**我的签名确认研究人员签名样张及职责分工表上的下列信息是准确的：**

**My signature confirms that the following information on the Trial Site Signature and Responsibility Log is accurate and that:**

我将对在本研究中心的临床研究的整体实施和报告的数据负责。

I will remain responsible for the overall conduct of the clinical study at the site and for the reported data.

我将监督任何我授权相关职责的任何个人或团队。

I will supervise any individual or party to whom I delegate study related duties.

我将授权此表中列出的每个研究团队成员负责研究特定职责。

I will authorize the delegation of study-specific tasks to each study team member listed in this log.

研究职责将只授权给针对角色接受过适当培训的合格的人员，并且遵守ICH GCP,当地法规，IRB/IEC要求以及研究中心特定要求。

The study tasks will be delegated only to qualified staff members appropriately trained for the role and in compliance with ICH GCP, local regulations, IRB/IEC requirements, site-specific requirements.

我将确保研究团队成员充分了解方案，研究药物和他们相关的职责，在适当的授权和针对他们角色的培训之前，不会执行任何授权的工作。

I will ensure that all study team members are adequately informed about the protocol, the investigational product and their study related duties, and will not perform any of the delegated tasks prior to appropriate delegation and completion of study-specific training appropriate for their role.

我将确保研究团队成员能及时收到与其角色相关的任何新信息。

I will ensure that the study team members receive, in a timely manner, any new information about the study relevant to their role.

我将确保在研究团队成员或授权特定任务中的任何变化都能及时记录（例如，发生变化和进行研究特定工作之前）。

I will ensure that any changes in the study site staff or in the study site staff or in the delegated study-specific tasks are recorded in a timely manner (i.e., as soon as changes occur and prior to study-specific tasks being performed).

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| **主要研究者签字/Signature of Principal Investigator:** |  | **日期/Date:** |  |

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| 说明：参与本研究操作的所有人员的姓名、签名、姓名缩写（首字母大写）、签字样张、研究人员角色、开始/终止日期、授权职责和签名必须记录在本表中。对于研究角色、授权职责，请记录以下提供的每个角色对应代码和每个职责对应编号。 | | | | | |
| 研究角色 | | 职责分工 | | | |
| A.主要研究者 |  | 1.受试者筛选、入组 | 13.样本采集 | 25.安全性事件报告 |  |
| B.研究者 |  | 2.获得知情同意 | 14.样本处理/储存/运输 | 26.EDC数据录入 |  |
| C.研究护士 |  | 3.受试者随机 | 15.IWRS/IVRS/IRT系统操作 | 27.数据质疑解答 |  |
| D.药品管理员 |  | 4.受试者随访 | 16.药物管理 | 28.EDC数据签名 |  |
| E.临床研究协调员 |  | 5.病史等原始资料收集、记录 | 17.研究药物处方 | 29.研究相关文档管理/维护 |  |
| F.影像医师 |  | 6.合并用药 | 18.研究药物配制 | 30.试验物资管理 |  |
| G.病理医师 |  | 7.体格检查（ECOG评分） | 19.研究药物输注 | 31.IRB/IEC沟通 |  |
| H.其他： |  | 8.临床医学评估 | 20.研究药物销毁 | 32.其他： |  |
|  |  | 9.影像审阅评估 | 21.研究药物回收 | 33.其他： |  |
|  |  | 10.病理切片 | 22.研究药物转运 | 34.其他： |  |
|  |  | 11.身高、体重测量 | 23.研究药物揭盲/破盲 |  |  |
|  |  | 12.生命体征测量 | 24.AE/SAE处理、评估、记录 |  |  |

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| 研究角色 | 主要研究者A | 研究者B | 研究护士C | | 药品管理员D | 临床研究协调员E | 影像医师F | 病理医师G | 其他H |
| 职责分工 | 1-9,11-12,15,17,23-31 | 1-9,11-12,15,17,  24-25,27,29-31 | 11-13,18-21,29-30 | | 15-16,21,29-30 | 14-15,22,26-27,  29-30 | 9 | 10 |  |
| 被授权人签名  （手签） | 姓名拼音全拼  （手签） | 姓名首字母缩写  （大写） | 研究角色  （代码） | PI签字及授权开始日期 | | | PI签字及授权终止日期 | | |
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