PARENT/LEGAL GUARDIAN INFORMATION AND INFORMED CONSENT FORM

For Parents or Legal Guardians of Pediatric Participants

Mechanisms of General Anesthesia-Induced Altered Consciousness via Cortical-Thalamic Network Modulation and Development of a Precision Anesthesia Depth Monitoring Device

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Institution	Beijing Chaoyang Hospital, Capital Medical University

Dear Parent or Legal Guardian,

We are conducting a research study entitled "Mechanisms of General Anesthesia-Induced Altered Consciousness via Cortical-Thalamic Network Modulation and Development of a Precision Anesthesia Depth Monitoring Device." Based on your child's current clinical circumstances, your child may meet the eligibility requirements for this study, and we are inviting you to consider allowing your child to participate. This form explains the purpose of the study, what participation involves, the possible benefits, risks, and discomforts, and your rights as a parent or legal guardian. Please read it carefully before deciding whether your child should take part.

When the investigator reviews this form with you, you may ask questions at any time and request an explanation of anything you do not understand. You may also discuss the study with family members, friends, or your child's treating physician before making a decision.

Your decision, and your child's willingness to participate, are entirely voluntary. The study has been reviewed and approved by the Ethics Committee of Beijing Chaoyang Hospital. If your child is currently participating in another clinical research study, please inform the study doctor or research staff.

1. Why is this study being conducted?

Study objectives

- To determine whether frontal-hub cortico-cortical and cortico-thalamic networks constitute core brain regions or circuits involved in changes in consciousness induced by general anesthetic drugs.
- To investigate the roles and mechanisms of cortico-cortical and cortico-thalamic circuits in anesthesia-induced alterations of consciousness.
- To evaluate the role and mechanisms of transcranial temporal interference stimulation (tTIS) during transitions in consciousness and to establish a clinical tTIS neuromodulation database.
- To establish a multimodal anesthesia-depth monitoring framework and develop a prototype device for precision monitoring of anesthetic depth.

Background

How general anesthetic drugs cause a reversible loss of consciousness remains a major scientific question in anesthesiology and limits the development of precision anesthesia. In current clinical practice, there is still a need for monitoring tools that can assess anesthetic depth more accurately on the basis of underlying mechanisms. Anesthesia that is too light may be associated with hemodynamic fluctuations, intraoperative awareness, or movement that interferes with surgery. Anesthesia that is too deep may suppress respiratory and cardiovascular function and, in severe situations, threaten patient safety.

General anesthesia also provides a controllable, reversible, and repeatable way to alter the level of consciousness, making it an important model for studying the neural basis of consciousness. A clearer understanding of how general anesthetics work may therefore contribute both to the development of more precise anesthesia-depth monitoring and to fundamental research on consciousness.

2. Who may be invited to participate?

Inclusion criteria

- Age 6 to 12 years.
- American Society of Anesthesiologists (ASA) physical status I.
- Written informed consent provided by the child's legal guardian.

Exclusion criteria

- A history of neurological or psychiatric disease, including epilepsy.
- Known hearing impairment or physical impairment that could interfere with completion of study tasks.
- A history of allergy to propofol, benzodiazepines, or other anesthetic drugs used in the study.
- Long-term use of sedative or analgesic medications for more than 1 month.
- Disrupted sleep patterns during the 14 days before the study.
- Communication difficulties or inability to cooperate with EEG data acquisition.

3. How many people will take part in the study?

The study is organized into four anesthetic-drug groups: propofol, remimazolam, esketamine, and dexmedetomidine. Each drug group includes three prespecified age subgroups: children aged 6-12 years, young adults aged 20-40 years, and older adults aged 65-80 years. The planned sample size is 20 participants per prespecified subgroup, with an overall target of 320 participant-visits across the clinical study components.

For the pediatric subgroup, participants are surgical patients. Only resting-state high-density EEG will be collected, and the recording will be completed in the operating room. Young-adult and older-adult groups consist of healthy volunteers monitored with 64-channel EEG. Across the study, EEG data are collected under different anesthetic drugs and during different states of consciousness, including wakefulness, loss of consciousness, and recovery.

