

CalPROTECTS USER GUIDE

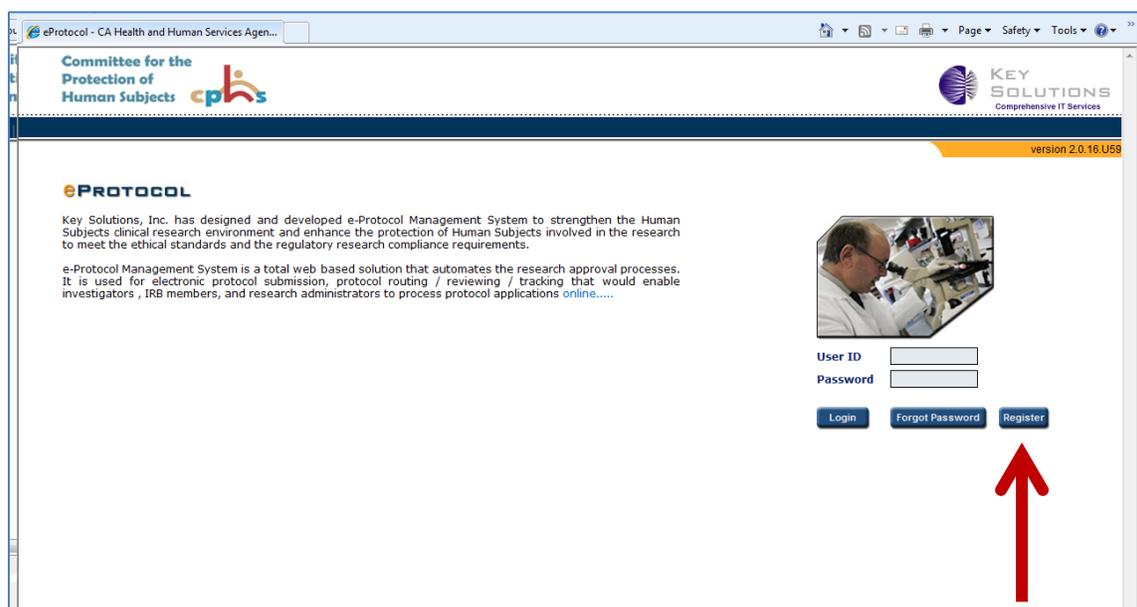
Helpful Tips

- In order for the CalPROTECTS system to work properly, you must **enable pop-ups** on your Web browser.
- **DO NOT** use the Web browser's back button to navigate the system; ALWAYS use CalPROTECTS' navigational tools and hyperlinks links.

Registration

Registration is required to submit projects through CalPROTECTS. ***The registration process can take up to three business days*** as the submissions must be reviewed and approved by CPHS staff before you can log into the system. All users who will be working on the project can gain access to the CalPROTECTS system, but are **REQUIRED** to register separately to gain access. Each protocol requires at least two users to be registered to complete a Protocol or Request for Determination of Research: the Principal Investigator (PI) and Responsible Official (RO). If there are multiple PIs on the project, they must also be registered separately. Additionally, if you require research and administrative staff the ability to work on the protocol, they must also register individually. Each registered person is required to complete their own registration. It is not permissible for a coworker or staff members to register.

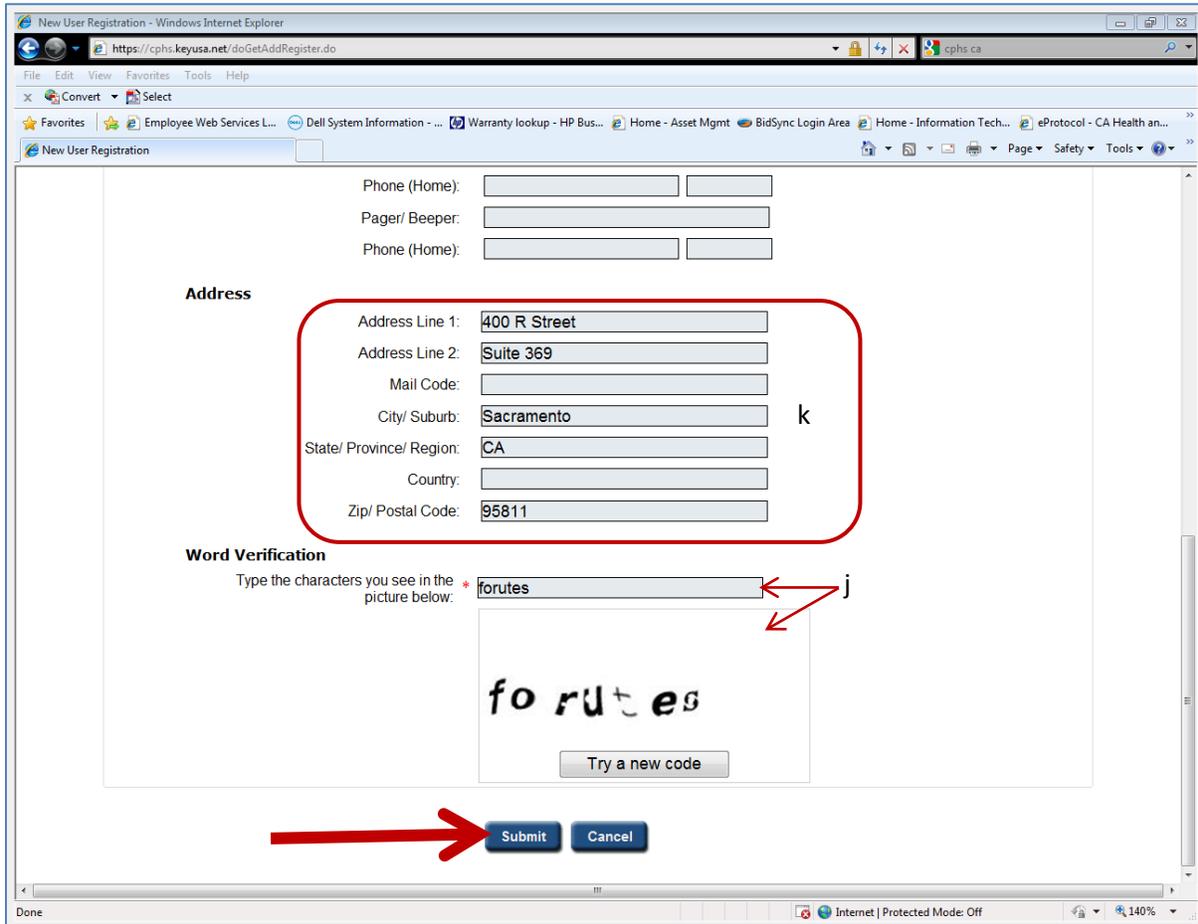
1. To register, visit our website at: <https://cphs.keyusa.net/>. Then, click on the "Register" button, as (see below).



