First Hospital of Shanxi Medical University

Clinical Research (Scientific Research) – Ethics Review Approval Document

Document code: SYDYY-KYLL-AF-003/01

Ethics approval number: **KYLL-2025-105**

Project Information:

Project title:

Association between the expression levels of MUC12, ENPP4, and FBXL3 genes and clinicopathological characteristics and prognosis of clear cell renal cell carcinoma

Study category:

☐ Initiated scientific research project

☑ Newly initiated clinical research

☐ Graduate training project

Department / Specialty:

Department of Urology

Principal investigator:

Yang Wenjie

Ethics Review Information:

Date of ethics review:

March 6, 2025

Review location:

Outpatient Building Conference Room

Approved materials

☑ Initial ethics review application form

☐ Ethics amendment application form

☐ Research progress report

- ☐ Annual review
- ☐ Final report

☐ Ethics correction application form

☑ Clinical research protocol (Version 1.0, dated February 10, 2025)

☐ Informed consent form (Version 2.0, dated March 21, 2025)

☑ Certificates of ethics/GCP training for the principal investigator

☑ Scientific research project approval documents

☐ Recruitment materials

☐ Case report form (CRF) (Version 1.0)

☑ Other: waiver of informed consent

Initial review method:
☑ Expedited review
☐ Full committee review

Initial review conclusion:
☑ Approved

Continuing review / annual review requirements

Continuing review frequency:
Every 12 months

Applicants are required to submit an annual or continuing review application (research progress report) at least one month before **March 21, 2026**.

Validity period of ethics approval

Approval validity period:
From **March 21, 2025** to **March 21, 2026**

- If the study has not started within the validity period, a new initial ethics review must be submitted.
- If the study exceeds the validity period without renewal, the ethics approval becomes invalid. All research activities, including interventions and data collection, must be immediately suspended.If suspension of research interventions may cause harm to participants, the study must follow ethics committee requirements to ensure participant safety.

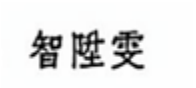
Notes

- In accordance with the ethical principles outlined in the Ethics Review Measures for Human Biomedical Research (2016) issued by the National Health Commission, the Medical Device Clinical Trial Quality Management Specifications (2022) jointly issued by the National Medical Products Administration and the National Health Commission, and the Clinician-Initiated Clinical Research in Medical and Health Institutions (Trial) (2021) issued by the National Health Commission, this clinical research has been approved by the Ethics Committee.

- Please ensure that the research team completes training on the protocol, informed consent, and participant protection before commencing the study, and retains records of this training for review.
- For research projects involving Chinese human genetic resources that require approval, commencement is only permitted after obtaining authorization from the Administrative Office of Chinese Human Genetic Resources.
- When conducting cross-border research, fully consider and comply with the laws, regulations, policies, and guidelines of the country/region where the research is carried out, as well as local social and cultural characteristics, and ensure proper participant protection.
- Upon completion of the clinical research, submit a research completion report/closure report. In the event of serious adverse events, unanticipated adverse events that affect the risk-benefit ratio of the study, or protocol violations, promptly report to this Ethics Committee; any suspension/termination of the research must also be reported to the Ethics Committee.
- If there are revisions to the clinical research protocol or informed consent form, or a change of the principal investigator, promptly notify the Ethics Committee for re-review and implement the changes only after obtaining approval.

Contact information

Ethics committee secretary:

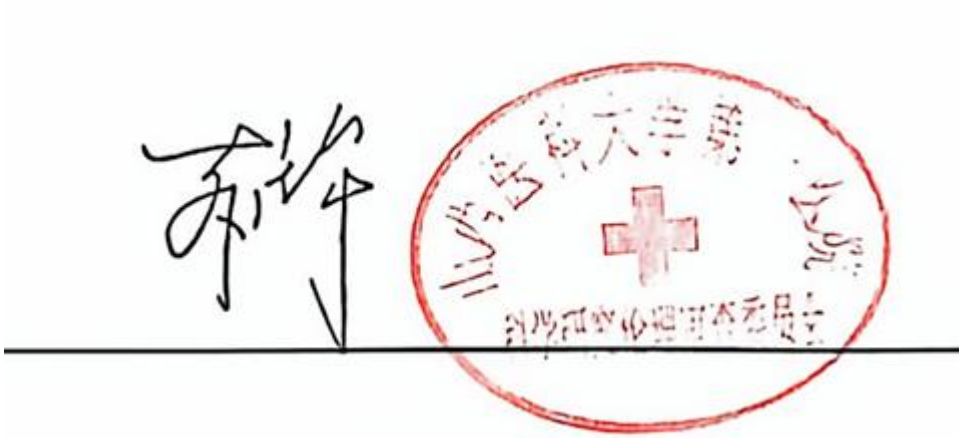


Contact phone number:
+86-351-4639021

Signatures and approval confirmation

Chairperson / Authorized ethics committee representative:
(Signature)

Official seal of the Ethics Committee
Date: March 21, 2025



Final statement

This Ethics Committee operates in accordance with Chinese GCP regulations and relevant laws and regulations.