Ascension Wisconsin Research Education and Quality Management

**Device Inventory Log Guidance Document**

This tool was created to document shipment dates, batch numbers, and method of shipment to allow for tracking of product batch, review or shipping conditions and accountability. Documentation ensures investigational product(s) has been used as per protocol.

**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 Receipt of Shipment**

* Column 1, Row 2: Complete the name of the device.
* Column 2, Row 2: Complete the date of receipt.
* Column 3, Row 2: Enter the amount received in shipment.
* Column 4, Row 2: Enter the initials of the individual logging the shipment.
* Column 5, Row 2: Enter the batch number or code mark. If not listed, enter NA.
* File any invoice that is sent with the shipment along with this form.

**Sample**

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Device** | **Date of Receipt** | **Amount Received** | **Received By** | **Batch number or Code Mark** |
| **XYZ patches** | **01/16/16** | **20** | **BMP** | **01234** |
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**DEVICE Inventory Log**

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

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| --- | --- | --- | --- | --- |
| **Name of Device** | **Date of Receipt** | **Amount Received** | **Received By** | **Batch number or Code Mark** |
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**Principal Investigator Signature: Date:**