**Principal Investigator**

*At a study site, only one person can act as Principal Investigator (PI). In case the PI changes during the course of the study, this shall be documented in the list below. The first person assuming PI responsibility at the site shall be listed as well. By signing below, the new PI confirms that the staff list remains valid & that he / she authorizes staff to continue to assume the study tasks assigned by the previous PI.*

*Whenever the log is updated, please send a copy to the sponsor. At study end, file the original log in the investigator site file & provide the sponsor with a copy unless otherwise agreed.*

*Note: A PI change qualifies as a substantial amendment, i.e. approval has to be sought from the Ethics committee before the change is implemented.*

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| **Principal Investigator first & last name** | **Start date** | **End date** | **Signature** | **Initials**(handwritten) |
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*By adding his / her initials under “PI initials”, the PI authorizes site staff to assume the study tasks as assigned. The PI him- / herself should be listed as well. Whenever the log is updated, please send a copy to the sponsor together with any training documentation as applicable. At study end, file the original log in the investigator site file & provide the sponsor with a copy, unless otherwise agreed.*

| **Site staff first & last name** | **Function**1 | **Study task(s)**2 | **Start date** | **End date** | **Signature** | **Initials**(handwritten) | **PI initials**  |
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| **1) Function:** | **2) Study tasks:** |
| **PI** | Principal investigator | **1** | Informing subject about study | **9** | Investigational product preparation / administration / dispensing |
| **SI** | Sub-investigator | **2** | Obtaining informed consent  | **10** | Investigational product accountability |
| **SC** | Study coordinator | **3** | Assessment of subject eligibility | **11** | CRF completion |
| **SN** | Study nurse | **4** | Subject clinical examination | **12** | CRF signing at study completion |
| **PH** | Pharmacist | **5** | Randomization | **13** | ISF maintenance |
| **OT1** | Other, specify: ……………………………. | **6** | Assessment of AEs / SAEs | **14** | Other, specify: ……………………………. |
| **OT2** | Other, specify: ……………………………. | **7** | Reporting of AEs / SAEs to Sponsor | **15** | Other, specify: ……………………………. |
| **OT3** | Other, specify: ……………………………. | **8** | Reporting AEs / SAEs to EC / regulatory authorities | **16** | Other, specify: ……………………………. |