Ethical Approval Letter

Fudan University Shanghai Cancer CenterInstitutional Review Board (SCCIRB)B-1 (Version 4.0 – October 19, 2020)

Ethics Approval No.: 2604-Exp427

Review Dates: April 19, 2026; April 24, 2026

Review Meeting Venue: NA

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

Department: Department of Anesthesiology

Principal Investigator: Zhang Jun

Sponsor: Investigator-Initiated

StudyReview Type: Expedited Review

Primary Reviewers: Wang Huaying, Hu Jie

Documents Submitted for Ethical Review

- National Medical Products Administration (NMPA) Approval Document: Not Submitted
- Study Protocol, Version V01 (2026.03.20): Submitted
- Project No. MA-202603-001: Submitted
- Informed Consent Form, Version V01 (2026.03.20): Submitted
- Drug Production License / Test Report / Medical Device Registration Certificate: Not Submitted
- Investigator Curriculum Vitae and Clinical Research Experience: Submitted
- Case Report Form (CRF), Version V01 (2026.03.20): Submitted

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Ethical Review Opinion

In accordance with the standard operating procedures (SOP) of the IRB, the Institutional Review Board conducted an expedited review of the study protocol, informed consent form, and other related documents submitted by Professor Zhang Jun from the Department of Anesthesiology.

The two primary reviewers completed their reviews on April 19, 2026 and April 24, 2026, respectively. Both reviewers provided a favorable opinion: APPROVED.

The Institutional Review Board hereby approves the study protocol Version V01 (2026.03.20) and the use of the informed consent form Version V01 (2026.03.20) for subjects at Fudan University Shanghai Cancer Center.

Terms and Requirements

1. This study will be subject to ongoing review by the IRB via expedited review.

This approval letter will be kept on file at each study site and its ethics committee. The frequency of ongoing review is 12 months from the date of approval. The IRB reserves the right to adjust the frequency according to actual study progress.

2. The study must be conducted strictly in accordance with the approved protocol, and comply with CFDA/GCP and the principles of the Declaration of Helsinki.

3. Please notify the IRB promptly if the study is suspended or terminated early.

4. Serious adverse events (SAEs) and unexpected events affecting the benefit-risk ratio must be reported to the IRB in a timely manner.

5. Any amendments to the approved protocol, informed consent form, or changes to the principal investigator must be submitted to the IRB for re-review and approval before implementation.

6. Any protocol violations must be reported to the IRB promptly.

7. An application for ongoing review must be submitted 1 month before the expiration date, regardless of whether the study has started.

8. This approval is valid for 1 year. The investigator shall submit annual or periodic reports within the validity period. Subsequent review results will be issued in an “Ethical Review Notice”.

9. A final study report must be submitted to the IRB for review upon study completion.

10. All review decisions of the IRB are fully stated in this approval letter.

Attachments:IRB Sign-in Sheet and Confidentiality Agreement; IRB Member Roster (for full board review projects)

Official Translation Certification

This English version is a faithful, complete, and accurate translation of the original Chinese ethical approval document. All content is consistent with the original Chinese version.

Fudan University Shanghai Cancer Center Institutional Review Board (SCCIRB)

Signature of Chairperson / Vice Chairperson: _____

Official Seal: _____

Approval Date: April 27, 2026