- When the *New User Registration* screen appears, enter the information as indicated. *CPHS strongly encourages users to use their permanent e-mail address as their User ID*. This will assist you to remember the User ID during future submissions.

- Enter your registration information. **NOTE:** Not all fields are required for registration.
 - First and Last Name:* Enter your full, legal first and last name.
 - Salutation:* Enter the appropriate salutation (e.g., Dr., Mr., Mrs.)
 - User ID:* Use an e-mail address or other identification that is easily identified by your staff.
 - Job Title/Designation:* Enter your job title at the institution where you will be conducting the research.
 - Degree:* What degree(s) you possess, you can be general (PhD) or specific (PhD in Behavioral Sciences).
 - Department (if applicable):* Select your department if you are able to locate it on our list.
 - Organization (if applicable):* Select your organization if you are able to locate it on our list.
 - E-mail:* Enter the e-mail address where you would receive all communication associated with this project. Example: e-mail address at the institution where the research is conducted.
 - Phone:* List your full phone number including area code. (Only numeric values will be accepted). If you have an extension, it may be entered in the second field (where you see 000 entered above).

- j. **Fax:** Enter a valid fax number where documents can be sent, if needed, at your institution. Use dashes between the area code, prefix and number (e.g., 000-000-0000).
- k. **Complete Address:** List your complete address (see below). You do not need to designate a country if you are located in the United States.
- l. **Word Verification:** Be sure to carefully enter the word verification (see below). If you are not confident with the letters, click the “Try a new code” button.



4. Once the page is completed, click “Submit” to complete your registration. You will be redirected to a browser page that includes the following message:

“Thank you for requesting New User Registration with CalPROTECTS. Your login details will be mailed to you after your application is reviewed by the Administrator and approved.”

5. After you submit your registration request, an automated e-mail is sent to you. If you do not receive an automated e-mail, check your junk mail folder and add an exception for e-mail from cphs-mail@oshpd.ca.gov. Contact your site or network administrator for instructions.

If you do not receive an e-mail confirmation of your registration request, you may have entered your e-mail incorrectly. Contact CPHS at (916) 326-3660 or cphs-main@oshpd.ca.gov and

request that CPHS staff change your email address. You should provide CPHS with the following information in messages or e-mail correspondence: first and last name, phone number, and corrected e-mail address.

6. Once CPHS staff completes their review and verification of your registration request, you will receive two e-mails:
 - The first e-mail will contain a confirmation that you have been added to the CalPROTECTS system. This e-mail will also include your login ID. **Keep a copy of this e-mail for future reference.**
 - The second e-mail will contain a temporary password.
7. Log into the CalPROTECTS system with your temporary password. You will be prompted to enter a new password and select a security question (see below). **Note! password ID is case sensitive.**

The screenshot shows a web browser window titled "ChangePassword - Windows Internet Explorer" with the URL "https://cphs-uat.keyusa.net/userLogin.do". The page features logos for "ePROTOCOL" and "KEY SOLUTIONS". The main content is a "Change Password" form with a "Submit" button. The form fields are as follows:

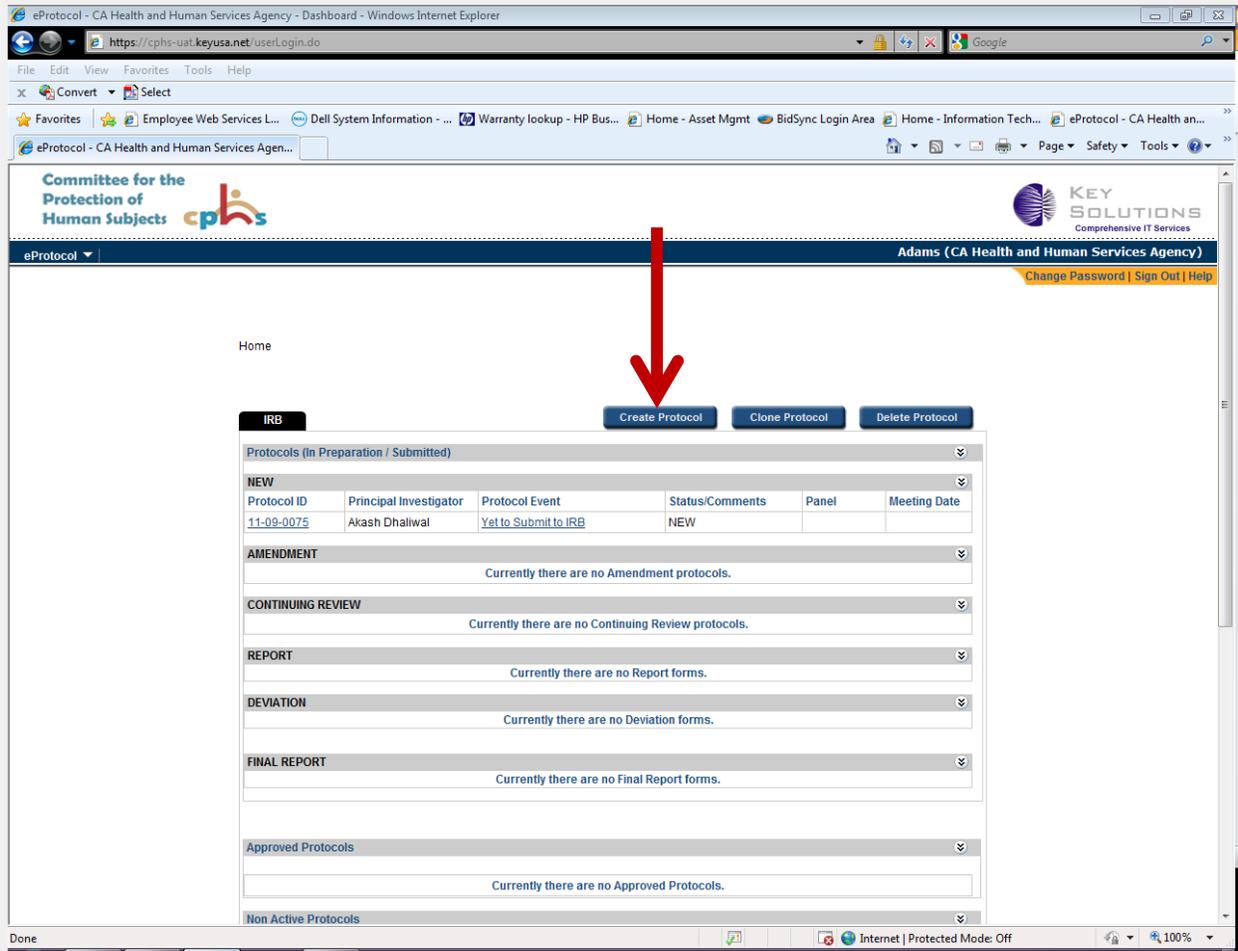
Change Password	
UserID	andrea.adams@oshpd.ca.gov
New Password*
Confirm New Password*
Hint Question*	Who was your childhood hero?
Answer*	Superman

