Translation for reference

Wu Jing
Director of ZLRB May 24, 2018

Ethical Review Approval Letter

Approval Letter No.	2016NL-033-03		
Title of Project	Exploration of the effect and mechanism of Total flavone of Abelmoschus manihot in the treatment of crohn's disease based on NOD2/RIP2 axis and MAPK/NF-κB signaling pathways		
Source of Funds	Supported by National Natural Science Foundation of China		
Research Unit	Jiangsu Province Hospital of Traditional Chinese Medicine (JSHTCM)		
Principal Investigator	Chen Yugen		
Review Category	Re-review	**Review Process**	Expedited review
Date of Review	2017-12-28	**Site of Review**	Room 402, Building 5, JSHTCM
Primary Reviewer	Gong Guanwen		
Approved Documents	Revised Protocol (Version No.:2.2 Date: 2017-12-28) Revised Informed Consent Form (Version No.: 2.1 Date: 2017-12-27)		

Review Opinions

According to the ethical principles of NHFPC: Measures for Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016), CFDA: Chinese Good Clinical Practice (2003), Provisions for Clinical Trials of Medical Devices (2016), WMA: Declaration of Helsinki and CIOMS: International Ethical Guidelines for Biomedical Research Involving Human Subjects, after review of IRB, the research is approved to be carried out in accordance with the approved protocol and informed consent form.

Please follow the principles of GCP, follow the protocol approved by IRB to conduct the clinical research, protect the rights and well-being of subjects. Please complete the clinical trial registration before starting the research. Please submit amendment's review application, if there is any change of principal investigator, or any modification to the protocol, informed consent form, recruitment documents, etc., in the course of research. Please submit SAE report timely if SAE occurs; after the emergency report, please submit a detailed follow-up report of SAE as soon as possible. Please submit research progress report one month before the expiration date according to the frequency of annual/regular continuing review stipulated by IRB; please submit written report to IRB timely if there is any situation that may significantly affect the research, or increase risks to subjects. The investigator should submit non-compliance/violation/deviation report, if there is any violation of the protocol and the principles of GCP, such as the subject who does not meet the inclusion criteria or meets the exclusion criteria is enrolled; subject is not withdrew from the study when criteria for termination are met; wrong therapy or dose is given; combination therapy which is prohibited by the protocol is given; or other conditions that may adversely affect subjects' rights and interests/well-being, as well as the integrity of the research. Please submit suspension/termination report timely, if applicant suspend or prematurely terminate the clinical research. Please submit final report of research, if clinical research is complete. The study should be implemented within one year from the date of approval, if not, the approval letter shall be

invalidated automatically.	
Frequency of Annual/Regular Continuing Review	2018-12-28
Valid period (Expiring Date)	12 months
Contact Person and Phone Number	Wu Jing 0086 25 86560515
Signature of Chair	Shang Wenbin
IRB	Affiliate Hospital of Nanjing University of TCM (Jiangsu Province Hospital of TCM) Ethics Committee
Date	2017-12-28