

The First Affiliated Hospital of Shandong First Medical University (Shandong Provincial
Qianfoshan Hospital)

Medical Ethics Committee Approval Reports

Lot No.: YXLL-KY-2023(018)

Applicant/Development Unit: The First Affiliated Hospital of Shandong First Medical University (Shandong Provincial Qianfoshan Hospital)					
Clinical Research Program Number: V2.0		Drug registration lot number:			
Clinical Research Leader: Yan Li					
Clinical Study Title: Effect of Azole/Echinocandin Use on Tacrolimus Pharmacokinetics in Kidney Transplant Patients					
Clinical Research Unit and Address: The First Affiliated Hospital of Shandong First Medical University (Shandong Provincial Qianfoshan Hospital), No. 16766, Jingshi Road, Jinan, China					
Name and Address of the Ethics Committee: Medical Ethics Committee of the First Affiliated Hospital of Shandong First Medical University (Shandong Provincial Qianfoshan Hospital), No. 16766, Jingshi Road, Jinan, China					
Submission of materials	Drug Registration Approval	No	Content of the review	Applicant's Qualification Certificate	meet the requirements
	Clinical Research Program	Yes		Methods of Obtaining Informed Consent	proper
	Researcher's Handbook	No		Opinion on the Research Program	acceptance
	Patient Informed Consent	No		Review Pathway	Expedited review
	Drug Test Compliance Report	No			
	Case Report Form	Yes			
	Attachment	Yes			
Conclusion	Consent				
Ethics Committee Approval Opinion: The lead reviewer of the ethics committee reviewed and discussed the project in strict accordance with GCP principles and relevant Chinese regulations and guidelines. Based on the results of the review, this committee agreed to carry out the research of this project from the date of approval, and requested the investigator and the sponsor to strictly abide by the National CFDA "Good Clinical Practice (GCP) for Drug Clinical Trials", conscientiously accept the constraints of the relevant national laws and regulations, and pay attention to the prevention of adverse effects and the protection of patients' rights and interests and safety. All information shall not be modified without the approval of the Committee; if any serious adverse events occur in the study, please notify the Committee immediately.					
Signature of the Director of the Ethics Committee:				Date: February 25, 2023	
Seal of the Ethics Committee:					