8. Congratulations! Your registration is complete.

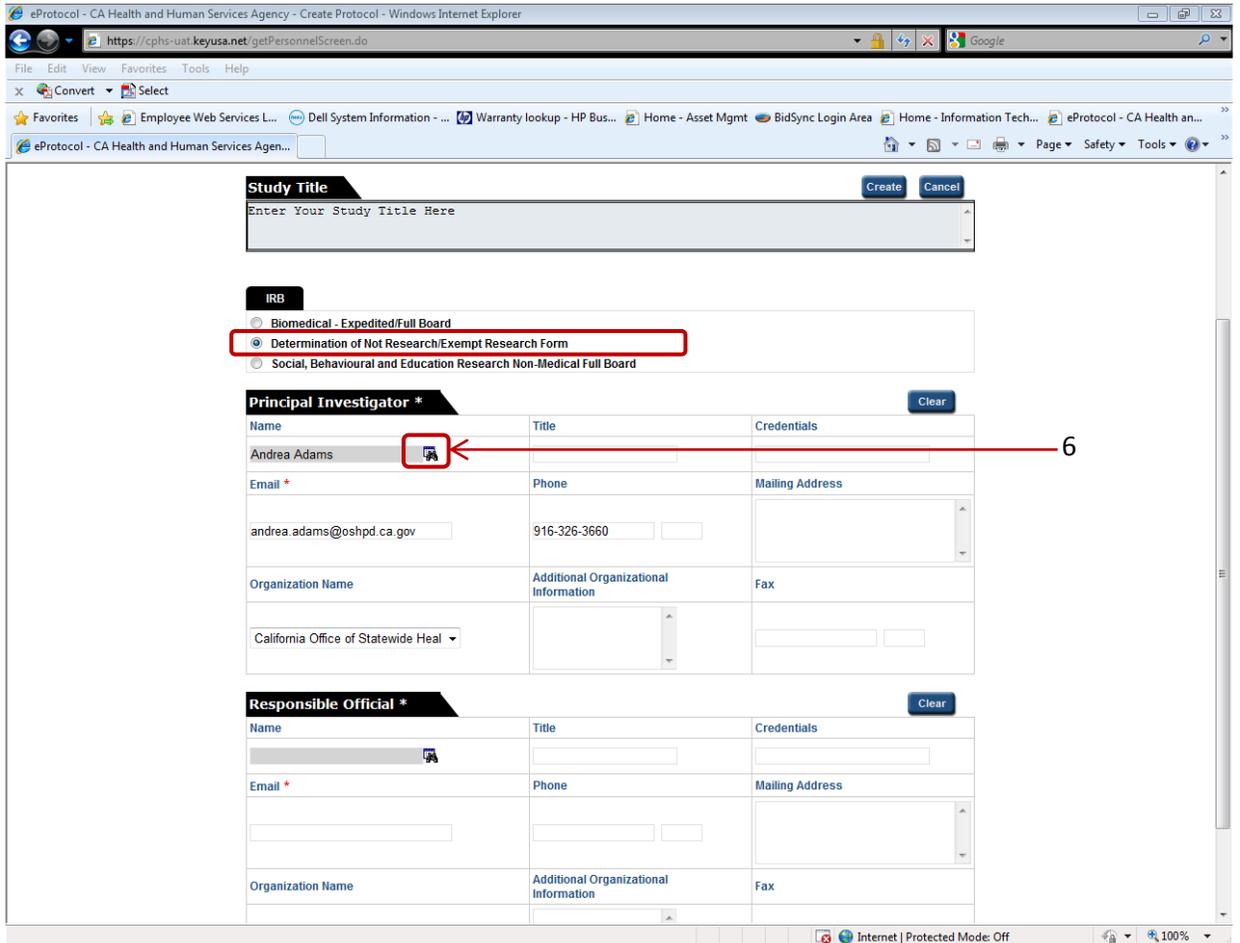
Determination of Whether Project Requires CPHS Approval

If your project requires CPHS approval, refer to the CPHS Instructions for Researchers at www.oshpd.ca.gov/Boards/CPHS/researchers.html. After reviewing this information, you may need to submit a request for Determination of Not Research/Exempt Research by following the following steps:

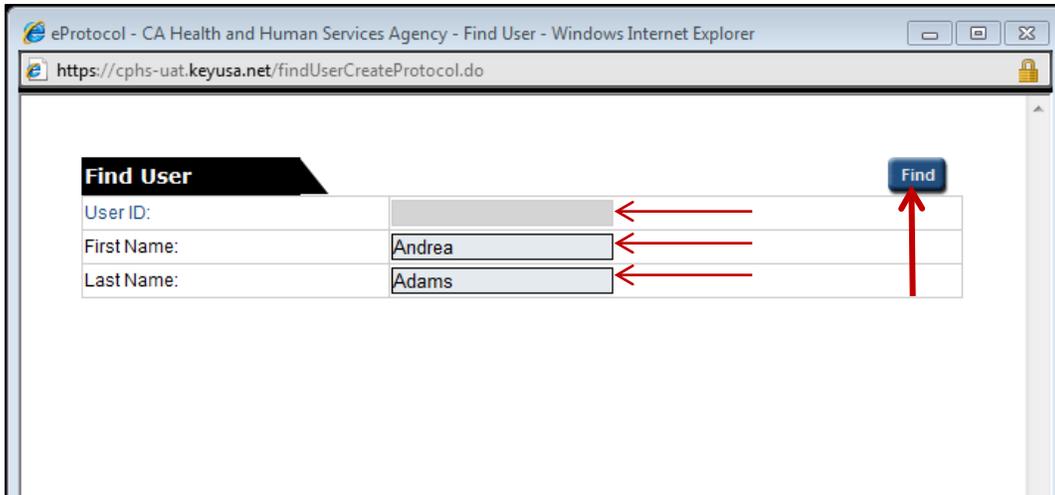
- I. Both the Principal Investigator (PI) and Responsible Official (RO) for the project must be registered and have obtained a user ID and password for the CalPROTECTS system. For further information on how to register and initial log in procedures, please see a previous section titled *Registration*.
- II. Log into the CalPROTECTS system by visiting <https://cphs.keyusa.net/> and enter the user ID and password that you received when you registered. You will be directed to a homepage shown below. Click on the “Create Protocol” button (see below).



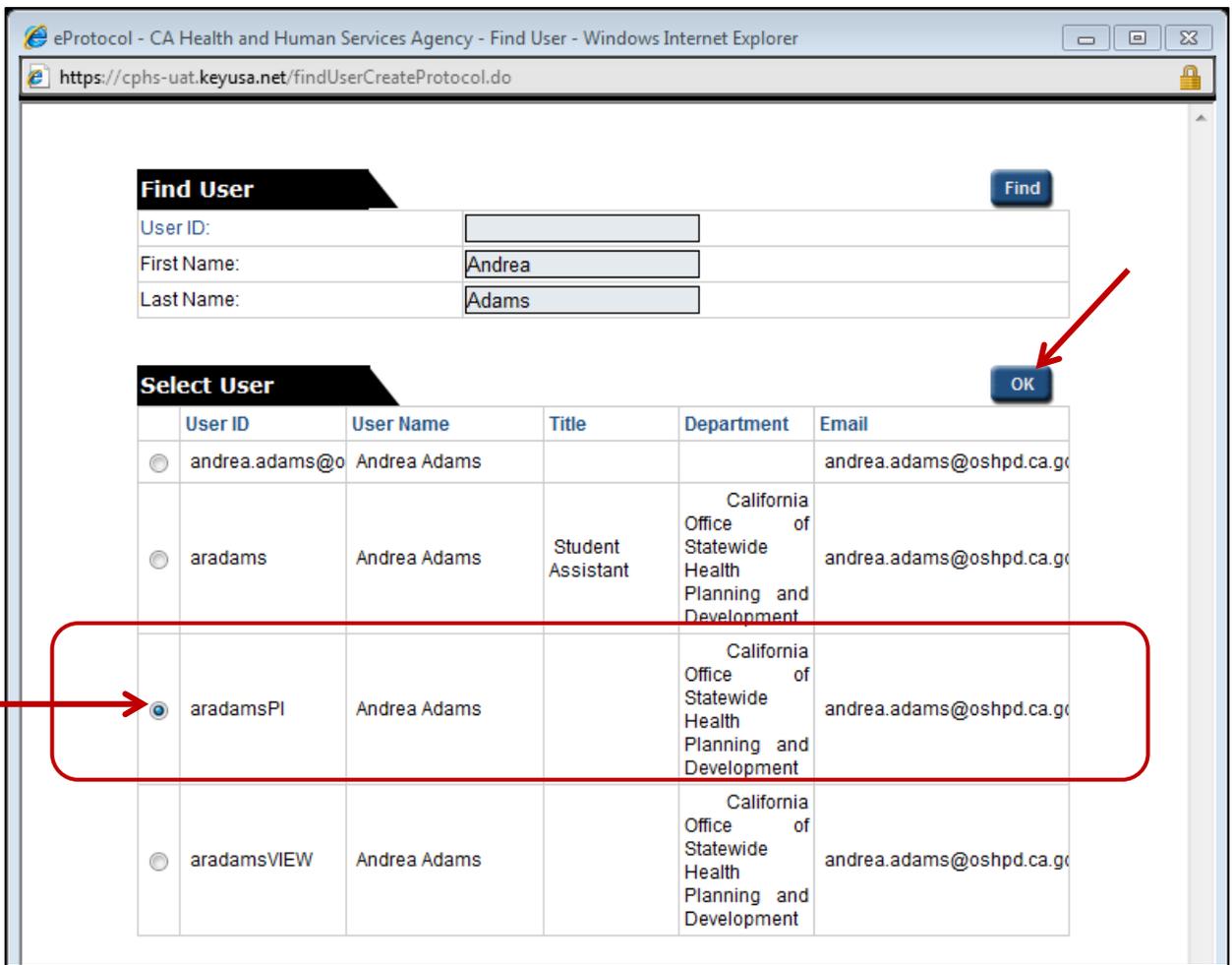
- III. You will be directed to the Create Protocol page.
 1. *Study Title box*: Complete the study title into the greyed out box with the actual title of the study to which you are applying for a determination.
 2. *IRB box*: Select the radio button (the small round button) next to the text “Determination of Not Research/Exempt Research” (see below).



3. *Principal Investigator*: If the person COMPLETING the project on CalPROTECTS is the Principal Investigator (PI), the Principal Investigator information will populate and no action is necessary. However, if the information is displaying incorrectly or if someone other than the PI is INPUTTING THE PROJECT, then click on the search button indicated in the picture below.
4. *Searching for a PI*: After clicking the search button, a pop-up window appears (see next page). In order to search for a PI, enter their User ID if it is known. If the User ID is unknown, enter the First Name or Last Name. Once you have entered this information, click on the “Find” button.

