# 山东大学齐鲁医院科研伦理委员会
# 伦理审查批件

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| 伦理批件号 | KYLL-202011-012 | | |
| 项目名称 | 急性铊中毒患者的早期诊断、治疗及预后研究 | | |
| 项目来源及编号 | 自筹 | | |
| 研究科室 | 老年医学科 | | |
| 项目负责人 | 王潭 | | |
| 审查类别 | 初始审查 | 审查方式 | 快速审查 |
| 审查日期 | 2020-12-25 | | |
| 审查文件 | 初始审查申请<br>伦理申请表<br>研究经济利益声明 | 知情同意豁免申请<br>研究方案 1.0 2020-11-20 | |

**审查意见：**

根据我国《涉及人的生物医学研究伦理审查办法》、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，同意按所批准的文件开展本项研究。

1. 请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。
2. 研究开始前，请申请人完成临床研究备案。
3. 研究过程中若变更主要研究者，对临床研究方案、知情同意书等的任何修改，请申请人提交修正案审查申请。
4. 发生严重不良事件，请申请人及时提交严重不良事件报告。
5. 请按照伦理委员会规定的年度/定期跟踪查频率，申请人在截止日期前 1 个月提交研究进展报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。
6. 申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。
7. 完成临床研究，请申请人提交结题报告。

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| 年度/定期跟踪审查频率 | 12 个月 |
| 有效期 | 20201225-20211225 |
| 主任委员签字 | |
| 伦理委员会 | 山东大学齐鲁医院科研伦理委员会 （盖章） |
| 日期 | 2020 年 12 月 25 |

# Ethical approval from Medical Ethics Committee of Qilu Hospital of Shandong University

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| Ethical approval number | KYLL-202011-012 | | |
| Project Title | Early diagnosis, treatment and prognosis study of patients with acute thallium poisoning | | |
| Project source | Self-financing | | |
| Department | Department of Geriatrics | | |
| Project manager | Wang Tan | | |
| Review categories | Initial review | Review method | Quick review |
| Review date | 2020-12-25 | | |
| Review documents | Initial review application, Ethics application form research, Economic interest statement, Informed consent, Research plan 1.0 2020-11-20 | | |
| Review opinion:<br>According to the ethical principles of China, including "Measures for the Ethical Review of Biomedical Research Involving Humans", WMA "Declaration of Helsinki" and CIOMS "International Ethical Guidelines for Human Biomedical Research", the ethics committee has reviewed and agreed to follow the approved documents carried out this research.<br>1. Please follow the protocol approved by the ethics committee to carry out clinical research to protect the health and rights of subjects.<br>2. Before starting the research, applicants are requested to complete the clinical research filing.<br>3. If the main investigator is changed during the research process, the applicant is requested to submit an amendment review application for any changes to the clinical research plan, informed consent, etc.<br>4. If a serious adverse event occurs, the applicant is requested to submit a serious adverse event report in time.<br>5. Please follow the annual/regular follow-up frequency set by the ethics committee, and applicants should submit a research progress report one month before the deadline. If there is any situation that may significantly affect the test progress or increase the risk of the subjects, the applicant is requested to submit a written report to the ethics committee in time.<br>6. If the applicant suspends or terminates clinical research early, please submit the suspension/discontinuation report in time.<br>7. When the clinical research is complete, the applicant is requested to submit the final report. | | | |
| Annual/regular follow-up review frequency | 12 months | | |
| Valid period | 2020.12.25-2021.12.25 | | |
| Chairman's signature | Li Chuanfu | | |
| Ethics Committee | Medical Ethics Committee of Qilu Hospital of Shandong University (seal) | | |
| Date | 2020.12.25 | | |