University of Redlands Institutional Review Board

Final Report

(Form revision date: June 13, 2014)

**Section A. Identification Information**

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

|  |  |
| --- | --- |
| Approval date: |  |

|  |  |
| --- | --- |
| Expiration date: |  |

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

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

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

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

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

**Section B. Information About Subjects**

B.1. How many subjects participated in the study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

B.2. Has new information become available that changes your analysis of the benefits-to-risk ratio described in your original application?

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

If “Yes,” explain.

B.3. Did any subject who participated in the study experience an adverse reaction?

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

If “Yes,” attach the submitted Incident Report form to this report.

B.4. Did any subject who participated withdraw from the study at any time?

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

If “Yes,” specify how many subjects withdrew and, if known, the reasons for their withdrawal.

B.5. Did any subject who participated have any complaints about his or her involvement or any aspect of the study or the research personnel?

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

If “Yes,” specify the nature of the complaints.

B.6. Did you make any changes to the protocol that was approved by the IRB?

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

If “Yes,” specify what changes were made and attach documentation showing that these changes were approved by the IRB.

B.7. Did you make changes to the subject recruitment, Informed Consent procedure and documents, or how data are being stored?

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

If “Yes,” specify what changes were made and attach documentation showing that these changes were approved by the IRB.

B.8. Were there any changes in research personnel?

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

B.9. If “Yes,” list the names and departments/offices of all new project personnel and anyone else who had contact with subjects or identifiable data from subjects.

|  |  |  |
| --- | --- | --- |
|  | Name | Department/Office |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |

B.10. If new research personnel were added to the study, did these persons complete the CITI training?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Yes |  | No |  | N/A |

If “No,” explain why not.

 **Section C. Certification that the Involvement of Human Subjects is Complete**

I certify that no more human subjects will be recruited or otherwise used in the approved study.

|  |  |
| --- | --- |
|  |  |
| Signature of PI | Date |

*Because the PI is a student, I accept that I am ultimate responsibility for ensuring that all answers and statements above are accurate and complete.*

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

*For IRB use only. Do not write or type below this line.*

**IRB oversight of this project is complete.**

|  |  |
| --- | --- |
|  |  |
| Signature of IRB Chair | Date IRB oversight of this project closed |