## 北京清华长庚医院医疗器械临床试验申请表

## Clinic Trial Project Application form of Beijing Tsinghua Changgung Hospital

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| --- | --- | --- | --- |
| 项目  Project |  | | |
| 申办者  Sponsor |  | | |
| 承担科室  Responsible Departments |  | | |
| **专业科室主要研究者评估Assessment of Principal Investigator in professional departments** | | | |
| 目标研究人群的招募  Recruitment of target study population | | 预期能按进度完成🞎，Anticipating to finish the project according to the schedule  有难度🞎，Difficult 很困难🞎， Very difficult | |
| 是否具备研究所需的理化检查的条件  Whether it satisfies the conditions of physical and chemical examination required by the research. | | 是🞎，Yes  否🞎，No | |
| 是否具备预期严重不良事件抢救的条件  Whether it satisfies the condition of anticipated rescue for serious adverse event. | | 是🞎，Yes  否🞎，No | |
| 主要研究者是否有充分的时间参加研究  Whether the Principal Investigator have adequate time to participate in the research or not. | | 是🞎，Yes  否🞎，No | |
| 评估意见  Assessments | | 同意立项🞎，Approved  不同意立项🞎，Disapproved | |
| 主要研究者（签字）  Signature of Principal Investigator | |  | |
| **专业科室负责人评估Assessment of head in professional departments** | | | |
| 评估意见  Assessments | | 同意立项🞎，Approved  不同意立项🞎 ，Disapproved | |
| 专业科室负责人（签字）  Signature of head in professional departments | |  | |
| 注：🞏内请打X | | | |
| **机构项目管理员评估Assessments of project managers** | | | |
| 研究项目是否专业对口  Whether the researching projects are  inconsistence with the specific majors. | | | 是🞎，Yes  否🞎，No |
| 承担科室在研临床试验项目数  The numbers of clinic trial projects in study by the responsible departments | | | 项  Project |
| 与试验医疗器械目标疾病相同的在研项目  Projects in study whose target disease is the same as that of investigational product. | | | 有🞎，Yes  无🞎，No |
| 是否同时承担不同申办者的相同种类医疗器械  Whether it is simultaneously responsible for products of the same species for different applicants | | | 是🞎，Yes  否🞎 No |
| 评估意见  Assessments | | | 同意立项🞎，Approved  不同意立项🞎，Disapproved |
| 机构项目管理员（签字）  Signature of project managers | | |  |
| **机构办公室审核 Department office verification** | | | |
| 审核意见  Opinion | | | 同意立项🞎，Approved  不同意立项🞎， Disapproved |
| 机构办公室主任（签字）  Signature of office director of the department | | |  |
| 日期  Date | | |  |

注：□内请打X