**SAE / SUSAR REPORT SUMMARY**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **STUDY PROTOCOL INFORMATION** | | | | | | | | | |
| **MMMC-RERC Code:** | |  | | | | | | | |
| **Study Protocol Title:** | |  | | | | | | | |
| **Principal Investigator:** | | <Title, Name, Surname> | | | | | | | |
| **No. of Events:** | |  | | | | | | | |
| **No. of Onsite Events:** | |  | | | | | | | |
| **Date Report** | **Report #** | **Case ID** | | **Number of**  **Events** | **Nature of Events** | | **Initial/**  **Follow Up** | **Follow Up of Event** | **Final Diagnosis/Outcome of Event (Resolved, Stable, Improving, Progressing, Death** |
|  |  |  | |  |  | |  |  |  |
|  |  |  | |  |  | |  |  |  |
|  |  |  | |  |  | |  |  |  |
|  |  |  | |  |  | |  |  |  |
|  |  |  | |  |  | |  |  |  |
| **Signature of Principal Investigator**  Date: <dd/mm/yyyy> | | | | | | | | | |
| **RECOMMENDED ACTION:**  Acknowledged/No further action  Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks  Recommend implementation of additional procedures for protecting/ safeguarding participants;  Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)  Request information  Recommend suspension of the entire study | | | | | | | | | |
| **JUSTIFICATION FOR RECOMMENDED ACTION** *(To be filled out by MMMC-RERC)* | | | | | | | | | |
| **PRIMARY REVIEWER** | | | Signature  Name | | |  | | | |
| Date: | | | <Title, Given Name, Surname> | | | |
| **CHAIR** | | | Signature | | | | | | |
| Date: | | | Name | | | <Title, Given Name, Surname> | | | |