A blank version of the Informed Consent for Guangzhou cohort

受试者知情同意书

尊敬的先生/女士：

我们将邀请您参加一项“结核病社区干预现场流行病学研究”的科学研究。

在您决定是否参加这项研究之前，请仔细阅读以下内容，它可以帮助您了解该项研究内容、为何要进行这项研究以及本研究可能给您带来的益处、风险和不适等。

以下是本项研究的介绍：

一、研究背景

本研究已通过本研究机构伦理审查委员会审查，其为国家科技重大专项项目。

二、研究目的

本研究旨在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，以及探索影响结核病发生发展的重要因素，包括宿主基因、免疫反应等。

三、具体程序和流程

本研究年限为 2018 年 1 月至 2020 年 12 月。本次科研分问卷、体格测量、抽血检验和粪便检测**四**部分内容。

四、如果参加研究，您需要做什么？

如果您同意参加这项研究，您需要提供您的一般情况（年龄、身高、体重、病史等）以建立档案。 您在参与过程中个人根据意愿贡献10毫升左右的静脉血和5克粪便，将由专业人员为您采血。

五、参加此项研究可能给您带来的受益

采集的样本免费检测结核结核感染相关指标，通过对您的标本进行检测将有助于对疾病做出诊断，为结核病预防或治疗提供必要的建议和帮助。

六、参加此项研究可能给您带来的不良反应、风险及风险防范措施

本研究项目的执行操作将严格按照无菌要求完成，但此过程可能会造成一些不良反应，现告知如下：标本的采集可能会有一些非常小的风险，包括短暂的疼痛、局部淤青。

在试验期间，也许会出现其他一些不适，请立即告诉您的研究者，他/她会对您出现的不适进行处理。此外，我们郑重承诺，将严格按照规范完成，将以上所述的风险及不良后果发生的概率降至最低。

七、费用情况说明

本研究涉及的项目费用均有我方支付。

八、参加此项研究的补偿，包括损伤赔偿

我们研究方将根据您的个人意愿，为您提供 30 至 300 元人民币不等经济和交通补偿。

如果您发生了与本试验研究有关的损伤，我们研究方将按国家有关法律法规的规定提供相应治疗、赔偿和补偿。

九、您个人信息的保密

您参加本项研究的信息均会记录在研究记录/病例报告表中。所有出现在原始医学记录中的试验结果（包括个人资料、化验单据等）均会在法律的允许范围内完全保密。您的名字不会出现在报告表中，仅仅出现您参加试验时分配的编号。相关研究总结、文章、公开刊物中，如有必要，也只会仅出现您的编号。

必要时，药品监督管理部门、伦理委员会或课题资助部门，按规定可以查阅参加研究的受试者资料。但未经允许，他们对参加研究的受试者资料不会用到其他的用途或泄露给其他的团体。

十、您必须参加此项研究吗？

是否参加本研究完全取决于您的自愿，您可以拒绝参加此项研究。

十一、是否中途可以退出此试验？

在研究过程中的任何时间，您都有权退出此研究。如果您选择退出本研究，您的本研究之外的健康权益将不会受到影响，也不会因此而受到歧视或不正当对待。

您的医生或研究者出于对您的最大利益考虑，可能会随时中止您参加本项试验。

如果您因为任何原因从试验中退出，您可能被咨询有关您使用试验药物的情况。如果医生认为需要，您也可能被要求进行实验室检查和体格检查。您也可以拒绝，并不会因此受到歧视或不正当对待。

同意声明

1. 我已经阅读了本知情同意书，项目相关责任人已经将此次试验的目的、内容、风险和受益情况向我作了详细的解释说明。

2. 我已经讨论并询问了有关本研究的相关问题，这些问题的解答令我满意。

3. 我有充足的时间作出决定。

4. 我是自愿同意参加本文说介绍的科学研究，并同意将我的研究数据用于本研究的发表。

5. 我同意药品监督管理部门、伦理委员会或课题资助部门代表查阅我的研究资料。

6. 我将获得一份经过签名并注明日期的知情同意书副本。

最后，我决定同意参加本项试验研究。

受试者签名：　　日期：

我确认已向受试者解释了本研究的详细情况，包括其权利以及可能的受益和风险，并给份签署过的知情同意书副本。

研究者签名：　　日期：

Informed Consent

Dear Sir/Madam：

We will invite you to participate in a scientific research on the "An epidemiological study on comprehensive community interventions of tuberculosis".

