**Signature Page**

<*Insert study title – delete this text on completion>*

*<Insert brief description of the protocol & what it should/ should not be used for, e.g. `This protocol describes the XXX trial and provides information for participants involved in this study. The protocol must not be used as a guide for the treatment of patients who are not taking part in the XXX study’. – delete this text on completion>*

**This protocol has been approved by:**

|  |  |
| --- | --- |
| **Name:**  <*print name – delete this text on completion>* | **Role:**  <*print role – delete this text on completion>* |
| **Signature:** | **Date:** |

|  |  |
| --- | --- |
| **Name:**  <*print name – delete this text on completion>* | **Role:**  **Sponsor Representative** |
| **Signature:** | **Date:** |

**Principal Investigator Declaration:**

I have read and understood the requirements and conditions of the study protocol. I am aware of my responsibilities as an Investigator under the guidelines of the Internal Conference on Harmonisation Good Clinical Practice (ICH GCP) standards, the Declaration of Helsinki, local regulations (as applicable) and the study protocol. I agree to conduct the study according to these guidelines and to appropriately direct and assist the study team assigned to me who will be involved in the study.

I agree to use the study material, including medication, only as specified in the protocol.

I understand that changes to the protocol must be made in the form of an amendment that must be approved by the Ethics Committee and Regulatory Authorities prior to its implementation.

I understand that non-compliance with the study protocol may lead to early termination of the study.

|  |  |
| --- | --- |
| **Investigator’s Name:**  <*print name – delete this text on completion>* | |
| **Signature:** | **Date:** |

Return the original wet signature\* page to the sponsor and retain a copy\* with the study protocol within the Investigator’s Site file.

\* *Reference to wet signature means signature in ink, copy can be a scanned copy or photocopy of the signature page.*