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| **结题资料目录—存放机构**   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **专业名称：** | | 【与伦理递交一致】 | **主要研究者：** | | | 【与伦理递交一致】 | | **试验编号：** | | 【与伦理递交一致】 | | **申办者：** | | 【与伦理递交一致】 | | | | **CRO：** | | 【与伦理递交一致】 | | | | **试验名称：** | | 【与伦理递交一致】 | | | | | | | | | | | 伦理批准日期： | | | | 年 月 日  【与首次伦理批件核对】 | | | | GCP药房： | □是 □否 | | | | 协议生效日期： | | | | 年 月 日  【与本院授权代表签字日期核对】 | | | | 筛选例数： | 例【与筛选入选表核对】 | | | | 项目启动日期： | | | | 年 月 日  【与启动会资料核对】 | | | | 入组例数： | 例【与筛选入选表核对】 | | | | 第一例受试者签署ICF日期： | | | | 年 月 日  【与筛选入选表及知情同意书核对】 | | | | 完成例数： | 例 | | | | 第一例受试者入组日期： | | | | 年 月 日  【与筛选入选表及原始病历核对】 | | | | 脱落例数： | 例 | | | | 最后一例受试者出组日期： | | | | 年 月 日  【与原始病历及病例报告表核对】 | | | | SAE例数： | 例 | | | | **序号** | **名称** | | | | **有无** | | **备注** | | | | | |  | 研究方案 | | | | □有 □无 | | 版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05（需PI签字及日期、申办方签字及日期并盖章）】  版本号/版本日期  研究方案修订列表  V旧版本→→V新版本【将修订列表放在所有方案最后】 | | | | | |  | 研究者手册 | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘，所有伦理批准的都需刻盘。不要混杂其他刻盘资料】  光盘 1 张，包含以下内容：  版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05（需申办方盖章）】  版本号/版本日期  研究者手册修订列表  V旧版本→→V新版本【将修订列表放在所有研究者手册最后】 | | | | | |  | 临床前研究相关资料 | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘。不要混杂其他刻盘资料】 | | | | | |  | 试验相关操作规程 | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘。不要混杂其他刻盘资料  例如：设盲试验的破盲程序（若有）】 | | | | | |  | 试验医疗器械的研制符合适用的医疗器械质量管理体系相关要求的声明 | | | | □有 □无 | | 页  【器械、试剂项目才会有该项】 | | | | | |  | 医疗器械产品技术要求 | | | | □有 □无 | | 页  【器械、试剂项目才会有该项】 | | | | | |  | 基于医疗器械产品技术要求的医疗器械产品检验报告 | | | | □有 □无 | | 份  【器械、试剂项目才会有该项】 | | | | | |  | 知情同意书（空表模版） | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘，所有伦理批准的都需刻盘。不要混杂其他刻盘资料】  光盘 1 张，包含以下内容：  版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05（需申办方盖章）】  版本号/版本日期  知情同意书修订列表  V旧版本→→V新版本【将修订列表放在所有知情同意书最后】 | | | | | |  | 原始记录（空表模版） | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘，所有伦理批准的都需刻盘。不要混杂其他刻盘资料】  □研究病历 □门诊病历 □住院病历  □其他  光盘 1 张，包含以下内容：  版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05（需申办方盖章）】 | | | | | |  | 受试者日记卡（空表模版） | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘，所有伦理批准的都需刻盘。不要混杂其他刻盘资料】  光盘 1 张，包含以下内容：  版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05（需申办方盖章）】 | | | | | |  | 各类评分表（空表模版） | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘，所有伦理批准的都需刻盘。