**Data Management System Approval Form**

**Trial Name:**

**IRAS Number:**

**Database Name:**

**Database Version and Date:**

**Database Developer Sign-off**

I confirm the database is built as per the specifications supplied to me

|  |  |
| --- | --- |
| Name  |  |
| Signature and Date |  |

**Chief Investigator Sign-off**

I confirm that user acceptance testing has been carried out and the data collected in the database matches the protocol and that it collects sufficient information to answer the research questions

|  |  |
| --- | --- |
| Name  |  |
| Signature and Date |  |

**Statistician Sign-off**

I confirm that the database matches the specification and the data to be collected will allow me to carry out statistical analysis

|  |  |
| --- | --- |
| Name  |  |
| Signature and Date |  |

**GCP and Governance Manager Sign-off**

I confirm that all required database documents are in place and that the database set up and testing complies with ICH GCP and sponsor requirements.

|  |  |
| --- | --- |
| Name  |  |
| Signature and Date |  |