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| **ELECTRONIC CASE REPORT FORM DATA REVIEW AND SIGN OFF BY THE PRINCIPAL INVESTIGATOR** |
| **Protocol Short Title:** |  <insert> | **Site Code:** | <insert> |
| **Sponsor:** |  <insert> |
| **Participating Site Name:** |  <insert> |

**Instructions for Form Completion:**

***ICH E6 R2*** *section 4.9.1 and* ***ICH E6 R3*** *section 2.12.5 indicates that the site principal investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the eCRFs and in all required reports at important milestones agreed upon with the Sponsor. In addition,* ***ICH E6 R2*** *section 8.3.14 and* ***ICH E6 R3*** *section C.2.10 and C.3.1 (i) requires the maintenance of the signed/dated and completed eCRF documentation, at site and at sponsor, to verify that the investigator or authorised member of the investigator’s staff confirms the observations recorded.*

*Please use this form to document Site Principal Investigator review and oversight of the completed eCRF for participants enrolled into the* <insert name> *trial and to provide final sign off for the complete eCRF.*

*This Form must be signed by the Site PI after all data has been entered and all queries have been resolved signifying that the data is accurate, complete and ready to be considered final. At this point, the trial database is ready for database lock by the Sponsor.*

*This Form must be completed at <insert the milestones as per protocol and/or trial risk assessment which should include at a minimum the time of each protocol-defined interim analysis (i.e. database soft lock) and the end of data collection for the trial (i.e. database hard lock)>.*

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| **Principal Investigator’s Signature Statement:** |
| I have reviewed the CRFs and confirm that, to the best of my knowledge, the data entered is accurate and complete for the participants enrolled into the trial. All entries were made either by myself or by a person under my supervision who has been delegated and signed the Delegation and Signature Log. |
| **eCRF Sign-Off Timepoint***[please select]* | Interim/Safety Analysis [Meeting no.<insert number>] | [ ]  |
| End of Recruitment (Primary Outcome) | [ ]  |
| End of Follow-Up | [ ]  |
| **Site PI’s (or delegate) Signature** |  |
| **Site PI’s (or delegate) Name** |  |
| **Date of Signature** *[DD/MM/YYY]* |  |
| **ONCE THIS FORM IS SIGNED, NO FURTHER CHANGES CAN BE MADE TO CRF DATA THAT HAS BEEN SIGNED OFF WITHOUT APPROVAL FROM THE SPONSOR.** |

**Return completed and signed forms to:** <insert central trial team contact email>

**A copy of the signed form must be filed in Folder 13.0 (Data Management Forms & Procedures) of your Investigator Site File (ISF) in Florence eBinders™.**