Ethics Review letter of the Science and Technology Ethical Committee

伦理审查号 Ethical Review Number	KJ2022-221-02		
项目名称 Project Name	Clinical Experiment on Isolating and Cultivating Calcifying Nanoparticles from Tissues Related to Cystic Echinococcosis of the Liver		
项目来源 Sponsor	Research Project of the Corps		
研究单位 Research institution	The First Affiliated Hospital of Shihezi University		
主要研究者 Main researchers	Yang Jian		
承担责任 Responsibilities	In charge ☑ Participate ☐		
研究分类 Classification	Clinical Research ☑ Medical Technology ☐ Others ☐ (Please specify)		
审查类别 Review type	Review after Initial Review	Review way	Expedited Review
审查日期 Review date	February 11, 2023	Review Address	The First Affiliated Hospital of Shihezi University
审查委员 Review Censors	Rui Dongsheng		
审查文件 Review items	1. Re-review Application Form 2. Research Protocol (Version No.: 2.0 Version Date: February 2, 2023) 3. Informed Consent Form (Version No.: 2.0 Version Date: February 2, 2023)		
审查意见 Evaluation Comments	1、Approval ☑ 2、Approval after modification ☐ 3、Retrial after modification ☐ 4、Disapproval ☐ 5、Decision to termination or suspension of the approved research☐ Frequency of continuous review: Submit a progress report to the hospital ethics committee every 12 months after the effective date of this approval letter. Expiration date of the approval letter: December 31, 2024. If an extension is required, please submit an extension application before the expiration date to obtain a new approval letter. The research shall be carried out in accordance with the protocol and informed consent form reviewed and approved by the ethics committee.		

联系人与联系电话 Contact& Office Tel	Yan Su 09932016530
主任委员签字 Signature of Chairman	
伦理委员会 Ethical Committee	Science and Technology Ethics Committee of The First Affiliated Hospital of Shihezi University (Seal)
日期 Date	February 20, 2023
审查声明 Statement	1、Researchers should follow the GCP principles and the protocol approved by the ethics committee to conduct clinical research and protect the health and rights of subjects. 2、Before the start of the research, the applicant shall complete the clinical trial registration. 3、In case of any change of the principal investigator during the research process, or any modification to the clinical research protocol, informed consent form, recruitment materials, etc., the applicant shall submit an amendment review application. 4、In case of serious adverse events, the applicant shall submit a serious adverse event report in a timely manner. 5、According to the annual/regular follow-up review frequency specified by the ethics committee, the applicant shall submit a research progress report one month before the deadline; the sponsor shall submit a summary report of the research progress of each center to the ethics committee of the leading unit; when any situation that may significantly affect the progress of the trial or increase the risk of subjects occurs, the applicant shall submit a written report to the ethics committee in a timely manner. 6、If the research includes subjects who do not meet the inclusion criteria or meet the exclusion criteria, fails to withdraw subjects when it meets the conditions for terminating the trial, gives wrong treatment or dosage, uses combined drugs prohibited by the protocol, etc., that is, fails to conduct the research in accordance with the protocol; or any situation that may have an adverse impact on the rights/health of subjects and the scientific nature of the research and violates the GCP principles, the sponsor/monitor/researcher shall submit a protocol violation report. 7、If the applicant suspends or terminates the clinical research in advance, please submit a suspension/termination research report in a timely manner. 8、After completing the clinical research, the applicant shall submit a project completion report.