**年度/定期跟踪审查报告**

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| 项目名称 | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| 申办方 | | | | | | | |  | | | | | | | 联系人/电话 | | | | | |  | | | | | | | | |
| 组长单位 | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| 项目类型 | | | | | | | | □境内II类  □境内III类 □进口II类  □进口III类  □体外诊断试剂 | | | | | | | | | | | | | | | | | | | | | |
| 研究科室 | | | | | | | |  | | | | | | 主要研究者 | | | | | | | | | |  | | | | | |
| 伦理委员会初审批准日期 | | | | | | | |  | | | | | | 批件号 | | | | | | | | | |  | | | | | |
| 伦理审查批件有效期 | | | | | | | |  | | | | | | 跟踪审查频率 | | | | | | | | | | \_\_\_\_\_\_个月 | | | | | |
| 试验方案版本号/日期 | | | | | | | |  | | | | | | 试验知情同意书版本号/日期 | | | | | | | | | |  | | | | | |
| 目前本中心研究阶段 | | | | | □研究尚未启动 □正在招募受试者（尚未入组）  □正在实施研究 □受试者的研究干预已经完成  □后期数据处理阶段 □其他\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | |
| 本次报告数据发生时间 | | | | | | | | | \_\_\_\_\_\_ 年 \_\_\_\_ 月 \_\_\_\_ 日至 \_\_\_\_\_\_ 年 \_\_\_\_ 月 \_\_\_\_ 日 | | | | | | | | | | | | | | | | | | | | |
| 1. 项目进展情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究启动日期 | | | 计划入组例数 | | | | | | | 筛选例数 | | | 入组例数 | | | | 完成例数 | | | | | | 未完成例数 | | | | | 退出例数 | |
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| 需要具体说明情况（如退出原因） | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. 本中心严重不良事件、预期/非预期不良事件情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 受试者  编号 | | 不良事件疾病诊断 | | | | | | | | | | | | | | 转归  情况 | | | 发生  日期 | | | 评价与试验关系 | | | 报告伦理委员会日期 | | | | 伦理委员会审查  意见 |
| SAE疾病名称 | | | | | 预期不良事件疾病 | | | | 非预期不良事件疾病 | | | | |
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| 共计\_\_\_\_例 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. 本中心违背方案情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 序号 | 违背方案  发生日期 | | | 受试者编号 | | | | 违背方案情况及处理措施 | | | | | | | | | | | | 上报伦理  委员会日期 | | | | | | | 伦理委员会  审查意见 | | |
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| 共计\_\_\_\_例 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. 修正研究项目情况 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 序号 | 修改日期 | | | | | 修改的具体文件 | | | | | | 修改后文件  版本号 | | | | | | 修改后文件  版本日期 | | | | | | | | 伦理委员会  批准日期 | | | |
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| 共计\_\_\_\_次修订 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. 本中心研究进展情况报告要点 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究是否按计划实施：□是，□否（请附书面材料说明） | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否存在影响研究进行的情况：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究中修改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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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（请附书面材料说明） | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究中是否发生严重不良事件、预期或非预期不良事件：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究中发生的严重不良事件、预期或非预期不良事件是否及时报告伦理委员会：□是，□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究的风险是否超过预期：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否存在可能影响研究风险与受益的任何事件或信息、新进展：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究中是否有违背方案情况：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究中违背方案的情况是否递交伦理审查并获得批准：□是，□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 研究中是否存在影响受试者安全、健康或权益的情况：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否存在需要暂停或提前终止研究的情况：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 暂停或终止研究是否会影响受试者的安全、健康或权益：□是（请附书面材料说明），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否申请伦理审查批件有效期延长：□ 是（延长时间： ），□否 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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。