**Protocol Signature Sheet**

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| **Study:****Site:****Principal Investigator:** | **Protocol Version:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Protocol Approval Date:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

I agree to the conditions relating to this study as set out in the above named protocol. I fully understand that any changes instituted by the Investigator(s) without previous discussion with the appropriate sponsor personnel would constitute a violation of the protocol, including any ancillary studies or procedures performed on study subjects (other than those procedures necessary for the well-being of the subjects).

I acknowledge that I have read the above named protocol and agree to carry out all of its terms in accordance with applicable regulations and law, to follow ICH GCP guidelines for good clinical practice, to obtain approval from the IRB/IEC prior to implantation, to allow direct access to source documents, and agree to inspection by PM/CRAs from the CCS Linz and regulatory authorities, as required by ICH GCP. I will assure that the investigational product(s) supplied by the sponsor will be used only as described in the above named protocol; if any other use is desired, written permission must be obtained from the sponsor.

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| **To be signed by all study team members at the site****(e.g. Principal Investigator, Co-Investigator, Pharmacist, Study Nurse, ...)** |
| **NAME**(print name) | **SIGNATURE** | **DATE** |
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