

### **IRBNet User's Guide**

# Instructions for On-line Submission of Research Protocols to the Institutional Review Board (IRB)

www.irbnet.org

If you have any questions regarding the submission of an IRB protocol, contact:

Claire Riner, M.P.A., CIP, ECoP Research Support Services Coordinator <u>irb@calstatela.edu</u> Phone: (323) 343-3792

http://www.calstatela.edu/orsca/research-human-subjects-irb

#### Section I

#### Instructions For Registering With IRBNet

#### Step-by-step instructional videos and pdf slide presentations are available at <u>www.irbnetresources.org/tresources/training.html</u> To access use the following log-in information: user name: calstatela password: training

- 1 Go to <u>http://www.irbnet.org</u>.
- 2 Click on the "**New User Registration**" link in the upper right-hand corner of the screen.
- 3 Create your username and password. Fill out the required information. Your password must contain 8 characters. Click "**Continue**".
- 4 Read and accept the Individual User Terms of Use.
- 5 To add your organization, type "Cal State LA" into the "Search for an Organization" box. Ensure only "Research Institutions" is checked. Click "Display" or "Search". Select "California State University, Los Angeles (Cal State LA)" from the organization box. [Or you may scroll down to "California State University, Los Angeles" and click on it.] Then click "Continue".
- 6 Enter your contact information. Enter the email address you would like to receive communications through the IRBNet system. (e.g. notification of committee decisions, communications from your research team or committee administrator). Click "Continue".
- 7 Review your provided information and edit as necessary. When you are satisfied, click "Register".

An email will be sent to the address you provided in Step 6 with "IRBNet Activation Required" in the subject line. You will need to click on the link provided in this registration email in order to activate your account.

Clicking on the link will take you to the IRBNet homepage.

Training & Credentials

8 Log- in

Click on "**User Profile**" (top right corner) Scroll down to "**Training & Credentials**" Click "Add New Record" and upload your proof of human subjects training. (To complete the training go to: <u>http://www.calstatela.edu/orsca/citi-training-online-tutorial</u>)

*Proof of completion of training is a <u>required document</u> for protocol submissions to the IRB. <u>ALL PERSONNEL</u> listed on the proposal <u>MUST</u> provide proof and later linked to each project.* 

#### Section II

#### Instructions For New Project Submissions

#### Step-by-step instructional videos and pdf slide presentations are available at <u>www.irbnetresources.org/tresources/training.html</u> To access, use the following log-in information: user name: calstatela password: training



After January 5, 2016, if you have an ongoing research project that was **NOT** submitted through IRBNet (i.e. prior to June 29, 2015) and need to submit additional information for this open project (e.g., a modification, continuation, or renewal), the original approved IRB proposal must be uploaded into IRBNet along with your new submission. See Section III of this Guide.

#### Instructions for Creating a New Project:

1. **"Log-in"** to <u>http://www.irbnet.org/</u> using your username and password. (*First time users must register in IRBNet. See* <u>Section I</u>)

The default page will be "My Projects," where you will have access to all of the projects you have created or that have been shared with you from other researchers.

- Click "Create New Project" button on the left bar, fill in the relevant information about your project, and click "Continue". Asterisk fields are required to be completed. An Internal Reference number is not needed, this section is for administrative use only.
- 3. You will now be on the Designer Page where you will submit and download forms and any guidance documents needed to help assemble a new project package.

There are 8 REQUIREMENTS for acceptance of your submission:

- 1. Completion of IRBNet Smart Form "Wizard" Application
- 2. Proof of human subjects training (IRB Training Certificate) for <u>ALL</u> project team members\*\*
- 3. Consent Form(s) and Assent Form(s) (if applicable)
- 4. Letters of Permission to recruit and conduct research if done off campus
- 5. All survey instruments or questionnaires
- 6. All contact letters, flyers, advertisements, scripts, emails, etc., if used to recruit subjects
- 7. Electronic signature of the PI and Co-PIs
- 8. Electronic signature of the Department Chair (if the Department Chair is part of the research team, an electronic signature from Dean/Associate Dean is needed)

\*\*Certificates must be uploaded to each team member's user profile and linked to projects. DO <u>NOT</u> SUBMIT AS A SUPPORTING DOCUMENT FOR THE PROJECT AS THIS WILL NOT BE ACCEPTED.

*IMPORTANT:* As of December 12, 2018, Cal State LA IRB is using the IRBNet Smart Form "Wizard" for submission of the application form. Applications submitted in the Microsoft Word document format will not be accepted.

