WEST VIRGINIA DEPARTMENT OF EDUCATION INTERNAL REVIEW BOARD

Adverse Event Report

An adverse event is any experience that has taken place during the course of a research project, which, in the opinion of the investigators, was harmful to a subject participating in the research, increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio. All adverse events must be reported to the WVDE IRB within 24 hours of the PI’s knowledge of the adverse event.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Title of research project | | | | IRB No. | | |
| Enter text. | | | | Enter text. | | |
| Principal investigator | | Date submitted (xx/xx/xxxx) | | | | Enter date. |
| Enter text. | | Date of adverse event (xx/xx/xxxx) | | | | Enter date. |
| PI phone | PI fax | | PI e-mail | | | |
| Enter text. | Enter text. | | Enter text. | | | |
| 1. Please attach a copy of the informed consent document(s) currently in use for this project. Check here to indicate that it is attached: | | | | | | |
| 1. Describe the adverse event (include date, time, and location of event and other pertinent details). | | | | | | |
| Enter text. | | | | | | |
| 1. Are you submitting for approval a revised version of the informed consent document to include as risks the adverse events being reported? | | | | | Yes  No | |
| * 1. If yes, attach your revised version and highlight the changes to be reviewed.   2. If no, indicate the reasons for not revising the consent document (e.g., already included under risks, consent document no longer in use because subject recruitment has ended). | | | | | | |
| Enter text. | | | | | | |
| 1. Are you submitting, for approval, a revised version of the study protocol?    1. If yes, attach a revised version of you protocol and highlight the changes.    2. If no, explain how you will prevent an event of this nature from happening again. | | | | | Yes  No | |
| Enter text. | | | | | | |
| 1. Are you going to inform the subjects who are already enrolled in the study about the risk associated with the adverse event? | | | | | Yes  No | |
| * 1. If yes, please indicate how and when the information will be conveyed to subjects. If it will be in writing, please attach the text for approval. | | | | | | |
| Enter text. | | | | | | |
| * 1. If no, please indicate why the subjects need not be informed of the information. | | | | | | |
| Enter text. | | | | | | |
| Submitted by  Principal investigator’s signature | | | | Enter text.  Date | | |
| Print, sign, and submit this form and attachments to  IRB Secretary  West Virginia Department of Education  Building 6, Room 722  1900 Kanawha Boulevard, East  Charleston, WV 25305 | | | | | | |

This form adapted from Eastern Michigan University, University Human Subjects Review Committee's Adverse Event Reporting Form Revised 01.30.13