**CHECKLIST FOR SAE/SUSARs REPORT**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *This form is required for submission for Checklist of SAE/SUSARs Report. Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in A4 size paper; then date and sign this form before submission.*

|  |  |  |
| --- | --- | --- |
| **MMMC-RERC CODE:** | | |
| **STUDY PROTOCOL TITLE:** | | |
| **PRINCIPAL INVESTIGATOR:** | | |
| **STUDY PROTOCOL APPROVAL DATE:** <dd/mm/yyyy> | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **STUDY SITE NAME:** | | |
| **STUDY SITE ADDRESS:** | | |
| **SPONSOR:** | | |
| **SPONSOR CONTACT PERSON:** | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **REPORT SUBMISSION DATE:** <dd/mm/yyyy> | | |

**SAE/SUSARS SUBMISSION CHECKLIST:**

**Offsite**

MMMC-RERC F-3-H: Suspected Unexpected Serious Adverse Reaction (SUSARs) Summary Report

MMMC-RERC F-3-I: CHECKLIST FOR SAE/SUSARSs REPORT

CIOMS SUSPECT ADVERSE REACTION FORM

INVESTIGATOR NOTIFICATION OF SUSAR

**SAE SUBMISSION CHECKLIST:**

**Onsite**

MMMC-RERC F-3-F: Serious Adverse Event/s Report

MMMC-RERC F-3-G: SAE Report Summary (Onsite)