| **可疑且非预期严重不良反应报告表** | | | | | | | | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 伦理受理号： | | | | | | | | | | | | | | | | | | |  | | |
| 项目名称/编号 | | |  | | | | | | | | | | | | | | | | | | |
| 项目类型 | | | □纵向课题：□国家级 □省级 □市级 □其他\_\_\_\_\_\_\_\_\_\_  □横向课题：□企业资助 □行业学会 □其他\_\_\_\_\_\_\_\_\_\_  □研究者自发开展： □是 □否  □涉及超说明用药： □是 □否  □涉及干细胞临床研究：□是 □否  □涉及医疗新技术： □是 □否 | | | | | | | | | | | | | | | | | | |
| 申办单位 | | |  | | | | | | | | | | | | | | | | | | |
| 专业/科室 | | |  | | | | | | | | 主要研究者 | | | | |  | | | | | |
| **事件概述** | | | | | | | | | | | | | | | | | | | | | |
| 受试者编号 | |  | | | | 出生年月 | |  | | | | 年龄 | |  | | | | 性别 | | □男 □女 | |
| 报告类型 | | □首次报告 □随访报告 □总结报告 | | | | | | | | | | | | | | | | | | | |
| 事件名称 |  | | | | | | 发生时间 | |  | | | | | | 研究者获知时间 | | | | | |  |
| **事件等级：** | | | | | | | | | | | | | | | | | | | | | |
| □导致住院 | | | | | □延长住院时间 | | | | | □伤残 | | | | | | | □死亡（ 年 月 日） | | | | |
| □功能障碍 | | | | | □导致先天畸形 | | | | | □危及生命 | | | | | | | □其他 | | | | |
| **受试者详细情况** | | | | | | | | | | | | | | | | | | | | | |
| **可疑且非预期严重不良反应（SUSAR）的详细情况（包括实验室检查结果）：** | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **受试者的转归情况：** | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **事件分析** | | | | | | | | | | | | | | | | | | | | | |
| **相关性诊断依据：** | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **是否增加研究人群的风险** | | | | | | □是 □否 | | | | | | | | | | | | | | | |
| **研究者/申办方处理措施及结果，后续防范措施：** | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **是否需要修改研究方案？**（如需要请说明） □是 □否 | | | | | | | | | | | | | | | | | | | | | |
| **是否需要修改知情同意书？**（如需要请说明） □是 □否 | | | | | | | | | | | | | | | | | | | | | |
| **研究者签名：** | | | |  | | | | | | | | | **日期：** | | | | | | | | |