Faculty/Staff IRB Online Application Submittal Process:

Step 1 – Review the instructions for submitting your application prior to initiating your request.

To begin the process, navigate to https://stockton.edu/research-sponsored-programs/irb.html and click on "New Online Application." Enter *your portal username and password* and click on "Login." **Note:** You must have a valid GO portal username and password to enter the system.

Application For Protocol Review

OFFICE OF RESEARCH AND
SPONSORED PROGRAMS

IRB Application Request

INSTRUCTIONS

PLEASE READ ALL INSTRUCTIONS BELOW BEFORE BEGINNING THE APPLICATION REQUEST

IRB Application Submittal Requirements:

1. Project Directors and co-investigators must have a valid Stockton Portal Username and Password.
2. Only Project Directors/Faculty Sponsors are eligible to submit application requests.
3. When a project involves co-investigator, the Project Director/Faculty Sponsor must obtain their portal username.
4. Project Directors/Co-investigators involved in Expedited or Full review must complete the **CITI Training Certification** Program prior to submitting an application request.
5. Once the application request has been submitted the co-investigators will be requested to electronically sign the application using their Portal Username and Portal Password via an automatic email request.
6. All communication regarding the application request will be handled through email.

IRB APPLICATION REQUEST

Please enter your Portal Username and Portal Password in the spaces provided below. When complete, click "Login" to continue.

goStockton Portal Username:	
goStockton Portal Password:	

Login

Step 2 – After completing the login, you will see a list of functions on the IRB Application Request page:

1. **New IRB Application**
2. **View** (existing approved applications and application that have **not** been completed with a final submit)
3. **Co-Signature view** (projects with co-investigators)

For a new application request, just click on "**New IRB Application**".

Application For Protocol Review

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Welcome, **levym**
Logout / IRB

IRB APPLICATION REQUEST

Click the link below to initiate a new IRB application request or to add documents/co-investigators to an existing application request. Additionally, if you are listed as a co-investigator, the opti
Electronically Sign that application will be available. **Please note:** *You will only have access to those applications which include your name.*

- New IRB Application

Your Applications -

IRB Number	Title	Submission Date	Status	R
2012.019	MA Thesis: Investigation of burglary using Crime Mapping and Crime Analysis Techniques	2/23/2012	Approved	
2012.030	A pilot study of knowledge regarding Institutional Review Board policies and procedures	4/18/2012	Change In Research	

Step 3 – Fill in the required fields of information and click the "**I agree**" button.

Note: Please make your best guess about the level of review needed. The IRB Chair will make the final determination and change the level of review, if necessary. *Projects requiring Expedited and Full review will not be approved if CITI training has not been completed when required. (Exempt review does not require CITI Training.)*

A. Example of review -

IRB APPLICATION REQUEST

Fill out fields below to submit a new IRB application request.

Project Title:	Test 100
Application Type:	Full Review ▼
	NOTE: If Expedited or Full Review, CITI Training *must* be completed
CITI Training Completed:	⦿ Yes ○ Not Applicable
Project Director/Faculty Sponsor:	Marissa P Levy
Director School:	SOBL ▼
Project Start Date:	10/10/2020 (m/d/yyyy)
Project End Date:	10/10/2021 (m/d/yyyy)
	(Request any date up to 5 years)

As the principal investigator, my signature testifies that I pledge to conform to the following:

- *As one engaged in study utilizing human participants, I acknowledge the rights and welfare of the human participant involved.*
- *I acknowledge my responsibility as an investigator to secure the informed consent of the participant by explaining the procedures, in so far as possible, and by describing the risks as weighed against the potential benefits of the investigation.*
- *I assure the Review Board that all procedures performed under the project will be conducted in accordance with those Federal regulations and University policies which govern research involving human participants. Any deviation from the project (e.g., change in principal investigator, research methodology, participant recruitment procedures, and so on) will be submitted to the IRB using the Change in Research Form for IRB approval prior to implementation.*
- *As the faculty sponsor, my signature testifies that I will oversee the research to its entirety, through to its termination. I understand that I am subject to random document checks. I will complete the CITI training and submit my certificates with the IRB application. If my data collection continues past the expiration date, I will renew my application.*

I AGREE

Step 4 – You can use the application navigation on the left to navigate the application.

