

Biomedical Research Ethics Committee of The Second Affiliated Hospital of Nanchang University

Approval Number: I-Research Ethics Review [2023] No. (6)

Project Title	Construction of a Precision Diagnosis and Treatment System for Complex Lumbar Diseases		
Review Time	2023.01.11	Review site	Conference Room, 10th Floor, Comprehensive Building
Category of research	☒ Intervention ☐ Diagnostic ☐ Observation ☐ Other		
Types of Research Grants	☐ Government ☐ Academic Organization ☐ Enterprise ☒ Institutional ☐ Self-funded ☐ Other		
Sponsor	The Second Affiliated Hospital of Nanchang University		
Specialty	department of orthopedics	Principal Investigator	XiGao Cheng
Review Mode	Meeting Review	Review category	Initial Review
Reviewed Documents	Clinical Trial Protocol (Version: V1.0, Date: January 8, 2023). Informed Consent Form (Version: V1.0, Date: January 8, 2023). Recruitment Materials (Version: V1.0, Date: January 8, 2023). CVs of Principal Investigators and Research Personnel Assignment Table		
Results of IEC			
A total of 14 committee members attended the meeting, with all 14 members voting and 0 members abstaining. Votes: Approved-14, Approved with revisions-0, Disapproved-0, Terminated/Suspended-0.			
Review decision	Approved, Continuing review required every 12 months.		
Attention	1、 If the principal investigator is changed or any modifications are made to the research protocol, the applicant must submit an amendment application for ethical review. 2、 In the event of a serious adverse event, the applicant must submit a serious adverse event report as required. 3、 Based on the Ethics Committee's policy on follow-up review frequency, the applicant must submit a follow-up review application one month before the due date, regardless of whether the trial has commenced. Late submission may affect project progress. 4、 If any protocol deviations occur, the sponsor or investigator must submit a deviation report. 5、 If the applicant suspends or terminates the clinical study early, a suspension/termination report must be submitted in a timely manner. 6、 If the project involves the international transfer of human biological samples for laboratory testing abroad, approval must be obtained from the China Human Genetic Resources Administration Office, and the approval document must be submitted to the Ethics Committee for filing before any transfer procedures can be carried out. 7、 Upon study completion, the applicant must submit a final study report as required. 8、 This approval is valid for one year. If the study is not conducted within this period, the approval will automatically become void.		
The Second Affiliated Hospital of Nanchang University Biomedical Research Ethics Committee (Seal) Date: 2023.01.12			

This Ethics Committee operates in strict compliance with Chinese GCP and relevant regulations.
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