江阴市人民医院

伦理委员会临床研究审批件

批件号：〔2018〕伦审研第（004）号

审查日期	2018.03.15	审查地点	行政五楼会议室
项目名称	CTEN 通过 VEGFA 调控乳腺癌血管生成的作用与机制研究		
项目类别	诊断☐ 治疗☐ 科研☑ 流行病学调查研究 ☐		
申办者	江阴市人民医院	组长单位	无
专业组	肿瘤内科	牵头单位	是 ☑ 否 ☐
专业负责人	茅卫东	职称	主任医师
主要研究者	赵 韬	职称	主任医师
审查方式	☐ 会议审查 ☑ 快速审查		
本伦理委员会联系方式	地址：江苏省江阴市寿山路 163 号江阴市人民医院行政楼五楼 电话：0510-86879012		
报送材料	伦理审查申请表、研究方案、知情同意书、主要研究者履历等		

伦理委员会审查意见

经本伦理委员会审查，同意开展该项研究。

意见及建议： 无 ☑ 有 ☐

该研究的进行过程中将接受伦理委员会的持续审查？ 是☑ 否☐

审查频度为研究批准之日起： 3 个月☐ 6 个月☐ 1 年☑

伦理委员会有权根据实际进展情况改变持续审查频度。

该批件有效期为 5 年，超过效期请继续提出申请。

请严格遵循《赫尔辛基宣言》、GCP 等相关法律法规开展该项研究。

暂停/提前终止临床研究，请及时通知伦理委员会。

对已批准的临床研究方案、知情同意书等材料的任何修改，请及时通知本伦理委员会重新审查，获得批准后执行。

请根据本伦理委员会规定的跟踪审查频率，在截止日期前一个月提交研究进展报告。

该研究的进行过程中发生严重不良事件请按规定报告伦理委员会。

研究结束请及时向伦理委员会递交结题报告。

主任委员签名： 日 期：2018.3.15

江阴市人民医院伦理委员会

声明：本伦理委员会严格遵循《药物临床试验质量管理规范》（简称 GCP）、ICH-GCP 及相关法律法规的要求组建、运作、实施各项操作程序。

Jiangyin People's Hospital

Clinical Research Approval Document by Ethics Committee

No. 2018004

Review date	2018-03-15	Review place	Executive meeting room on 5th floor
Project Name	CTEN regulate Tumor Angiogenesis and Growth by Targeting VEGFA in Breast Cancer		
Project category	Research		
Sponsor	Jiangyin People's Hospital	Team leader unit	None
Major	Oncology	Leader	Yes
Professional responsibility	Weidong Mao	Title	Chief Physician
Researcher	Tao Zhao	Title	Chief Physician
Review style	Quick review		
Address of Ethics Committee	Jiangyin People's Hospital, No.163 Shoushan Road, Jiangyin, Jiangsu Province,214400, P.R.China. Phone: 0510-86879012		
Submit materials	Ethical Review Application Form; Research proposal; Informed consent; curriculum vitae		

Comments from Ethics Committee

After reviewing by Ethics Committee, this project was approved.

Comment and suggestion: No.

The research will be subject to continuous review by the ethics committee during the course of the study: Yes.

Review frequency: every year

The ethics committee has the right to change the frequency of continuous review based on actual progress.

The validity period of the visit approval document is 5 years, please continue to apply after the validity period.

Please strictly follow the Declaration of Helsinki, GCP and other relevant laws and regulations to carry out this research.

Suspend/terminate clinical research early, please notify the ethics committee in time.

Please notify the ethics committee to review any changes to the approved clinical research protocol, informed consent and other materials, and implement it after approval.

Please submit a research progress report one month before the deadline according to the follow-up review frequency set by this ethics committee.
If serious adverse events occurred during the course of the study, please report to the ethics committee as required.
After the research, please submit the final report to the ethics committee in time.

Chairman: Date: 2018-3-15

Statement: This ethics committee strictly complies with the requirements of the "Quality Management Practices for Drug Clinical Trials" (GCP), ICH-GCP and related laws and regulations to establish, operate, and implement various operating procedures.