Or you can complete each screen as it is presented. Be sure to answer each question and to click "Save Project Info" at the bottom of each screen.

Test 100 - PROJECT

Request Submitted

The research will be carried out in cooperation with the following institution(s):

Categories of Human Subjects to be studied:
Proposed Age Group of Subjects (range):
Proposed # of Subjects:
Males:

Is your research study targeting any of the following?

- **Minors** (If so, include Informed Consent Form for the guardian and an Assent Form for the child.)
  ○ Yes ○ No
- **Non-English Speaking** (If so, include all documents including the Informed Consent Form, survey, questionnaire, recruitment flyer and any other materials in English and the second language.)
  ○ Yes ○ No
- **Your Own Students** (If so, you'll need to be clear about the benefits, risks, and inducements that will be given to students.)
  ○ Yes ○ No
- **Individuals with Impaired Decision-Making** (Be sure to discuss how these participants will be protected. Include an Informed Consent form for the guardian if the participant is not considered his or her own guardian.)
  ○ Yes ○ No
- **Individuals who are Economically or Educationally Disadvantaged** -(Explain why you will target a specific group.)
  ○ Yes ○ No
- **Prisoners** (If so, you'll need to be very clear about the benefits, risks, and inducements that will be given.)
  ○ Yes ○ No

Note: If any of these populations will be included in your study, fully explain the rationale for including these vulnerable populations and the ways in which they will be protected in question #3 of the Study Design section.

Conflict of Interest Statement:
Do any of the investigators have a direct or indirect personal financial interest or advisory relationship to the sponsor, manufacturer, or to the owner of the text materials?
○ Yes   ○ No   ○ Not Applicable

If yes, please describe:

Save Project Info

Step 5 – If you have co-investigators to add, be sure to click "Application Home" and add your co-investigators. If the co-investigators are Stockton faculty students or staff add the First Name, Last Name, and Stockton portal username in this area. <u>PLEASE NOTE:</u> You must have co-investigator's <u>exact</u> GO Portal <u>username</u> when completing the application. The system will use this to send an automatic email for signature.

If you mistakenly add a co-investigator, or otherwise need to remove an investigator from your project, you can click the "X" next to the name and the investigator will be removed.

Once an internal investigator is added to the project an auto-generated email will be sent to the investigator's Stockton email address.
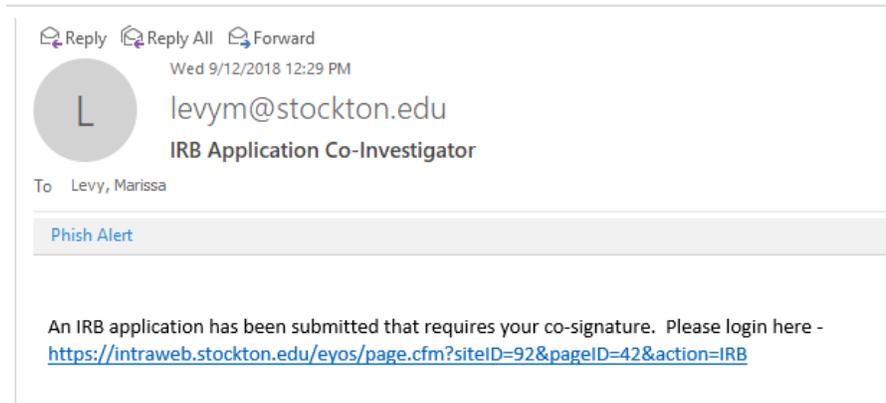
The investigator will click the link and be asked to sign in to our IRB system. The application that requires a signature will be at the top of the screen.

The investigator should click the title of the project then click "Co-Sign" on the next screen.

Once Co-sign is clicked, "yes" will appear next to the investigator's name in the "Signed" column.

