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|  | **JOSE MARIA COLLEGE**  FOUNDATION, INC.  **RESEARCH ETHICS COMMITTEE** | JMCFI-REC Form No. | 6.5 |
| Revision No.: | 2 |
| **Protocol Violation/**  **Deviation Report** | Approval Date: | August 19, 2022 |
| Effective Date: | August 26, 2022 |

***Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.***

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| **General Information** | | | | |
| Title of the Study: |  | | | |
| REC Code: |  | | Study Site: |  |
| Name of Researcher/s |  | | Contact  Information | Tel. No.: |
| Mobile No.: |
| Co-researcher/s (if there’s any) |  | | Fax No.: |
| Email: |
| Institution of Researcher/s: |  | | | |
| Address of Institution: |  | | | |
| Effective Period of Ethical Clearance: | From: To: | | | |
| Deviation Report | | | | |
| 1. Start of study: | | 1. Expected end of the study: | | |
| 1. Number of enrolled participants: | | 1. Number of required participants: | | |
| 1. Number of participants who withdrew: | | | | |
| 1. Deviations from the approved protocol: | | 1. Explanation for deviation/violation: | | |
| 1. Impact of deviation/violation on participants’ risks/harms and integrity of data: | | 1. Actions taken to prevent future deviation/violation: | | |