On the **Designer Page**, click on the **"Start a Wizard"** tab to start the fillable Smart Form "Wizard" application. Follow the instructions on the pages that follow. To view your Wizard application as a PDF, click on "Preview" on the lower left. Your Wizard is complete when you see the page that says "Application Form Complete" with a **checklist** of required follow-up items.

1		IRBNet Document Wizard
Cal St	ate LA IRB Ap	pplication - [60949-2] Smart Form Testing- FULL BOARD Elia Amaro
	Jump To:	Application Form Complete
	Application	n Form Complete
	Interest, subm	r completing the <b>Cal State LA IRB Application Form</b> . If investigators checked yes for Conflict of nit the disclosure form to the appropriate office for processing. If investigators checked yes for act the college dean and department chair to ensure HIPAA compliance.
<b>–</b>	Before invest	stigators submit this IRBNet Package, these follow-up items must be completed:
	submit Each rr Profile State L Upload If any c instituti If any c to IRBF Upload Since i transla Upload	d interview questions. investigators will obtain oral informed consent, upload a written document and script (including ated versions, if applicable). These documents MUST be submitted as WORD documents. d a debriefing sheet or script to the IRBNet Documents.
		ining Experience and Pertinent Licenses: ne other professional training.
	Save and E	Exit Preview Previous

On the Designer page, the Wizard application form (titled Cal State LA Application") will now appear as a new document in the package. By clicking the "View this Document" button (document icon, as shown in screenshot below), you can download a **PDF file** version of their completed Wizard application Form. The last page includes instructions and same **checklist** of all applicable documents/forms that need to be submitted in IRBNet in addition to the study application. The items on this page generate based on the your responses within the Wizard application form (**NOTE**: If the investigator goes back to previous sections of the form and makes any revisions that affect the items included in this list, the listed items will change based on the revised responses):

				Designer
50949]				
		L Mark Pavisia	ns Complete   (V	When should I do this?)
ackage: 🔻 60949-2 Continui	ng Review/Progress Report			ng   View History
	Click to add a package	-		
<del>ل</del>	Click to add a package t	description of notes.		
	age here. You can add new proje I link your project team's Training		sting project docu ckage.   Learn mo	
ocument Type	Description		Last Modified	<b>•</b>
Cal State LA IRB Application	Cal State LA IRB Applica	ition	04/16/2020 06:23 PM	<u>]</u> 다 🖉 🗙
here is 1 Training & Credent	ials record linked to this package	e.   View All Links   Link /	Un-Link Training Re	cords

#### Do not submit your package on IRBNet until all checklist amd follow-up items and are completed.

For supporting documents, on the Designer Page, please select "California State University, Los Angeles (Cal State LA)" from the "Select a Library" drop down menu. Select a document and then click "Download". Open and/or save to your computer file or desktop. Complete the form(s) required for submitting a research protocol to the IRB. Repeat this step for additional forms/documents.

#### You may also click "Forms and Templates" on the left menu to access templates and guidance documents. As a reminder, application forms are now submitted using the Wizard, so there will be no downloadable application forms listed in "Forms and Templates".

To attach your documents, click "Add New Document" from the Designer Page, select the appropriate Document Type, add a description of the document (the document description should be a helpful description). Click "Browse" to look for the document where it is saved on your computer. Click on the document, click "open" so the file is moved into the "file" field. Then click "Attach"



Your attached document will appear under "Step 2" on the Designer Page. The icons to the right side of the attached document allow you to view the document, update the document by replacing it with a new version, or delete the document. (See Section III)

4. You may Share this project with your research team. Click the "Share this Project" button on the left bar, and then click the blue "Share" link to grant access to this project.

Select "California State University, Los Angeles (Cal State LA)" from the organization box. Click "Select Organization" and search for registered users with whom you'd like to share this project (e.g., co-investigators, research assistants, faculty advisor, department chair, collaborative researcher from another institution, etc.)

To "Share" your project with someone, she/he must be registered with IRBNet. You may enter the person's name with whom you would like to share your project in the "Search for a User" box. You can do this by typing all or part of their first or last name and clicking "Search." You can search for multiple names by inserting a comma between names.

#### Grant each user a level of access:

**Read**: User may only view project documents. Recommended for department chair, research assistants.

Write: User may add/delete/edit project documents, collaborate with other users, add their signatures; but cannot grant access to other users, submit the project or perform any other administrative functions.

Full: User may perform all functions without restrictions, add/edit/delete project documents, grant access to other users, and submit the project. Individuals with full access to a project will receive auto-notifications when an action has been taken regarding the project. [It is recommended that only project owners with day to day responsibility be granted full access.]



Selected users will be notified automatically via email that a project has been shared with them. You may also enter comments in the comment box to be included within the email.

Click "Save."

