The application for IRB approval may appear daunting at first, but most questions are straightforward. For those that may require some interpretation or specialized knowledge, this guide (which is essentially a copy of the application with some pointers added) aims to provide some assistance. Pointers appear in this document contained in a red-bordered, grey-shaded rectangle, just like this paragraph. All other text is as it appears in the IRB application.

IRB APPLICATION CHECKLIST

NO RESEARCH CAN PROCEED PRIOR 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.

☐ The researcher has completed the online PI Certification Training within the last two years:
the NIH *Protecting Human Research Participants* course[1], or
the Collaborative Institutional Training Initiative's (CITI) IRB course.[2]

Include a copy of the certificate of completion with your IRB application. You should submit one for each person involved in the research project.

☐ 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.

☐ If the study is led by a student applicant, he or she must identify the CI faculty member who will supervise the research, have this supervisor review the application before submission to the IRB, and carbon-copy (a.k.a., CC:) this supervisor when they submit the application package to the IRB for review.

For student-led research, it is recommended that the supervising faculty or staff member also provide a certificate of successful completion of IRB training.

☐ If the study is led by a CI staff member, he or she must identify a supervisor who understands the ethics and guidelines for research involving human subjects and carbon-copy (a.k.a., CC:) this supervisor when they submit the application package to the IRB for review.

☐ The researcher agrees to send notification via email to RSP when the research project is finished or will submit a continuation form to IRB annually for approval of an extension.

[1] This course can be found online at http://phrp.nihtraining.com/.
[2] This course can be found online at http://www.citiprogram.org.

Guide to completing the CSU Channel Islands IRB Application Form, September 2016.

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

***Completed by IRB*:**

INSTITUTIONAL REVIEW BOARD (I.R.B)

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 to allow reviewer to comment in the application using the track changes functionality.**

The IRB is officially "going electronic". All documents can be submitted electronically to the IRB from official CI email addresses.

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.

If the PI anticipates the project lasting more than three years, the PI will need to recertify, but they may retake the IRB Certification at any time.

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

☐ **Exempt/Expedited Review** ☐ **Full Review**

The PI may suggest a classification for review, but the IRB will make the final determination of how to classify the proposed research. Projects approved at any level may be published or publicly disseminated. Full review is required when project risks are high or subjects belong to a protected or vulnerable population. Full review can take several weeks. See the Code of Federal Regulations, Title 45 Part 46[3], subparts B and C for what constitutes vulnerable populations.

SECTION II:

1. Name of Principal Investigator	Phone:	Email:

Investigator is (CLICK ON CHECK BOX): ☐ **Faculty** ☐ **Staff** ☐ **Graduate Student** ☐ **Undergraduate**

2. Name of ☐ Co-PIs ☐ Research Collaborator:	Phone:	E-mail:

[3] This can be found at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.

3. Program Affiliation:	4. Sponsor (if funded):
5. Amount of Award: $	6. ☐ Internal Funding or ☐ External Funding

Leave questions 4-6 blank if there is no funding associated with the project (e.g., student wages, data analysis costs, participant payments).

7. Title of Project:	Project Start Date:	End Date:

The project title will be used in correspondence and in IRB records.

A project can be proposed to last multiple years, but the project will need to be renewed with the IRB each calendar year. (There's a form for that available on the IRB website.) When the project comes to an end, the PI must notify the IRB. (There's a form for that, too, on the IRB website.)

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:

If you plan to use existing data from existing databases, that would be considered a secondary source of data. Please identify the dataset that you will be using and how will you access it.

13. ☐**Yes** ☐**No**	**Will subjects receive payment or extra credit point compensation for participation? If yes, detail amount, form, and conditions of award.**

Explanation:

Payment or other compensation may reflect the time and effort a subject is expected to invest in their participation. Compensation that exceeds this value may be viewed as coercive, and the IRB will ask the PI to reduce it from the proposed protocol or remove it altogether.

14. ☐Yes ☐No	**Will access to subjects be gained through a cooperating institution? If yes, indicate the cooperating institution(s) and attach a copy of a signed approval letter from that institution (*e.g.*, copy of cooperating institution's IRB approval, copy of approval letter from school board, *etc.*). Letters from other institutions should be on their letterhead.**

Explanation:

It may be wise to have that letter include the name of the project's contact at that institution. This would be the person who will give the PI access to subjects at the cooperating institution. The letter must be on official letterhead. A sample letter is available on the IRB website.

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.**

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:

IRB requires that human subjects be informed about the scope of the project and how it will affect them, its benefits, and any risks involved. However, sometimes a complete disclosure upfront may compromise the study. An example would be a clinical study where some patients may take a placebo and others may take a drug active to determine the affect of the new drug. In this case, the patients may not know who is taking the placebo and who is not. However, at the end of the study the human subjects are informed what they were taking. If your project requires deception, you need to provide a good justification here, and also a plan for when, how, and who will share the details with participants at the conclusion of the project.

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

17. Describe the objectives and significance of the proposed research below.

Project significance can include significance to the PI's research project, significance to the PI's academic discipline, and significance to society.

18. Describe methods for selecting subjects and assuring that their participation is voluntary. Attach a copy of the consent form that will be used. If no consent form will be used, explain the procedures used to ensure that

participation is voluntary. (Sample consent forms and related information can be found on the IRB website.)

It is important that subjects are selected in a fashion that is free from bias and that leads to a subject pool that is diverse in as many ways as possible (e.g., gender, primary ethnic background). Consent forms are strongly encouraged; the IRB expects strong and clear reasoning to support some other method of gaining and documenting consent from subjects. It is also strongly encouraged that you insure that participation is voluntary and that there will not be repercussions on those who choose not to participate. An example consent form is 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.

Questionnaires, test instruments, and technical descriptions from grant proposals should be included as attachment the IRB application, and each should be cross-referenced here by name (e.g., filename and document title if a document has one). If the proposed research includes elements of risk, those should be included here but the PI's discussion of the risks and how they will be managed should be addressed below in question 21.

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.

The security of project data is very important. Please detail the length of time that the data will be kept and stored, where it will be stored, and how it will be destroyed when the project has ended. Describe the security measures that will be taken to protect the data. Note that data is stored on a CI desktop, server, or network is not assumed to be secure.

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.

In addition to publication in a peer-reviewed journal, dissemination includes presentations at conferences, writing a report, posting results on a web site or social media, *etc.*

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[4], 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.

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

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.

Full Name _____ **Submission Date: _____**
Principal Investigator (Student, Faculty, Staff**)**

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

[4] 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.