4. How long will my child participate?

Your child's participation is expected to occur during the peri-anesthetic period on the day of surgery. Most study procedures will take place in the operating room and will consist of EEG monitoring and recording of related information before anesthesia, during anesthesia, and during recovery from anesthesia. The exact duration will depend on the actual surgical and anesthetic schedule.

As a general rule, no additional return visits are planned solely for this study. The research team may review your child's medical record for a short period after surgery to document anesthetic recovery and other perioperative information. This review will not add extra examinations or treatment and should not create a meaningful additional time burden for your child.

5. What will happen if my child participates?

In the operating room, research staff will place EEG monitoring electrodes on your child's scalp to record electrical brain activity before anesthesia, during administration of anesthesia, and during recovery. EEG is a noninvasive recording technique in which electrodes attached to the scalp detect brain electrical activity; the electrodes do not deliver electrical current into the body.

In addition to EEG data, the study team will record necessary clinical information related to the surgery and anesthesia, such as age, sex, height, weight, anesthetic medications, vital signs, and recovery from anesthesia.

Participation in the study will not replace, reduce, or delay your child's planned surgery or anesthesia. Your child's clinical anesthetic plan will continue to be determined according to medical needs. If at any time the study doctor determines that continued participation is not appropriate, the study procedures will be stopped or adjusted as needed, with your child's medical safety taking priority.

6. How might participation affect my child's daily life?

Once the surgery and anesthesia are complete and the required EEG and clinical information have been collected, your child's active participation will generally be finished. The research team may continue to organize and analyze the collected information, but your child will usually not need to return to the hospital or undergo additional research examinations.

There is no single list of medications that is prohibited for every participant; medication decisions will be individualized by the doctor. Please consult your child's study doctor before your child begins any new prescription medication during the study period. For your child's safety and to protect the validity of the study results, your child should not participate in another clinical study involving a drug or medical device while participating in this study.

7. What are the possible risks, side effects, or discomforts?

7.1 Risks related to anesthetic drugs

Depending on the anesthetic drug used clinically, your child may experience known or expected adverse reactions, including the following:

Anesthetic	Possible adverse reactions
Propofol	Low blood pressure; slowed heart rate or abnormal heart rhythm; respiratory depression or apnea; reduced blood oxygen; airway obstruction; and burning, stinging, or pain at the injection site. In children, the risk of severe bradycardia may increase when propofol is used together with fentanyl or similar medicines.
Remimazolam	Low oxygen levels, low blood pressure, bradycardia, slowed breathing, inadequate ventilation, or apnea. Concomitant use with opioid analgesics or other sedative-hypnotic drugs may increase the risk of deep sedation and respiratory depression.
Esketamine	Emergence reactions such as dreams, nightmares, dizziness, or agitation; increased blood pressure and heart rate; nausea, vomiting, increased salivation, blurred vision, and respiratory effects during anesthesia. Allergic reactions, arrhythmias, or low blood pressure may occur in a small number of patients.
Dexmedetomidine	Common adverse reactions include low blood pressure, bradycardia, and dry mouth. Transient high blood pressure may also occur. In rare cases, marked bradycardia or even sinus arrest may occur.

7.2 Additional risks and discomforts related to the research

The main additional research procedure is high-density EEG monitoring. EEG is generally safe, noninvasive, and painless, and the electrodes do not send electrical current into the body. During placement, fixation, or removal of the electrodes, however, your child may experience localized scalp redness, mild itching, discomfort,

or temporary skin irritation. A small number of children may develop a blister or superficial skin injury. These effects are usually mild and temporary and generally improve after the electrodes are removed.

7.3 Rare but serious risks

All anesthetic drugs carry a small risk of serious adverse reactions, including severe allergic reactions, significant respiratory depression, persistent low oxygen levels, major blood-pressure changes, and serious arrhythmias. Because these events are most likely to occur during the peri-anesthetic period, the study will be conducted in the operating room by experienced anesthesiologists and clinical staff, with continuous monitoring and prompt treatment if needed.