- After you share your project with your team members you need to link their Training and Credentials (T&C). On the Designer page click the "Link / Un-Link Training Records" (blue text in the middle of the page) and select the appropriate T&C for each team member.
- 6. There are required signatures before the package is submitted. The Principal Investigator, Co-Investigators, AND the department chair MUST sign the package before the IRB will accept your submission. The department chair must sign as "Department Head" for IRB purposes. Click the "Sign This Package" button on the left menu. Choose your project role from the drop down menu by clicking the arrow on the box. Then click the "Sign" button. (Package must be shared to acquire department chair signatures.)

Research projects will not be sent for review if required signatures are missing. All submissions will require the approval of the department/division chair or school director, supervisor, or faculty advisor. If the department chair is the faculty advisor or an investigator for the project, the Associate Dean or Dean must sign for the project. Everyone who has to sign off on a project needs an IRBnet account so the project can be shared with them.

7. Click "Submit This Package" button on the left bar. Select "California State University, Los Angeles (Cal State LA)" or type all or part of University name "Search for Organization" box. Select "California State University, Los Angeles". Then click the "Continue" button. In the Submission Type drop-down menu, select "New Project" and click "Submit."

Once a decision letter is formulated, an automatic email will be sent to everyone who has full access and the letter and any supporting documents can be printed. (See **Section IV**)

Did you submit an incomplete package?

The project package is <u>locked</u> upon submission. If you need access to this package for additions or revisions <u>prior</u> to review, please contact your IRB analyst:

Claire Riner, M.P.A., CIP, ECoP, Research Support Services Coordinator, <u>irb@calstatela.edu</u> **Phone: 323-343-3793** 

#### **HELPFUL TIPS!**



- When submissions are incomplete you will receive an IRBNet Project Mail message directing you to the Request for Information letter, which lists what is missing or changes that need to be made. Please follow the instructions to complete your submission.
- The My Projects screen can be found by clicking on "My Projects" on the left bar. This will show you the list of studies to which you have access.
- Clicking on the Title of any project will take you to the "Project Overview" for the selected project which contains project details. On the Project Overview page you may click on "Review Details" to see more about the status of your project, including Board Decision documents. (See <u>Section IV</u>)
- Projects which have not been "**Submitted**" to a committee are labeled "**Work in Progress**" in the Status Column.
- An automatic email message will be sent to everyone with full access to the project when someone has signed the submission.
- To Un-Share a project with someone, follow the same steps in "Share This Project" and click on "No Access"
- You may click "Send Project Mail" on the left bar to send communications to your Project Team or Committee Contacts for any submitted package. Your message will also be automatically posted to "Messages and Alerts." Messages sent from this page become part of the project record and can be viewed by the Project Team, other users granted access, committee members and committee administrators.
- Make sure to "Mark Revisions Complete" using the Designer Page once you are done with your revisions. This will notify the analyst/reviewer that you are finished making changes and it is their turn to look at your application again.
- Print and keep handy all INSTRUCTIONAL documents found in the IRBNet document library.



: Step-by-step instructional videos and pdf slide presentations are available at <u>www.irbnetresources.org/tresources/training.html</u> To access, use the following log-in information: user name: calstatela password: training

#### Section III

#### Instructions for Submitting a Subsequent Package in a Project (Modifications, Continuations, Renewals, etc.)

etc. for an open or ongoing project that was not submitted through IRBNet (i.e. prior to June 29. 2015). the original approved proposal must be uploaded into IRBNet as a supporting document for the renewal, modification, continuation, etc.

Use these instructions for the following submission types (for projects that were originally submitted through IRBNet:

- a) Modifications/Amendments for an approved study.
- b) Continuing reviews for an approved study.
- 1. Log-in to <u>www.irbnet.org.</u> This will take you to the "**My Projects**" page. This is where all of the projects that you have access to will be housed.
- 2. Click on the **Title** of the project that you would like to amend, renew, etc. (If the project is not listed on your My Projects page then you should contact your committee administrator.) Then click on "**Project History**".
- 3. Create a new project if the approved project was not submitted on IRBNet originally.
- 4. Click on the "**Create New Package**" button to add an additional package to your IRBNet project. (The additional package will have a new number, such as 116011-2).

You will now be in the "**Designer**" Page where you can work on the Smart Form "**Wizard**" and documents for the new package.

# *IMPORTANT:* As of December 12, 2018, Cal State LA IRB is using the IRBNet Wizard for submission of the application form. Applications submitted in the Microsoft Word document format will not be accepted.

