly prolonging hospital stays, increasing mortality rates and medical costs, while causing marked long-term cognitive deterioration. Recent years have witnessed heightened attention toward delirium in neurocritical care patients. However, the limitations of conventional ICU screening tools—particularly their reliance on low consciousness levels or aphasia symptoms—have become apparent. The gold standard, the Diagnostic and Statistical Manual of Mental Disorders (DSM), requires high professional expertise and time-consuming implementation, posing particular challenges in intensive care units. These diagnostic bottlenecks have impeded both clinical and research progress in identifying delirium among neurocritical patients. This situation underscores the urgent need for objective, precise evaluation metrics and diagnostic frameworks. Current advancements in computer vision and pattern recognition technologies have proven effective in automatically distinguishing certain neuropsychiatric disorders. Notably, delirious patients exhibit significant emotional differences compared to healthy individuals, manifesting through altered postures, facial expressions, vocal patterns, and semantic variations—where facial expressions serve as the most potent emotional indicator. To address this, our project focuses on neurocritical patients, targeting consciousness, cognitive impairment, and emotional disturbances in delirium cases, with the goal of developing specialized facial expression collection experiments for this population. By leveraging collected data and computer vision technology, this project automatically identifies emotional states in delirious patients. Using facial action units (AUs) as digital features, it conducts quantitative research on behavioral patterns of delirious expressions and extracts corresponding high-level features to build a facial expression-based delirium recognition model. This initiative may provide a novel approach for diagnosing delirium, offering more precise and efficient methods for identifying delirium in critically ill neurological patients. It holds significant implications for optimizing the management of such patients.

**2. How many people will take part in this study?**

About 3,180 people will take part in the study at Beijing Tiantan Hospital, affiliated to Capital Medical University.

**3. Who should be selected for the study?**

At Beijing Tiantan Hospital's Comprehensive ICU, we provide intensive care for critically ill neurological patients, including those recovering from neurosurgery, stroke patients, and others

admitted to the ICU for neurological conditions. All patients must sign an informed consent form. Participation in this study will be determined by a physician after a thorough evaluation.

**4. Who should not participate in the study?**

Patients who meet any of the following criteria are excluded from this study: 1) Age under 18 years; 2) Persistent coma (GCS ≤ 8) within 7 days before and after surgery, making delirium assessment impossible; 3) Severe dementia, cognitive impairment, or psychiatric disorders that prevent delirium evaluation; 4) Surviving less than 24 hours in the ICU; 5) Patients with facial paralysis, post-traumatic facial damage, or other conditions that may severely impair facial recognition; 6) Patients with dementia, Parkinson's disease, depression, or other conditions affecting facial emotional expression.

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

The study will run from January 2023 to December 2025. You may withdraw from the study at any time without forfeiting any benefits you are entitled to. However, if you decide to withdraw during the study, we encourage you to first consult with your physician Life negotiation. Considering your safety concerns, a relevant check may be carried out after withdrawal.

**6. How was the study conducted?**

If you agree to participate in this study, please sign this informed consent form. You will undergo the following tests and procedures to further confirm your suitability for participation:

- Physical examination and medical history inquiry;
- Important signs (e.g. respiration, body temperature, heart rate, etc.);
- An electrocardiogram used to record electrophysiological activity.

In this part of the study, attention and consciousness changes and disorganized thinking were important criteria for delirium diagnosis. Therefore, our experimental design should capture distinct facial expression responses during patients 'impaired consciousness, attention deficits, and disorganized thinking. We developed mobile app software using questions from the CAM-ICU (Critical Care Intensive Unit) Delirium Assessment Tool for evaluating consciousness, attention, and cognition. The app captures patients' facial expressions while they answer questions. Attention assessment includes: "Read me 10 numbers. When you hear 8, squeeze my hand. 6-8-5-9-8-3-8-8-4 -7" and "Please extend these fingers (the examiner demonstrates with several fingers in front of the patient). Now use your other hand to replicate this gesture." Cognitive questions include: "Does a stone float on water? Are there fish in the ocean? Is one jin heavier than two jin? Can an iron hammer be used to nail wood?" or "Can leaves float on water? Are there elephants in the ocean? Is two jin heavier than one jin?" During video recording, examiners simultaneously document answer correctness and facial expressions. The app dynamically displays consciousness status throughout the recording process. Data processing features include standardized normalization, face cropping, alignment, and Data enhancement and other preprocessing operations.Throughout the study, we will collect information about your health and your test through a series of tests and steps.

**7. What obligations do I have to follow when participating in the study?**

During the study, you will need to do the following:

1) If you have taken a drug prohibited by the study before participating in the study, you must stop taking the drug for 4 weeks before participating in our study. If you need to stop taking the drug, you should consult your research doctor about how to stop taking the drug to ensure your safety.

