University of Redlands Institutional Review Board

Application for Continuation of Approval

and/or to Revise an Approved Protocol

(Form revision date: June 27, 2021)

**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: |  |

 If PI is a student, complete the following:

|  |
| --- |
|  |

 Name of sponsor:

|  |
| --- |
|  |

 Email of sponsor:

|  |
| --- |
|  |

 Telephone number of sponsor:

Do all research personnel listed above have current CITI training?

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

** ***If the answer to the previous question was “No,” stop completing this application until all personnel renew/complete the CITI training. Do not submit this application for IRB review.***

**Section B. Type of Request**

B.1. Indicate what you are requesting by checking all that apply:

[ ] application for continuation of approval (complete Section C)

[ ] revision to currently approved protocol (complete Section D)

**Section C. Continuation of Approval**

** ***If not requesting a continuation of approval, skip to Section D.***

C.1. Has the study begun?

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

C.2. If “Yes,” is the study ongoing?

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

C.3. How many subjects have participated in the study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

C.4. 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.

C.5. Did any subject who participated in the study experience an adverse reaction?

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

If “Yes,” complete an Incident Report form and submit it along with this application.

C.6. 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.

C.7. 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.

C.8. So that the IRB can determine whether the research continues to meet the criteria for approval, describe your research progress to date including the reasons for continuing the research. If not requesting a continuation of approval, enter ‘N/A’ in the box below.

**Section D. Revision of Approved Protocol**

** ***If requesting a revision, attach a copy of any new materials – e.g., advertisements, consent forms, questionnaires, CITI training for any new research personnel, etc. – that will be used if the revisions sought are approved by the IRB.***

D.1. Indicate the type of revision by checking all that apply:

[ ] no revision requested

[ ] revision to currently approved method of recruitment

[ ] revision to currently approved consent form

[ ] revision to the location of the study

[ ] revision to add new surveys, instruments, or interview questions

[ ] other

 *Specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

D.2. Indicate what effect, if any, this revision has on the risks to the subjects who will enroll in the study:

[ ] This revision does not increase risks to the subjects who participate in the study.

[ ] This revision does increase risks to the subjects who participate in the study.

If you answered that the revision does increase the risks, explain the risks and what steps will be taken to minimize these risks.

D.3. Specify the revision, including justification for the revision.

D.4. Do you plan to make changes to how data will be stored?

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

If “Yes,” specify the nature of the changes as well as a justification for the changes.

D.5. Will there be any changes in research personnel?

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

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

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

D.6. If new research personnel have been added to the study, have these persons completed the CITI training?

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

** ***If the answer to the previous question was “No,” stop completing this application until the new personnel complete the CITI training. Do not submit this application for IRB review.***

**Section E. Certification for Continuing Research and/or Revisions**

*I certify that to the best of my knowledge the information provided above is complete and accurate and does not, except as indicated, contradict information presented in the approved application.*

*I agree to obtain approval from the IRB for any modifications of the above protocol as described.*

*I accept responsibility for ensuring that the rights, welfare, and dignity of the subjects in this study have been protected and are in accordance with applicable federal/state/local laws and regulations and the University's Institutional Guidelines for the Treatment of Human Subjects in Research.*

*I will provide progress reports to the IRB at least annually, or as requested.*

*I will report promptly to the IRB all unanticipated problems or adverse events involving the subjects.*

*I will follow the IRB approved consent process for all subjects.*

*I will ensure that all personnel conducting the work of this protocol have or will receive appropriate training in the use of human participants in experimentation.*

*I certify that this research does not unnecessarily duplicate research already published.*

*I understand that IRB approval is normally for 1 year.*

*I will not collect data after the IRB’s approval has expired.*

*I will submit a request for continuation of approval if I plan to collect data after the IRB’s approval has expired.*

*I will submit a final report once the data have been collected.*

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

*Since the PI is a student, I accept that I am ultimately responsible for ensuring that this study complies with all the obligations listed above for the PI.*

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

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

**IRB Decision**

[ ] Continuation Approved

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

|  |  |
| --- | --- |
| Date continuation approval starts: |  |

|  |  |
| --- | --- |
| Date continuation approval ends: |  |

[ ] Continuation Not Approved (The PI must submit a new application before she or he can continue with this study.)

[ ] Approve Revisions

|  |  |
| --- | --- |
| Date revised approval starts: |  |

|  |  |
| --- | --- |
| Date revised approval ends: |  |

[ ] Revisions Not Approved

|  |  |
| --- | --- |
|  |  |
| Signature of IRB Chair | Current date |