



SAN JUAN DE DIOS EDUCATIONAL FOUNDATION, INC
INSTITUTIONAL REVIEW BOARD

Philippine Health Research Ethics Board (PHREB) Level 3 Accreditation No. L3-2020-035-03
 SIDCER (Strategic Initiative for Developing Capacity in Ethical Review)-Forum for Ethical Review Committees
 in Asia and the Western Pacific Region (FERCAP) Recognition



REPORTABLE NEGATIVE EVENT FORM
(SJDEFIIRB FORM 3.7)

Instructions to the Researcher: Please accomplish this form and attach reference documents you have checked in the SJDEFIIRB Form 2.2 (Document Receipt Form)

| GENERAL INFORMATION | | | | | |
|----------------------------------------------|-----------------------------------------------------------|--------------------|-------------------------------------------------------------------------|-----------------------|--|
| IRB Reference No. | | | | Protocol No. | |
| Protocol Title | | | | | |
| Principal Investigator & Contact Information | | | | Tel. No. | |
| | | | | Mobile No. | |
| | | | | Email | |
| Sponsor & Contact Information | | | | Tel. No. | |
| | | | | Mobile No. | |
| Study Site | | | | | |
| Approval Date (MM/DD/YYYY) | | Start of the study | | Expected End of Study | |
| Number of Enrolled Participants | | | No. of Required Participants | | |
| Negative Event Report | Description of Negative Events (e.g. harms, risks) | | Actions taken to prevent future RNEs, interventions and Outcomes | | |
| <i>Involving Participants</i> | | | | | |
| <i>Involving Members of the Study Team</i> | | | | | |
| <i>Involving Data safety and integrity</i> | | | | | |
| Recommendations | | | | | |

| | | |
|--------------|-----------|------|
| Reported by: | | |
| Name | Signature | Date |
| Received by: | | |
| Name | Signature | Date |

