Ascension Wisconsin Research Education and Quality Management

**Study Team Tracking Log Guidance Document**

This tool was created to document and track the study team’s training documentation to ensure the Regulatory Binder is current, accurate and complete.

**Tips for GCP Documentation**

* Use black ink.
* Use proper error correction method – if an error is present, draw a single line through the error, initial and date with today’s date. 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. If you need to clarify a number or information documented, use the proper error correction method.
* 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 repeated information. Do not use an arrow or ditto marks to indicate information repeats.

**Tips for Completing the Form**

* Print the form and maintain in the Regulatory Binder.
* Complete Investigator Name, Study Title and IRB #.
* Column 1: Enter the name of the study team member.
* Column 2: Enter the date the Human Research Protection Training was completed.
* Column 3: Make a checkmark upon filing of the CV or resume.
* Column 4-6: Add “other” as needed such as training on the Protocol version 1.
* Column 5: Enter the date the study team member was approved by the IRB.
* Column 6: If the individual is removed from the study team, enter the date he/she is removed.
* Update the log as Amendments are filed with the IRB to add study team members.

**Sample**

|  |  |
| --- | --- |
| **Principal Investigator:** | **Joe Smith, MD** |
| **Study Title/IRB #:** | **Nursing Care Survey/IRB #0123** |
| **Name of Study Team Member** | **Human Research Protection Training** | **Curriculum Vitae** | **Other: Protocol Training version 1** | **Other** | **Other:** | **Date added to study team** | **Dated left study team** |
| **Amy Smith, RN** | **01/01/16** | **X** | **01/06/16** |  |  | **01/01/16** |  |
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**Study Team Tracking Log**

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

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of Study Team Member** | **Human Research Protection Training** | **Curriculum Vitae** | **Other:** | **Other:** | **Other:** | **Date added to study team** | **Date left study team** |
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