Ethical Review Approval Document

Zhejiang Hospital Ethics Committee (IRB)

Approval No.	ZJHIRB-004K
Effective Date	14 Jan 2025
Study Title	Development of an ICU Healthcare-Associated Infection (HAI) Risk Prediction System Based on Environmental Multimodal Feature Fusion
Sponsor / Funder	Zhejiang Hospital
Acceptance No.	2025-003 (K)
Principal Investigator	Lü Xiaochun
Responsible Department	Intensive Care Unit (ICU)
Category of Review	Initial Review
Type of Review	Expedited Review
Date of Review	13 Jan 2025
Location of Review	Ethics Office

Items Reviewed

1. Initial Review Application Form
2. PI's Responsibilities Statement, Curriculum Vitae, and Conflict-of-Interest Declaration
3. Clinical Study Protocol (Version 1.0, dated 2025-01-06)
4. Application for Waiver/Alteration of Informed Consent
5. Data Collection Form (Version 1.0, dated 2025-01-06)
6. Research Materials Integrity Commitment
7. Proposed Presentation and Publication Plan

Evaluation

Following expedited review, the Ethics Committee found the protocol and its risk-benefit assessment ethically acceptable and approved the study. Because this is a retrospective analysis of previously collected clinical records that excludes personally identifiable information and involves no more than minimal risk, the Committee granted a waiver of informed consent, provided that investigators strictly protect participant privacy in accordance with applicable laws and regulations of the People’s Republic of China (PRC) and disclose no identifiable data in any publication or report.

Decision

Approved

Chair Signature	Mao Wei (signed and sealed)

Stamp of EC

[Official Seal of the Ethics Committee]

Period of Validity

The study must be initiated at this institution within one year of the date of initial approval. If not initiated within this period, this approval automatically lapses.

Continuing Review

Continuing review is required every 12 months from the date of approval. The first progress report is due no later than one month before 13 Jan 2026. The Committee reserves the right to adjust the review frequency according to the study's actual progress.

Statement

The responsibilities, membership composition, operating procedures, and record keeping of this Ethics Committee adhere to the Regulations on Ethical Review of Biomedical Research Involving Humans, the International Ethical Guidelines for Health-related Research Involving Humans, the Declaration of Helsinki, Good Clinical Practice (GCP), ICH-GCP, and all relevant laws and regulations of the People's Republic of China.

Notes

1. Conduct the study in strict accordance with applicable laws, regulations, and ethical principles.
2. Conduct the study strictly as per the EC-approved documents (protocol, informed-consent forms, recruitment materials, etc.). Any changes must receive EC approval before implementation to safeguard participants' rights and well-being.
3. All SAE/SUSARs occurring at this site and annual safety updates must be reported to the EC in accordance with the latest NMPA/GCP requirements. SAE/SUSARs occurring at other participating sites must be submitted in summarised and assessed form.
4. The EC reserves the right to re-evaluate the study and issue further decisions as warranted by the reports received.
5. Regardless of whether the study has begun, submit a progress report at least one month before the due date of each continuing review.
6. The sponsor should submit aggregate progress reports from all sites to the leading-site EC. Any situation that may significantly affect study conduct or increase risk to participants must be reported to this EC promptly in writing.
7. Protocol deviations—including enrolling participants who fail to meet inclusion/exclusion criteria, failure to withdraw participants meeting termination criteria, dosing errors, prohibited concomitant medications, or any violation that may affect participants' safety, rights, or data integrity—must be reported as protocol deviation reports by the sponsor, monitor, or investigator.
8. If the study is suspended or terminated early for any reason, submit a suspension/termination report to the EC without delay.
9. Upon completion of the study, submit a final report to the EC.
10. Studies involving collection or use of Chinese human genetic resources must obtain approval from the China Human Genetic Resources Administration Office before being conducted at this site.
11. For studies approved by this EC, the applicant must register the study in the applicable national and regulatory clinical trial registration systems (e.g., NHC, CDE) before initiation.

Ethics Committee Membership Roster (2024-09-01 to 2026-08-25)

Name	Gender	Institution / Title	Specialty	Role
Mao Wei	M	Chief Physician, Zhejiang Hospital	Cardiology	Chair
Chen Xinyu	F	Chief Physician, Zhejiang Hospital	Gastroenterology	Vice-chair
Zhang Hong	F	Associate Chief Physician, Zhejiang Hospital	Gastroenterology	Vice-chair
Qiao Song	M	Chief Physician, Zhejiang Hospital	Neurology / Critical Care	Member
Huang Hong	F	Associate Chief Physician, Zhejiang Hospital	Endocrinology	Member
Ding Fang	F	Chief Physician, Zhejiang Hospital	Cardiology	Member
Chen Xiaofeng	M	Associate Chief Physician, Zhejiang Hospital	Thoracic Surgery	Member
Chen Hui	M	Associate Chief Physician, Zhejiang Hospital	General Surgery	Member
Xu Liyu	M	Associate Chief Physician, Zhejiang Hospital	Geriatrics	Member
Ye He	F	Associate Chief Pharmacist, Zhejiang Hospital	Pharmacy	Member
Zhang Yu	M	Chief Physician, Zhejiang Hospital	Oncology	Member
Gu Zenghui	M	Chief Physician, Zhejiang Hospital	Orthopedics	Member
Ma Yelin	F	Associate Chief Physician, Zhejiang Hospital	Traditional Chinese Medicine	Member
Ji Conghua	M	Professor, Zhejiang Chinese Medical University	Clinical Epidemiology & Evidence-based Medicine	Member
Ye Qingsong	M	Lawyer, Dacheng (Hangzhou) Law Firm	Law	Member
Wang Zhaosu	M	Assistant Researcher, PUMC School of Population Medicine & Public Health	Medical Ethics	Member
Xie Yijing	F	Lecturer, Hangzhou Medical College	Medical Ethics	Member
Li Wei	F	Assistant Researcher, Zhejiang Hospital	Discipline Inspection / Nutrition & Food Hygiene	Member / Secretary

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This English document is a true and accurate translation of the original Chinese Ethical Review Approval Document (Approval No. ZJHIRB-004K) issued by the Zhejiang Hospital Ethics Committee on 14 January 2025.

Translator / Preparer: Lin Kai Date: 27 Jun 2025