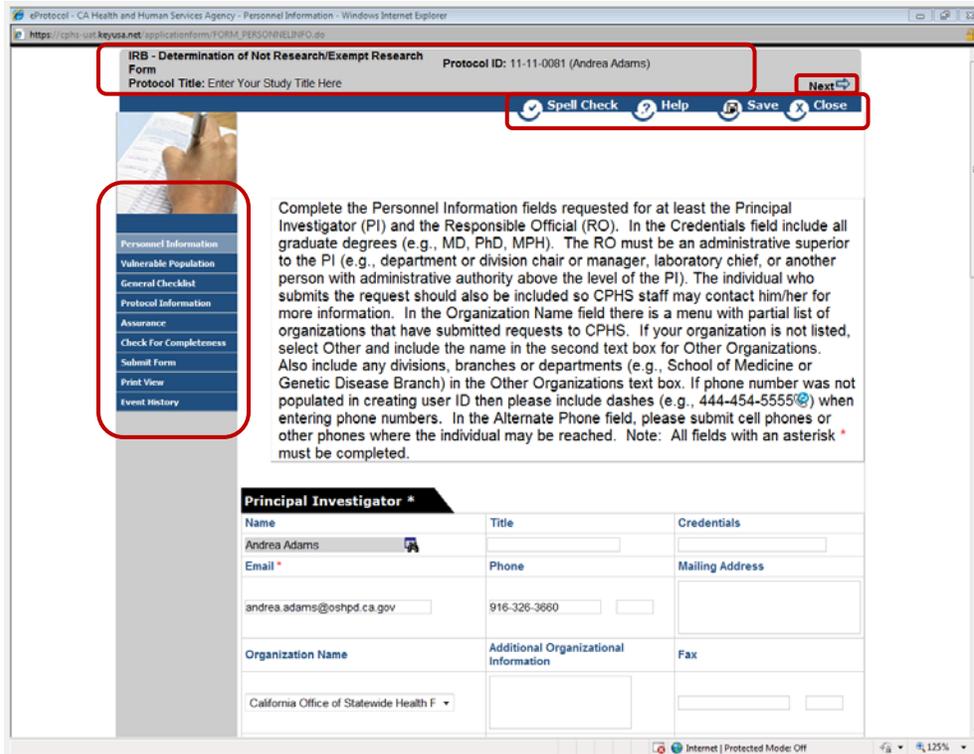


5. *Selecting a User:* Once you have selected the “Find” button, a list of registered users will appear (see below). The list may contain a variety of names. Find the correct user by the information provided (User ID, User’s Name, Title, Department, and E-mail) and select the radio button next to the name of the PI. Then select the “OK” button (see below).



6. *Responsible Official*: A responsible official must be named in the protocol. Repeat steps 3-5 with the content under the Responsible Official heading to select a Responsible Official.
7. *Create Protocol*: Once a Responsible Official has been selected, select the “Create” button at the bottom of the page.

IV. Once you have a protocol, another pop-up window will appear (see below). Complete the protocol information for each of the sections listed on the left navigation bar (e.g., Personnel Information, Vulnerable Population). At the top of the protocol, the type of protocol, Protocol Title, and Protocol ID will appear. It is important to note the “Spell Check,” “Help,” “Save,” “Close,” and “Next” buttons.



1. *Personnel Information*: In this section enter additional information for all personnel associated with the project.
 - a. **Note** as described in the Registration section above, every member of the personnel staff listed on the project must be registered before they can be added to the project.
 - b. If there is supporting personnel, their information is entered in this section at this time under one or more of the following headings: Co-Principal Investigator, Administrative Contact, and Other contact. For each individual you wish to add, select the search button and follow instructions in the previous section.
 - c. Once all personnel information has been entered and verified click on the “Next” button (there is a “Next” button at both the top and bottom of each page).
2. *Vulnerable Population*: For Determination of Research, Vulnerable Population is not needed. In order to proceed with submission, select “Not Applicable,” then proceed to General Checklist.
3. *General Checklist*: Indicate whether you are requesting Not Research Determination, Exempt Research Determination, or both (see below). Also, select the type of institution you are

represent (e.g., Government, For-Profit, Nonprofit).

The screenshot shows a web application interface with a blue header bar containing 'Spell Check', 'Help', 'Save', and 'Close' buttons. On the left is a vertical navigation menu with items: Personnel Information, Vulnerable Population, General Checklist (highlighted), Protocol Information, Assurance, Check For Completeness, Submit Form, Print View, and Event History. The main content area features a text box with a note: 'Note that a request may be made for CPHS to determine if the project is considered research. Also, a request may be made for CPHS to decide if a research project may be exempt from CPHS review. Both determinations may be requested at the same time. If either determination is made, the project is not required to be approved or renewed by CPHS. After the initial determination, if the project does change to a point that it may be research or not be exempt research, another request must be submitted to CPHS for a determination prior to implementing the changes. If your institution is classified as a for-profit, CPHS may not be able to review your project unless you are able to affiliate with a qualifying organization'. Below this is a 'General Checklist' form with two sections: 'Request Type' and 'Institution Type'. Each section has a header and three radio button options.

