|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Persons Affected**(Use participant ID or job title) | **Description of Device Deficiency** | **Actions Taken** | **Device Serial Number** | **Could Device Deficiency have led to SADE?**(If yes, complete Safety Report Form) | **PI Assessment** | **PI Signature & date** | **CI Assessment** | **CI Signature & date** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

**JRMO SOP 26d Associated Document 4**

**Device Deficiency Log**