

**IRB APPLICATION CHECKLIST**

**NO RESEARCH CAN PROCEED PRIOR TO IRB APPROVAL**

Use the following list to confirm that all required steps of the IRB Application process are completed. Complete this form by clicking on the boxes and submit a copy along with your IRB Application.

**Additional guidance and templates available on the** [**IRB website**](https://www.csuci.edu/irb/)**.**

 [ ]  The researcher has completed the online PI Certification Training within the last three years:

 the NIH [*Protecting Human Research Participants*](http://phrp.nihtraining.com/) course[[1]](#footnote-1), or

 the Collaborative Institutional Training Initiative's (CITI) [IRB course](http://www.citiprogram.org).[[2]](#footnote-2)

[ ]  The researcher has submitted her or his electronic IRB Application for IRB Review from their official CI email account to irb@csuci.edu.

[ ]  The researcher attached copies of protocol, informed consent forms, and other instruments that will be used for research. These documents have been submitted by email with the electronic IRB application package.

[ ]  If the proposed study includes minors, the researcher has included an informed consent form for the parent/guardian for minors (under age 18) and an informative letter or script that explains the project to the minor, written in language appropriate for the participant’s age.

[ ]  CI staff members conducting projects must cc their supervisors when submitting protocols to the IRB.

[ ]  The researcher agrees to send notification via email to irb@csuci.edu when the research project is finished or will submit a continuation form to irb@csuci.edu annually for approval of an extension for non-exempt protocols or protocols approved at greater than minimal risk.

**All Email inquiries should be directed to:** **irb@csuci.edu**

|  |
| --- |
| ***Completed by IRB:*** |
| **IRB PROJECT #:**  |
| **[ ]  Exempt/Expedited Review:**  |
| **[ ]  Full Review:**  |
| **[ ]  Revised:** |



***Completed by IRB*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**INSTITUTIONAL REVIEW BOARD (I.R.B)**

**FACULTY/STAFF APPLICATION FOR THE REVIEW OF RESEARCH
INVOLVING HUMAN SUBJECTS**

**Directions:** Please complete Sections I - IV. ***In all cases, no research may proceed on- or off-campus unless approved by the IRB.***

**Submission Instructions:** Email an electornic copy of the completed IRB Application, proposal and attachments to **irb@csuci.edu**in the following format**:**

1. **IRB application should be saved electronically having a filename that obeys the following pattern: full last name of the Principal Investigator followed by their first initial, then “IRB Application”. For example: an application by John Smith should be named “smithj IRB Application”.**
2. **Email subject heading:** *IRB Application*
3. **Attachments:** *Include all attachments (surveys, consent forms, letters)*
4. **Application materials should be submitted in MS Word format so reviewers may comment in the application using the track changes functionality.**
5. **If submitting a revised form, please check the Revised box above and highlight ALL CHANGES in yellow.**

**Before research starts, the PI must have a PI Certification that will be valid for the life of the proposed project. PI Certification lasts for three years.**

**SECTION I: Review Type Requested (CLICK ON CHECK BOX)**

**[ ]  Exempt/Expedited Review** **[ ]  Full Review**

**SECTION II:**

|  |  |  |
| --- | --- | --- |
| **1. Name of Principal Investigator**  | **Phone:**  | **Email:** |
|        |        |       |

|  |  |  |
| --- | --- | --- |
| **1a. Name of Supervisor (Required for staff PIs only)** | **Phone:**  | **Email:** |
|        |        |       |

**Investigator is (CLICK ON CHECK BOX):** **[ ]  Faculty** **[ ]  Staff**

|  |  |  |
| --- | --- | --- |
| **2. Name of** **[ ]  Co-PIs** **[ ]  Research Collaborator:**  | **Phone:**  | **E-mail:** |
|        |        |       |

|  |  |
| --- | --- |
| **3. Program Affiliation:** | **4. Sponsor (if funded):** |
|       |       |
| **5. Amount of Award: $**  | **6.** **[ ]  Internal Funding or** **[ ]  External Funding** |

|  |  |  |
| --- | --- | --- |
| **7. Title of Project:**  | **Project Start Date:** | **End Date:** |
|        |        |       |

**8. Age Range of Subjects:**

**9. Type of subject:** **[ ]  Adult** **[ ]  Non-student** **[ ]  Minor** **[ ]  CI Student**

**[ ]  Other (describe):**

**10. Subjects (CLICK ON CHECK BOX):** **[ ]  Normal Volunteer** **[ ]  In-patient** **[ ]  Out-patient** **[ ]  Mentally disabled** **[ ]  Pregnant women & fetuses** **[ ]  Individual with limited civil freedom**

**11. Estimated # of Subjects/participants:**

 **# of Treatment Subjects *(If Applicable)*:** **# of Control Subjects *(If Applicable*):**

**SECTION III:**

**Please check the appropriate response for questions 12 to 16. Please be brief and concise in your responses to each of these questions. Failure to respond to any questions will cause significant delays.**

|  |  |
| --- | --- |
| **12.** **[ ] Yes [ ] No**  | **Does this project involve secondary analysis of private data sets? If yes, you need only answer questions 17, 20, 22 and 23 below. Also, please provide the following information in the box below: name of the data set, and the name of the organization that owns the data. Please also attach documentation that you have permission to use the data.** |

**Explanation:**

|  |  |
| --- | --- |
| **13.** **[ ] Yes** **[ ] No**  | **Will subjects receive payment or extra credit point compensation for participation? If yes, detail amount, form, and conditions of award. If compensation will be provided via a drawing or lottery, please see guidance on IRB website.** |

**Explanation:**

|  |  |
| --- | --- |
| **14.** **[ ] Yes** **[ ] No** | **Will access to subjects be gained through cooperating institution? If yes, include name of cooperating institution and attach copy of approval letter from that institution (*e.g.*, copy of cooperating institution’s IRB approval, copy of approval letter from school board, *etc.*).**  |

**Explanation:**

|  |  |
| --- | --- |
| **15.** **[ ] Yes** **[ ] No**  | **Does this project involve investigator(s) at another institution? If yes, identify investigator(s) and institution and attach a copy of an agreement to cooperate for each institution.** |

**Explanation:**

**DIRECTIONS: In a total of no more than four pages, please answer the questions 16-23. Please be brief and concise in your responses to each of these questions. Failure to respond to any questions will cause significant delays.**

|  |  |
| --- | --- |
| **16.** **[ ] Yes** **[ ] No**  | **Will the subjects be deceived, misled, or have information about the project withheld? If so, identify the information involved, justify the deception, and describe the debriefing plan if there is one.** |

**Explanation:**

**Research Protocol Description (Please attach surveys and instruments to the IRB Application):**

|  |
| --- |
| **17. Describe the objectives and significance of the proposed research below.** |

|  |
| --- |
| **18. Describe methods for selecting subjects and assuring that their participation is voluntary. Attach a copy of the consent or assent forms and/or recruitment flyer/poster that will be used. If no consent form will be used, explain the procedures used to ensure that participation is voluntary. Sample consent/assent forms and recruitment flyer/poster as well as related information are available on the IRB website.** |

|  |
| --- |
| **19. Describe the details of the procedures that relate to the subject's participation below. Attach copies of all questionnaires or test instruments. In addition, attach a copy of the technical portion of the grant application if this project is part of a sponsored funding request.**  |

|  |
| --- |
| **20. Describe below the methods that will be used to ensure the confidentiality of all subjects' identities and the stored data (include how data will be handled after research is completed). Confidentiality of data is required.** |

|  |
| --- |
| **21. Describe below the risks to the subjects and precautions that will be taken to minimize the risks to the subjects. Risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional, employment, legal, and/or behavioral risk. (Note: There is always minimal risk (s) associated with a project.)** |

|  |
| --- |
| **22. Describe below the benefits of the project to science and/or society. Also describe benefits to the subject, if any exist. The IRB must have sufficient information to make a determination that the benefits outweigh the risks of the project.** |

|  |
| --- |
| **23. Describe below how the results of your study will be disseminated.** |

 **APPLICATION FOR THE REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS**

## SECTION IV – ASSURANCES

This protocol review form has been completed and typed. By submitting this form to the CSU Channel Islands Institutional Review Board by email, from my CI email account[[3]](#footnote-3), I affirm that I am familiar with the ethical and legal guidelines and regulations (i.e. The Belmont Report, The Code of Federal Regulations Title 45 Part 46, and CI’s Policy) and will adhere to them. Should material changes in procedure involving human subjects become advisable, I will submit them to the IRB for review prior to implementing the change. I understand that I have to notify the IRB when the project is completed. Furthermore, if any problems involving human subjects occur, I will immediately notify the IRB. I understand that IRB review must be conducted annually and that continuation of the project beyond one year requires submission of Research Continuation Form for IRB approval.

Top of Form

 Check this box to indicate that you affirm the above statement.

Bottom of Form

**Signatures**: Because access to CI email accounts are authenticated and limited to the account holder, the IRB regards documents sent from a CI email as authentic communication from the account holder. Therefore, signatures are not required for execution of this application.

**Principal Investigator Name Signature Date**(Faculty or Staff only)

**End of Application** – THIS SECTION MUST BE COMPLETED FOR IRB REVIEW.

1. This course can be found online at http://phrp.nihtraining.com/. [↑](#footnote-ref-1)
2. This course can be found online at http://www.citiprogram.org. [↑](#footnote-ref-2)
3. In the rare instance when a PI is not a CI employee or student (e.g., when the IRB has entered into a formal service agreement with another organization), the IRB may allow the use of a non-CI, official work email address. [↑](#footnote-ref-3)