Before you decide whether to participate in this study, please read the following carefully. It can help you understand the content, purpose, procedure and period of the study, and the benefits, risks and discomforts that this study may bring to you.

Introduction of this research：

1. Research background

This research has passed the review of the ethics review committee of this research institution, and it is a major national science and technology project.

2. Research purposes

This research aims to 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, obtain experience in the prevention and control of major infectious diseases suitable for this demonstration area and suitable for promotion to the whole country, and explore the impact important factors for the occurrence and development of tuberculosis include host genes and immune response.

3. Specific procedures and processes

The study period is from January 2018 to December 2020. This scientific research is divided into four parts: questionnaire, physical measurement, blood test and stool test.

4. If you participate in the research, what do you need to do?

If you agree to participate in this study, you need to provide your general information (age, height, weight, medical history, etc.) to create a file. During the participation process, you personally contribute about 10 ml of venous blood and 5 gram stool. A professional will collect blood for you.

5. The possible benefits of participating in this research

The blood samples collected will be tested for free-of-charge related indicators of tuberculosis infection. Testing your specimens will help diagnose the disease and provide necessary advice and help for tuberculosis prevention or treatment.

6. Participating in this research may bring you adverse reactions, risks and risk prevention measures

The implementation of this research project will be completed in strict accordance with the sterility requirements, but this process may cause some adverse reactions. Now I am informed as

follows: The collection of specimens may have some very small risks, including short-term pain and local bruises.

During the trial, some other discomforts may occur. Please tell your investigator immediately and he/she will deal with your discomfort. In addition, we solemnly promise that we will strictly follow the specifications to minimize the occurrence of the above-mentioned risks and adverse consequences.

7. The cost

All the project expenses involved in this research are paid by us。

8. Compensation for participating in this study, including damage compensation

Our research party will provide you with economic and transportation compensation ranging from RMB 30 to RMB 300 according to your personal wishes. If you have an injury related to this trial study, our project will provide corresponding treatment, compensation and compensation in accordance with relevant national laws and regulations.

9. Confidentiality of your personal information

The information about your participation in this study will be recorded in the study record/case report form. All test results (including personal data, laboratory test documents, etc.) appearing in the original medical records will be completely confidential to the extent permitted by law. Your name will not appear in the report form, only the number assigned when you participated in the trial. If necessary, only your number will appear in relevant research summaries, articles, and public publications.

When necessary, the drug regulatory department, ethics committee or project funding department can consult the data of the subjects participating in the research according to regulations. But without permission, they will not use the data of the participants in the study for other purposes or disclose it to other groups.

10. Do you have to participate in this research?

Whether to participate in this study is entirely up to your volition, you can refuse to participate in this study at any time.

11. Can I withdraw from this experiment halfway?

At any time during the research process, you have the right to withdraw from this research. If you choose to withdraw from this research, your health rights outside this research and the relationship with the investigator will not be affected, nor will you be discriminated against or treated improperly.

Your doctor or investigator may suspend your participation in this trial at any time for your best interests.

If you withdraw from the trial for any reason, you may be consulted with your use of the trial drug. You may also be asked for laboratory tests and physical examinations if the doctor thinks it is necessary. You can also refuse, and you will not be discriminated against or treated improperly.

Consent statement

1. I have read this informed consent form, and the person in charge of the project has given me a detailed explanation of the purpose, content, risks and benefits from this experiment.

2. I have discussed and asked related questions about this research, and the answers to these questions are satisfactory to me.

3. I have plenty of time to make a decision.

4. I voluntarily agree to participate in the scientific research introduced in this article, and agree to use my research data for the publication of this research.

5. I agree to the representative of the drug regulatory department, ethics committee or project funding department to consult my research data.

6. I will get a signed and dated copy of the informed consent form.

Finally, I decided to agree to participate in this study.

