The ethical board approvals for Guangzhou cohort

医学伦理委员会审查报告

研究项目名称	结核病社区综合干预现场流行病学研究
研究内容及意义	基于“十二五”综合防治示范区和现场研究的成果，推进防治结核病规模化现场流行病学和干预研究，评价干预效果。实践和验证国家重大专项取得的科技成果，促进成果转化，探索有效的社区防治和干预策略，取得适合本示范区、并适宜推广至全国的防治重大传染病的经验；通过现场研究，对“十三五”综合防治示范区所覆盖队列人群的科学干预和随访调查，有效实现“三病两率”的降低，为后续的全国范围的推广提供实施策略和方法，为降低我国结核病重大传染病发病率、病死率提供科技支撑，为制定相关政策提供依据、指南和规范。
项目负责人	周琳
项目类别	国家科技重大专项
研究年限	2018 年 1 月-2020 年 12 月

医学伦理委员会审批意见：

同意该项目在获得受试者同意前提下进行研究。

广东省结核病控制中心

医学伦理委员会

2019 年 3 月 29 日

Medical Ethics Committee Review Report

Research Project Name	An epidemiological study on comprehensive community interventions of tuberculosis
Research Content	Based on the results of the "Twelfth Five-Year Plan" comprehensive prevention and control demonstration area and field research, this project promote the large-scale field epidemiology and intervention research of tuberculosis prevention and treatment, and evaluate the intervention effect. Practice and verify the scientific and technological achievements obtained in major national special projects, promote the transformation of results, explore effective community prevention and intervention strategies, and obtain experience in the prevention and control of major infectious diseases suitable for this demonstration area and suitable for promotion to the whole country; Through field research, scientific intervention and follow-up surveys of cohorts covered by the "13th Five-Year Plan" comprehensive prevention and control demonstration area will effectively reduce the "three diseases and two rates", and provided implementation strategies and methods for subsequent nationwide promotion. Provide scientific and technological support for reducing the incidence and mortality of tuberculosis in this country, and provide bases and guidelines for formulating relevant intervening policies.
Principle Investigator	Zhou, Lin
Project Source	National Science and Technology Major Projects
Research Period	January 2018-December 2020

Approval Opinions of the Medical Ethics Committee:

It is OK that the project could be performed with the consent of the subjects.

Guangdong Center for Tuberculosis Control
Medical Ethics Committee
March 29, 2019

The ethical board approvals for Shenzhen cohort

深圳市第三人民医院（原东湖医院）伦理委员会审核批准文件

（科研类）

编号：深三院科伦审字（2012003）号

<table>
<tr><td>项目名称及编号
研究方案名称</td><td colspan="5">宿主基因 SNP 对I型 IFN 应答的调控作用及其与结核感染转归的相关性研究</td></tr>
<tr><td>项目类型</td><td colspan="2"></td><td>研究类型</td><td colspan="2">1☐ 2☐ 3☐ 4☐ 5☐
6☐ 7☐ 8√</td></tr>
<tr><td>申请单位</td><td colspan="2">深圳市第三人民医院</td><td>主要研究者</td><td colspan="2">张国良</td></tr>
<tr><td>参加单位</td><td colspan="5"></td></tr>
<tr><td>审查文件</td><td colspan="5">1、 研究方案
2、 知情同意书</td></tr>
<tr><td>审查模式</td><td colspan="5">会议投票审查☐ 快速审查☑</td></tr>
<tr><td>参与投票委员
（适用于会议审查模式）</td><td colspan="5"></td></tr>
<tr><td rowspan="2">会议投票情况
（适用于会议审查模式）</td><td>同意</td><td>做必要修改后同意</td><td>做必要修改后重申</td><td>不同意</td><td>中止或者暂停正在进行的实验</td><td>弃权</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

1. 评审意见和建议：

经我院伦理委员会审议，该研究的实验设计和实施方案设计科学、合理、可行。并尽最大限度保护受试者个人信息，研究内容和结果不存在利益冲突，符合伦理要求。

2. 根据以上意见和建议，委员会的审查决定如下：

经医院伦理委员会讨论
同 意

主任委员/副主任委员签名：

日期：2012-3-5

深圳市第三人民医院（原东湖医院）医学伦理委员会（盖章）

深圳市第三人民医院 伦理委员会

修改后审查意见		主任委员签名	

备注：1=药物临床试验I期；2=药物临床试验II期；3=药物临床试验III期；4=药物临床试验IV期；5=国际多中心药物临床试验；6=其他类别药物临床试验；7=医疗新技术的临床研究；8=科研课题

日期：2012年 3 月 5 日

The Ethics Committee of Shenzhen Third People's Hospital (formerly Donghu Hospital)

Reviewed and Approved Documents

(Research)

No.: Shenzhen Third People's Hospital Kelun Review (2012003)

