**医疗器械临床试验立项申请表**

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| **项目名称** | | |  | | | | | | |
| **临床试验批件号** | | |  | | **试验器械类别** | | |  | |
| **伦理审查批件日期** | | |  | | **计划例数** | | |  | |
| **专业科室名称** | | |  | | **项目负责人** | | |  | |
| **研**  **究**  **团**  **队** | **姓名** | | **在项目中承担的工作** | | **姓名** | | | **在项目中承担的工作** | |
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| **科室是否有正在开展的同类医疗器械临床试验项目？ □是 □否** | | | | | | | | |
| **申办方** | **单位名称** | |  | | | | | | |
| **联系人** | |  | | **电话/Email** |  | | | |
| **CRO** | **单位名称** | |  | | | | | | |
| **联系人** | |  | | **电话/Email** |  | | | |
| **试验用**  **医疗器械** | | **名称** | | **规格/型号** | **批号** | | **有效期** | | **供应方式** |
|  | |  |  | |  | |  |
| **对照**  **医疗器械** | | **名称** | | **规格/型号** | **批号** | | **有效期** | | **供应方式** |
|  | |  |  | |  | |  |
| **申请人** | |  | | | **日期** | |  | | |
| **研究科室意见：□同意 □不同意**  **科主任（或专业负责人）签字**  **日期** | | | | | | | | | |
| **机构办公室意见：□同意 □不同意**  **主任签字**  **日期** | | | | | | | | | |