Application For Protocol Review

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Welcome, levym
Logout / IRB

IRB Application

IRB Co-Signed

Below is the IRB submitted on 9/12/2018

Project Title:	Test 100
Application Type:	Full Review ▼
Project Director/Sponsor:	Marissa P Levy
Director School:	SOBL ▼
Project Start Date:	10/10/2020
Project End Date:	10/10/2021

Co-Investigators

Name	Username	Signed
Marissa Levy	levym	Yes

Documents

NOTE: You will not be able to submit your application for review until ALL co-investigators have signed.

If you have co-investigators who **are not from Stockton (EXTERNAL Co-Investigators)**, be sure to complete the "EXTERNAL Co-Investigators" area with the First and last name, description (title or degree – whatever is relevant) and add the investigators email address.

About Stockton   Academics   Admissions, Scholarships & Aid   Campus Life   Athletics & Recreation   Arts & Culture   Support Stockton

Application For Protocol Review

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Welcome, levym
Logout / IRB

Test 100 - APPLICATION HOME

APPLICATION NAVIGATION

Application Home
Project
Type of Research
Study Design
Documentation
Preview

Below is your IRB initially entered on 9/12/2018

Project Title:	Test 100
IRB Number:	2018.148
Application Type:	Full Review ▼
Project Director/Sponsor:	Marissa P Levy
Director School:	SOBL ▼
Project Start Date:	10/10/2020
Project End Date:	10/10/2021
Approval Expiration:	

Co-Investigators

Name	Username	Signed
	None Added	

Co-Investigator First Name:	**Last Name:**
Co-Investigators Username:	Add Co-Investigator

* Add as many names as apply to the application

EXTERNAL Co-Investigators

Name	Desc	Signed
	None Added	

Co-Investigator First Name:	**Last Name:**
Co-Investigator Description:	
Co-Investigator E-Mail:	
	Add External Co-Investigator

* Add as many names as apply to the application

As with the internal co-investigators, if you mistakenly add a co-investigator, or otherwise need to remove an investigator from your project, you can click the "X" next to the name and the investigator will be removed.

Once you add the EXTERNAL Co-investigator's first and last name, description, and email address, the EXTERNAL Co-Investigator will be sent an email with a link that will expire in 7 days.

Since the EXTERNAL Co-Investigator does not have a portal username and password the link will land here where the investigator will click "Confirm Co-Investigator" in order to sign the application.

Application For Protocol Review

OFFICE OF RE:
SPONSOREI

Welcome, levym
Logout / IRB

Institutional Review Board External Co-Investigator Project Signature

Please confirm your role as Co-Investigator by clicking the button below –

Principal Investigator: Marissa P Levy
Project Title: Test 100

Confirm Co-Investigator

One the investigator clicks the link, the signature will be recorded and confirmed with this screen.

Application For Protocol Review

OFF
SI

Welcome, levym
Logout / IRB

Institutional Review Board External Co-Investigator Project Signature

Your acknowledgement was recorded, thank you for your participation!

NOTE: As with internal Co-Investigators, you will not be able to submit your application for review until ALL co-investigators have signed. You will know when a co-investigator has signed when the "No" turns to a "Yes" in the "Signed" column.

Co-Investigators

Name	Username	Signed	
Marissa Levy	levym	Yes	X

Co-Investigator First Name: _____ Last Name: _____
Co-Investigators Username: _____ Add Co-Investigator

Add as many names as apply to the application

EXTERNAL Co-Investigators

Name	Desc	Signed	
Marissa Levy	Research Associate	Yes	X

Co-Investigator First Name: _____ Last Name: _____
Co-Investigator Description: _____
Co-Investigator E-Mail: _____
Add External Co-Investigator

Add as many names as apply to the application

Step 6 - In the "Documentation" screen researchers are able to upload any documents that are necessary. Common documents include:

- Informed Consent Forms

- Assent Forms (for participants who are children)

- Permission from agency to conduct research

- Data Collection Instruments including surveys, research questions, focus group questions, etc.

- Example Videos

Please do not upload documents such as literature reviews, dissertations, MA theses, or academic articles in lieu of answering questions in the "Type of Research Activity" and "Study Design" screens.