Subject's signature: Date：

I confirm that I have explained the details of this study to the subject, including their rights and possible benefits and risks, and gave them a copy of the signed informed consent.

Researcher’s signature: Date：

A blank version of the Informed Consent for Shenzhen cohort

知情同意书

尊敬的志愿者：

目前我们拟开展一项宿主基因 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，特邀请您参加这项研究。在您决定是否参加这项研究之前，请您仔细阅读以下内容，它会帮助您了解该项研究的内容、目的、程序和期限，参加研究可能给您带来的益处、风险和不适。以及您拥有的各项权利。如果您愿意，您也可以和您的亲属、朋友一起讨论，帮助您做出决定。

（一）本研究项目简介

本项目主要从健康人群及结核阳性病人抽取外周血并收集粪便标本进行分析。

（二）试验的目的

阐明健康人群和活动性结核患者的肠道菌群差异以及人类结核感染中宿主基因是如何通过调节有益肠道菌的丰度以影响活动性结核患者的疾病严重程度，为结核诊断、治疗及疫苗开发提供新的科学依据。

（三）哪些人不宜参加研究

1.小于 16 或者大于 80 岁的人群；

2.孕妇。

（四）如果参加本试验您将需要做什么

本研究的期限为 2012 年 3 月至 2018 年 3 月，志愿者只需在参与本研究时根据个人意愿贡献 20 毫升左右的外周血，5 克粪便标本。本研究不涉及试验任何药物或者医疗器械。志愿者不需交任何费用。

（五）您可能的受益、不良反应、风险、不适及可获得的处理

本研究不涉及在病人或者其他研究对象中试验任何药物、试剂、医疗器械等。极少部分人士有可能会出现晕血或者在采血过程中出现对针头或真空采血管的不适反应。如果出现类似情况，建议志愿者暂停参与实验并向采血现场的专门医护人员及研究人员咨询，从而采取适当的防护及医疗措施。

（六）有关费用

所有的费用均由研究方支付。此外，我们将根据志愿者个人意愿，给每位参与实验的志愿者提供 20 至 400 元人民币不等的营养及来往交通补贴。

（七）个人信息

您的研究记录（检测结果等）使用权归属研究方，不会提供给研究以外的任何其他人员和单位。在法律允许范围内，本研究收集的所有关于您的信息和检查结果将被严格保密。您的所有研究记录和检测结果，仅限于研究人员、研究方指

定的检查员、学院及学校伦理委员会分析处理和核查。

（八）信息获得

您可以在任何时间向本项目主要研究人员提出有关本研究的任何问题，并得到相应的解答。如果在研究过程中有任何重要的新信息，可能影响您继续参加研究的意愿时，研究人员将会及时通知您并征求您的意见。

（九）自愿参加和退出

是否参加本试验完全取决于您的意愿。您可以拒绝参加此试验，或在试验过程中的任何时间退出本研究，这都不会影响您和研究人员间的关系。出于对您的最大利益考虑，研究人员可能会在试验过程中随时中止您继续参加本项研究。如果您因为任何原因从研究中退出，您可能会被询问有关您参与研究的情况。

