



CALIFORNIA STATE UNIVERSITY
FULLERTON[™]

Modification Request

Cayuse IRB

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Link: [Cayuse IRB Log-In](#)


Updated 10/2022


How to use this tutorial


- This tutorial is for researchers (PIs) who **already have an approved** IRB protocol and wish to request a modification for their study.

+ New Study

 **0**
In-Draft

 **0**
Awaiting
Authorization

 **0**
Pre-Review


 **0**
Under Review

My Studies

HSR-22-23-68	Test Study
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[View All](#)

My Tasks


All Tasks Complete

Submissions by Type

Renewal	0
Initial	1
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0

Approved Studies

HSR-22-23-68	Test Study
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Studies Expiring in 30 days ▾

Expired Studies

Click to access the study you want to close



+ New Submission

Study Details

Submissions

Approved

HSR-22-23-68 Test Study

PDF Delete

Approval Date: 08-17-2022	Expiration Date: N/A	Organization: Child & Adolescent Studies Current Policy Post-2018 Rule	Active Submissions: N/A Sponsors: N/A
Admin Check-In Date: N/A	Closed Date: N/A		

You'll be taken to this page.
Click on the blue button for
"+ New Submission"



Key Contacts ⓘ

Attachments

Team Member	Role	Number	Email
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+ New Submission

Study Details

Submissions

Approved

HSR-22-23-68 Test Study

PDF

Delete

Approval Date:
08-17-2022

Expiration Date:
N/A

Admin Check-In Date:
N/A

Closed Date:
N/A

Organization:
Child & Adolescent
Studies
Current Policy
Post-2018 Rule

Active
Submissions:
Sponsors:

Key Contacts ⓘ

Attachments

Team Member

Role

Select
Modification

- Renewal
- Modification
- Incident
- Closure

Renewal = extending the study for up to a year, before the approved protocol expires.

Modification = submitting a change or amendment to the protocol

Incident = reporting an adverse event

Closure = you are finished collecting data for the study



Unsubmitted

Modification

HSR-22-23-68 - Test Study

Edit PDF Delete

PI:

Review Type:
N/A

You're taken to this page.
Click on "Edit" to provide a
final progress report to close
out the study.

Required Tasks:

- [Assign PI](#)
- [Assign PC](#)
- [Complete Submission](#)

Approvals Task History Attachments

Research Team

Name	Role	Result	Date
No entries			



- Sections <
- Amendment Form ✓
- Introduction ✓
- Funding Information ✓
- Project Description... ✓
- Participant Informa... ✓
- Data Collection ✓
- Risk and Benefits ✓
- Informed Consent ... ✓
- Anonymity and Co... ✓
- Subject Matter ✓
- Debriefing ✓
- Conflict of Interest ✓
- Routing ✓
Send to PI for certification?
- COMPLETE SUBMISSION >

Amendment Form

1. Fill out the form

Any change to an approved research protocol, including research plan, consent process and form, co-investigators, to research personnel, and/or methods of participant recruitment, requires submission of an Amendment. You will be required to attach any revised instruments, questionnaires, letters of cooperation, informed consent forms, etc.

Amendments to protocols may not be initiated until IRB approval has been obtained.

* Provide a brief explanation of the purpose for your amendment (minimum of 200 words). Proceed by completing the sections below and uploading any documentation, if needed.

...

* The following change(s) is/are being proposed for the above protocol:

Title change
Insert title change here:

...

- Addition of research personnel (Update CV/resumes)
- Change in Principal Investigator
- Removal of research personnel
- Addition, deletion, or change of research instruments, questionnaires, advertisement flyers, funding sources, etc.
- Additional or deletion of cooperating institutions
- Change in Number of Participants
- Change in Population

2. When you have completed the "Amendment Form", click on "Complete Submission"



IRB NUMBER: HSR-22-23-68

Test Study - Modification

< SUBMISSION DETAILS

CREATE PDF

COMPARE

SAVE

Amendment Form

Introduction

Funding Information

Project Description...

Participant Informa...

Data Collection

Risk and Benefits

Informed Consent ...

Anonymity and Co...

Subject Matter

Debriefing

Conflict of Interest

Routing

Send to PI for certification?

COMPLETE SUBMISSION >

SUBMISSION ROUTING

Are you sure you want to continue?

CANCEL

CONFIRM

- * Provide a brief explanation of the purpose for your amendment (minimum of 200 words). Proceed by completing the sections below and uploading any documentation, if needed.

...

- * The following change(s) is/are being proposed for the above protocol:

Title change

Insert title change here:

...

Addition of research personnel / Update CITI training.

Change in Principal Investigator

Removal of research personnel

Addition, deletion, or change of recruitment instrument, oral script, survey instrument, web-based instruments, questionnaires, advertisement flyers, funding sources, etc.

Additional or deletion of cooperating institutions

Change in Number of Participants

Change in Population

Revised Informed Consent Form

Change in Methodology

Other

Click on
"CONFIRM"





Awaiting Certification

Initial

HSR-22-23-68 - Test Study

[View](#) [PDF](#) [Delete](#)

Routing:

[Return](#) [Certify](#)

PI: Current Analyst: Decision:
N/A N/A

Review Type: Review Board: Meeting Date:
N/A N/A N/A

You will then be redirected to the submission details page. You will need to “**CERTIFY**” to finalize the submission. Certification says you knowingly mean to take this action (to renew, amend/modify, or close).



Approvals Task History Attachments

Research Team

Name	Role	Result	Date
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Certify



As Principal Investigator of this study, I assure the IRB that the following statements are true:

The information provided in this form is correct.

I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment.

I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.

I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.

I will report in writing any significant new findings which develop in the course of this study which may affect the risks and benefits to participation.

I will not begin my research until I have received written notification of final IRB approval.

I will comply with all IRB requests to report on the status of the study.

I will maintain records of this research according to IRB guidelines.

The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application.

In the case of student protocols, the faculty adviser and the student share responsibility for adherence to policies.

If these conditions are not met, I understand that approval of research could be suspended or terminated.

Cancel

Confirm

After you have clicked “**Certify**” under the Submission Details page, review the PI Certification Statement. After you read the statement click “**Confirm**”





Under Pre-Review

Initial

HSR-22-23-68 - Test Study

[View](#) [PDF](#) [Delete](#)

PI:	Current Analyst:	Decision:
	N/A	N/A
Review Type:	Review Board:	Meeting Date:
N/A	N/A	N/A

[Approvals](#) [Task History](#) [Attachments](#)

Research Team

Name	Role	Result	Date

After you have certified and confirmed your submission, you will notice your study is **“Under Pre-Review”** which means it’s with the IRB office to officially begin the review process. You and any co-PIs should receive an email confirmation of the action and submission type you’ve just submitted.



If you have any issues or questions, please contact

IRB Office: irb@fullerton.edu
or **(657) 278-7719**