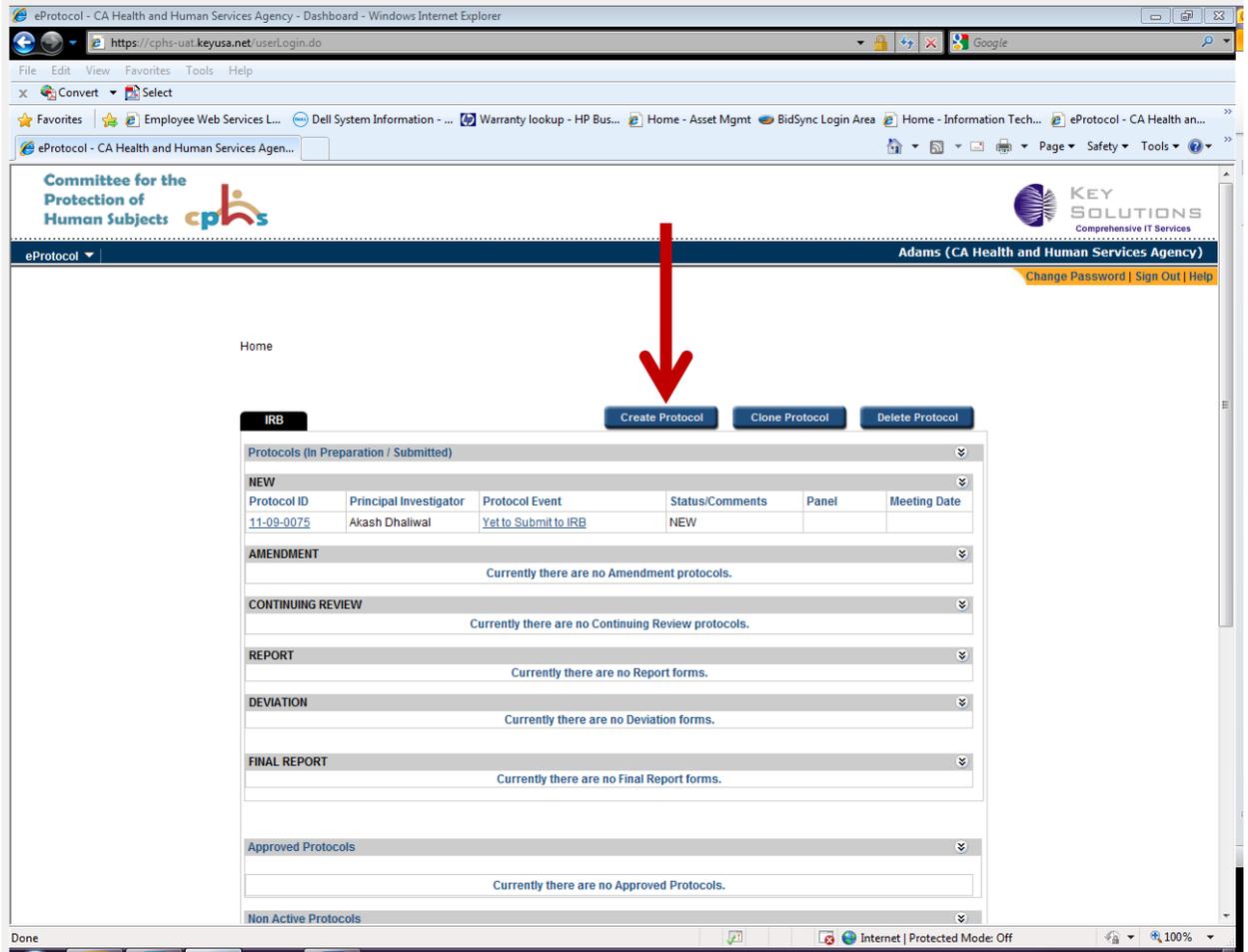
General Checklist	
Request Type	
Indicate if you are requesting:	
<input type="checkbox"/>	Not Research Determination
<input type="checkbox"/>	Exempt Research Determination
<input type="checkbox"/>	Not Research and Exempt Research Determination
Institution Type	
<input type="checkbox"/>	Governmental
<input type="checkbox"/>	For-Profit
<input type="checkbox"/>	Nonprofit

4. *Protocol Information*: Once you begin inputting the details on your study, you will be asked questions about the nature of your project and why your project is either not research, exempt research or both.

New Protocols

Once you have registered and logged into the CalPROTECTS system, you may begin working on a protocol.

1. To create a new protocol, click on the "Create Protocol" button near the top of the login screen (see below).



2. You can Clone protocols to create a new project that is very similar to an existing protocol.

3. Select “Social, Behavioral and Education Research Non-Medical Full Board” after entering the title of your project.

The screenshot shows a web browser window with the URL <https://cphs.keyusa.net/getPersonnelScreen.do>. The page title is "eProtocol - CA Health and Safety". The main heading is "Create Protocol".

Study Title section: A large text input field with "Create" and "Cancel" buttons to its right.

IRB section: Two radio button options are shown. The first is "Determination of Not Research / Exempt Research". The second, "Social, Behavioural and Education Research Non-Medical Full Board", is selected and highlighted with a red arrow pointing to it.

Principal Investigator * section: A "Clear" button is to the right. The form is divided into three columns: Name, Title, and Credentials. The Name field contains "Akash Dhaliwal". The Title field contains "Student Assistant". The Credentials field is empty. Below this are fields for Email, Phone, and Fax. The Email field contains "CPHS-Mail@oshpd.ca.gov". The Phone field contains "916-326-3663". The Fax field is empty. Below these are fields for Organization Name, Additional Organizational Information, and Mailing Address. The Organization Name field has a dropdown menu with "Select One" selected. The Additional Organizational Information and Mailing Address fields are empty text areas.

Co-Principal Investigator section: A "Clear" button is to the right. The form is divided into three columns: Name, Title, and Credentials. The Name field is empty. The Title field is empty. The Credentials field is empty. Below this are fields for Email, Phone, and Fax. The Email field is empty. The Phone field is empty. The Fax field is empty. Below these are fields for Organization Name, Additional Organizational Information, and Mailing Address. The Organization Name field has a dropdown menu with "Select One" selected. The Additional Organizational Information and Mailing Address fields are empty text areas.

Administrative Contact section: A "Clear" button is to the right. The form is divided into three columns: Name, Title, and Credentials. The Name field is empty. The Title field is empty. The Credentials field is empty. Below this are fields for Email, Phone, and Fax. The Email field is empty. The Phone field is empty. The Fax field is empty.

4. Ensure all project personnel have registered in order to properly complete the following sections.

- When selecting a user for each role, click on the binoculars to the right of each name

Home » Create Protocol

Study Title Create Cancel

IRB

Determination of Not Research / Exempt Research
 Social, Behavioural and Education Research Non-Medical Full Board

Principal Investigator * Clear

Name	Title	Credentials
Akash Dhaliwal 	Student Assistant	
Email *	Phone	Fax
CPHS-Mail@oshpd.ca.gov	916-326-3663	
Organization Name	Additional Organizational Information	Mailing Address
Select One		

Co-Principal Investigator Clear

Name	Title	Credentials
		
Email *	Phone	Fax
Organization Name	Additional Organizational Information	Mailing Address
Select One		

Administrative Contact Clear

Name	Title	Credentials
		
Email *	Phone	Fax

and a pop-up will appear enabling you to search for the correct user account to tie to the protocol. Once the correct person has been found, select the user account and click 'OK.'

eProtocol - CA Health and Human Services Agency - Find User - Google Chrome

https://cphs.keyusa.net/findUserCreateProtocol.do

Find User Find

User ID:

First Name:

Last Name:

Select User

	User ID	User Name	Title	Department	Email
<input checked="" type="radio"/>	adhaliwal	Akash Dhaliwal	Student Assistant		CPHS-Mail@oshpd.ca.gov

OK

- a. Note the two required personnel, denoted by an asterisk, are Principal Investigator (PI) and Responsible Official (RO). The RO can be a department head or organization leader, any official overseeing the project.
6. Once all applicable personnel are entered, select the 'Create' option to begin working on your protocol.
7. Your protocol will appear at the top of your dashboard page. Select the link to the new protocol ID to begin updating it. You will be given the option to View or Edit your protocol when the protocol ID appears on the website.. Once a protocol is submitted to CPHS, only the View mode will be available.

