首都医科大学宣武医院伦理委员会
科研伦理审批件

临研文审[2018]005 号

研究名称	实用导管吸栓治疗 8 例肠系膜上动脉栓塞：单中心经验		
项目来源	无		
项目编号	NA		
项目承担科室	血管外科	**研究负责人**	刘一人
科室负责人	谷涌泉		
审查方式	快速审查	**审查时间**	2018 年 11 月 12 日
跟踪审查频率	该研究进行过程中□不会接受，■接受　伦理委员会的持续审查： 审查频率为研究批准之日起 □3 个月　□6 个月 ■12 个月　□ 其他：_____		
有效期	2018 年 11 月 12 日～2019 年 11 月 12 日		

审查结果：

根据国家卫生部《涉及人的生物医学研究伦理审查办法》、CFDA《药物临床试验质量管理规范》、《医疗器械临床试验质量管理规范（2016）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，**同意进行该项临床研究。**

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人向伦理委员会提交“修正案审查申请”，经伦理委员会重新审查并获得批准后执行。

发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交“严重不良事件/非预期不良事件审查申请表”。

请按照伦理委员会规定的年度/定期**跟踪审查频率**，申请人在截止日期前 1 个月提交“年度/定期跟踪审查申请表”，伦理委员会有权根据实际进展情况改变跟踪审查频度。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交“不依从/违背方案报告表”。

申请人暂停或提前终止临床研究，请及时提交“提前终止试验的审查报告表”。

完成临床研究，请申请人提交“结题报告表”，及概述研究发现和结论的总结（如有）。

本批件将在本机构伦理委员会备案。

主任委员签名：

2018 年 11 月 12 日

首都医科大学宣武医院 伦理委员会

声明：本伦理委员严格按照中国 GCP 及相关法规组成和工作

伦理委员会地址：北京市西城区长椿街 45 号，**邮编：**100053

伦理委员会办公室联系人及联系电话：张卓然；010-83199270

Ethics committee of Xuanwu Hospital, Capital Medical University

Approval Letter about the Ethical Review of Clinical Scientific Research

Number of Approval Letter: 临研文审[2018]005 号

Title of the Clinical Research	Aspiration Therapy Using Guiding Catheter for Acute Embolic Occlusion of Superior Mesenteric Artery in Eight Patients : a Single-Center Experience		
Project Source	None		
Project Number	NA		
Hosted by	Vascular Surgery Department, Xuanwu Hospital, Capital Medical University	**Primary Investigator**	Yi-ren Liu
Department Head for hosting the research	Dr. Yong-quan Gu		
Review approaches	Review at ☐Full Board Meeting ■Expedited Review	**Date of Review**	November 12th ,2018
Will the research process be subject to the continuous review by the Ethics Committee? ■Yes ☐No			
From the date on which the research is approved, the review frequency: ☐3 months ☐6 months ■12 months ☐other:_____			
Period of Validity for the Approval Letter	From November 12th ,2018 to November 12th ,2019		

Ethics committee of Xuanwu Hospital, Capital Medical University

Review Opinion of the Ethics Committee:

This clinical scientific research is approved after reviewed by this ethics committee.

Note: (please read carefully)

1. This approval letter has the validity of 1 years and application shall be continued if beyond this validity.
2. This approval document will be filed at center institutions and ethics committee. If various opinions are made for the feasibility (including the qualification and experience of investigators, equipment, conditions and the like) of the program in your institution, please contact with the ethics committee timely.
3. The projects approved shall be performed according to the program approved by the ethics committee and shall be in compliance with the principle in CFDA-GCP and Declaration of Helsinki.
4. Please inform the ethics committee of the suspension/early termination of the clinical research timely.
5. Please report the serious adverse events and the unexpected events influencing the research/risk return ratio to the ethics committee timely.
6. Any modification to the approved clinical research program, informed consents and other information as well as change in investigators shall be notified to the ethics committee timely for review and shall be performed after being approved.
7. Any violation of the trial program, if found, shall be reported to the ethics committee.
8. Application for the continuous review shall be made one mother before the continuous review date is due, whether the trial is started or not, according to the opinion of the ethics committee to the frequency of continuous review. The ethics committee has the right to change the frequency of the continuous review depending on the actual progress.
9. Please submit the concluding report to the ethics committee for review after the clinical research is finished.
10. This document will be kept on record by the ethics committee.

Signature of the chairman: Wang Xiang ping

Date: 2018.11.12

Statement: The composition and obligations of this Ethics Committee are completely compliant to CFDA-GCP and other relevant regulations.

Contact Information of this Ethics Committee:

(1)Address: No.45, Changchun St., Xicheng District, Beijing, P.R.China 100053

(2)Contact Person and Tel: Zhang Zhuo-ran, +86 10 8319 9270