To upload a document, click on "Choose File" and navigate to the document you wish to upload.
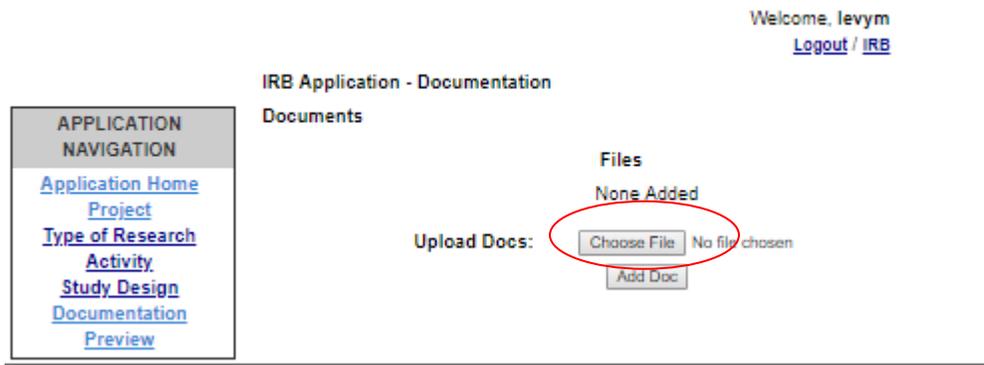
Once you select a document the title of the document will appear next to the "Choose File" box.
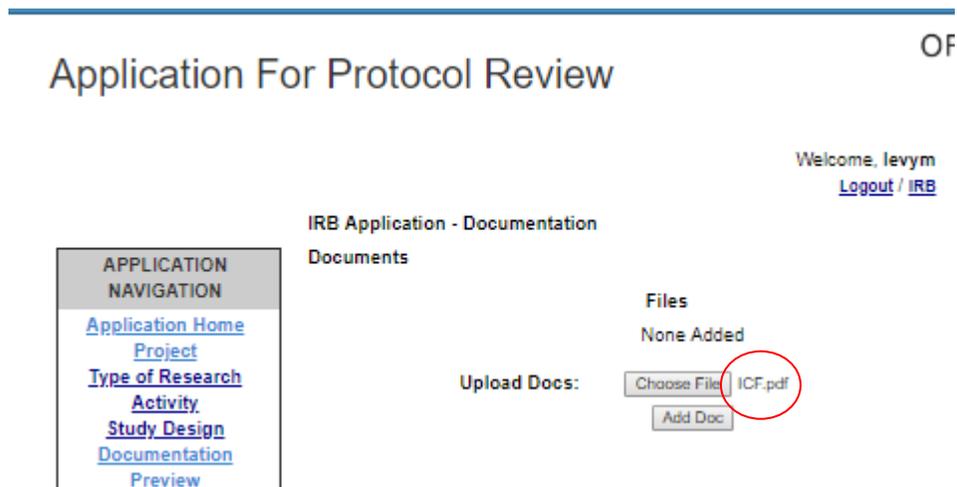
If this is the correct document, click "Add Doc."

