

APPROVAL OF ETHICAL REVIEW

For Use in Research Project Submission and International Communication

Approval No.: SZZYYY-KY-2026-01

Research Title:

Unexpected Red Blood Cell Antibodies in Transfusion Recipients: A 10-Year Retrospective Analysis of Prevalence, Specificity, and Clinical Significance

Investigating Institutions:

Department of Laboratory, Traditional Chinese Medicine Hospital of Shizong County,
Yunnan Province

Nature of Study:

This is a non-interventional, retrospective observational study analyzing de-identified historical medical records from January 2014 to December 2023. The research involves no direct interaction with human subjects and utilizes only anonymized laboratory data collected during routine pre-transfusion antibody screening procedures.

The dataset includes demographic and clinical information such as age, sex, blood group, prior transfusion history, and obstetric history, all of which have been stripped of personal identifiers and assigned unique coded identifiers for research purposes. Given the exclusively retrospective nature of the study and the use of anonymized secondary data, it has been determined that individual informed consent is not required under applicable ethical guidelines for secondary data analysis involving minimal risk to privacy.

Ethical Review Conclusion:

The study protocol has been reviewed and approved by the Ethics Review Committee of Traditional Chinese Medicine Hospital of Shizong County, Yunnan Province. The research was conducted in accordance with the ethical principles outlined in the Declaration of

Helsinki (2013 revision) and complies with national regulations on human subject research, including the Measures for Ethical Review of Biomedical Research Involving Humans (National Health Commission, 2023). The review was carried out through an expedited review process appropriate for studies posing minimal risk.

The requirement for written informed consent was waived due to the retrospective design, the absence of interventions, and the exclusive use of fully de-identified data. The Committee confirms that the study poses negligible risk to patient confidentiality and that all data handling procedures meet institutional standards for data protection and privacy preservation.

Issuing Authority:
Ethics Review Committee

Traditional Chinese Medicine Hospital of Shizong County (云南省师宗县中医医院)
Yunnan Province, China

Date Issued: March 1, 2026

