Protocol Database Template

1. **Initial Review**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Submission No.** |  |  |  |  |  |  |
| **Study Protocol title** |  |  |  |  |  |  |
| **Protocol code** |  |  |  |  |  |  |
| **Sponsor/Funding Agency** |  |  |  |  |  |  |
| **Principal Investigator/Lead Researcher** |  |  |  |  |  |  |
| **Institution/**  **Department** |  |  |  |  |  |  |
| **Type of the study** |  |  |  |  |  |  |
| **Research category** |  |  |  |  |  |  |
| **Date Received** |  |  |  |  |  |  |
| **Received from** |  |  |  |  |  |  |
| **Type of Review** |  |  |  |  |  |  |
| **Date distributed to PRs** |  |  |  |  |  |  |
| **Date returned from PRs** |  |  |  |  |  |  |
| **Date of meeting deliberated** *(If full board)* |  |  |  |  |  |  |
| **Review Decision** |  |  |  |  |  |  |
| **Date of Action letter** |  |  |  |  |  |  |

1. **Resubmission**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Revision 1** |  |  |  |  |  |  |
| Document Submitted |  |  |  |  |  |  |
| Date of submission |  |  |  |  |  |  |
| Date Distributed to the PRs |  |  |  |  |  |  |
| Date Returned from the PRs |  |  |  |  |  |  |
| Review Decision |  |  |  |  |  |  |
| **Revision 2** |  |  |  |  |  |  |
| Document Submitted |  |  |  |  |  |  |
| Date of submission |  |  |  |  |  |  |
| Date Distributed to the PRs |  |  |  |  |  |  |
| Date Returned from the PRs |  |  |  |  |  |  |
| Review Decision |  |  |  |  |  |  |
| **Revision 3** |  |  |  |  |  |  |
| Document Submitted |  |  |  |  |  |  |
| Date of submission |  |  |  |  |  |  |
| Date Distributed to the PRs |  |  |  |  |  |  |
| Date Returned from the PRs |  |  |  |  |  |  |
| Review Decision |  |  |  |  |  |  |
| **Further revision** |  |  |  |  |  |  |
| Document Submitted |  |  |  |  |  |  |
| Date of submission |  |  |  |  |  |  |
| Date Distributed to the PRs |  |  |  |  |  |  |
| Date Returned from the PRs |  |  |  |  |  |  |
| Review Decision |  |  |  |  |  |  |

1. **Approval**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date of Approval |  |  |  |  |  |  |
| Status |  |  |  |  |  |  |
| Date of Expiration of Approval |  |  |  |  |  |  |

1. **Post Approval**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Progress Report** |  |  |  |  |  |  |
| Date of Submission of Progress Report |  |  |  |  |  |  |
| Date of Progress Report submitted |  |  |  |  |  |  |
| **Amendment to Protocol** |  |  |  |  |  |  |
| Protocol code |  |  |  |  |  |  |
| Document submitted |  |  |  |  |  |  |
| How submitted |  |  |  |  |  |  |
| Date of Submission |  |  |  |  |  |  |
| Review Decision |  |  |  |  |  |  |
| Date of Approval |  |  |  |  |  |  |
| **Protocol Deviation (PD)** |  |  |  |  |  |  |
| Date submitted |  |  |  |  |  |  |
| Protocol code |  |  |  |  |  |  |
| Document submitted |  |  |  |  |  |  |
| How submitted |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| **Reportable Negative Events (RNE)** |  |  |  |  |  |  |
| Date submitted |  |  |  |  |  |  |
| Document submitted |  |  |  |  |  |  |
| How submitted |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| **Serious Adverse Event** **(SAE)** |  |  |  |  |  |  |
| Date submitted |  |  |  |  |  |  |
| Document submitted |  |  |  |  |  |  |
| How submitted |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| Suspected Unexpected Serious Adverse Reaction **(SUSAR)** |  |  |  |  |  |  |
| Date submitted |  |  |  |  |  |  |
| Document submitted |  |  |  |  |  |  |
| How submitted |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| **Early Termination Report** |  |  |  |  |  |  |
| Date submitted |  |  |  |  |  |  |
| How submitted |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| **Continuing Review Application** |  |  |  |  |  |  |
| Date of application |  |  |  |  |  |  |
| Protocol code |  |  |  |  |  |  |
| Documents submitted |  |  |  |  |  |  |
| How submitted |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| **Renewal/Final Report** |  |  |  |  |  |  |
| Date of Submission |  |  |  |  |  |  |
| Protocol code |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
|  | | | | | | |
| **OTHERS** |  |  |  |  |  |  |
| **Appeals** |  |  |  |  |  |  |
| Date of Submission |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| **Site Visits** |  |  |  |  |  |  |
| Date of Submission |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
| **Queries and Complaints** |  |  |  |  |  |  |
| Date of Submission |  |  |  |  |  |  |
| Received from |  |  |  |  |  |  |
| Remarks/Decision |  |  |  |  |  |  |
| Date decision forwarded to PI |  |  |  |  |  |  |
|  | | | | | | |
| **Archiving** |  |  |  |  |  |  |
| Date of archiving |  |  |  |  |  |  |
| **Disposal** |  |  |  |  |  |  |
| Date of disposal |  |  |  |  |  |  |