Clinical Trial Approval
of the Ethics Committee of First Affiliated Hospital, Army Medical University, PLA

Approval No.: (A) KY2025190

Project Name	Accelerated intermittent theta burst stimulation (iTBS) for the upper limb recovery after subacute stroke: a single blinded multicenter randomized controlled trial
Classification	☐GCP: ☐Drug registration ☐Medical device registration ■Clinical Scientific Research
Clinical Stage	For Drug: ☐PhaseI ☐Phase II ☐Phase III ☐Phase IV ☐Other For Medical Device: ☐Clinical Test ☐Clinical Verification ☐Other

Application Department: Department of Rehabilitation

Principal Investigator: Jingming Hou

Post Title of PI: Associate Chief Physician

Submitted Materials:

1. Initial Review Application Form;
2. Re-submission Application Form;
3. Protocol (Version: 3.0; Date: 2025.09.03);
4. Informed Consent Form (Version: 2.0; Date: 2025.09.03);
5. CRF (Version: 2.0; Date: 2025.09.03);
6. References;
7. CV of PI (GCP);
8. Scientific review approval document;
9. Project assignment paper;
10. List of participating research units;
11. User manual, registration certificate and other qualification certification materials

Description: Ethics committee members had reviewed the study by full board meeting on Aug. 19, 2025, with the voting result was Resubmission (See Letter of Amendment Advice). PI revised protocol and resubmitted. Ethics committee had reviewed the re-submission by expedited review and assumed that: (1) the researchers are qualified for the clinical trial; (2) the submitted data are complete; (3) the protocol and informed consent form meet the requirement of ethical principles.

Final Result: Approve

Frequency of Continuing Review: ☐3 months ☐6 months ■12 months ☐Other

Expiry Date: In accordance with expected study time period, this approval is valid from Sep. 10, 2025 to Sep. 9, 2028

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Notes:

1. Please conduct this study in accordance with approved protocol and follow GCP guidelines;
2. Modifications about protocol, ICF, recruitment advertisement cannot be made without the consent from the ethics committee;
3. Once happen, serious adverse events must be reported to the ethics committee within 24 hours;
4. The progress report should be submitted one week in advance before continuing review;
5. Once happen, serious protocol deviation and continuous protocol deviation must be reported to the ethics committee;
6. Please submit Termination& Suspension Report if this study is going to be terminated or suspended;
7. Please submit progress report 10 days before expiry date of approval letter;
8. A final report must be submitted to the ethics committee at the end of research.

Ethics Committee of First Affiliated Hospital
of Army Medical University, PLA (stamp)
Date: Sep. 10, 2025

Statement: The composition and working procedures of the present ethics committee are in strict compliance with the ethical principles from the *Ethical Review Measures for Biomedical Research Involving Human Beings (NHC 2016)* and *Chinese Good Clinical Practice (NHC&NMPA 2020), Rules on Clinical Research for Medical Devices (NHC&NMPA 2022), Ethical Review Measures for Life Science and Medical Research Involving Human Beings (NHC et al. 2023), Measures for Ethical Review of Science and Technology (Trial) (MOST et al. 2023), Declaration of Helsinki, International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2002)* and *ICH GCP.*

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