University of Redlands Institutional Review Board

Adverse Incident Report Form

(Form revision date: March 2, 2011)

All adverse reactions experienced by human subjects must be reported to the IRB within 24 hours of the event. Submit a hardcopy of this form and email an electronic copy to the Chair of the IRB. If the PI is a student, the faculty or administrator sponsor must complete the Adverse Incident Report form.

**Section A. Identification Information**

|  |  |
| --- | --- |
| Current date: |  |

|  |  |
| --- | --- |
| IRB approval number: |  |

|  |  |
| --- | --- |
| Title of project: |  |

|  |  |
| --- | --- |
| Name of principle investigator (PI): |  |

|  |  |
| --- | --- |
| Email of PI: |  |

|  |  |
| --- | --- |
| Telephone number of PI: |  |

|  |  |
| --- | --- |
| Name of faculty or administrator sponsor: |  |

|  |  |
| --- | --- |
| Email of sponsor: |  |

|  |  |
| --- | --- |
| Telephone number of sponsor: |  |

|  |  |
| --- | --- |
| Department or office of sponsor: |  |

**Section B. Adverse Incident Information**

B.1. Where did the event occur?

B.2. When did the event occur?

B.3. How would you characterize the severity of the event?

[ ] mild reaction

[ ] moderate reaction

[ ] intense reaction

B.4. Describe in detail the adverse event.

B.5. Was this event an anticipated risk that was described in the approved application?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

B.6. In your judgment, was the adverse reaction likely caused by the study’s procedures?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  | Maybe |

Explain your answer.

If “Yes,” describe the procedures that were in place to reduce the likelihood of such an event occurring.

**Section C. Actions Taken**

C.1. What actions were taken to stop or otherwise alleviate the person’s adverse reaction?

C.2. Who performed the actions summarized in the previous answer?

C.3. At the time that this report is being completed, how would you characterize the subject’s recovery?

[ ] complete

[ ] moderate

[ ] minimal

[ ] unresolved

[ ] no basis for judgment

C.4. Will the informed consent process or any other aspect of the research protocol be modified as a result of this event?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

If “Yes,” describe what changes you plan to make to the consent process or protocol.

***Do not make any changes to the approved protocol without written permission from the IRB Chair. You must obtain permission in writing from the IRB Chair for any changes to the approved protocol.***

**Section D. Certification About Information in this Report**

*I certify that to the best of my knowledge the information provided above is complete and accurate, and that I will not make any changes to the approved protocol without written permission from the IRB.*

|  |  |
| --- | --- |
|  |  |
| Signature of PI (if not a student) | Date |

|  |  |
| --- | --- |
|  |  |
| Signature of Faculty/Administrator/Staff Sponsor | Date |