

首都医科大学附属北京安贞医院南充医院  
南充市中心医院医学伦理委员会 快速审查批件

编号：2025 年审（108）号

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                        |                                                                                                                                    |             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 项目名称                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 单细胞测序结合孟德尔随机化分析探讨膀胱癌相关的分子机制                                                                                                                                            |                                                                                                                                    |             |
| 项目来源                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 研究者发起的临床研究                                                                                                                                                             |                                                                                                                                    |             |
| 审查类别                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input checked="" type="checkbox"/> 初始审查 <input type="checkbox"/> 复审 <input type="checkbox"/> 修正后审查 <input type="checkbox"/> 跟踪审查                                      |                                                                                                                                    |             |
| 主要研究者                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 伍季                                                                                                                                                                     | 职 称                                                                                                                                | 主任医师        |
| 申请科室                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 泌尿外科                                                                                                                                                                   | 联系电话                                                                                                                               | 13018227829 |
| 审查文件                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 1、伦理审查申请表<br>2、临床研究方案<br>3、免除知情同意书申请书<br>4、研究者利益冲突声明<br>5、主要研究者责任声明                                                                                                    |                                                                                                                                    |             |
| 结论：                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <input checked="" type="checkbox"/> 同意 <input type="checkbox"/> 修正后同意 <input type="checkbox"/> 修正后重审 <input type="checkbox"/> 不同意 <input type="checkbox"/> 终止或暂停先前批准实验 |                                                                                                                                    |             |
| 有效期：2026.06.13                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 年度 / 定期跟踪审查频率                                                                                                                                                          | <input type="checkbox"/> 3 个月 <input type="checkbox"/> 6 个月 <input type="checkbox"/> 12 个月 <input checked="" type="checkbox"/> 不适用 |             |
| 评审意见：<br>该研究内容及试验设计符合医学伦理要求，能有效保障参与研究的受试者权益。经本伦理委员会审查，同意按所批准的临床研究方案开展本研究。<br>注意：<br>请遵循我国相关法律、法规和规章（《涉及人的生物医学研究伦理审查办法》等）以及 WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》，遵循伦理委员会批准的方案和知情同意书开展临床试验（研究）。<br>在研究开展期间应采取有效措施充分保障受试者权益，确保受试者隐私和个人信息不被泄露。<br>研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。<br>发生严重不良事件，请申请人及时提交严重不良事件报告。紧急报告之后，24 小时内提交详细的严重不良事件随访报告。<br>请按照伦理委员会规定的年度 / 定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。<br>申请人暂停或提前终止临床研究，请及时提交暂停 / 终止研究报告。<br>完成临床研究，请申请人提交研究完成报告。<br>未经伦理审查批准，不能开展临床研究。<br>本批件有效期为一年，逾期未实施的，则自行废止。 |                                                                                                                                                                        |                                                                                                                                    |             |
| 主任委员签名                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                        |                                                 |             |
| 日期：2025 年 06 月 13 日                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                        | 南充市中心医院 医学伦理委员会                                                                                                                    |             |

地址：四川省南充市顺庆区人民南路 97 号

邮编：637000

电话：0817-2712055

**Beijing Anzhen Hospital Affiliated to Capital Medical University, Nanchong Hospital**  
**The Medical Ethics Committee of Nanchong Central Hospital quickly reviewed the approval**

No. : 2025 Audit (108)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                     |                                                                                                                                                              |                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Name of project                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Single-cell transcriptomic profiling combined with Mendelian randomization illuminates molecular drivers of bladder cancer                                                                                                          |                                                                                                                                                              |                 |
| Source of project                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Investigator-initiated clinical trial                                                                                                                                                                                               |                                                                                                                                                              |                 |
| Categories of review                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <input checked="" type="checkbox"/> Initial review <input type="checkbox"/> Review again <input type="checkbox"/> Review after amendment <input type="checkbox"/> Follow up review                                                  |                                                                                                                                                              |                 |
| Principal Investigator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Ji Wu                                                                                                                                                                                                                               | Professional title                                                                                                                                           | Chief Physician |
| Application Department                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Urology                                                                                                                                                                                                                             | Contact Number                                                                                                                                               | 13018227829     |
| Review of documents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1. Application Form for Ethical review<br>2. Clinical study protocol<br>3. Application for exemption of informed consent<br>4. Statement of researcher's conflict of interest<br>5. Principal Investigator responsibility Statement |                                                                                                                                                              |                 |
| Conclusions: <input checked="" type="checkbox"/> Consent <input type="checkbox"/> Consent after amendment <input type="checkbox"/> Etrial after amendment <input type="checkbox"/> Disagreement<br><input type="checkbox"/> Termination or suspension of previously approved experiments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                     |                                                                                                                                                              |                 |
| Expiry date: 2026.06.13                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Annual/periodic tracking of review frequency                                                                                                                                                                                        | <input type="checkbox"/> 3 Months <input type="checkbox"/> 6 Months <input type="checkbox"/> 12 Months<br><input checked="" type="checkbox"/> Not applicable |                 |
| <p>Review Comments:</p> <p>The content and design of this study meet the requirements of medical ethics, and effectively protect the rights and interests of the subjects involved in the study. After review by our ethics committee, consent was given to conduct this study in accordance with the approved clinical research protocol.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                     |                                                                                                                                                              |                 |
| <p>Note:</p> <p>Please follow the relevant laws, regulations and rules of China (Ethical Review Measures for Biomedical Research involving Human Subjects, etc.), WMA Declaration of Helsinki and CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and follow the approved protocol and informed consent form to carry out clinical trials (research).</p> <p>Effective measures should be taken to fully protect the rights and interests of the subjects and ensure that the privacy and personal information of the subjects are not exposed.</p> <p>Applicants are invited to submit an application for amendment review if the principal investigator is changed during the course of the study, and any changes to the clinical study protocol, informed consent, recruitment materials, etc.</p> <p>If a serious adverse event occurs, the applicant is requested to submit a serious adverse event report in time. After urgent reporting, detailed follow-up reports of serious adverse events were to be submitted within 24 hours.</p> <p>According to the annual/regular follow-up review frequency stipulated by the Ethics committee, the applicant should submit the research progress report one month before the deadline: The sponsor should submit a summary report of the research progress of each center to the ethics committee of the group leader's institution: In case of any situation that may significantly affect the conduct of the trial or increase the risk of the subjects, the applicant is requested to submit a written report to the Ethics committee in a timely manner.</p> <p>If the applicant suspends or terminates the clinical study in advance, please submit the suspension/termination report in time.</p> |                                                                                                                                                                                                                                     |                                                                                                                                                              |                 |

To complete the clinical study, the applicant is requested to submit the study completion report.

Clinical research cannot be carried out without ethical review approval.

This approval shall be valid for one year. If it is not implemented within the time limit, it shall be annulled by itself.

Signature of the Chairman: Dacheng Wu

Date: June 2025

Address: 97 Renmin South Road, Shunqing District, Nanchong City, Sichuan Province

ZIP code: 637000

Tel: 0817-2712055