Ethics Approval of Guang'anmen Hospital of China Academy of Chinese Medical Sciences

Project Title	Efficacy of acupuncture in improving the quality of life of patient's with moderate or severe acne vulgaris: protocol for a randomized controlled trial		
Approval No.	2018-137-KY-01	Project Sponsor	Investigator
Research Organization	Guang'anmen Hospital of China Academy of Chinese Medical Sciences		
Applicant	None		
Site PI	Zliishun Liu		
Review Attribute	Initial Review	Review Methods	Review Conference
Review Date	December 20,2018	Review Place	Conference Room, the 4th Floor of the Administrative Building of Guang'anmen Hospital
Review Committee	Haibo Yin, Lan Lin, Xinghua Feng, Limin Xie, Ling Feng, Ping Wu, Lizhen Gu, Mei Han		
Approval Files	1. Study Protocol (Version No. 2018120301; Version Date: Dec 03,2018) 2. Case Report Form (Version No. 2018120301; Version Date: Dec 03,2018) 3. Informed Consent (Version No. 2018120301; Version Date: Dec 03,2018) 4. Recruiting Advertisement (Version No. 2018120301; Version Date: Dec 03,2018) 5. Researchers' Handbook Version No. 2018120301; Version Date: Dec 03,2018)		
Review Comments	According to "ethical review methods for biomedical study involving human subjects" issued by the Ministry of Health, "Good Clinical Practice'', "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "management specifications for ethical review of TCM clinical studies" issued by State Administration of Traditional Chinese Medicine, "Declaration of Helsinki'', and " International ethical guidelines for biomedical research involving human subjects" issued by Council for International Organizations of Medical Sciences, this clinical research was reviewed by the institutional review board (IRB) of Guang'anmen Hospital of China Academy of Chinese Medical Sciences. And the study protocol, informed consent, and the recruitment files of this research were approved. Please conduct this clinical study following the GCP principles and the study		

	protected throughout the whole study. The ethical approval will invalid if the study didn't carry out within 3 years. Th researchers are required to apply for ethical review once again. An application should be submitted if a change of the principle investigator (PI), o any modification of the study protocol, informed consent, or the recruitment files are made. A report of the severe adverse events (SAE) should be submitted within 15 days i any SAE or any other un-anticipated AE, which will affect the risk- reward ratio o this study, occurs. A report should be submitted immediately if lethal adverse event are aware of. Researchers should submit report of the study progress one month before th deadline according to ethical review frequency. A summary report of the study progress of each site should be submitted by the site PI to the IRB of the leading sit In any condition which will greatly affect the progress of the study or increase th potential risk of the subjects, a written report should be submitted by the site PI to th IRB. A protocol deviation report should be submitted by the site P I/mon itor/researc her if any of the following occurs: 1) conditions that violate th study protocol: subjects who did not meet the inclusion criteria, or should b excluded according to the exclusion criteria, were wrongly included in the study subjects do not withdraw from the study when he/she meet the rules of withdrawal incorrect treatment or dose was given; prohibited combined medicine was used; 2 conditions that violate GCP principle: subjects' rights and health are badly affected the science of study was badly affected. A final report should be submitted when the study is finished completely or terminated prematurely.
Validity Period of the Approval	From Dec 25,2018 to Dec 24,2019
Frequency of Follow-up Review	12 months Deadline of Follow-up Review Dec 24,2019
Contact	Contact person: Jie Qiao Contact telephone: +86 01088001552 E-mail: gamhec@126.com
Director/Vice Director Signature	Haibo Yin

IRB of Guang'anmen Hospital of China Academy of Chinese Medical Sciences (Seal)
Date: Dec 24, 2018