7.4 What will happen if my child has an adverse reaction or discomfort?

If your child experiences any discomfort, unusual reaction, or side effect during the study, please tell the study doctor or clinical staff immediately. The study doctor will take appropriate measures based on the situation, which may include closer monitoring, oxygen supplementation, adjustment or discontinuation of relevant medications, symptomatic treatment, and, when necessary, further emergency treatment or resuscitation.

If the study doctor believes that continued participation would not be in your child's best interest, or if your child cannot tolerate the discomfort, participation may be stopped at any time. You may also withdraw your child from the study. This will not affect your child's subsequent routine treatment. Monitoring equipment, oxygen, assisted ventilation, and emergency medications required during the peri-anesthetic period will be prepared in accordance with clinical standards.

8. Are there any possible benefits to my child?

Your child may not receive a direct medical benefit from taking part in this study. However, the information obtained may provide new scientific knowledge that could help improve the safety and effectiveness of anesthesia-related care for children in the future.

9. What are the alternatives if my child does not participate?

You may choose not to allow your child to participate. If your child does not take part, your child will still receive the routine surgery, anesthesia, and perioperative care selected by the treating doctors according to the medical condition and surgical needs. Refusal will not affect your child's normal medical care, nursing care, or future treatment arrangements.

This study mainly adds EEG monitoring and study-related data collection to routine clinical care. The alternative to participation is therefore to receive routine medical and anesthetic care without the research-related EEG and data collection.

10. Does my child have to participate and remain in the study?

No. Your child's participation is entirely voluntary. You may refuse participation without any negative effect on your child's current or future medical care. Even after you have agreed, you may change your mind at any time and tell the research team that you want your child to withdraw. This will not affect your child's access to normal medical services. If you decide to withdraw your child, please inform the study doctor so that appropriate advice and guidance can be provided regarding your child's health.

During the study, new information relevant to treatment or participation may become available. The research team will inform you of important new information so that you can decide whether your child should continue in the study. If your child withdraws, the study team may recommend safety follow-up; you have the right to decline such follow-up. If new information relevant to your child's health or rights becomes available after withdrawal, the study team may contact you again.

After withdrawal, no new study data related to your child will be collected. The research team will explain how information collected before withdrawal, including data related to an adverse reaction, will be handled.

As a general principle, information collected before withdrawal will be stored securely until final destruction and will not be routinely used or disclosed further. In rare circumstances, authorized government or regulatory authorities may need to review study records for supervision, inspection, or statistical purposes; these records may include information collected while your child was participating.

11. Why might my child's participation be stopped?

- You or your child asks to withdraw. You may decide at any time that your child should leave the study without affecting normal treatment or medical rights. If your child does not agree to participate, the study doctor will not force participation even if you have given permission.
- The study doctor believes that continued participation may be harmful or unsafe for your child, for example because your child develops discomfort, an abnormal reaction, or another safety concern.
- Your child's medical condition, surgical plan, or anesthetic plan changes and participation is no longer appropriate.
- The study team discovers that your child does not meet the inclusion criteria or meets an exclusion criterion.
- Required study procedures cannot be completed, for example because EEG monitoring or related data collection cannot be completed.
- Equipment failure, protocol modification, a requirement from the Ethics Committee, or a decision by the investigator or funding party to terminate the study early makes continued participation impossible.

If your child withdraws or participation is stopped for any of these reasons, the study doctor will explain the reason as appropriate and will continue to provide any necessary routine medical care. Leaving the study will not affect your child's subsequent surgery, anesthesia, or other normal treatment.

12. Are there any costs, payments, or reimbursements?

Your child will receive compensation for participation in accordance with the study arrangements. If your child is eligible and completes the study, compensation covering items such as transportation and nutrition allowances will total RMB 500. If your child is enrolled and begins the study but does not complete all study procedures, compensation may be provided in proportion to the study activities actually completed.

If a participant is required to withdraw because of deliberate noncompliance with study requirements, the research team may withhold part or all of the compensation in accordance with the International Ethical Guidelines for Health-related Research Involving Humans (2016).

