**研究完成/总结报告**

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| 项目名称 | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 项目编号 | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 申办单位 | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 合同研究组织CRO | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 组长单位 | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| 主要研究科室 | | | | | | | | |  | | | | | | | 主要研究者 | | | | | | | | |  | | | |
| 伦理委员会初审批准日期 | | | | | | | | |  | | | | | | | 研究开始日期 | | | | | | | | |  | | | |
| 初审伦理意见号 | | | | | | | | |  | | | | | | | 跟踪审查频率 | | | | | | | | | \_\_\_\_\_\_个月 | | | |
| 研究方案版本号 | | | | | | | | |  | | | | | | | | 研究方案版本日期 | | | | | | | |  | | | |
| 知情同意书版本号 | | | | | | | | |  | | | | | | | | 知情同意书版本日期 | | | | | | | |  | | | |
| 研究计划完成时间 | | | | | | | | |  | | | | | | | | 研究实际完成时间 | | | | | | | |  | | | |
| 1．项目完成情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 计划入组受试者数 | | | | 筛选  人数 | | | | | 入组  人数 | | | | 退出  人数 | | | | | 完成  人数 | | | | | 未完成  人数 | | | | 最后1例  出组时间 | |
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| 需要具体  说明情况 | | | | | 如退出原因 | | | | | | | | | | | | | | | | | | | | | | | |
| 2．修正研究项目情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 序号 | 修正日期 | | | | | | | 修正的具体文件 | | | | | | 修正后文件版本号 | | | | | | 修正后文件  版本日期 | | | | | | | 伦理委员会  审查意见 | |
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| 共计\_\_\_\_次 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3．严重不良事件、预期/非预期不良事件报告情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 受试者  编号 | | | 不良事件疾病诊断 | | | | | | | | | | | | 转归  情况 | | | | 评价与试验关系 | | | 发生  日期 | | | | 报告伦理委员会 日期 | | 伦理委员会意见 |
| SAE疾病名称 | | | | | | | 预期 | | 非预期 | | |
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| 共计\_\_\_\_例 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4.方案偏离报告情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 序  号 | | 方案偏离发生日期 | | | | | 受试者编号 | | | | 方案偏离情况及处理措施 | | | | | | | | | | 报告伦理委员会日期 | | | | | | 伦理委员会审查意见 | |
|  | |  | | | | |  | | | |  | | | | | | | | | |  | | | | | |  | |
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| 共计\_\_\_\_次/例 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. 本中心研究完成/总结报告要点 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究是否按计划实施 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究执行的方案与知情同意书是否是伦理委员会批准的版本 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中是否有修正研究方案和知情同意书 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中修正研究方案和知情同意书是否递交伦理审查并获得批准 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 是否按期向伦理委员会递交年度/定期跟踪审查申请并获得批准 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中是否发生严重不良事件、预期或非预期不良事件 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中发生的严重不良事件、预期或非预期不良事件是否报告伦理委员会 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究的风险是否超过预期 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中是否有违背方案情况 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中方案偏离的情况是否递交伦理审查并获得批准 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中是否存在影响受试者安全、健康或权益的情况 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 研究中发生的影响受试者安全、健康或权益的情况是否递交伦理审查 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 是否需要采取进一步保护受试者的措施 | | | | | | | | | | | | | | | | | | | | | | | | □是，□否,□不适用 | | | | |
| 需要向伦理委员会说明的情况，请具体说明： | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 主要研究者签名：  日期： 年 月 日 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 临床试验机构意见：  签名： 日期： 年 月 日 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

注：填表须知：表格中每一项内容请详细填写，备选项的方框中请画“■或✓”表示选中，主要研究者

手写签名后递交伦理委员会。本院为项目组长单位，提交各中心情况。