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Informed Consent Form

Changes in Information Integration and Brain Networks During Unresponsiveness Induced by Propofol, Dexmedetomidine, and Esketamine

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Informed Consent Form For Clinical Research

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Study Title: Changes in Information Integration and Brain Networks During Unresponsiveness Induced by Propofol, Dexmedetomidine, and Esketamine

Protocol Number:

Protocol Version: 01, 03, 20, 2026

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Institution: Fudan University Shanghai Cancer Center

Principal Investigator: Jun Zhang

You are being invited to take part in a clinical research study. This informed consent form provides information to help you decide whether to participate. Please read it carefully. If you have any questions, please ask the research staff in charge of this study.

Your participation in this study is voluntary. This study has been reviewed and approved by the Institutional Ethics Committee of this research institution.

1. Background and Purpose of the Study

General anesthesia is a drug-induced reversible state of unconsciousness. Traditional EEG monitoring such as BIS cannot accurately reflect the level of consciousness induced by different anesthetics and shows large individual differences. Commonly used intravenous anesthetics—propofol, dexmedetomidine, and esketamine—act on different molecular targets but can induce a common endpoint: unresponsiveness. However, their EEG characteristics are significantly different.

Current high-density EEG-based power spectrum, functional connectivity, and brain network analysis can more accurately reveal the mechanisms of anesthesia-induced loss and recovery of consciousness, which may help improve clinical monitoring. Many studies have shown that anesthesia-induced unconsciousness is associated with disrupted functional connectivity, reduced network efficiency, and limited functional states. Although several theories attempt to explain consciousness, findings from different anesthetics are inconsistent. Therefore, distinguishing drug-specific effects from state-related effects is critical for building a complete theory of consciousness.

This study will analyze the neural mechanisms of unconsciousness induced by these three drugs from the perspectives of information integration and brain networks, to provide evidence for accurate monitoring of consciousness during surgery. We will use spatial and

frequency-domain EEG analysis to explore the macroscale neural correlates of anesthesia-induced unresponsiveness (used as a surrogate marker for unconsciousness). This study may help develop EEG-based indicators and devices to more accurately judge consciousness under general anesthesia.

2. Study Procedures

A total of 120 subjects will be enrolled and randomly assigned to three groups: propofol group, dexmedetomidine group, or esketamine group. All subjects will be randomly assigned with equal probability.

One day before surgery, you will receive a preoperative visit to collect basic information, medical history, and test results, and you will sign the routine anesthesia consent form. You will then be randomly assigned to one group by drawing lots.

After you sign this informed consent form, on the day of surgery you will be re-evaluated in the operating room. Routine monitoring (ECG, blood pressure, pulse oximetry) and a high-density EEG electrode cap will be applied. You will wear earplugs to reduce noise and receive supplemental oxygen.

After resting with eyes closed for 5 minutes, one study drug will be infused to achieve sedation according to the random group assignment. EEG activity will be recorded continuously. Routine anesthesia induction and intubation will follow. All stored EEG data will be analyzed later

using specialized software.

All clinical procedures follow the standard anesthesia practice of the Department of Anesthesiology, Fudan University Shanghai Cancer Center. Drug dosages and administration follow clinical guidelines and international anesthesia practice until surgery is completed.

On the first postoperative day, you will be followed up to assess anesthesia satisfaction and any anesthesia-related complications.

If you agree to participate, we will discuss the study details with you or your family. Each participant will be assigned a unique study code, and medical records will be established.

3. Risks and Discomforts

The study procedure is nearly identical to routine anesthesia care. The only differences are that you will wear earplugs and an EEG electrode cap. No additional drugs beyond standard general anesthesia medications will be used.

For specific risks of general anesthesia, please refer to the **Anesthesia Informed Consent Form** of Fudan University Shanghai Cancer Center.

4. Benefits and Compensation

You may not receive direct personal benefit from participating in this study. However, the results will provide valuable information about the relationship between anesthetics and consciousness states, offer important

clinical evidence for developing improved depth-of-anesthesia monitors, and support future research on the treatment of pathological unconsciousness.

This study uses standard clinical general anesthesia; there is no financial compensation for participation.

5. Subject Responsibilities

To participate in this study you agree to:

- Provide accurate information about your medical history and current health status.
- Inform research staff of any discomfort you experience during the study.
- Disclose if you have participated in another clinical trial in the past 3 months or are currently enrolled in another study.

6. Privacy and Confidentiality

Your participation and personal data will be kept confidential. Your high-density EEG data will be identified by a study code, not your name. Your identity will not be disclosed to anyone outside the research team without your permission. All researchers and sponsors are required to protect your privacy.

Your records will be stored in locked cabinets accessible only to research staff. Regulatory authorities or Ethics Committee members may review your records as required by law to ensure study compliance. No personal identifying information will be disclosed in any publications resulting

from this study.

7. Injury Compensation

If you sustain injury directly resulting from your participation in this study, you will receive free medical treatment and compensation in accordance with applicable laws and regulations of China.

8. Costs

There are no additional costs to you for participating in this study.

9. Compensation

There is no financial or other form of payment for participation.

10. Right to Withdraw

You may choose not to join or may withdraw from this study at any time by notifying the investigator. Your data will not be used in the final analysis, and your medical care and rights will not be affected.

The investigator may discontinue your participation if you require alternative treatment, fail to follow the study plan, suffer a study-related injury, or for any other valid reason.

11. Contact Information

You may obtain study information and updates at any time. If you have questions about the study, experience discomfort or injury, or have concerns about your rights as a research subject, please contact:

Xiaoge Liu

Telephone: 18516534948

For ethical concerns related to this study, please contact the Ethics Committee Office:

Address: Room 216, Building 2, 270 Dong'an Road

Telephone: 021-64175590-88503

Informed Consent Statement

I have read this informed consent form.

I have been given the opportunity to ask questions, and all questions have been answered to my satisfaction.

I understand that participation in this study is voluntary.

My personal identity and data will be kept confidential.

I may choose not to participate or withdraw at any time without affecting my medical care or rights.

I understand the investigator may discontinue my participation if I need other treatment, fail to follow the study plan, experience a study-related injury, or for other valid reasons.

I will receive a signed copy of this informed consent form.

Subject Name: _____

Subject Signature: _____

Date: _____ / _____ / _____

I have accurately explained this document to the subject, who has read it carefully and had the opportunity to ask questions. I confirm that consent is given voluntarily.

Investigator Name: _____

Investigator Signature: _____

Date: _____ / _____ / _____

(Note: If the subject lacks decision-making capacity, signature by a legally authorized representative is required.)
