Ascension Wisconsin Research Education and Quality Management

**Device Accountability Log Guidance Document**

This tool has been created to ensure adequate record of shipments, receipt, use and disposition of investigational study device(s).

**Tips for GCP Documentation**

* Use black ink.
* Use proper error correction method –draw a single line through the error, initial and date with today’s date and write the correct information as close to the error as possible.
* Ensure numbers are written clearly.
* Do not put a line through the number “0” and “7” when written.
* No write overs.
* Include the month, date and year when documenting a date.
* Do not use correction fluid or “white out”.
* Data much be written in each column or row, even if it is repeats. Do not use an arrow or ditto marks.

**Tips for Completing the Form**

* Print form and maintain in the Regulatory Binder.
* Complete Investigator Name, Study Title and IRB #.

**Complete Upon Device Dispensing**

* Column 1: Complete date the device was received.
* Column 2: Complete the initials of the individual logging in the device.
* Column 3-5: Complete the model #, serial # and lot # (if applicable). If not applicable, list “NA”.
* Column 6: Enter the subject’s initials receiving the device.
* Column 7: Enter the date the device was used.
* Column 8: Enter the date the device was returned (if applicable). If not applicable, list “NA”.
* Column 9: Enter the date the device was destroyed (if applicable). If not appliablce, list “NA”.
* Column 10: Enter any comments to explain entries or discrepancies within the log.

**Sample**

|  |  |
| --- | --- |
| **Principal Investigator:** | **Joe Smith, MD** |
| **Study Title/IRB #:** | **Nursing Care Survey/IRB #0123** |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date Received** | **Received By**  **(initials)** | **From Label** | | | **Device Disposition** | | | | **Comments** |
| **Model #** | **Serial #** | **Lot #** | **Subject** | **Date Used** | **Date Returned** | **Date Destroyed** |  |
| 01/01/17 | BMP | XXX | 012 | 023 | ABC | 01/01/1 |  |  |  |

**DEVICE ACCOUNTABILITY LOG**

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| --- | --- |
| **Principal Investigator:** |  |
| **Study Title/IRB #:** |  |

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| **Date Received** | **Received By**  **(initials)** | **From Label** | | | **Device Disposition** | | | | **Comments** |
| **Model #** | **Serial #** | **Lot #** | **Subject** | **Date Used** | **Date Returned** | **Date Destroyed** |  |
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**Principal Investigator Signature: Date:**