Ascension Wisconsin Research Education and Quality Management

**Study Site Signature & Delegation of Responsibility Log Guidance Document**

This tool was created to document study staff signatures/initials and their research related responsibilities delegated by the Principal Investigator.

**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 #.
* Update this log when study staff and/or delegated responsibilities change.

**Tips for Completing the Form**

* Column 1: Print the name of the study team member. If additional members are added to the study team during the study, add them to the form.
* Column 2: Complete the title of the staff member (investigator, sub-investigator, research assistant).
* Column 3: Obtain the signature of the staff member.
* Column 4: Have the staff member enter their own initials.
* Column 5: List the study tasks the investigator has delegated to the individual.
* Column 6: Complete the date the study team starting working on the study.
* Column 7: If the staff member is removed from the study team, enter the end date.
* Column 8: Obtain the PI initials when the staff member has signed the form.

**Sample**

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

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Print Staff Name | Title | Signature | initials | **\***study tasks | start date | end date | PI Initials |
| John Smith, MD | Investigator | actual signature | actual initials | 1, 2, 3 | 01/01/17 | 05/01/18 | Xkkxk |
|  | Sub-investigator  |  |  |  |  |  |  |
|  | Research Assistant |  |  |  |  |  |  |

**Study Site Signature/Delegation of Responsibility Log**

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

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| List delegated study related tasks and dates of involvement for each staff member All IRB approved study staff should sign and initial this log. The PI should acknowledge delegation by signing his/her initials after each entry and at study ‘close out’ to attest to the fact that the list is complete, accurate and that all staff are accounted for. Update this log in a timely manner as new personnel are added and/or study roles change. |
| Print Staff Name | Title | Signature | initials | **\***study tasks | start date | end date | PI Initials |
|  | Investigator |  |  |  |  |  |  |
|  | Sub-investigator  |  |  |  |  |  |  |
|  | Research Assistant |  |  |  |  |  |  |
|  | Research Assistant |  |  |  |  |  |  |
|  | Research Assistant |  |  |  |  |  |  |
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| **Key for Delegated Study Tasks:** These are most common examples. Add/delete as necessary to meet your study needs |
|  | Obtain Informed Consent | 1. 2
 | Assess Eligibility Criteria |  | CRF Queries |  | Maintain IRB documents |  | Other:      |
|  | Obtain Medical History |  | Dispense Study Drug/device |  | Query completion |  | Data Monitoring |  | Other:      |
|  | Perform Physical Exam |  | CRF Completion |  | Maintain Regulatory Docs |  | Safety Monitoring |  | Other:      |

**PI Signature (Close Out): Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**