The screenshot shows the 'eProtocol - CA Health and Human Services' interface. At the top, there are logos for the 'Committee for the Protection of Human Subjects cphs' and 'KEY SOLUTIONS Comprehensive IT Services'. The user is logged in as 'Dhaliwal (CA Health and Human Services Agency) - Investigator'. A notification message in a red box states: '12-03-0014 protocol has been created. Please click on Protocol ID to open Protocol in View or Edit mode.' Below this, there are buttons for 'Create Protocol', 'Clone Protocol', and 'Delete Protocol'. A table titled 'Protocols (In Preparation / Submitted)' lists several protocols. The first row, '12-03-0014', is highlighted, and a red arrow points from the notification message to this row. The table has columns for Protocol ID, Principal Investigator, Protocol Event, Status/Comments, Panel, and Meeting Date. Below the table are sections for 'AMENDMENT', 'CONTINUING REVIEW', 'REPORT', 'DEVIATION', and 'FINAL REPORT', each with a message indicating no forms are currently available. At the bottom, there are sections for 'Approved Protocols' and 'Non Active Protocols', also with messages indicating no protocols are currently available.

Protocol ID	Principal Investigator	Protocol Event	Status/Comments	Panel	Meeting Date
12-03-0014	Akash Dhaliwal	Yet to Submit to IRB	NEW		
12-01-0007	Lisa Prefach	SUBMITTED TO IRB	SUBMITTED	CPHS	
12-01-0005	Lisa Prefach	SUBMITTED TO IRB	SUBMITTED	CPHS	
12-01-0004	Megan Wright	SUBMITTED TO IRB	SUBMITTED	CPHS	
12-01-0003	Lisa Prefach	SUBMITTED TO IRB	SUBMITTED	CPHS	

8. Once in the protocol confirm that all of the contact information is accurate and select 'Next.'
 - a. The protocol can be navigated by either selecting the 'Next' or 'Previous' arrows, or by selecting different sections from the left-hand column.

The screenshot shows a web browser window with the URL https://cphs.keyusa.net/applicationform/FORM_PERSONNELINFO.do. The page title is "eProtocol - CA Health and Human Services Agency - Personnel Information - Google Chrome". The main content area displays the "Principal Investigator" form for Protocol ID: 12-03-0014 (Akash Dhaliwal). The form includes fields for Name, Title, Credentials, Email, Phone, Fax, Organization Name, Additional Organizational Information, and Mailing Address. A red arrow points from the "Next" button at the top right to the "Name" field of the Principal Investigator section.

Principal Investigator		
Name	Title	Credentials
Akash Dhaliwal	Student Assistant	
Email *	Phone	Fax
CPHS-Mail@oshpd.ca.gov	916-326-3663	
Organization Name	Additional Organizational Information	Mailing Address
Select One		
Alternate Phone		
Curriculum Vitae	View CV	
Training data is not currently needed.		

Co-Principal Investigator		
Name	Title	Credentials
Email *	Phone	Fax
Organization Name	Additional Organizational Information	Mailing Address
Select One		
Alternate Phone		
Curriculum Vitae	View CV	
Training data is not currently needed.		

Administrative Contact		
Name	Title	Credentials
Email *	Phone	Fax
Organization Name	Additional Organizational Information	Mailing Address
Select One		
Alternate Phone		
Curriculum Vitae	View CV	
Training data is not currently needed.		

9. Enter your 'Vulnerable Population' and 'Study Location' information as it applies to your project. If you have selected one or more of the 'Vulnerable Populations,' be sure to include the corresponding checklist form in the Attachments section (see [Instructions for Researchers](#) for more information). Continue on to the General Checklist. This is the section of the protocol process which will allow you to indicate your project type. Once you select your project type, all other options will be greyed out and you can move on to the next section.

eProtocol - CA Health and Human Services Agency - General Checklist - Google Chrome
 https://cphs.keyusa.net/applicationform/FORM_PERSONNELINFO.do

IRB - Social, Behavioural and Education Research Non-Medical Full Board
 Protocol ID: 12-03-0014 (Akash Dhaliwal)
 Protocol Title: User Guide Protocol

← Previous Next →
 ✓ Spell Check ? Help Save X Close



General Checklist

Project Type :

Common Rule

Information Practices Act

Death-Data Only

Select All That Apply :

[International Research](#)

[Cooperating Institution\(s\)](#)

Human blood, cells, tissues, or body fluids (tissues)

Subjects will be compensated for participation

Minimal risk

[Deception](#)

[Waiver of written consent](#)

[Waiver of consent](#)

Behavioral observation

Interview

Study of existing data

Survey/questionnaire

HIPAA

Waiver or alteration of HIPAA

Grant funded

Spanish translations

Other language translations

Adverse event/Unanticipated Problem Report

← Previous Next →

- a. Note your left-hand column has a few more options after selecting the project type which you can see below.

10. If the project is funded, t 'Add' the information or select 'None.'
- a. If you select 'None,' the option to add funding information will disappear.

vices Agency - Funding - Google Chrome

m/FORM_PERSONNELINFO.do

IRB - Social, Behavioural and Education Research Non-Medical Full Board Protocol ID: 12-03-0014 (Akash Dhaliwal)
Protocol Title: User Guide Protocol

← Previous Next →

✓ Spell Check ? Help Save X Close



Funding Checklist

None

Funding Add

Please click on Add to add Funding

← Previous Next →

11. Once you begin inputting in the protocol information you will be asked a series of questions about the nature of your project. Fill out the information as completely include the **“Original Protocol Number”** for projects approved prior to April 2012.

