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| 单位名称: （单位公章）  填表日期： 年 月 日 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **干细胞临床研究和应用自查情况调查表** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 单位地址 | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | 邮政编码 | | |  | | | | | | 开展干细胞治疗项目总数 | | | | |  | |
| 单位法人 | | | |  | | | | | 单位性质 | | | | □ 1.公司 □ 2. 医院 级 等 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 自查工作负责人 | | | |  | | | | | 职务/职称 | | | |  | | | | | | | | 手机 | | | | |  | | | | | | | | | | | | | 电子邮箱 | | | | | |  | | | | | | |
| 自查工作联系人 | | | |  | | | | | 职务/职称 | | | |  | | | | 联系电话 | | | |  | | | | | 传真 | | | | |  | | | | |  | | | 填表人 | | | | | |  | | | | | | |
| **一、项目资质情况自查** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 项目名称 | | | | | | | | 项目牵头单位 | | | | | 项目来源（如：863计划） | | | | | 项目经费 | | | | 审批机构性质 | | | | | | | | | | | | | | | | | | | |  | 批件文号 | | | | | 批准时间 | | | |
| 卫生部 | | | 国家药监局 | | | | 其它（列出机构名称） | | | | | | | | | 未审批 | | | |
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| **二、干细胞制剂制备情况自查** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 干细胞制剂名称 | |  | | | | 干细胞制剂是否有质量标准 | | | | 是 | |  | | | 采用标准名称 | | | | |  | | | | 制剂和标准是否经过相关部门检验、复核 | | | |  | | | | 是 | |  | | | 检验、复核部门名称 | | |  | | | | | | | 检验报告编号 | | | |  |
| 否 | |  | | |  | | | | 否 | |  | | |
| 干细胞来源 | | | | 干细胞获取方法 | | | | | | | | | | | | | | | | 干细胞是否经体外处理 | | | | | | | 干细胞制备方式 | | | | | | | | | | 是否有完整的临床前研发技术资料和实验记录 | | | | | | | | | | | | | | |
| 自体 | 异体 | | | 外周血 | | | 脐带 | | | | 骨髓 | | | 其它（请注明具体组织） | | | | | | 是 | | | 否 | | | | 自制 | | | | | | 他人提供 | | | | 是 | | | | | | | 否 | | | | | | | |
|  |  | | |  | | |  | | | |  | | |  | | | | | |  | | |  | | | |  | | | | | |  | | | |  | | | | | | |  | | | | | | | |
| 是否有完整的干细胞制备和质检实验记录 | | | | 是 | | |  | | | | 干细胞制备车间或实验室是否通过GMP认证 | | | | | 是 | | |  | | | | 认证单位 | | | |  | | | | | | | | | | 设备投入(万元) | | | | | | |  | | | | | | | |
| 否 | | |  | | | | 否 | | |  | | | | 面积(m2) | | | |  | | | | | | | | | | 技术人员数 | | | | | | |  | | | | | | | |
| **三、项目伦理情况自查** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 是否通过伦理委员会审批 | | | | 是 | | |  | | | | 伦理委员会设置单位 | | | | | | | | | |  | | | | | | | | | | | | | | 伦理批件号及时间（多个批件一并列出） | | | | | | | | |  | | | | | | | |
| 否 | | |  | | | |
| 是否签署患者知情同意书 | | | | 是 | | |  | | | | 知情同意书是否明确告知收费情况 | | | | | | | | | | 是 | | | | |  | | | | 是否制订治疗风险处理预案及上报制度 | | | | | | | | | | | | | | 是 | | | | |  | | |
| 否 | | |  | | | | 否 | | | | |  | | | | 否 | | | | |  | | |
| **四、项目临床研究和应用情况自查** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 开展干细胞临床研究和应用的起始时间 | | | | |  | | | | | 研究和应用总例数 | | | |  | | | 是否收费 | | | | 是 | | | | |  | | | | | 收费标准 | | | | | |  | | | | 收费依据 | | | | |  | | | | | |
| 否 | | | | |  | | | | |
| 适应症 | | | 1 | | | | 不良反应 | | | 1 | | | | | | | 是否属新药临床试验 | | | | 是 | | | | |  | | | | | 阶段 | | | | | | | | | | 治疗组例数 | | | | | 对照组例数 | | | | | |
| 2 | | | | 2 | | | | | | | Ⅰ期 | | | | | |  | | | |  | | | | |  | | | | | |
| 3 | | | | 3 | | | | | | | Ⅱ期 | | | | | |  | | | |  | | | | |  | | | | | |
| 4 | | | | 4 | | | | | | | Ⅲ期 | | | | | |  | | | |  | | | | |  | | | | | |
| 5 | | | | 5 | | | | | | | 否 | | | | |  | | | | |  | | | | | |  | | | |  | | | | |  | | | | | |

注：请在上表中的选择类栏目下标注“√”，在填写类栏目下填写文字内容。需提供的附件：1. 所有批件的复印件；2. 收费文件的复印件。