（十）您的权利

是否参加本项研究由您自己（和您的家人）决定。

在您做出参加试验的决定前，请尽可能考虑清楚，必要时向研究人员询问有关问题。

感谢您阅读以上材料。如果您决定参加本试验，请告知研究人员，他/她会为您安排一切有关参加本项研究的事务。请您保留这份资料。

知情同意书同意签字页

研究名称：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

研究单位：深圳市第三人民医院

同意声明

我已经阅读了上述有关本试验的介绍，而且有机会就此项研究与研究人员讨论并提出问题。我提出的所有问题都得到了满意的答复。

我知道参加本试验可能产生的风险和受益。我知晓参加研究是自愿的，我确认已有充足时间对此进行考虑，而且明白：

- 我可以随时向研究人员咨询更多的信息。
- 我可以随时退出本试验，而不会受到歧视或报复，权益不会受到影响。
- 我同样清楚，如果我中途退出试验，特别是由于体质测试或实验室检测退出试验时，我将我的身体状况变化告诉研究人员，并完成相应的检查，这将对整个研究十分有利。
- 如果因身体情况明显变化我需要采取任何其他的处理措施，我会在事先征求研究人员的意见后决定。
- 我清楚我的隐私在试验中会得到保护，任何有关本试验研究结果的公开报告都不会披露我的个人身份。我也同意研究人员、研究方指定的监查员、学院及学校伦理委员会可以查阅我的记录。
- 我清楚如果我在研究过程中发生与研究有关的不良事件，研究方将按照相关规定为我的损害提供治疗费用及相应的经济补偿。
- 我将获得一份经过签名并注明日期的知情同意书副本。

最后，我决定同意参加本项研究，并保证尽量遵从试验方案。

受试者签名：_____ _____ 年 _____ 月 _____日

联系电话：_____

我确认已向受试者解释了本试验的详细情况，包括其权力以及可能的受益和风险，并给其一份签署过的知情同意书副本。

研究人员签名：_____ _____ 年 _____月 _____日

研究人员的工作电话：_____

Informed Consent

Dear volunteer:

We are carrying out a research of The regulation of host gene SNP on type I IFN response and its correlation with the tuberculosis infection outcomes, so we invite you to participate in this research. Before you decide whether to participate in the research, please read the following carefully. It will help you understand the contents, the purpose, procedures and deadlines of the research, and the benefits, risks and discomfort of participating in the research, and the rights you will have. If you agree, you and your relatives, friends can join in the discussion to help you make a decision.

1. About this project

The project is mainly to collect the peripheral blood and fecal samples from healthy controls and patients with active TB infection. We will analyze the host genetic variants, immune functions and mechanism of these blood cells, and gut microbiota of fecal samples.

2. The purpose of this project

To clarify the differences between the gut bacteria of healthy controls and active tuberculosis patients, and how human genetics modulate compositional shifts of gut bacteria and elicit varying degrees of TB pathogenicity and severity in different individuals, and provide a new scientific basis for vaccine, drug, and diagnosis methods for preventing/treatment of tuberculosis.

3.Who should not participate in the study

(1) People younger than 16 or older than 80 years;

(2) Pregnant women.

4. If you participate in this study, what will you needs to do?

The duration of this research project is from March 2012 to March 2018. About 20 ml of peripheral blood will be drawn from the volunteers and 5 gram fecal samples will be collected from the volunteers. Volunteers do not need to pay any fees.

5. The benefits, adverse reactions, risk, and the availability of treatment you may get

No drugs or medical devices will be tested in the patients or other research objects. The potential risks to blood donor are minimal and parallel those associated with the donation of blood including, adverse reactions to anticoagulants, starch additives for blood separation, and ethylene oxide residues used to sterilize tubing during blood collections. The potential risks to subjects from veni puncture are minimal and include discomfort and bruising from needle sticks. There is no or very little adverse reactions or risk may happen for donations of fecal samples.

6. Related costs

All the cost of the test will be paid by the researchers. We will also provide compensation about 20 to 400 RMB for nutrition and communication, depending on the situations and willingness of volunteers.

7. Personal Information

Your research records (test results, etc.) and any other personal information will be locked by researchers, and these records and information will not be provided to any other personnel and units. Within the scope permitted by law, information about your research records will be confidential. Only researchers, research-designated inspectors, college and school ethics committee can analyze and inspect all your research records and test results.

8. Access to information

You can ank any questions about this research at any time and get answers. If there are any important new information that may affect your willingness to continue participation in the study in the research process, the researchers will notify you and ask for your opinions.

9. Voluntary participation and exit

It totally depend on your wiliness whether or not to participate in this research projects. You can refuse to participate in this research or exit this research at any time during the research. To protect your interest, researchers may stop the research any time. If you are not willing to participate in the research anymore, researchers may discuss with you about your participation in the research.

10. Your rights

It totally depend on your wiliness whether or not to participate in this research projects. Before you make a decision to participate in the study, please consider as carefully as possible. If necessary, you can ask any relevant questions to researchers.

Thank you for reading the above materials. If you decide to participate in this study, please inform researchers, he/she will arrange you to participate in this research. Please keep this document.

Informed Consent signature page

Project title : The regulation of host gene SNP on type I IFN response and its correlation with the tuberculosis infection outcomes

Research Unit: Shenzhen Third People's Hospital

Declaration of Consent

I have read the above description of the research, and have the opportunity to discuss the research with researchers and ask questions. All my issues have been answered satisfactorily.

I know that participating in this trial may have risks and benefits. I know participating in the study is voluntary. I confirm that I have sufficient time for consideration and understanding:

- I can always consult with the researchers for more information.
- I could quit from participating the experiment at any time, without discrimination or revenge, and rights and interests will not be affected.
- I also know that if I quit from research, especially due to physical testing or laboratory testing during the study, I will give my information about body changes to the researchers, and complete the appropriate body checks, which will benefit the research.
- If I need to take any other measures because of obvious body condition changes, I will make decisions before consulting with researchers.
- I know my privacy will be protected during the test, the test results of any public reports will not disclose my personal information. I also agree with the researchers, research-designated inspectors, college and school ethics committee may review my records.
- I know If I have reversed reactions related to the study during the study, researchers will provide the cost of treatment and the corresponding economic compensation based on the situation of my reversed reactions.
- I will receive a signed and dated copy of informed consent.

Finally, I decided to agree to participate in this research, and to ensure as far as possible to comply with the protocol.

Signature of Subject: Date:

Contact:

I confirm that I have explained the test subjects in details, including its rights and potential benefits and risks, and give a signed copy of the informed consent.

Signature of researchers: Date:

Researchers work phone:

A blank version of the Informed Consent for Foshan cohort

知情同意书

方案名称：结核感染与肠道微生态的相关性研究

方案版本号：01，2 019 年 1月3 日

知情同意书版本号：01，2 019 年 1月 3 日

研究机构：佛山市第四人民医院

主要研究者（负责研究医师）：王威

您将被邀请参加一项科学研究。本知情同意书提供给您一些信息以帮助您决定是否参加此项科学研究。请您仔细阅读，如有任何疑问请向负责该项研究的研究者提出。

您参加本项研究是自愿的。本次研究已通过本研究机构伦理审查委员会审查。

研究目的：结核是由结核分枝杆菌感染引起的。 但是，不同结核病患者的状况差异很大。 这项研究将探索为什么同一菌株的结核菌会引起个体结核病的严重差异。 我们将从宿主基因，肠道细菌，免疫应答等方面解释其机制，为结核病的诊断，治疗和预防提供新的理论基础。

研究过程：如果您同意参与这项研究，我们将对每位受试者进行编号。在研究过程中我们需要采集一些您的标本，将由专业人员为您取样，例如从您的胳膊上抽取静脉血 20 毫升，共需 1 次。此外，您需要提供 5 克粪便。您的样品仅用于本研究。

风险与不适：对于您来说，所有的信息将是保密的。您的样本采集将严格按照无菌要求操作，标本的采集可能会有一些非常小的风险，包括短暂的疼痛、局部青紫。

受益：通过对您的标本进行检测将有助于对疾病作出诊断，为您的治疗提供必要的建议，或为疾病的研究提供有益的信息。

作为研究受试者，您有以下职责：提供有关自身病史和当前身体状况的真实情况；告诉研究医生自己在本次研究期间所出现的任何不适。

隐私问题：如果您决定参加本项研究，您参加试验及在试验中的个人资料均属保密。您的血液标本将以研究编号数字而非您的姓名加以标识。可以识别您身份的信息将不会透露给研究小组以外的成员，除非获得您的许可。所有的研究成员和研究申办方都被要求对您的身份保密。您的档案将保存在有锁的档案柜中，仅供研究人员查阅。为确保研究按照规定进行，