On the **Designer Page**, click on the **"Start a Wizard"** tab to start the fillable smart form "Wizard" application appropriate to your new package. Follow the instructions on the pages that follow. To view the Wizard application as a PDF, click on "Preview" on the lower left. Your Wizard is complete when you see the page that says "Application Form Complete" with a checklist of required follow-up items. **Do not submit your package on IRBNet until all follow-up items are completed.** 

Supporting documents can be uploaded to the new package via two methods, described below:

a) You may attach (add) a new document (Use this option when the document you are adding is <u>NOT</u> a revised or updated version of an existing project document):

Select "California State University, Los Angeles (Cal State LA)" from the "Select

**a Library**" drop down menu. Select a document and then click "**Download**." Open and/or save to your computer file or desktop. Complete the form(s) required. Repeat this step for additional forms/documents.

## All required forms are to be downloaded, completed and saved to your computer. Completed forms, proposal and other documents should then be "UPLOADED" into your IRBNet package.

To attach your documents, click "**Add New Document**" from the Designer Page, select the appropriate Document Type, add a description of the document (the document description should be a helpful description). Click "**Browse**" to look for the document where it is saved on your computer. Click on the document, click "**open**" so the file is moved into the "**file**" field. Then click "**Attach**."

### b) You may revise a previously submitted document (Use this option when you want to add or create a new version of an existing project document):

At the bottom of the "**Designer**" page, first download the document by clicking on the Document Type or the paper icon to the right.

Make necessary changes and save the revised document to your computer file or desktop.

Click on the **"pencil**" icon of the document. Click **"Browse**" to look for the document in your computer file or desktop.

Click on the document and click "**open**" so the file is moved into the "**file**" field. Make appropriate changes in the Document Type and Description Fields.

Click the "**Update**" button. When you click Update, the revised document will appear in the "**New and Revised Documents in this Package**" Section of the Designer Page.

All versions of the document may be viewed by clicking on the stack of paper icons (Revision History).

5. You may Share this project with your research team. Click the "**Share this Project**" button on the left bar, click the blue "**Share**" link to grant access to this project.

Select "California State University, Los Angeles, Cal State LA" from the organization box. Click "**Select Organization**" and search for registered users with whom you'd like to share this project (e.g. co-investigators, research assistants, faculty advisor, department chair, collaborative researcher from another institution, etc.)

**Read**: User may only view project documents, recommended for department chairs, team members.

Write: User may add/delete/edit project documents, collaborate with other users, add their

signatures; but cannot grant access to other users, submit the project or perform any other administrative functions.

**Full**: User may perform all functions without restrictions, add/edit/delete project documents, grant access to other users, and submit the project. Individuals with full access to a project will receive auto-notifications when an action has been taken regarding the project. [It is recommended that only project owners with day to day responsibility be granted full access.

Selected users will be notified automatically via email that a project has been shared with them. You may also enter comments in the comment box to be included within the email.

Click "Save."

Note: To "Share" your project with someone, they must be registered with IRBNet.

6. There are required signatures before the package is submitted. The Principal Investigator, Co-Investigators, AND the department chair MUST sign the package before the IRB will accept your submission. The department chair must sign as "Department Head" for IRB purposes. Click the "Sign This Package" button on the left menu. Choose your project role from the drop down menu by clicking the arrow on the box. Then click the "Sign" button. (Package must be shared to acquire department chair signatures.)



Research packages will not be scheduled for review if required signatures are missing. All student submissions will require the approval of the faculty advisor.

7. Click "Submit This Package" button on the left bar. Select "California State University, Los Angeles" or type all or part of the university name in the "Search for Organization" box. Select "California State University, Los Angeles, Cal State LA". Then click the "Continue" button. In the Submission Type drop-down menu, select the appropriate Submission Type (e.g. Response/Follow-up, Revision, Modification/Amendment, etc.) and click "Submit."

The project package is <u>locked</u> upon submission. If you need access to this package for additions or revisions <u>prior</u> to board review, please contact your IRB analyst:

Claire Riner, M.P.A.,CIP, ECoP, Research Support Services Coordinator, <u>irb@calstatela.edu</u> Phone: 323-343-3793

#### Section IV

#### Instructions For Locating Your Committee Decision Letters and Documents

- 1 Log-in to <u>www.irbnet.org</u>. This will take you to the "My Projects" page.
- 2 Click on the Title of the project for which you would like to retrieve the decision letter or documents.
- 3 Click on "**Project History**" and then click the Package Type of the specific submission.
- 4 Click on "**Review Details**" at the top right of the screen. The decision letters or documents are located in the "Board Documents" section at the bottom of the page.
- 5 Click on the Document Type or the paper icon to open and read/save.

Credit to Renee Siegel from the University of Sciences in Philadelphia for initial format.