**伦理审查批件**

| 伦理审查编号 | KYYL-2022014 |
|--------------|--------------|
| 项目名称     | 全人群“互联网+老年照护”技术应用示范与优化方案研究 |
| 项目负责人及科室 | 护理部-马月珍 |
| 申请单位     | 山东省立第三医院 |
| 审查文件     | □项目申报书 □项目批文/任务书 □研究者手册
   □ 研究方案 □知情同意书 □病例报告表
   □项目负责人及参加人员列表与简历 □其他，请说明： |
| 审查方式     | □会议审查 □快速审查 □跟踪审查 |
| 审查决定     | □批准 □不批准 □修改后批准 □修改后再审 □暂停或终止 |
| 审查意见     | 参加该项目的伦理委员会根据有关法律法规、赫尔辛基宣言等伦理原则，经对该项目提交的文件进行了审核，认为研究者的资格、经验符合试验要求，研究方案符合科学性和伦理原则的要求，获得知情同意的方法适当，受试者可能遭受的风险程度与研究预期的受益相比合适。同意按照研究方案开展研究。 |

**主任委员/副主任委员签字** 张新元

**日期** 2022年3月1日

**注意事项：**
1. 已批准项目应遵循已经伦理委员会批准的方案实施，需符合SFDA/GCP和《赫尔辛基宣言》的原则。
2. 修改后复审的研究方案在提交复审方案前，应按评审意见书逐条修改并在修改处做出标记或说明，修改后方案连同初审意见一同递交伦理委员会申请复审。
3. 不批准和暂停或终止的研究方案，申请者和研究者可就伦理委员会的意见和建议中提及的问题作书面申诉，并陈述理由。
4. 研究过程中对研究方案和知情同意书等文件所作的任何修改，均需得到伦理委员会审查同意后方可实施。
5. 本中心发生的严重不良事件或意外不良事件需向伦理委员会作出书面通报，伦理委员会有权根据对其评估做出新的决定。
6. 请在跟踪审查前一个月向医学伦理委员会提交跟踪审查报告，完成临床研究的项目，须向伦理委员会提交结题报告。
Ethical Approval Letter

| Ethical review number | KYLL-2022014 |
|-----------------------|--------------|
| Project name          | "Internet + rehabilitation nursing " technology application for the whole population |
| Project leader and department | Nursing Department - Ma Yuezhen |
| Sponsor               | Shandong Provincial Third Hospital |
| Review documents      | ☐project declaration ☐Project approval/task book ☐Investigator Handbook ☐research proposal ☐informed consent ☐case report form ☐Project leader and participant list and resume ☐Other, please specify: |
| Review method         | ☐Meeting Review ☐Express Review ☐Track Review |
| Review decision       | ☐Approval ☐Disapproval ☐Approval after Modification ☐Review after Modification ☐Suspension or Termination |
| Review opinion        | The ethics committee participating in this project has reviewed the documents submitted by the project in accordance with relevant laws and regulations, Helsinki Declaration and other ethical principles, and believes that the qualifications and experience of the investigators meet the requirements of the trial; the research protocol conforms to scientific and ethical principles. The method of obtaining informed consent is appropriate, and the degree of risk that the subject may suffer is appropriate in relation to the expected benefit of the study. Consent to conduct research in accordance with the research protocol. |
| Signature of the chairman/deputy | date |

Medical Ethics Committee of Shandong Provincial Third Hospital ( seal )

Note:
1. Approved projects should follow the protocol approved by the ethics committee, and should comply with the principles of the SFDA/GCP and the Declaration of Helsinki. 
2. Before submitting the revised research plan for retrial, it shall be revised item by item according to the review opinions, and mark or explain the modification. The revised plan shall be submitted to the Ethics Committee for review together with the preliminary review opinions. 
3. For the disapproval and suspension or termination of the research program, the sponsor and the investigator can make a written appeal on the issues mentioned in the opinions and recommendations of the ethics committee, and state the reasons.
4. For the research program that is not approved, suspended or terminated, the sponsor and the researcher may make a written appeal on the issues mentioned in the opinions and suggestions of the ethics committee and state the reasons. 
5. Serious adverse events or unexpected adverse events occurring in the center shall be notified in writing to the ethics committee, which has the right to make new decisions based on its evaluation.
6. Please submit a follow-up review report to the Medical Ethics Committee one month before the follow-up review, and a final report must be submitted to the Ethics Committee for completed clinical research projects.