**Research and Development Unit, BDMS Health Research Center Clinical Study Staff Signature and Delegation of Responsibility Log**

|  |  |
| --- | --- |
| Protocol ID |  |
| Protocol Title |  |
| Name of Principal Investigator (PI) |  |
| Name of Clinical Study Site |  |

1. List clinical study staff who have been delegated significant study-related duties

2. Update this log in a timely manner when a new clinical study staff is included or study or study responsibilities are revised

3. Maintain this log in the study file

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Print Name  | Role (a)  | Study Specific Responsibilities (b)  | Signature  | Initials | Date of Responsibilities  | PI initials and Dates for Approval |
| Start Date  | End Date  |
|  |  |  |  |  |  |  |  |
|  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |

Signature of Principal Investigator: (c) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Log Page (d) \_\_\_\_\_\_ of \_\_\_\_\_\_

**Note for the log completion instruction**

(a) Role of assigned clinical study staff e.g. sub-investigator/co-investigator, clinical study coordinator, pharmacist, lab technician

(b) Clinical study responsibilities:

Use below list to complete the “Study Specific Responsibilities” column. Please enter the block letter in front of each responsibility that corresponds to the responsibilities of the individual into the column. For responsibilities that are not indicated in the list, please add them in the empty spaces provided below.

Following is the list of clinical study responsibilities:

A. Administer informed consent

B. Obtain medical history

C. Perform physical examination

D. Determine study eligibility of potential subjects

E. Randomize eligible subjects

F. Dispense study drug/device and monitor compliance

G. Complete drug/device accountability record

H. Handle storage and inventory of study drug/device

I. Make follow-up appointment and reminding phone call

J. Complete source documents

K. Complete and correct case record form (CRF)

L. Final review CRF

M. Handle data queries

N. Assess and report adverse events

O. Provide medical care

P. Handle blood/specimen collections

Q. Evaluate lab/diagnostic test results

R. Administer questionnaire

**Instruction Note for the log completion** (continue)

S. Maintain study files

T. Coordinate Institutional Review Board (IRB)/Independent Ethics Committee (IEC)

U. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

V. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

W. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

X. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Y. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Z. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(c) The Principal Investigator (PI) signs and dates at the conclusion of the clinical study to confirm accuracy of the record

(d) Identify page number of this delegation log at the conclusion of the clinical study (not include the Instruction Note for Log Completion pages)