<table>
<tr><td>Project name and number or Research project name</td><td colspan="6">The regulatory effect of host gene SNP on type I IFN responses and its correlation with the tuberculosis infection outcomes</td></tr>
<tr><td>Project type</td><td colspan="2"></td><td>Type of Study</td><td colspan="3">1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8√</td></tr>
<tr><td>Applicant</td><td colspan="2">Shenzhen Third People's Hospital</td><td>Principle Investigator</td><td colspan="3">Zhang, Guoliang</td></tr>
<tr><td>Participating Unit</td><td colspan="6"></td></tr>
<tr><td>Review documents</td><td colspan="6">1. Research plan
2. Informed Consent</td></tr>
<tr><td>Review mode</td><td colspan="6">Conference voting review ☐ Quick review √</td></tr>
<tr><td>Voting committee
(Suitable for meeting review mode)</td><td colspan="6"></td></tr>
<tr><td rowspan="2">Conference voting
(Suitable for meeting review mode)</td><td>Agree</td><td>Agree after making necessary changes</td><td>Reiterate after making necessary changes</td><td>Disagree</td><td>Abort or suspend ongoing experiments</td><td>Abstain</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="7">1. Review comments and suggestions:
After deliberation by the ethics committee of our hospital, the experimental design and implementation plan of the study are scientific, reasonable and feasible. Please Protect the personal information of the subjects. The research content and results have no conflict of interest, and meet the ethical requirements.

2. Based on the above opinions and suggestions, the committee's review decision is as follows:
Agree

Signature of Director / Deputy Director:
Date:
Medical Ethics Committee of Shenzhen Third People's Hospital (formerly Donghu Hospital) (seal)</td></tr>
<tr><td colspan="2">Review comments after revision</td><td colspan="2"></td><td>Director's signature</td><td colspan="2"></td></tr>
<tr><td colspan="7">Remarks: 1=Phase I drug clinical trials; 2=Phase II drug clinical trials; 3=Phase III drug clinical trials; 4=Phase IV drug clinical trials; 5=International multi-center drug clinical trials; 6=Clinical trials of other types of drugs ; 7=Clinical research on new medical technology; 8=Scientific research project</td></tr>
</table>

Date:

The ethical board approvals for Foshan cohort

临床试验审查批件

批件编号：2019011　　审查日期：2019年1月8日

评审项目	项目名称 （方案编号）	结核病感染与肠道微生态的相关性研究
申请单位	申办方：佛山市第四人民医院	
	本中心试验科室：实验室	本中心主要研究者：王威
审阅文件	审阅文件： ■临床试验方案　■知情同意书 □其他：详见结论。	
项目类型	□药物　□器械　■其他	
审查类别	■初始审查　□复审　□修正案　□跟踪审查　□其他	
审查方式	□会议审查　■快速审查　□紧急会议审查	
结　论	■同意 □作必要修正后同意 □作必要修正后重审 □不同意 □终止或暂停已批准的试验审查意见。 批准使用： **1. 临床研究方案（包括研究中可能出现的不良反应或可能发生的不良事件及其处理对策）** 临床研究方案：包括研究中可能出现的不良反应或可能发生的不良事件及其处理对策。（版本日期：2019年1月3日）； **2. 知情同意书** 研究知情同意书(第1.0版版本日期：2019年1月3日)； 该批件有效期为12个月，请在有效期届满前1个月递交研究进展报告申请延期。	
主任委员	周杰	主任委员签名： 日期：　年　月　日
盖　章	佛山市第四人民医院医学伦理委员会	

备注：

1. 研究项目须在伦理委员会批准后启动；
2. 若获取人类遗传资源办公室批件，请报本委员会审查备案；
3. 中止或终止研究，方案违背、SAE和SUSAR等，须定期汇总递交本委员会，其中本中心的SAE和严重方案违背须及时递交；
4. 本委员会依据《涉及人的生物医学研究伦理审查办法》和GCP等国家法规以及ICH-GCP的要求操作。

Clinical Research Review Approval

Approval Number: 2019011 Date of Review: January 8, 2019

Project	Project name (Project number)	Study on the correlation between tuberculosis infection and intestinal microecology
Applicant	Sponsor: Foshan Fourth People's Hospital	
	Laboratory of our center: laboratory	The Principle Investigator of This Center : Wang, Wei
Review files	Review files: ■ Clinical research protocol ■ Informed Consent □ Others : See conclusion for details.	
Project type	□ Drug □ Instrument ■ Others	
Review category	■ Initial review □ Review □ Amendment □ Follow-up review □ Others	
Review method	□ Meeting ■ Quick review □ Emergency Review	
Conclusion	■ Agree □ Agree after making necessary amendments □ Review after making necessary corrections □ Disagree □ Termination or suspension of approved trial review opinions. Approved for use: 1. **Clinical research plans (including possible adverse reactions or adverse events that may occur during the study and their treatment strategies)** Clinical research plans: including possible adverse reactions or adverse events that may occur during the study and their treatment strategies. (Version date: January 3, 2019); 2. **Informed Consent** Study informed consent form (version 1.0 version date: January 3, 2019); The approval document is valid for 12 months. Please submit a research progress report for extension one month before the expiration of the validity period.	
Director	Zhou, Jie	Signature of Director: Date:
Stamp	Medical Ethics Committee of Foshan Fourth People's Hospital	

Remarks:

1. The research project must be started after the approval of the ethics committee;
2. If you obtain the approval from the Office of Human Genetic Resources, please report to this committee for review and record;
3. Suspension or termination of research, plan violations, SAE and SUSAR, etc., must be summarized and submitted to the committee regularly, and SAE and serious plan violations of the center must be submitted in time;
4. This committee is based on the "Measures for the Ethical Review of Biomedical Research Involving Humans", GCP and other national regulations and the requirements of ICH-GCP.