Protocol Deviation/ Non-Compliance Report Form

|  |
| --- |
| **Submission Guidelines** |
| 1. Original handwritten or electronic signatures from the Principal Investigator (PI)) are accepted for the submission. 2. The Principal Investigator (PI) should ensure that the form is duly completed and submitted. This will only be processed by the ACMS IRB upon complete submission. 3. The right footer must indicate the version number and date (e.g. Version 1 dated dd/mm/yyyy) of the document being submitted. For the first submission, the file name should be in the following format “Protocol Deviation Report V1 [YYYY-MM-DD] ([PI’s Institution Initials])” (e.g. **“Protocol Deviation Report V1 2019-01-01 (SNH)”**). 4. With finalizing the form, please remove this page on the Submission Guidelines and those text in yellow highlight. 5. **Text formatting\*:**  * Headings : Arial, font size 12, Bold, All caps * Sub-headings : Arial, font size 11, Bold * Text (Description) : Arial, font size 11 * Line spacing : 1.0  1. **Softcopy submission**   Email the soft copy of the report to: reserach@academycms.org |

|  |  |
| --- | --- |
| **Basic Study Information** | |
| ACMS IRB Reference No: |  |
| Protocol Title: |  |
| Principal Investigator: |  |
| Designation: |  |
| Department: |  |
| Institution: |  |

**Section A: Description of Event**

|  |
| --- |
| **A1. Please describe in detail the nature of the event including the date of occurrence. (If participants are involved, please indicate the study participant number/code. If this a multi-site study, please indicate the study site.)** |
|  |
| **A2. Please describe why or how the event occurred. Describe the outcome.** |
|  |
| **A3. In your judgement, did the event affect the safety, rights or well-being of the participant (and/or others)?** |
|  |
| **A4. Please describe any corrective action, if applicable, taken for the event.** |
|  |
| **A5. Please describe any preventive action plan to prevent the recurrence of the event in future.** |
|  |
| **A6. Any other comments.** |
|  |
| **A7. Has this event been reported to the Study Sponsor or Grant Agency?**  **If no – Please provide rationale for not reporting.** |
|  |

**Section B: Declaration Of Principal Investigator**

|  |
| --- |
| **I confirm that the information in the report is true and accurate at the date of submission.** |
| |  |  | | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_ | | Signature of Principal Investigator | Date | |