**Signature and Delegation of Responsibility Log**(Sample Template to consider for use)

|  |  |
| --- | --- |
| REB ethics #: |  |
| Principal Investigator(s): |  |
| Effective Date: |  |
| Protocol Number and Title: |  |

Copy and paste for each instance as needed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | | |  |
| Name (please print) | | | | | Title |
|  | | | | | |
| General Responsibilities\* | | | | | |
|  |  |  |  | | |
| Core | PHIA | C.V. | Signature | | |
| Dates or responsibilities | |  |  |  |  |
| From (dd/mmm/yy) | To (dd/mmm/yy) |  | Initials(PI) |  | Approved  (PI initials) |
|  |  |  |  |  |  |

This log should include the investigator and co—investigator(s), study coordinator (s) and all other personnel who routinely see study participants and who have specific data collection/interpretation responsibilities. This log should also include any contract specialist performing protocol required examinations. New or replacement staff should be added as appropriate.

**PLEASE MAINTAIN THIS LIST WITH YOUR REGULATORY FILE**

**(THIS DOES NOT REQUIRE SUBMISSION TO THE REB)**

**Signature and Delegation of Responsibility Log**

**Legend**

**Use legend to complete the “General Responsibilities” column. Please enter the letter (s) (i.e. a, c, f that corresponds to the responsibilities of the individual). For responsibilities that are not already indicated in the legend, add them in the empty spaced provided below.**

a Obtains informed consent \*

b Participant recruiting

c Assess Inclusion and Exclusion Criteria \*

d Completion of CRFs and Data Collection Forms

e Correction of CRFs and Data Collection Forms

d Review of CRFs (must be investigator or sub-investigator)

e Interviews participants

f Adverse Event (AE) and Unanticipated Events (UE) Inquiry and Reporting

g AE/ Serious Adverse Event(AE) or UE interpretation (severity/relationship to intervention) \*

h Submit and Maintain Research Ethics Board (REB) documents

i Maintain Regulatory Documents

j Administrative Duties

k Randomization

l Drug dispensing and accountability

m Data Analysis

n Study Data Monitoring

o

p

q