**IMP-Approval Form**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **Site Information (Section 1 and 2 has to be filled in by Manufacturer/IMP Supplier/Sponsor only)** | | | | | |
| **Study No:** |  | **Site ID:** |  |
| **Sponsor/Manufacturer/**  **Supplier:** |  | **Principal Investigator:** |  |
| **Courier Service:** |  | | | |
| **Date of shipment:**  (DD-MM-YYYY)**:** |  | **Shipment No:** | **NA** |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Shipment Information (Section 1 and 2 has to be filled in by Manufacturer/IMP Supplier/Sponsor only)** | | | |
| **IMP name:** |  | **Typ**: | Please select type of IMP. |
| **Number of IMP:** |  | **Batch No:** | |
| **Expiry date** (DD-MM-YYYY)**:** |  |
| **Comments:** | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | | |
| 1. **Receipt Information (to be filled by study center)** | | | | |
| **Date of IMP receipt** (DD-MM-YYYY): |  | **Time of receipt** (hh:mm)**:** | |  |
| **IMP receipt correctly:** | YES  NO | damaged (please comment)\* | | |
| **Number of IMP received:** | according to shipment list | other quantity received (please comment) | | |
| **Only fill in, if shipment is temperature controlled:** | | | | |
| **IMP received in cooled condition**  (e.g. by: alarm during transport, confirmation of courier, visible marks on a logger…)**:** | | YES | ☐ NO (please comment)\* | |
| **Comments:** | | | | |

***\*If IMP is not received within the temperature condition or damaged DO NOT USE the IMP! Store per protocol conditions, quarantine and contact your responsible clinical monitor.***

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Responsibilities** | | | |
| **IMP received and stored appropriately by:** | | **After signing fax/email this form to:** | |
| **Position:** |  | **Name:** | ***-> please prefill with contact details of Sponsor*** |
| **Name:** |  | **Fax:** |  |
| **Signature:** |  | **E-Mail:** |  |
| **Date:** |  | **Phone:** |  |

|  |
| --- |
|  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. **IMP-Approval by Sponsor/Manufacturer/Supplier** | | | | | | |
| **Form received and complete:** | YES | NO (please comment)\* | **Deviation reported:** | YES (please comment)\* | NO |
| **Comments\*:** | | | **If yes, Stability Statement or Deviation Report available:** | YES  NO | |
| **IMP Approval given:** | YES  NO (IMP has to be quarantine) | |  | | | |
| **Name:** |  | | **Date (DD-MM-YYYY):** |  | | |
| **Position:** |  | | **Signature:** |  | | |