Quality Audit Checklist of Serious Adverse Events Reporting

Ethics and Governance Working Group (EGWG) is conducting an online quality audit of Serious Adverse Events **(**SAE) reporting to:

1) Assess whether current practices of SAE reporting are in line with ethical guidelines

2) Identify areas for improvement in reporting processes and adherence to standard guidelines

3) Make recommendations to the senior management team for implementation of best practice

SAE are untoward occurrences temporarily associated with human participation in a research study, resulting in injury or harmful effect from an intervention or research. SAE(s) could result in 1) Death 2) Life threatening situations 3)Requirement of immediate hospitalization or result in prolongation of hospitalization 4) Significant or persistent disability/incapacity, 5) Change of the risk/benefit ratio of the study.

An **unexpected adverse event** is one that is not listed in the study information sheet because it is not expected or else is not expected at the severity that has been observed. Also if study information sheet is not required or available, UAE is not consistent with the risk information described in the general research plan.

If your work involves interaction with research participants, please answer the following questions. We request you to be honest; there is no right or wrong answer, nor will it affect your workplace relations and status. Your anonymity will be respected, and your data will be treated as confidential. Thank you for your participation in this audit and for contributing towards the organizational development and improvement.

1) **Have you had any training on reporting SAEs?**
   - ☐ Yes
   - ☐ No (Please go to question no. 4)
2) **If yes, how often is this training conducted?**
   - ☐ Only at the beginning of the project
   - ☐ Monthly
   - ☐ Twice a month
   - ☐ Twice a year
   - ☐ Yearly
3) **Who conducts these trainings?**
   - ☐ Trial manager
   - ☐ Site lead
   - ☐ Supervisors
   - ☐ Other: _____

4) If you have not had a SAE training till now, can you give the reason?

- ☐ Not offered
- ☐ Did not have the time to attend

5) Are you familiar with the SAE reporting form that is used at PILL?

- ☐ Yes
- ☐ No (Please go to question no. 7)

6) If yes, do you have a copy of the SAE reporting form?

- ☐ Yes
- ☐ No

7) Whenever a SAE occurred during research, whom did you report the event in the first instance?

- ☐ Site lead
- ☐ Trial manager
- ☐ Operations manager
- ☐ Principle Investigator
- ☐ Supervisor
- ☐ Other: _____

8) How do you report the SAE in the first instance?

- ☐ Communicate verbally
- ☐ Written email
- ☐ Use a standard form

9) Within how many days are you typically required to report the SAE?

- ☐ Immediately
- ☐ 2 days
- ☐ 5 days
- ☐ 7 days
- ☐ 15 days
- ☐ More than 15 days

10) In actual, within how many days do you report the SAE?

- ☐ Immediately
- ☐ 2 days
- ☐ 5 days

- ☐ 7 days
- ☐ 15 days
- ☐ More than 15 days

11) Do you report unexpected adverse events as well?

- ☐ Yes
- ☐ No (Please go to question no. 14)

12) If yes, within how many days are you required to report this?

- ☐ Immediately
- ☐ Within 2 days
- ☐ Within 5 days
- ☐ Within 7 days
- ☐ Within 15 days
- ☐ More than 15 days

13) In actual, within how many days do you report the unexpected adverse events?

- ☐ Immediately
- ☐ Within 2 days
- ☐ Within 5 days
- ☐ Within 7 days
- ☐ Within 15 days
- ☐ More than 15 days

14) If several participants are involved in a similar adverse event, how would you report this?

- ☐ Use a separate reporting form for each participant
- ☐ Use a single reporting form for all participant
- ☐ Other: _____

15) Do you take actions to resolve the adverse events?

- ☐ Yes
- ☐ No (Please go to question no. 17)

16) If yes, what are those actions? Please mention at least three most commonly taken actions.

1. _____
2. _____
3. _____

17) Do you have a medical consultant/psychiatrist on board to resolve adverse events reported during research?

- ☐ Yes
- ☐ No

18) Do you feel the necessary information, instructions, and training is being given to the researchers to report SAEs?

- ☐ Yes
- ☐ No

19) Are you satisfied with the number of trainings being offered to report SAE?

- ☐ Yes
- ☐ No

20) In your opinion, how often should these trainings be held?

- ☐ Monthly
- ☐ Twice a month
- ☐ Twice a year
- ☐ Yearly
- ☐ Other: _____

21) Do you think researchers typically adhere to SAE reporting guidelines?

- ☐ Yes
- ☐ No

22) Are there any barriers to adherence to SAE reporting guidelines?

- ☐ Yes
- ☐ No

23) If yes, in your experience what have been the main barriers in reporting SAE according to the guidelines provided?

1. _____
2. _____
3. _____

30) Do you have any suggestions to improve the SAE reporting process?

_____

_____

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Any other comments?

_____

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We are very thankful to you for your time to complete this checklist.

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