伦理审查批准函

Approval Letter

声明：本机构伦理委员会按照国家卫健委和 CFDA 有关法规组成和工作，其审查和工作过程不受机构伦理委员会以外任何组织及个人的影响

批件编号 20220140		伦理委员会方案编号 2022K242	
研究方案名称	混合现实智能化最佳穿刺路径设计及针轨呈现辅助老年患者腰椎穿刺的研究		
申办者	上海市卫生健康委员会新兴交叉领域研究专项经费		
主要研究者	顾卫东	研究科室	麻醉科
伦理审查方式	☑快速审查		
审查类别	☑ 初始审查 ☐修正案审查 ☐复审 ☐其他：		
审查委员	宋晓华		

审查文件：

1, 伦理审查申请表

2, 临床研究方案 01，2022 年 09 月 14 日

3, 知情同意书_01，2022 年 09 月 14 日

4, 主要研究者简历;参加研究人员简介

1. 经本机构伦理委员会审查,同意进行该项临床研究。
   意见和建议：☑无 ☐有
2. 该研究进行过程中将接受伦理委员会的跟踪审查？☑是 ☐否
   审查频率为该研究批准之日起每 12 月一次。
3. 伦理委员会有根据实际进展情况改变跟踪审查频率的权利。
4. 自批件之日起一年内项目未启动,该批件自动失效。

主任/副主任委员签名：

复旦大学附属华东医院伦理委员会（盖章）：

日期：2022.12.1

注意：（请仔细阅读）

1.本机构伦理委员会批准的项目为涉及人体的生物医学研究，必须严格按照所批最新版本的研究方案和知情同意书开展研究，并遵循国内相关法规指南要求。

2.凡是涉及人类遗传资源出口或者按照国家规定必须经有关部门专项审批的内容，均需在项目执行前向有关部门申报并获得批准。

3.本批件可能用于其他中心伦理委员会参考，如果对方案审查存在不同意见，请及时与本机构伦理委员会沟通。

4.对已批准的研究方案、知情同意书等材料的任何修改及主要研究者更换等，须及时通知本机构伦理委员会重新审查，获得批准后执行。

5.发生严重不良事件及影响研究风险受益比的非预期事件，须及时报告本机构伦理委员会。

6.根据机构伦理委员会对年度/定期跟踪审查频度的意见，无论研究开始与否，请在年度/定期跟踪审查日到期前1个月提出年度/定期跟踪审查的申请。

7.发现不依从/违反方案情况须及时报告伦理委员会审查。

8.暂停/提前终止临床研究，请及时通知机构伦理委员会。

9.完成研究，须提交结题报告供机构伦理委员会审查。

地址：上海市延安西路 168 号 309 室；**邮编**：200040；**电话**：021-62483180*720322

Approval Letter

It is clarified that the Ethics Committee of this institution is composed and operates in accordance with the relevant regulations of the National Health Commission and CFDA, and its review and work process is not influenced by any organizations or individuals outside the Ethics Committee.

Approval Document Number: 20220140		**Ethics Committee Project Number:** 2022K242	
Name of the Research Plan:	A Study on the Design of Optimal Puncture Path and Needle Trajectory Presentation Assisted by Mixed Reality Intelligence for Lumbar Puncture in Elderly Patients.		
Sponsor	Shanghai Municipal Health Commission New Interdisciplinary Research Special Fund		
Principal Investigator	Gu Weidong	**Research Department**	Anesthesiology
Ethics Review Method		☑Rapid Review	
Review Category	☑Initial Review ☐ Amendment Review ☐ Re-review☐ Other		
Review Committee Members	Song Xiaohua		

Review Documents:

1. Ethics Review Application Form
2. Clinical Research Plan 01, dated September 14, 2022
3. Informed Consent Form 01, dated September 14, 2022
4. Resume of the Principal Investigator; Brief Introduction of Participating Researchers

1. After review by the Ethics Committee of this institution, the clinical research is approved.

Opinions and Suggestions:☑ None ☐There are

2. The research will be subject to follow-up review by the Ethics Committee during the process? ☑Yes ☐No

The review frequency is once every 12 months from the date of approval of this research.

3. The Ethics Committee has the right to change the frequency of follow-up reviews based on the actual progress.

4. If the project is not initiated within one year from the date of this approval, this approval will automatically become invalid.

Signature of the Director/Deputy Director:
Ethics Committee of Huadong Hospital Affiliated to Fudan University (Seal)
Date: 2022.12.1

Attention: (Please read carefully)

1. The project approved by the Ethics Committee of this institution involves biomedical research on humans and must be carried out strictly according to the latest approved version of the research plan and informed consent form, and in compliance with domestic laws and guidelines.

2. Any content involving the export of human genetic resources or that requires special approval from relevant departments according to national regulations must be declared and approved by the relevant departments before the project is implemented.
3. This approval may be used for reference by other center Ethics Committees. If there are different opinions on the plan review, please communicate with the Ethics Committee of this institution in a timely manner.
4. Any modifications to the approved research plan, informed consent form, and other materials, as well as changes in the principal investigator, must be notified to the Ethics Committee of this institution for re-review and implemented after approval is obtained.
5. Serious adverse events and unexpected events that affect the risk-benefit ratio of the research must be reported to the Ethics Committee of this institution in a timely manner.
6. According to the opinions of the institution's Ethics Committee on the frequency of annual/regular follow-up reviews, regardless of whether the research has started, please submit an application for the annual/regular follow-up review one month before the expiration date of the annual/regular follow-up review day.
7. Non-compliance/violation of the plan must be reported to the Ethics Committee for review in a timely manner.
8. If the clinical research is suspended or terminated in advance, please notify the institution's Ethics Committee in a timely manner.
9. Upon completion of the research, a final report must be submitted for review by the institution's Ethics Committee.

Address: Room 309, No. 168 West Yan'an Road, Shanghai, Postal Code: 200040, Phone: 021-62483180*720322