Ascension Wisconsin Research Education and Quality Management

**IRB Communication Log Guidance Document- HUDs**

**Purpose:** This tool was created to assist in tracking IRB activities and remind the HUD team what actions need to be completed or are outstanding with the IRB.

**Tips for GCP Documentation**

* Use 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 Submission or Notification from the IRB**

* Column 1: Complete the date of the document.
* Column 2: Complete the type of report.
* Column 3: Complete date of submission to IRB.
* Column 4: Complete the Date of acknowledgement from the IRB.
* Column 5: Complete if an action is/is not needed.
* Column 6: Initial and date.

**Sample**

|  |  |
| --- | --- |
| **Main Responsible Physician’s Name:** | **Joe Smith, MD** |
| **HUD Title/IRB #:** | **XYZ Device/IRB #012** |

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| --- | --- | --- | --- | --- | --- |
| **Date of Report** | **Type of Report** | **Date of Submission to IRB** | **Date of Acknowledgement from IRB** | **Action Needed** | **Initial and Date** |
| 01/24/17 | Amendment #1 | 01/25/17 | 01/26/17 | Use Patient Information Sheet for all new patients | BMP 01/26/17 |
| 05/01/17 | Amendment #2 | 05/02/17 | 05/03/17 | Approved – No action Needed | BMP 05/03/17 |
| 05/02/17 | Safety Report | 05/03/17 | 05/05/17 | Acknowledged – No Action Needed | BMP 05/06/17 |

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| **Date of Report** | **Type of Report** | **Date of Submission to IRB** | **Date of Acknowledgement from IRB** | **Action Needed** | **Initial and Date** |
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