**伦理审核申请表**

**IRB APPLICATION FORM**

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| **概况Overview** |
| 项目名称 （中文）Project Name (Chinese) |  |
| 项目名称（英文）Project Name (English) |  |
| 是否隶属于某个项目？——项目名称Is the project affiliated to a major project? ——Project Name |  |
| 申请人姓名Name of Applicant |  | 项目负责人姓名（英文）Project Leader (English) |  |
| 所在系/研究中心Department/ Research Center |  |
| 申请人职称Academic Rank |  | 邮箱地址Email |  |
| 电话 Phone number |  |
| 研究开始日期Starting Date | 年/月/日 | 研究结束日期Ending date  | 年/月/日 |
| 研究地点Study Sites |  | 预计研究所需时间Project Length |  |
| 是否包括基因分析Whether genetic analysis is included |  | 是否包括辐射Whether Radiation is included |  |
| 有无利益冲突Is there any conflict of interest |  | （如有）请说明If there is, please specify |  |
| **研究团队 Research Team** |
| 成员姓名 Member’s Name | 职称Academic Rank | 隶属单位/部门Department/Unit | 角色/分工Role/Task | 存在利益冲突？Conflict of Interest？ | 签字Signature |
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| **合作单位 Collaborating Institutions** |
| 合作研究单位Collaborating Institution |  |
| 合作方负责人Person in Charge |  | 联系电话 Tel: |  |
| **资助方情况 Profile of the Sponsor** |
| **资助方类型****Type of sponsor** |  政府government  基金会foundation  公司corporation  国际组织 international organization  其他others 请说明please specify： |
| **资助方名称（中文）****Name of Sponsor (Chinese)** | **资助方名称（英文）****Name of Sponsor (English)** | **资助方联系人****Contact Person of Sponsor** | **联系方式** **Contact Information** |
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| **受试者情况 Participant Information** |
| 年龄范围age range |  | 性别要求gender requirement |  仅男性male only  仅女性female only  无要求non |
| 整个研究要求受试者总人数Total participant required |  | 受试者来自何处Source of participant |  |
| 是否涉及敏感受试者：(is there any vulnerable participant? ) 无 non 18岁以下的未成年人minors under 18 years：  孕妇或哺乳期妇女pregnant woman or lactating woman：  智力严重障碍无行为能力者severe mental retardation and incapacitation person：  其他敏感人群other vulnerable groups：  |
| 对于需要特殊保护的敏感受试者，如何提供特殊保护：How to provide special protection for vulnerable participant who require special protection? |
| 受试者参与时长duration of participant participation： |
| 受试者的补偿compensation for participant： |
| 受试者入选标准participant selection criteria： |
| 排除标准exclusion criteria： |
| 同意程序consent procedures：知情同意的8个要素是否已经包括?Have the 8 elements of informed consent been included? 是否要求免除《知情同意书》签字?Waived for the signature of Written Informed Consent Form?  |
| **研究计划介绍 Introduction of Research Plan** |
| 1. 简介Introduction：（简单说明研究的目的和意义Briefly explain the purpose and significance of the research）
2. 研究假设Research hypothesis：
3. 研究设计Research design：（包括受试人群的背景信息、受试者数目（样本大小），分组方式、所用程序和方法以及取样次数等。Including background information of the participant, number of participant (sample size), grouping method, procedures and methods used, and sampling frequency etc.）
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| 受益或好处Benefit or advantage:（概述本研究可能提供给个人受试者、受试者或社会的可能受益或好处。如果研究设计并不使受试者个人直接获益，请在前面说明。An overview of possible benefits or benefits that may bring to individual participant or society. If the study design does not directly benefit the individual participant, please state above.） |
| 不适或风险Discomfort or risk：（概述研究可能给受试者带来的不适和风险。风险是指可能或潜在的伤害，包括对受试者群体可能的不良影响，及从轻度不适或不便到敏感信息暴露的可能。如果认为受试者可能受到身体上、心理上、社会适应上或者其他方面的伤害，要说明这些风险及用来评估和减少这些风险的程序和安全措施，制定谁来负责医疗监督及整个研究过程中受试者的安全，简单说明负责此工作的人员职称、单位和联系方式。An overview of possible discomfort and risks to the participant of the study. Risk refers to possible or potential harm, including possible adverse effects on the participant, ranging from mild discomfort or inconvenience to the possibility of exposure to sensitive information. If there might be some physical, psychological and social adaptation or other aspects of harm to the participant, they should state the risks and make safety procedures and measures to reduce the risks. To establish a mechanism and delegate a responsible person for the medical supervision and the safety of participant in the process of research, please state the position, contact information and employer of the responsible person.）  |
| 保护受试者Participant protection:（介绍保护受试者和使危险或者不适最小化的措施。Specify measures taken to protect the participant and minimize risk or discomfort.） |