The file will then appear clickable so you can view your file. If you have selected a file in error, use the X to remove the file and select another, if necessary.
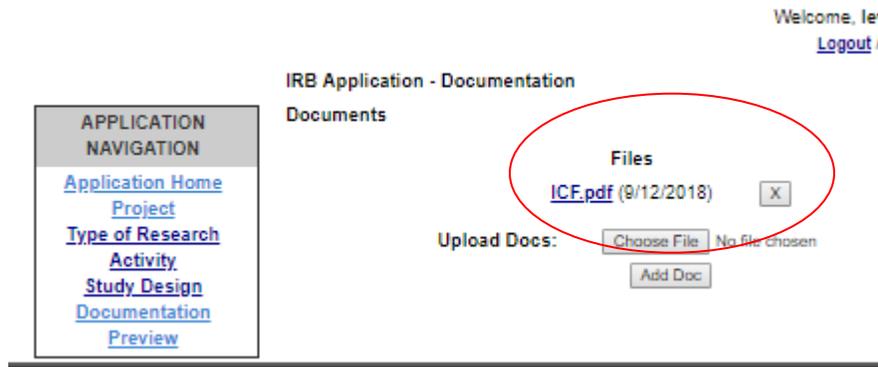
Step 7 – Once all screens are complete, all co-investigators have signed, and all documents are uploaded, use the Preview button in the Application Navigation to preview the submission. Once you are satisfied with your application, click the "FINAL SUBMIT" button.
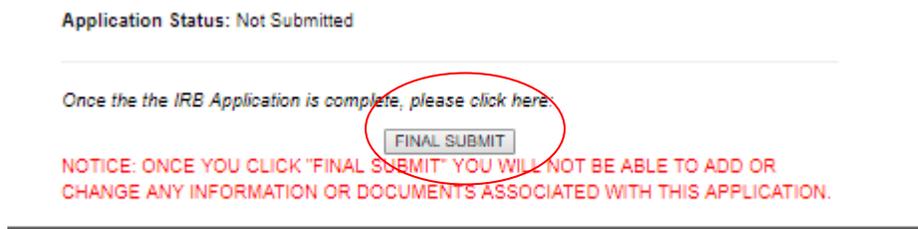
When your application is successfully submitted, the main IRB screen will show your IRB number (circled in green), the date of submission (circled in blue), and the word "submitted" (circled in red). Please reference the IRB number if you have a question.

You will also receive an email confirmation that your submission was completed.

NOTE: Exempt and Expedited applications are reviewed weekly. Full review applications are reviewed monthly. Please see the schedule on the IRB website for projects requiring full review.

You will be notified by the Committee Chair/Designee: Once the project has been reviewed by the chair (expedited and exempt) or the committee (full review), an email message will be sent to the Project Director with the determination of either "approved," "needs revisions," or "not approved." For approved projects, the approved Informed Consent Form (if applicable) will be stamped and uploaded to the Project by the committee chair. The Project Director will be able to print the Informed Consent Form, as needed. When the project is approved the word "Submitted" will change to "Approved."

Additional Functions

There are 4 additional functions to an __approved__ IRB Online Application:

1. Renewal of Project
2. Close Project
3. Change In Research
4. Unanticipated Problems Reporting

Once the application is approved, enter the project by clicking on the title and scroll to the bottom of the "Application Home" screen. You will see these options.

Test 100 - APPLICATION HOME

Below is your IRB initially entered on 9/12/2018

APPLICATION NAVIGATION
Application Home
Project
Type of Research
Study Design
Documentation
Preview

Project Title:	Test 100
IRB Number:	2018.148
Application Type:	Exempt Review ▼
Project Director/Sponsor:	Marissa P Levy
Director School:	SOBL ▼
Project Start Date:	10/10/2020
Project End Date:	10/10/2021
Approval Expiration:	9/12/2019

Co-Investigators

Name	Username	Signed
Marissa Levy	levym	Yes

EXTERNAL Co-Investigators

Name	Desc	Signed
Marissa Levy	Research Associate	Yes

Application Status: Approved

Project Approval Date: 9/12/2018

Renewal Of Project

In order to Renew this project, please enter a new project end date below and click the Renew button.

Project End Date: [　　　　] *(m/d/yyyy)* [Renew!]

Close Project

To update the status of this project as CLOSED, please click the Close Project button below.

[Close Project]

Change In Research

To submit a "Change In Research", please download the following fillable PDF, complete, save and upload the form.

Submit Change In Research:
[Choose File] No file chosen
[Submit!]
Change In Research Fillable PDF

Unanticipated Problems Reporting

To submit "Unanticipated Problems Reporting", please download the following fillable PDF, complete, save and upload the form.

Submit Unanticipated Problems Reporting:
[Choose File] No file chosen
[Submit!]
Unanticipated Problems Reporting Fillable PDF

1. **Renewal of Project**

If nothing has changed with your project, **this includes investigators, methodology, and informed consent**, and you wish to continue your research past the expiration date, you may simply enter in a new project end date and click "renew." You will receive an automated email that your request was submitted. Upon review and approval, you will receive another email with the approval information and new expiration date.

Renewal Of Project

In order to Renew this project, please enter a new project end date below and click the Renew button.

Project End Date: [   ] (m/d/yyyy) [Renew!]

