Ethical Approval Letter

NO. ZYYECK【2019】049

Protocol Title	Cinical standardized research and mechanism research on the prevention and treatment of bronchial asthma based on the theory of treating winter disease in summer		
Objective	□Phase I clinical trial;□Phase II clinical trial; □Phase III clinical trial;□Phase IV clinical trial;□Bioequivalence test;□Clinical trial of import drug registration; □Reevaluation of drugs on the market;□Experiment on protective varieties of traditional Chinese Medicine; ■scientific research;□Clinical trial of medical instruments; □Clinical verification of medical devices; □postgraduate education; □ Other		
Department /Specialties	Acupucture	**Principal Investigator**	Jun He
Approved Documents	1.Application for Ethical Review; 2.Study Protocol(Ver2.0); 3.Informed Consent Form(Ver2.0); 4.Resume of Principle Investigator and GCP Cetification; 5.Case Report Form(V5.27， 20190527); 6.Declaration of Conflict of Interest.	**Sponsor**	The First Affiliated Hospital of Guangzhou University of TCM
Review modes	Mode of the initial review: □Expedited review ■Full Board Review(Date:20-06-2019)	**Decision**	Final decision: Approve
Annual Follow-Up Review Frequency	12 months (please submit annual / periodic follow-up review documents 1 month before 1July 2020)	**Expiry of Approval Letter**	1 year（If the research project has not been launched within 1 year, please resubmit the initial ethical review application）
Attentions	According to the *Approaches to Ethical Review of Biomedical Research Involving Human Beings*(2016,China), the SFDA *Good Clinical Practice for Medical Devices*(2016, China), the*Guiding Principles for Ethical Review of Drug Clinical Trials* (2010, China), *WMA Declaration of Helsinki,* and *International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS),* It is agreed to carry out this clinical research after ethicalreview. After the research completed, please submit the conclusive report. Serious adverse events, protocol violation, suspension/termination of the research and unexpected events affecting the risk-to-benefit ratio of research shall be reported to the committee in a		

	timely manner. If the study protocol and informed consent form have been modified or the main researcher changed, the ethics committee shall be notified in time. The research shall be reviewed again and execute after approved by the committee.
Contact/ EC Member& Secretary	Xinying Li Tel:020-36588667 or 020-36591965 Fax:020-36591346 Email:gztcmlunli@163.com
Signature of the Chair/ Authorized Person	Date:01-07-2019

Statement: The Ethics Committee organizes and works in strict accordance with Chinese GCP and related laws and regulations.