| 保密Confidentiality:（说明如何确保受试者的秘密。介绍在从样本资料去掉标识的程序。如果标识符必须保留，说明原因。说明何时销毁（书写的或用其他方式记录的）研究资料。如果研究结束时，资料没有销毁，介绍资料保存在何处和保存多久，说明在未来将如何使用保存的资料，以及如何让受试者同意，允许在未来使用他们的资料。Explain how to ensure the participant's secrets. Introduce the procedure for removing the logo from the sample data. If the identifier must be retained, explain why. Describe when to destroy (written or otherwise recorded) research data. If the data is not destroyed at the end of the study, where is the information stored and how long it is kept, indicating how the saved data will be used in the future, and how to allow the participant to agree to allow their data to be used in the future.）  |
| 招募受试者Recruitment of participant:（说明招募受试者的方式和程序，包括介绍如何接触受试者。Explain methods and procedures for recruiting participant, including how to contact the participant.） |
| 知情同意Informed consent:（说明知情同意将如何获得，由哪些人负责，并简单说明负责此工作的人员基本情况，包括姓名、职称、单位和联系方式。研究人员必须获得受试者的书面同意。在知情同意书中应明确陈述获得知情同意的程序以及可能的风险。在由于不识字、不信任、怀疑或者签署知情同意书可能会证实受试者参与了某种敏感的研究而给自己带来麻烦或其他考虑的情况下，允许采用口头知情同意的方法，但须在知情同意书上写明“口头同意”的理由，留有音像或者获得与研究无关的第三者签字证明作为证明文件。若采用“口头同意”，请简要说明口头知情同意的程序和与研究无关的第三者的条件。若受试者为未成年人或智力严重障碍无行为能力者，说明如何获得他们的同意及从什么人那里获得代理同意。Explain how informed consent will be obtained, who is responsible for it, and briefly explain the basic information of the person responsible for the work, including his/her name, position, employer and contact information. The researchers must obtain written consent from the participant. The procedures for obtaining informed consent and the possible risks should be clearly stated in the informed consent form. Oral informed consent is allowed in cases where illiteracy, distrust, suspicion, or signing of informed consent may prove that the participant has participated in a sensitive study and has caused trouble or other considerations for him/herself. The reason for "verbal consent" is stated on the informed consent form, and the audio visual or the third party signature certificate unrelated to the study is obtained as a supporting document. If “oral consent” is used, please briefly describe the procedures for oral informed consent and the conditions of third parties not related to the study. If the participant is a minor or a mentally handicapped person, explain how to obtain their consent and the agent’s consent.） |
| 受试者权力rights of the participant:（说明采取什么措施保证受试者理解他们可自由的不参加和对同意参与的承诺、中断参与研究，这不会使他们受到在常规治疗或其他方面的不良影响。）Explain what measures are in place to ensure that participants understand that they are free to participate and agree to participate in the study, discontinue participation in the study, which will not expose them to adverse effects in routine treatment or otherwise.  |
| 受试者的询问/释疑Participant inquiry/debriefing:（说明研究释疑流程，包括受试者参加完毕后是否会得知关于研究目的的解释，以及如何回答受试者对研究程序的询问，具体由谁回答受试者的询问，简要说明其姓名、职称、单位及其联系方式。Explain the debriefing procedure, including whether participants will be informed the purpose of the research after participation, and how to answer the participant's inquiry about the research procedures, who will answer the participant's inquiry, and briefly explain their name, position, employer and contact information.） |
| 研究结果的发表Publication of research results:（说明研究结果如何宣布和发表，如何使受试者知道这些结果。Explain how the results of the study are announced and published, and how to make the participant aware of the results.） |
| 其他可供选择的程序Other alternative programs:（如果涉及治疗实验，请说明对病人有利的其他任何可供选择的程序。If a trial treatment is involved, please describe any other alternatives that are beneficial to the patient.) |
| 可预期的设计改变Predictable design change:（在研究进程中，在选择受试者、获得知情同意、选择程序或研究设计方面会有何种变化。在做出改变以前必须通知委员会，并由委员会批准在研究中采取的改变，受试者的招募方可实施。In the course of the research, what changes will be made in selecting participant, obtaining informed consent, selection procedures, or research design. The committee must be notified before the change is made, and the committee shall approve the changes in the study, then the recruitment of the participant can be implemented.） |
| 不良效应Adverse effects:（如果这是审查委员会以前批准的一个研究计划的延长，请概述任何不良效应或其他问题。If this is an extension of a research program previously approved by the Review Committee, please outline any adverse effects or other issues.） |
| 请附上知情同意书、实验过程说明（experiment instruction）、研究释疑书。Please attach informed consent, experiment instruction, debriefing. |
| 心理系评审小组意见Comments of the Department：日期Date: |
| 评审委员会评审意见Comments of the Review Board:日期Date: |
| 主任委员签字Signature of Chair of the Review Board:日期Date: |