**附件编号Appendix No.：AMD-JG-015-04-R2**

# **医疗器械临床试验申请表**

**Application form for a clinical trial of medical devices**

申请日期Date of Application：： 年(Y) 月(M) 日(D)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 试验项目名称  Project Name  Test Project Name |  | | | | |
| 试验种类  Trial species | □ 首次注册研究Initial registration study □ 上市后再注册研究Renewal registration study □ 非注册性研究 A study not for registration | | 试验起止时间  Start and End Date |  | |
| 试验材料  Trial materials | □免费赠送Complimentary □优惠价Price □正常购买Normal purchase | | | | |
| 承担试验专业  Department |  | | 项目负责人  Project Leader | |  |
| 临床试验目的  Objective |  | | | | |
| 申办方/CRO  Sponsor / CRO |  | | | | |
| 牵头单位  Initiating site  Initiating site |  | | 负责人/电话  Person in charge/Tel phone | |  |
| 申办者递交的资料：  Documents from sponsor | | |  | | --- | | □ NMPA批件NMPA Approval Documents | | □ 动物试验报告 Animal Testing Report | | □ 医疗器械检测报告Inspection Report of Medical Devices | | □ 申办者资质证明Documents Evidencing Qualifications of Sponsors | | □ 组长单位伦理委员会成员表及批件Ethics Committee Members and Approval Documents of Initiating site | | □ 研究者手册Investigators Brochure | | （版本号Version No.： 版本日期Date： ） | | □ 病例报告表Case Report Form | | （版本号Version No.： 版本日期Date： ） | | □ 知情同意书Informed Consent Form | | （版本号Version No.:： 版本日期Date： ） | | □ 试验方案Protocol | | （版本号Version No.:： 版本日期Date： ） |   □ 其他：others | | | |
| 项目负责人意见：  Suggestion of project leader  根据申办者申请，已审阅所有临床试验前相关资料，同意负责该临床试验。在临床试验全过程中，我将严格执行国家药品监督管理局颁布的《医疗器械临床试验质量管理规范》，客观、真实提供试验数据，充分保障受试者合法权益，并按要求保存试验资料。按时完成临床试验任务。  According to the sponsor’s application, all the information related to the clinical trials, which has been agreed to be taken charge of, has been reviewed. During the whole process of clinical trials, I will strictly implement the *Good Clinical Practices for Medical Devices*, promulgated by NMPA, objectively and veritably offer the trail data, protect the rights and interests of human subjects adequately, keep the trail files as demand of the regulations, and complete the task punctually.  本研究项目参与人员与该项目有无相关利益冲突：□ 无(No) □ 有(Yes)  Conflict of interest statement for investigators  签名Signature： 年(Y) 月(M) 日(D) | | | | | |
| 机构办公室审查意见：  Comments of examination of the office  机构办公室人员与该项目有无相关利益冲突：□ 无(No) □ 有(Yes)  Conflict of interest statement for institution office staffs  签名Signature： 年(Y) 月(M) 日(D) | | | | | |

申办者联系人Contact of Sponsor： 联系方式Contact Information：

CRO 联系人Contact of CRO： 联系方式Contact Information：

临床试验机构办公室联系方式Clinical Trial Institution office contact Information：027-65796809