必要时，政府管理部门或伦理审查委员会的成员按规定可以在研究单位查阅您的个人资料。这项研究结果发表时，将不会披露您个人的任何资料。

如果您因参与这项研究而受到伤害：如发生与该项临床研究相关的损害时，您可以获得免费治疗和／或根据中国法律获得相应的补偿。

您可以选择不参加本项研究，或者在任何时候通知研究者要求退出研究，您的数据将不纳入研究结果，您的任何医疗待遇与权益不会因此而受到影响。

我已经阅读了本知情同意书。

我有机会提问而且所有问题均已得到解答。

我理解参加本项研究是自愿的。

我可以选择不参加本项研究，或者在任何时候通知研究者后退出而不会遭到歧视或报复，我的任何医疗待遇与权益不会因此而受到影响。

我将收到一份签过字的“知情同意书”副本。

受试者姓名：_____

受试者签名：_____

日期：_____年_____月_____日

我已准确地将这份文件告知受试者，他/她准确地阅读了这份知情同意书，并证明该受试者有机会提出问题。我证明他/她是自愿同意的。

研究者姓名：_____

研究者签名：_____

日期：_____年_____月_____日

（*注：如果受试者不识字时尚需见证人签名，如果受试者无行为能力时则需代理人签名*）

Informed Consent

Project name: Study on the correlation between tuberculosis infection and intestinal microecology

Plan Version Number: 01, January 3, 2019

Informed Consent Version Number: 01, January 3, 2019

Research Institution: Foshan Fourth People's Hospital

Principle Investigator: Wang, Wei

You will be invited to participate in a scientific research. This informed consent form provides you with some information to help you decide whether to participate in this scientific research. Please read it carefully. If you have any questions, please ask the researcher in charge of the study.

Your participation in this study is voluntary. This study has been reviewed by the ethics review committee of this research institution.

Research purposes: Tuberculosis is caused by *Mycobacterium tuberculosis* infection. However, the condition of different tuberculosis patients varies greatly. This study will explore why the same strain of tuberculosis bacteria can cause serious differences in individual tuberculosis. We will explain the mechanism of this from host genes, intestinal bacteria, immune response, etc., to provide a new theoretical basis for the diagnosis, treatment and prevention of tuberculosis.

Research process: If you agree to participate in this research, we will number each subject. During the research, we need to collect some of your specimens. Professionals will take samples of you. For example, 20 ml of venous blood is drawn from your arm, which takes 1 time, and you need to provide 5 grams of stool specimens. Your sample is only used for this study.

Risks and discomfort: For you, all information will be confidential. Your sample collection will be performed in strict accordance with the sterility requirements. The collection of samples may have some very small risks, including short-term pain and local bruising.

Benefits: Testing your specimens will help diagnose the disease, provide necessary recommendations for your treatment, or provide useful information for disease research.

As a research subject, you have the following responsibilities: provide the true information about your medical history and current physical condition; tell the research doctor about any discomfort you have experienced during the study.

Privacy issue: If you decide to participate in this study, your personal information about participating in the experiment and in the experiment will be kept confidential. Your blood sample will be identified by the study number instead of your name. Information that can identify you will not be disclosed to members other than the research team unless you have your permission. All research members and research sponsors are required to keep your identity confidential. Your files will be kept in a locked filing cabinet for research personnel only. To ensure that the research is conducted in accordance with the regulations, when necessary, members of the government management department or the ethics review committee can consult your personal data in the research unit as required. When the results of this research are published, no personal information about you will be disclosed.

If you are harmed as a result of participating in this research: In the event of damage related to this clinical research, you can get free treatment and/or corresponding compensation according to Chinese law.

You can choose not to participate in this study, or notify the investigator to withdraw from the study at any time, your data will not be included in the study results, and any of your medical treatment and rights will not be affected.

I have read this informed consent form.

I have the opportunity to ask questions and all questions have been answered.

I understand that participation in this study is voluntary.

I can choose not to participate in this research, or I will withdraw after informing the researcher at any time without being discriminated against or retaliated. Any of my medical treatment and rights will not be affected by this.

I will receive a signed copy of the "Informed Consent".

Subject's name:_____

Subject's signature:_____

Date: _____

I have accurately informed the subject of this document, he/she accurately read the informed consent form, and proved that the subject has the opportunity to ask questions. I certify that he/she consented voluntarily.

Researcher's name:_____

Researcher's signature:_____

Date: _____

(Note: If the subject is illiterate, the witness is required to sign, and if the subject is incapacitated, the agent's signature is required)