**医疗器械临床试验核心文件受控盖章申请表**

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| **项目名称** |  | | | | |
| **临床试验机构** |  | | | | |
| **申办者/CRO** |  | | | | |
| **专业组** |  | **PI** |  | **计划入组例数** |  |
| 经与项目相关人员沟通讨论，以下文件记录的内容与试验医疗器械的安全性评估、有效性评估数据关系密切，应按照“核心受控文件”进行严格受控管理，特申请进行核心文件受控盖章，并按照《医疗器械临床试验项目文件受控的标准操作规程》进行管理： | | | | | |

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| **序号** | **文件名称** | **版本号** | **份数** | **页码数** | **备注** |
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申办者：

日期：