不要混杂其他刻盘资料】  光盘 1 张，包含以下内容：  版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05（需申办方盖章）】 | | | | | |  | 病例报告表（空表模版） | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘，所有伦理批准的都需刻盘。不要混杂其他刻盘资料】  光盘 1 张，包含以下内容：  □纸质CRF □电子CRF  版本号/版本日期  版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05 】 | | | | | |  | 招募广告 | | | | □有 □无 | | 【不收纸质版，资料刻一张光盘，所有伦理批准的都需刻盘。不要混杂其他刻盘资料】  光盘 1 张，包含以下内容：  版本号/版本日期 【例如：V1.0/2019.01.01；伦理批准日期：2019.03.05（需申办方盖章）】 | | | | | |  | 本院伦理审查批件/CFDA临床试验批件/临床试验批准通知书/第三类医疗器械临床试验批件或通知书/药物临床试验登记与信息公示平台登记信息/国家医学研究登记备案信息系统/临床试验申请表（立项/伦理） | | | | □有 □无 | | 本院伦理审查批件 份【首次伦理批件需要：伦理委员会成员表】  CFDA临床试验批件 页  临床试验批准通知书 页  第三类医疗器械临床试验批件或通知书 页  药物临床试验登记与信息公示平台登记信息 页  国家医学研究登记备案信息系统 页  临床试验申请表（立项/伦理） 份 | | | | | |  | 中国人类遗传资源批件及申请书 | | | | □有 □无 | | 份【若申请书很厚，批件存纸质版，申请书请刻盘】  【批件号/批件日期  例如：国科遗办审字[2019]1289号/2019.04.30】 | | | | | |  | 医疗器械临床试验备案表 | | | | □有 □无 | | 页  【器械、试剂项目才会有该项】 | | | | | |  | 创新医疗器械特别审批申请审查通知单/公示结果截图 | | | | □有 □无 | | 页  【器械、试剂项目才会有该项】 | | | | | |  | 药审中心或器审中心沟通会会议纪要（如有） | | | | □有 □无 | | 页  【器械、试剂项目才会有该项】 | | | | | |  | 研究者会签到表及会议资料 | | | | □有 □无 | | 签到表 页，研究者会资料 份  【若研究者会资料太多请刻盘保存】 | | | | | |  | 临床试验启动会签到表及启动会资料 | | | | □有 □无 | | 签到表 页，启动会资料 份 | | | | | |  | 研究者相关培训记录 | | | | □有 □无 | | 页【按照培训时间先后顺序存放】 | | | | | |  | 研究者分工授权表 | | | | □有 □无 | | 页 | | | | | |  | 研究者签名样张 | | | | □有 □无 | | 页 | | | | | |  | 研究者履历、GCP证书、执业证书 | | | | □有 □无 | | 人份  【按照研究者分工授权表顺序整理存放、一个人的履历+执业证书+GCP证书+本项目其他相关培训证书+保密协议+财务纰漏，用订书器装订】 | | | | | |  | 实验室正常值范围 | | | | □有 □无 | | 页  【若为中心实验室，请将试验过程中用到的中心试验室手册各版本刻盘】 | | | | | |  | 实验室室间质评证书/医学或实验室室间质控证明（医疗器械、试剂） | | | | □有 □无 | | □中心实验室 □本地实验室  年、 年、 年 | | | | | |  | 仪器校准证书、合格证、说明书等 | | | | □有 □无 | | 【例如：  离心机 1 份  心电图机 1 份】 | | | | | |  | 受试者筛选入选表 | | | | □有 □无 | | 页【按照时间先后顺序存放】 | | | | | |  | 受试者鉴认代码表 | | | | □有 □无 | | 页， 例 | | | | | |  | 受试者完成编码目录 | | | | □有 □无 | | 页 | | | | | |  | 受试者领取补偿费用登记表 | | | | □有 □无 | | 页 | | | | | |  | 药品/器械/试剂接收记录、运送温度记录及检验报告/说明书/标签 | | | | □有 □无 | | 次，首次接收日期：  【按照接收时间先后顺序存放、快递单请复印】 | | | | | |  | 器械安装调试记录 | | | | □有 □无 | | 页  【器械项目才会有该项】 | | | | | |  | 器械维护/保养记录 | | | | □有 □无 | | 页  【器械项目才会有该项】 | | | | | |  | 器械/试剂使用记录 | | | | □有 □无 | | 页  【器械、试剂项目才会有该项】 | | | | | |  | 器械/试剂治疗分配记录 | | | | □有 □无 | | 页  【器械、试剂项目才会有该项】 | | | | | |  | 药物配制、输注/注射、速率调整记录 | | | | □有 □无 | | 页 | | | | | |  | 药品/器械/试剂发放记录 | | | | □有 □无 | | 页 | | | | | |  | 试验用药品领取/返还记录表及转运过程中的温度记录 | | | | □有 □无 | | 次 | | | | | |  | 药品/器械/试剂回收记录 | | | | □有 □无 | | 页 | | | | | |  | 药品/器械/试剂保存记录 | | | | □有 □无 | | 页  记录区间： 至  【例如：记录区间：2019.05.05 至 2019.10.15】 | | | | | |  | 药品/器械/试剂退回记录 | | | | □有 □无 | | 次【快递单请复印】 | | | | | |  | 药品/器械/试剂销毁记录 | | | | □有 □无 | | 页 | | | | | |  | 药品/器械/试剂销毁单位资质 | | | | □有 □无 | | 页 | | | | | |  | 生物样本采集记录 | | | | □有 □无 | | 页 | | | | | |  | 生物样本处理/出入库记录 | | | | □有 □无 | | 页 | | | | | |  | 临床试验用样本编盲记录/揭盲记录（如需，仅体外诊断试剂） | | | | □有 □无 | | 页 | | | | | |  | 生物样本使用记录 | | | | □有 □无 | | 页 | | | | | |  | 临床试验用样本发放/回收/出入库记录（如需，仅体外诊断试剂） | | | | □有 □无 | | 页 | | | | | |  | 生物样本保存记录 | | | | □有 □无 | | 页  记录区间： 至  【例如：记录区间： 2019.05.05 至 2019.10.15】 | | | | | |  | 生物样本运送记录及运送温度记录 | | | | □有 □无 | | 次【快递单请复印】 | | | | | |  | 生物样本的留存记录 | | | | □有 □无 | | 页 | | | | | |  | 生物样本销毁记录 | | | | □有 □无 | | 页 | | | | | |  | 生物样本销毁单位资质 | | | | □有 □无 | | 页 | | | | | |  | 物资接收记录 | | | | □有 □无 | | 次【快递单请复印】 | | | | | |  | 物资退回记录 | | | | □有 □无 | | 次【快递单请复印】 | | | | | |  | 监查员访视记录及随访信 | | | | □有 □无 | | 访视记录 页；【按照访视时间先后顺序存放】  随访信共 份，PSV 份、SIV 份、RMV 份、COV 份 | | | | | |  | 现场访视之外的相关通讯、联络记录（往来信件/会议记录/电话记录） | | | | □有 □无 | | 【存放光盘  例如：光盘 1 张】 | | | | | |  | SAE、SUSAR、DSUR报告及其他安全性资料/其他严重安全性风险信息的报告（医疗器械、试剂） | | | | □有 □无 | | 【存放光盘  例如：光盘 1 张  注意：本中心SAE存放纸质版原件】 | | | | | |  | 阶段性报告 | | | | □有 □无 | | 【存放光盘  例如：光盘 1 张（研究者向伦理委员会提交的进展报告；申办者向药品监督管理部门提交的进展报告）】 | | | | | |  | 临床试验数据表（体外诊断试剂） | | | | □有 □无 | | 份 | | | | | |  | 统计报告 | | | | □有 □无 | | 份 | | | | | |  | 统计疑问表/数据疑问表 | | | | □有 □无 | | 份 | | | | | |  | 分中心小结表 | | | | □有 □无 | | 份 | | | | | |  | 总结报告 | | | | □有 □无 | | 份 | | | | | |  | 专业质控表 | | | | □有 □无 | | 份 | | | | | |  | 试验完成文件 | | | | □有 □无 | | 份【研究者向伦理委员会提交的试验完成文件】 | | | | | |  | 受试者保险的相关文件 | | | | □有 □无 | | 份 | | | | | |  | 临床试验合同 | | | | □有 □无 | | 份 | | | | | |  | 治疗分配记录 | | | | □有 □无 | | 份 | | | | | |  | 破盲证明 | | | | □有 □无 | | 份 | | | | | |  | 说明 | | | | □有 □无 | | 【各种说明请保存  例如：××××说明 1 页】 | | | | | |  | 目录中没有列出来的项目直接在结题资料目录本项之后添加 | | | |  | |  | | | | | |  | …… | | | |  | |  | | | | | |  | …… | | | |  | |  | | | | | |

筛选成功受试者筛选号：

筛选失败受试者筛选号：

未完成受试者筛选号：

ICF使用情况一览表

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| 受试者筛选号 | 版本号/版本日期：  *（请在此处填写）* | 版本号/版本日期： | 版本号/版本日期： |
| 伦理批准日期：  *（请在此处填写）* | 伦理批准日期： | 伦理批准日期： |
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备注：相应列，请填入相应受试者签署ICF日期；未签署的请合并单元格并标明原因（如筛选失败、已出组等）。