Ascension Wisconsin Research Education and Quality Management

**Screening and Enrollment Log Guidance Document**

This tool was created to document screening and enrollment for a study.

**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 Investigator Name, Study Title and IRB #.

**Complete Upon Screening**

* Column 1: Enter the date the subject is screened for the study.
* Column 2: Enter the subject’s age and male/female.
* Column 3: Enter if subject was enrolled or not enrolled.
* Column 4: Enter method of recruitment (i.e. print advertisement, tv, chart review).
* Column 5: If inclusion criteria not met, enter reason. If criteria met, enter NA.
* Column 6: If exclusion criteria is not met, enter reason, if criteria met, enter NA.
* Column 7: Enter subject screening number.
* Column 8: If the subject is enrolled, enter the enrollment number. If subject is not enrolled enter NA. (If this is an investigator initiated study the enrollment number may be the same as the screening number.)

**Sample**

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Date** | **Age and Sex** | **Enrolled Yes/No** | **Method of recruitment** | **Inclusion Criteria not Met** | **Exclusion Criteria not met** | **Screening #:** | **Enrollment #:** |
| 01-01-2017 | 39/Male | No | Print ad | NA | History of COPD | 001 | NA |
| 02-05-17 | 42/Female | Yes | TV | NA | NA | 002 | 001 |
| 02-06-17 | 37/Female | No | TV | Didn’t sign consent | NA | 003 | NA |

**Screening and Enrollment Log**

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Date:** | **Age and Sex:** | **Enrolled Yes/No:** | **Method of recruitment:** | **Inclusion Criteria not met:** | **Exclusion Criteria not met:** | **Screening #:** | **Enrollment #:** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |