

STUDENT IRB APPLICATION CHECKLIST

NO RESEARCH CAN PROCEED UNTIL YOU HAVE RECEIVED 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.

Use the following checklist to determine that your application is complete. If any of the boxes are not checked off the application is incomplete.

- The researcher has completed the PI Certification Training. **Attach co copy of the certificate.**
<http://phrp.nihtraining.com/users/register.php>
- The researcher using human subjects completed an electronic IRB Application for IRB Committee Review. **E-mail an e-copy to irb@csuci.edu.**
- The IRB Application was submitted both as hard copy and electronically to the Research and Sponsored Programs office (RSP).
- The researcher submitted one electronic copy, two hard copies, and the signed original of the completed IRB Application, a total of three copies. All proposals/applications should be received no later than close of business on Monday to make the Thursday review cut off for that week.
- The researcher attached copies of protocol, informed consent forms, and other instruments that will be used for research. (see example consent forms)
- 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.
- The researcher answered question # 22 of the IRB application in detail. For example, give the length of time that the data will be stored, where it will be stored, and when it will be destroyed. Data is not secure if it is stored on the CSU Channel Islands (CI) network, server, or desktop.
- The researcher has identified appropriate storage. If storing data on CD Rom remember that 7 year-old CDs will not retain data and data will need to be backed-up often.
- The researcher agrees to send notification via email to the RSP when the research project is finished or will submit a continuation form to IRB annually for approval of an extension.
- The researcher signed all paper copies of the IRB Application and obtained appropriate signatures on the last page.
- The researcher reviewed application with their faculty member and signed application before submitting to the IRB.

E-mail inquiries should be directed to: irb@csuci.edu

The IRB Chair and RSP **meet every Thursday** to review category 1 Research: Exempt/Expedited proposals. The IRB Committee meets as needed for category 2 Research: Full-review proposals.

All proposals/applications **should be received no later than 5:00 pm on Monday** to make the Thursday exempt/expedited review weekly meeting.



<i>Completed by IRB:</i>	
IRB PROJECT #:	
<input type="checkbox"/>	Exempt/Expedited Review: _____
<input type="checkbox"/>	Full Review: _____

INSTITUTIONAL REVIEW BOARD (I.R.B)

The text in red offers some guidance in completing the application. For additional information contact the irb at irb@csuci.edu.

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 electronic copy of the completed IRB Application, proposal and attachments to irb@csuci.edu in the following format:

1. **IRB application should be saved as: First letter of the first name and the last name of the Principal Investigator (Example: John Smith = jsmith IRB Application)**
2. **Email subject heading: IRB Application**
3. **Attachments: Include all attachments (surveys, consent forms, letters)**
4. **Interoffice mail or hand deliver: 2 copies and 1 signed original IRB Application and attachments to RSP at Solano Hall, Office # 1177**
5. **DO NOT SUBMIT IN PDF FORMAT**

All IRB Applications and proposals must be submitted **by 5:00pm on Monday to make the Thursday review.** An IRB Application is incomplete without the signature of the Principal Investigator and Program Chair/Administrator on the last page of the application. Before research starts the PI must take the PI Certification Training and present proof to RSP. <http://phrp.nihtraining.com/users/register.php> The certification is good for only three years.

SECTION I: Review Category Requested. **CLICK ON CHECK BOX - You may check a requested category below; however, the final determination will be made by the IRB.**

- Category 1 Research: Exempt/Expedited Review Category 2 Research: Full Review

SECTION II: You may check an appropriate box for the PI, and provide name and contact information.

1. Name of Principal Investigator (<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student):	Phone:	Email:

Check the appropriate box, and students will include supervising faculty name and the other PI's may include the name(s) of other collaborators.

2. Name of <input type="checkbox"/> Responsible Supervising Faculty <input type="checkbox"/> Research Collaborator:	Phone:	E-mail:

Identify the program at CI sponsoring the proposed study. In the case of a funding agency identify the agency.

3. Program Affiliation:	4. Sponsor (if funded):
5. Amount of Award: \$	6. <input type="checkbox"/> Internal Funding or <input type="checkbox"/> External Funding

Use a brief title of the project here.

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

8. Investigator is (CLICK ON CHECK BOX): Faculty Staff Graduate Student Undergraduate

9. This application is for (PLEASE SELECT FROM LIST BY CLICKING ON TEXT): New Project

Identification of demographics is an important consideration in the IRB review process; please check appropriate categories below for your project.

10. Age Range of Subjects:

11. Type of subject: Adult Non-student Minor CI Student
 Other (describe):

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

13. Estimated # of Subjects/participants: # of Treatment Subjects (If Applicable):
of Control Subjects (If Applicable):

SECTION III:

Please check the appropriate response for questions 14 to 18. Please be brief and concise in your responses to each of these questions. Failure to respond to any questions will cause significant delays.

14. <input type="checkbox"/> Yes <input type="checkbox"/> No	Does this project involve secondary analysis of public data sets? If yes, skip questions 20, 21 and 23 of the IRB application. Please provide the following information in the explanation box below (name of the data set, public URL address, and the name of the organization)
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Explanation: If you plan to use existing data from existing databases, those would be considered the secondary source of data. Please identify the dataset that you will be using, where will you access it. If you check NO, this means that you will not be conducting any surveys or interviews.

15. <input type="checkbox"/> Yes <input type="checkbox"/> No	Will subjects receive payment or extra credit point compensation for participation? If yes, detail amount, form, and conditions of award.
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Explanation: Describe how much compensation will be offered to participants if any, and in what form. What would be the expectation in return from these participants?

16. <input type="checkbox"/> Yes <input type="checkbox"/> No	Will access to subjects be gained through cooperating institution? If yes, indicate cooperating institution and attach copy of approval letter from that institution. (e.g. Copy of institution's IRB approval, copy of approval letter from school board, etc.)
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Explanation: If you plan to access human subjects for your study at a participating institution, then the IRB requires a letter from that institution indicating their approval and permission to access human subjects at their institution. This permission needs to be in writing on their letterhead. The letter needs to be signed by an authorized official of the institution, such as the Principal of a School, Director of an organization etc.

17. <input type="checkbox"/> Yes <input type="checkbox"/> No	Does this project involve investigator(s) at another institution? If yes, identify investigator(s) and institution and attach copy of agreement to cooperate.
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Explanation: If an investigator at another institution will be involved, provide name of the investigator, name of the institution and a copy of the agreement letter. If human subjects at another College/University are going to be accessed, then you would need to seek approval from their IRB for conducting research on their campus, and CI would need the IRB approval letter as part of your IRB application to CI.

DIRECTIONS: In a total of no more than four pages, please answer the questions 18-24. Please be brief and concise in your responses to each of these questions. Failure to respond to any questions will cause significant delays. It is critical that your responses are concise, no more than a 1/2 to a short paragraph is required. Do not attach copies of your proposal funded by funding agencies or paste proposal narratives to answer the questions below.

18. <input type="checkbox"/> Yes <input type="checkbox"/> 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.
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Explanation: IRB requires that human subjects be informed about the scope of the project and how it will affect them, 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. The studies conducted at CI, will generally not require deception; however, if your project requires deception, you need to provide a good justification here, and also a plan when, how and who will then be sharing the details with participants at the conclusion of the project.

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

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

Briefly describe why you are doing the research, what you hope to accomplish, and how will it help the society.

20. 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. (See attached: sample/standard consent form and guide)

Describe how you will select human subjects to participate in your study, and how will you ensure that participation is voluntary with no negative consequences for those who do not want to participate. You must attach an informed consent form with this application that you will have participants sign prior to their participation. Examples of appropriate informed consent forms are available at the IRB website for your convenience.

21. Describe the details of the procedures that relate to the subject's participation below. Attach copies of all questionnaires or test instruments. Additionally, (NOT IN LIEU OF) attach a copy of the technical portion of the grant application if this project is part of a sponsored funding request.

If you plan to use a questionnaire to seek participants' responses, attach a copy of the questionnaire to this application. If you plan to interview participants, attach a copy of all questions that will be asked and how, such as a focus group or one-on-one interviews. Will you be using audio and/or video recording devices, and how will you ensure confidentiality of the participants.

22. 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.

Briefly explain plans you will implement to keep the identity of participants confidential. How will the data be stored, electronically or hard copy, where and for how long. When will the data be destroyed?

23. 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.)

Briefly describe the risks associated with participation in this study, and the magnitude of the risk. You must consider any type of potential risk, and what measures you will put in place to minimize the risk.

24. 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.

IRB considers risks and benefits in evaluating the application; briefly describe the overall benefits of the study to the society at large or in advancing the knowledge in a given discipline that will better serve the society or the individual participants.

25. Describe below how the results of your study will be disseminated.

Identify the modes of dissemination of the results, such as publication in journals, publication in a book, presentations at conferences or other settings, a report, on the web, YouTube, press releases, newspaper etc.

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SECTION IV – ASSURANCES – The signature below provides assurance that the information provided in this application is correct and the PI commits to following the proposed protocol in this application upon IRB's approval, it attests the PI's obligations and commitment to adhere to the human subject research guidelines.

This protocol review form has been completed and typed. 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.

_____/_____
Principal Investigator (Student) / Date

_____/_____
Supervising Faculty Member / Date

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