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|  | **JOSE MARIA COLLEGE** FOUNDATION, INC.**RESEARCH ETHICS COMMITTEE** | JMCFI-REC Form No. | 6.7 |
| Revision No.: | 2 |
| **Onsite SAE/SUSAR****Report/s** | Approval Date: | August 19, 2022 |
| Effective Date: | August 26, 2022 |

The following information must be filled out by the lead researcher/s:

|  |
| --- |
| **GENERAL INFORMATION** |
| Title of the Study: |  |
| REC Code: |  | Study Site: |  |
| Name of Lead Researcher/s: |  | Contact Number: | Mobile No.: |
| Email: |
| Co-researcher/s: |  | Mobile No.: |
| Email: |
| Institution: |  |
| Address of the Institution: |  |
| Effective Period or REC Approval | From: | To: |
| **SAE/SUSAR Report** |
| 1. Start of the Study
 | 1. Expected End of the Study
 |
| 1. Number of Enrolled Participants
 | 1. Number of Required Participants
 |
| 1. Description of Negative (harms, risks)
2. Involving participants
3. Involving members of the study team
4. Involving data safety and integrity
 |
| 1. Actions taken to prevent future SAEs/SUSARs, interventions, and outcomes
 |
| 1. Recommendations
 |

**FOR JMCFI-REC USE**

**Received by:**

**Date:**

**Signature:**

**Name (REC Member Secretary):**

**Primary Reviewer’s Comments/Recommendations:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Receiver’s Name: |  | Signature: |  | Date: |
|  |  |  |  |  |
| Changes to the protocol recommended? No YesComments:Recommendation: |
| Changes to the informed consent from recommended? No YesComments:Recommendation: |