2) If you are a fertile woman/guy, you will need to use contraception throughout the study. Please consult your study physician about which method and when to use it. Some methods of contraception are not approved during the study.

3) You will not be able to participate in any other clinical research related to drugs or medical devices during the study period.

**8. What are the costs involved in participating in the study?**

This study will provide you with free assessment of delirium and face image recording.

**9. What are the benefits of participating in the study for my treatment?**

Participation in this study may or may not lead to improvement of your condition, and the information obtained from this study will help determine which treatment is safer and more effective for other patients with similar conditions.

**10. Are there other treatment options?**

Participation in this study may improve or not improve your health. If you do not participate in this study, you will not have to undergo facial image recording.

**11. What are the risks of participating in the study?**

As non-invasive examinations involving facial image recording, this study may potentially infringe upon patients' right to portrait and privacy. We will sign informed consent agreements with participants to ensure the protection of personal information and prevent unauthorized disclosure of facial images. The sponsor shall bear all treatment costs in accordance with national regulations and provide appropriate financial compensation to participants. Even if you have signed this INFORMED consent form, you still reserve all your legal rights.

**12. Can I voluntarily participate in the study and withdraw from the study?**

Participation in this study is completely voluntary. You may refuse to participate in this study or withdraw from the study at any time during the study without giving any reason. This decision will not affect your doctor's treatment, and your medical treatment and rights will not be affected.

For your best interest, the physician or investigator may discontinue your participation in this study at any time during the course of the study.

If you withdraw from this study for any reason, and if your physician deems it clinically necessary, you may also be asked to undergo laboratory tests and physical examinations that are in your health's best interest.

**13. What happens if new information is available about the investigational drug?**

New information about the study drug may sometimes be available. If there is any new information that may affect your willingness to continue the study, we will inform you and discuss with you whether it is appropriate for you to continue the study.

**How will taking part in this study affect my life?**

You may feel that these visits and tests will be inconvenient and require special arrangements. In addition, some of the tests may make you feel uncomfortable. If you have any questions about the tests and procedures in the study, you may consult your research physician.

You are not allowed to use sedatives, analgesics, or hypnotics during the study. Your study physician will tell you which medications you can take and which you cannot take during the study. Consult your study physician before taking any new prescription medications.

If you have taken a study-prohibited medication prior to participation in this study, you must discontinue the medication for 4 weeks before participating in our study. If you need to discontinue the medication, you should consult your study physician about how to discontinue the medication to ensure your safety.

If you are a woman/guy of childbearing age, you will need to use contraception throughout the study. Please consult your study physician to determine which method and duration of contraception to use. Certain forms of contraception are not approved during the study.

You will not be able to participate in any other clinical study involving drugs or medical devices during the study.

**15. Is my personal information confidential?**

Your medical records will be kept at the hospital, and researchers, research authorities and ethics committees will be allowed to access them. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information within the scope permitted by law.

**16. Related advice**

*If you have any questions related to this study, please contact Guobin Zhang at 13705955517*

*010-59975098。*

If you have any questions about your rights and interests, or if you want to report dissatisfaction and concerns about participating in the study process

For enquiries, please contact the National Clinical Trial Institution Office of Beijing Tiantan Hospital at 010-59975178, or the Ethics Committee Office of Tiantan Hospital at 010-59978555. Email: ttyyirb@163.com.

**Subject consent statement**

**Agree to participate in the clinical study of facial expression behavior pattern based on neurocritical patient delirium recognition (PX2023021)**

By signing here, I agree that:

1. I have read this informed consent and the researcher has explained the study to me.
2. I have discussed and asked questions about this study, and the answers to these questions satisfy me.
3. I understand that I may be compensated by the sponsor in the event of any study-related injury.
4. I have had sufficient time to make a decision.
5. I have voluntarily consented to participate in the clinical study described herein.
6. I have been informed of the list of researchers I should consult in the study.
7. As stated in this INFORMED consent, I agree that researchers and other relevant personnel at Tiantan Hospital have access to my medical and personal information.

Signature of the subject:_____ Date:_____
Name in regular script:_____ Tel:

Signature of legal representative (if any):_____ Date:_____
Name of legal representative:_____ Tel:
Relationship between legal agent and patient:

Statement of the impartial witness:

I was present in the whole process of knowing the information, and the contents of the informed consent form and other written materials were accurately explained to the subjects or legal agents, who fully understood the meaning of the contents and expressed their consent to participate in the trial

examine。

Signature of impartial witness (if any):_____Date:_____
Name of impartial witness in regular script:_____ Tel:

Researcher signature:_____ Date:_____
Researcher's name in regular script:_____ Tel: