Ascension Wisconsin Research Education and Quality Management

**Patient HUD Log Guidance Document**

This tool was created to document the name of the patient that received a device.

**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 the form and maintain in the Regulatory Binder.
* Complete Physician’s Name, Title and IRB #.

**Complete Upon Deploying the Device**

* Column 1: Complete the medical record # of the patient.
* Column 2: Complete the name of the patient.
* Column 3: Complete the date received HUD.

**Sample**

|  |  |
| --- | --- |
| **Primary Responsible Physician’s Name:** | **Joe Smith, MD** |
| **Title/IRB #:** | **Device XYZ/IRB #0123** |

|  |  |  |
| --- | --- | --- |
| **Medical Record #:** | **Name of Patient:** | **Date Received HUD** |
| **001** | **Joe BMP** | **01/01/16** |
|  |  |  |

**Patient HUD Log**

|  |  |
| --- | --- |
| **Primary Responsible Physician’s Name:** |  |
| **Title/IRB #:** |  |

|  |  |  |
| --- | --- | --- |
| **Medical Record#:** | **Name of Patient:** | **Date received device:** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |