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| **FORM 3.4 SERIOUS ADVERSE EVENT REPORT** |

Whenever there is any Serious Adverse Event (SAE) in any research approved by the West Visayas State University Unified Research Ethics Review Committee, it has to be reported by the Principal Investigator (PI) to the URERC. Section 1 of this form should be filled out by the PI.

**SECTION 1**

|  |  |  |  |
| --- | --- | --- | --- |
| URERC Protocol Number |  | | |
|  |  | | |
| Sponsor Protocol Number |  | Date of Submission |  |

|  |  |
| --- | --- |
| Principal Investigator/ Researcher |  |

|  |  |
| --- | --- |
| Title |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of the Study Medicine/Device |  | Onset Date | |  |
|  |  |  | Initial | |
|  |  |  | |
|  |  | Follow Up | |

|  |  |  |
| --- | --- | --- |
| Sponsor |  | Date of First Use |
|  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Subject’s Initials / Number Code | |  |  |  | Male |
|  |  | | | | |
| Age | |  |  |  | Female |

|  |  |  |
| --- | --- | --- |
| Subject’s History |  | Laboratory Findings |
|  |  |

|  |
| --- |
| Serious Adverse Event (SAE) |
|  |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Seriousness | | | | |  | Classification | | | | | |
|  | | | | |  |  | | | | | |
|  | Death | |  | Life Threatening |  |  | Drug Related |  | Unrelated to Drug | | |
|  |  | |  |  |  |  |  |  |  | | |
|  | Hospitalization: | | | |  |  | Expected |  | Unexpected | | |
|  |  | |  |  |  |  |  |  | | | |
|  |  | Initial |  | Prolonged |  | Treatment Outcome | | | | | |
|  |  | |  |  |  |  |  |  | | | |
|  | Disability/Incapacity | | | |  |  | Resolved |  | On-going |  | Not Applicable |
|  |  | | | |  |  |  |  | | | |
|  | Congenital Anomaly | | | |  |  |  |  | | | |
|  |  | | | |  |  |  |  | | | |
|  | Others | | | |  |  |  |  | | | |

***Note: PI should attach standard SAE Report Form to this ERC Form.***

**SECTION 2(To be filled out by URERC)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  | Changes to the Protocol Recommended |  | No |  | Yes |
|  | Comments: |  |  |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  | Changes to the Informed Consent Form Recommended? |  | No |  | Yes |
|  | Comments: |  |  |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | URERC Final Action: | | Type of Review: | | |  |
|  |  | |  |  |  |  |
|  |  | Request an amendment to the protocol or the consent form. |  | Expedited | |  |
|  |  |  |  |  |  |  |
|  |  | Request further information. |  | Full Review | |  |
|  |  |  |  |  |  |  |
|  |  | Suspend or terminate the study. |  | Date of Full Board Meeting | |  |
|  |  |  |  |  |  |  |
|  |  | Take note and no further action needed. |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  | Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Reviewer |  | Signature |  | Date |
|  |  |  |  |  |
|  |  |  |  |  |

Documents Received By:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name |  | Signature |  | Date |
|  |  |  |  |  |
|  |  |  |  |  |