This is an English version, the original Chinese version is attached.

Approved Document-Scientific Research Ethics Working Group of Medical Ethics Committees of Mianyang Central Hospital

Approval No.：S-2018-085 Review date：Sep. 2018

Project	Development and Evaluation on In-Vitro Diagnostic Traceability System for chronic kidney disease
Department	Department of Laboratory Medicine
Leader	Yu-wei Yang
Status	☑ New Approach ☐ Revised Approach after Necessary Modification
Inspection Way	☐ Quick Review ☑ Meeting to Review ☐ Emergency Meeting to Review
Submitted Materials	1、☑ Proposal of this project 2、☑ Application form for ethical review of Mianyang Central Hospital 3、☑ Informed consent form 4、☑ Subject instructions 5、☐ Others _____
Review decision	☑ Consent ☐ Agree with the necessary amendments ☐ Review after necessary modification ☐ Termination or suspension
Member for Quick Review	
Voting Results of Review Meeting	Attending situation: There are 11 members who should attend, among which 5 are on leave, 0 are absent, and 6 actually attend. Voting result: 5 votes agree, 1 vote agree after necessary amendment, 0 vote review after necessary amendment, 0 vote terminate or suspend. There are 0 recused members.
Attentions	1. All materials shall not be modified without approval of research ethics management; 2. In the process of the experiment (implementation), if main investigator, implementation conditions and any modification of Proposal or informed consent are changed, please submitte a new amendments for ethical review again without delay; 3. Report serious adverse events in time; 4. Timely submit a written report to ethics committee in case of any situation that may significantly affect the conduct of the trial (study) or increase the risk to the subject; 5. If suspending or terminating the test (study) in advance, please submit the suspension/termination report; 6. Complete the study and timely submit the conclusion report.
Review Comment	Approved by the ethics committee, this project document conform to basic ethical principles, and the study is agreed to carry out in accordance with the approved research approach and informed consent. Please follow the relevant laws, regulations and rules, WMA “Declaration of Helsinki” and CIOMS “International Ethical Guidelines for Biomedical Research Involving Human Subjects”, National Health Commission of the Peaple’s Republic of China "Ethics Review Method for Biomedical Research Involving Human Subjects" for research.

Ethics Committee of Mianyang Central Hospital (Stamp)

Chairman/deputy chairman (Sign)

Oct. 9, 2018

绵阳市中心医院科研伦理管理组审查批件

审批号：S-2018-085　　审查日期：2018 年 9 月

评审项目	体外诊断慢性肾病的可溯源系统研发及临床评价
申请部门	医学检验科
项目负责人	杨渝伟
申请状态	☑ 新方案　☐ 作必要修改后的重审案
审查方式：	☐快速审查　☑会议审查　☐紧急会议审查
报送材料：	1、☑ 项目申报书 2、☑ 绵阳市中心医院伦理审查申请表 3、☑ 知情同意书 4、☑ 受试者须知 5、☐ 其他 _____ 。
审查决定	☑同意　☐做必要修正后同意　☐做必要修改后重审　☐终止或暂停
快速审查委员	
会议审查 投票结果	本次应到人数 11 人，请假 5 人，缺席 0 人，实到人数 6 人。 投票结果：同意 5 票，作必要修正后同意 1 票，作必要修改后重审 0 票，终止或暂停 0 票。 回避委员 0 人
注意事项	1、所有资料未经本科研伦理管理组批准，不得作任何修改； 2、在试验（开展）过程中，若变更主要研究者，主要实施条件，及对研究实施方案、知情同意书等任何修改，及时提交修正案重新申请伦理审查； 3、发生严重不良事件，及时上报不良事件报告； 4、当出现任何可能显著影响试验（研究）进行或增加受试者风险的情况，及时向伦理委员会提交书面报告； 5、暂停或提前终止试验（研究），及时提交暂停/终止试验（研究）报告； 6、完成试验（研究），及时提交结题报告。
审查意见	经本伦理委员会审查，认为该项目审查文件基本符合伦理原则，同意按所批准的研究方案、知情同意书开展本项研究，请遵循相关法律、法规和规章、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》、国家卫健委《涉及人的生物医学研究伦理审查办法》等要求开展研究。

绵阳市中心医院伦理委员会（盖章）

主任委员/副主任委员（签名）

2018 年 10 月 9 日