13. What happens if my child experiences a research-related injury?

If your child experiences any discomfort or unexpected event during the study, please notify the study doctor promptly. The doctor will assess the situation and provide appropriate medical care. If your child is harmed as a result of a study-related drug or a diagnostic examination required by the study protocol, the study team will provide active medical treatment and will bear the related treatment costs and provide appropriate financial compensation in accordance with applicable Chinese laws and regulations.

14. What do I need to do if my child participates?

- Provide accurate information about your child's past medical history and current medical condition.
- Tell the study doctor about any health problem your child experiences during the study.
- Tell the study doctor about any new medicine, drug, vitamin, or herbal product your child takes during the study.
- Unless approved by the study doctor, your child should not take any medication or receive any treatment during the study, including prescription medicines and over-the-counter products such as vitamins and herbal products.
- Do not enroll your child in another medical research study while participating in this study.
- Follow the instructions of the study doctor and research staff.
- Ask the study team at any time if anything is unclear.

15. Will my child's personal information be kept confidential?

If your child participates, information about your child's participation and personal study data will be kept confidential. Information that directly identifies your child will not be disclosed to people outside the research team unless you have given permission. All study personnel are required to protect your child's identity.

Study records will be stored in locked filing cabinets and will be accessible only to authorized research personnel. When necessary to ensure that the study is being conducted properly, authorized government authorities or members of the Ethics Committee may review your child's personal information at the study site in accordance with applicable requirements. Any publication or public report of the study results will not disclose information that personally identifies your child.

16. Who can I contact if I have questions or concerns?

Reason for contact	Contact	Telephone
Questions about the study		13810678936
Questions about your child's rights as a research participant	Medical Ethics Committee of Beijing Chaoyang Hospital	010-85231484 Weekdays, 08:00-17:00

17. What will happen to any leftover samples?

This study is an observational study and collects clinical data only. No examination samples will be collected from your child for this study.

You may also refuse the use of any residual samples. Refusal will not have any negative effect on your child's access to routine medical care. If you refuse, any residual study samples will be destroyed after completion of the study in accordance with applicable national requirements and procedures and will not be used for other research.

INFORMED CONSENT SIGNATURE PAGE

Parent/Legal Guardian Information and Informed Consent Form

Parent/Legal Guardian Statement

The researcher has explained to me the background, purpose, procedures, possible risks, and possible benefits of the study "Mechanisms of General Anesthesia-Induced Altered Consciousness via Cortical-Thalamic Network Modulation and Development of a Precision Anesthesia Depth Monitoring Device." I have had sufficient time and opportunity to ask questions, and I am satisfied with the answers I received. I know whom to contact if I have questions or need additional information.

I have read this informed consent form and agree to allow my child to participate in the study. I understand that my child may leave the study at any time without giving a reason and that withdrawal will not affect my child's normal medical care. I have been told that I will receive a copy of this informed consent form containing my signature and the signature of the person who obtained consent.

Use of my child's information in other research:

☐ I AGREE that my child's data, medical records, and examination samples may be used for research other than this study.

☐ I DO NOT AGREE that my child's data, medical records, and examination samples may be used for research other than this study.

Participant name (print)			
Guardian 1 name (print)		**Date**	____ / ____ / _____
Guardian 1 signature		**Relationship to participant**	
Mobile phone			
Guardian 2 name (print)		**Date**	____ / ____ / _____
Guardian 2 signature		**Relationship to participant**	
Mobile phone			

Researcher Statement

I have explained to the participant and the participant's legal guardian the background, purpose, procedures, possible risks, and possible benefits of the study "Mechanisms of General Anesthesia-Induced Altered Consciousness via Cortical-Thalamic Network Modulation and Development of a Precision Anesthesia Depth Monitoring Device." I provided sufficient time for them to read the informed consent materials, discuss the study with others, and ask questions, and I answered the questions raised. I provided contact information for study-related questions and explained that the participant may leave the study at any time without giving a reason.

Signature of person obtaining consent		**Date**	____ / ____ / _____
Mobile phone			