The status of the IRB application will change to "Renewal Submitted" on your main IRB screen.

| 2018.162 | ORSP Trial 1 | | 9/24/2018 | Renewal Submitted |

Once the change is approved, the status will become "Approved."

2. **Close Project**

If you wish to close the project, click closed. Please note that you will not be able to reopen the project but the project and all documents associated with it will remain in your IRB portal for future reference.

Close Project

To update the status of this project as CLOSED, please click the Close Project button below.

[Close Project]

The status of the IRB application will change to "Closed" on your main IRB screen.

| 2018.149 | Test 100 | | 9/12/2018 | Closed |

3. Change in Research

If you need to change an investigator, any aspect of the methodology, or the informed consent form (whether or not the project is up for renewal) please download the Change in Research Form that is found here, on the IRB website, and also in the "Application Home" screen of the approved application. Once you download the form, complete the form and upload the form in the Change in Research area.

Change In Research

To submit a "Change In Research", please download the following fillable PDF, complete, save and upload the form.

Submit Change In Research:

Choose File | No file chosen

Submit!

Change In Research Fillable PDF

If you have other documents to upload, click the "Documentation" tab and upload any other documents in the upload docs area. Note that you will also see the Change in Research form loaded here.

Welcome, levym
Logout / IRB

IRB Application - Documentation

Documents

APPLICATION NAVIGATION	**Files**
Application Home	Change_In_Research_20180912.pdf (9/12/2018) X
Project	
Type of Research	**Upload Docs:** Choose File No file chosen
Activity	Add Doc
Study Design	
Documentation	
Preview	
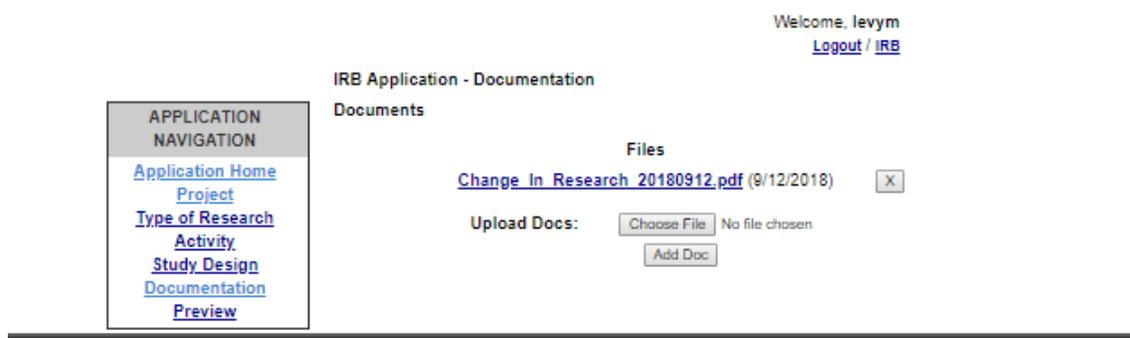
Be sure to use the "Preview" screen to view all your documents. Once you are sure all of your documents pertaining to the Change in Research have been submitted, click the **Final Submit** button.

The status of the IRB application will change to "Change in Research" on your main IRB screen.

| 2018.137 | Sept Test | | 9/6/2018 | Change In Research |

Once the change is approved, the status will become "Approved."

4. Unanticipated Problems Reporting Form

If your study experiences an unanticipated problem or unanticipated event, you will need to submit the Unanticipated Problems Reporting Form. Please download the Unanticipated Problems Reporting Form that is found here, on the IRB website, and also in the "Application Home" screen of the approved application. Once you download the form, complete the form and upload the form in the Unanticipated Problems Reporting area.

Unanticipated Problems Reporting

To submit "Unanticipated Problems Reporting", please download the following fillable PDF, complete, save and upload the form.

Submit Unanticipated Problems Reporting:

Choose File   No file chosen
Submit!

Unanticipated Problems Reporting Fillable PDF

Once you click "Submit!" this process is complete. You will receive an email verifying that the Unanticipated Problems Form was submitted and you will receive a response within 24 hours directing your next steps.