The screenshot shows a web browser window with the URL https://cphs.keyusa.net/applicationform/FORM_PERSONNELINFO.do. The page title is "eProtocol - CA Health and Human Services Agency - Protocol Information - Google Chrome". The form is titled "IRB - Social, Behavioural and Education Research Non-Medical Full Board" and "Protocol ID: 12-03-0014 (Akash Dhaliwal)". The protocol title is "User Guide Protocol".

Navigation buttons include "Previous", "Next", "Spell Check", "Help", "Save", and "Close". A sidebar on the left contains a menu with items: "Personnel Information", "Vulnerable Population Checklist", "Study Location", "General Checklist", "Funding", "Protocol Information", "Obligations", "Check For Completeness", "Submit Form", "Print View", and "Event History".

At the top of the form, there are buttons for "Expedited Paragraph(s)", "1-3", "4", "5", "6,7", "8-10", "11", "12", "13", "14", "15", and "Attachments".

The main form area contains the following fields and sections:

- Original Protocol Number (e.g., 04-04-0001)**: A text input field with a red border.
- Title (Please indicate if the protocol title is different from the proposal title)**: A text input field containing "User Guide Protocol".
- Start Date**: A date input field.
- End Date**: A date input field.
- Complete Sections 1 - 11. Specify N/A as appropriate. Do not leave any sections blank.**
- 1. Purpose of the study**
 - a) Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public. Below this is a large text input area.
 - b) What is the major research question to be addressed in this project? Below this is a text input area.
- 2. Study Procedures**
 - a) Describe all study procedures. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the [Attachment](#) section. Below this is a large text input area.

CalPROTECTS will automatically generate a new project number. This project number is to be used on all future correspondence with CPHS staff and Committee Members.

12. Continue through protocol sections 1-10 and check the appropriate comments under section 11: **Conflict of Interest**. To view the topics for each section, hover your cursor over the pages icons at the top of the screen.

The screenshot shows a web browser window displaying the 'Conflict of Interest' section of a protocol form. The browser address bar shows the URL: https://cphs.keyusa.net/applicationform/FORM_PERSONNELINFO.do. The page title is 'eProtocol - CA Health and Human Services Agency - Protocol Information - Google Chrome'. The form header includes 'IRB - Social, Behavioural and Education Research Non-Medical Full Board' and 'Protocol ID: 12-03-0014 (Akash Dhaliwal)'. The protocol title is 'User Guide Protocol'. Navigation buttons include 'Previous', 'Next', 'Spell Check', 'Help', 'Save', and 'Close'. A 'Expedited Paragraph(s)' navigation bar shows sections 1-3, 4, 5, 6,7, 8-10, 11 (selected), 12, 13, 14, 15, and Attachments. A left sidebar contains a menu with options: Personnel Information, Vulnerable Population Checklist, Study Location, General Checklist, Funding, Protocol Information, Obligations, Check For Completeness, Submit Form, Print View, and Event History. The main content area is titled '11. Conflict of Interest' and contains the following text: 'Describe any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings.' Below this is a list of financial relationships to be disclosed, including ownership of stock, payment of expenses, sale of intellectual property, and receipt of money. A question asks if any study team member has significant financial interests, with 'Yes' and 'No' radio buttons. A list of personnel with financial conflicts of interest is provided, including Akash Dhaliwal and Lisa Prefach. A text box is provided for listing other team members. A final question asks if all members have answered the financial interests question, with 'Yes' and 'No' radio buttons.

13. Continue through sections 12 and 13, adding documents for Informed Consent and Assent, if applicable. Once you have read section 14 and answered all three questions related to HIPAA. If you have answered 'Yes' to any of these questions, then you are able to add HIPAA Background.

The screenshot shows a web browser window titled "eProtocol - CA Health and Human Services Agency - Protocol Information - Google Chrome". The URL is "https://cphs.keyusa.net/applicationform/FORM_PERSONNELINFO.do". The page content includes a navigation menu on the left with items like "Personnel Information", "Vulnerable Population Checklist", "Study Location", "General Checklist", "Funding", "Protocol Information", "Obligations", "Check For Completeness", "Submit Form", "Print View", and "Event History". The main content area is titled "14. Health Insurance Portability Accountability Act (HIPAA)". It contains three questions with "Yes" and "No" radio button options, all of which are selected as "Yes". Below the questions, there is a note: "If you answered 'YES' to any of the questions above, you are subject to HIPAA and must complete a HIPAA authorization or waiver request with your protocol." and a section titled "HIPAA" with a text box: "You can add HIPAA Background only when Yes is selected for one of the questions above." Navigation buttons for "Previous" and "Next" are visible at the top and bottom of the form.

14. Once the protocol has all of the information relevant to the study entered, you can attach all required project documents in the 'Attachment' section.
- These documents can be uploaded in any rendition of Microsoft Word (.doc/.docx) or Adobe (.pdf).

The screenshot shows a web browser window titled "eProtocol - CA Health and Human Services Agency - Attachments - Google Chrome". The URL is "https://cphs.keyusa.net/applicationform/FORM_ATTACHMENTS.do". The page features a "Note: * denotes mandatory field." and a section titled "Attachments" with "Save" and "Cancel" buttons. The form includes three fields: "Document Type *" with a dropdown menu currently set to "Select One"; "Attachment *" with a "Choose File" button and the text "No file chosen"; and "Document Name" with an empty text input field.

- If a specific category of attachment was indicated earlier in the protocol, you must attach that document with the correct **Document Type**. Otherwise, attach documents without explicit categories under "Other supplemental documents"

15. Once the protocol is completed, the PI and RO must review the Obligations boxes.. **Note:Both boxes must be checked.**

The screenshot shows a web browser window with the URL https://cphs.keyusa.net/applicationform/FORM_PERSONNELINFO.do. The page title is "IRB - Social, Behavioural and Education Research Non-Medical Full Board" and the protocol ID is "12-03-0014 (Akash Dhalliwal)". The protocol title is "User Guide Protocol".

The main content area is titled "Obligations (Researcher's Responsibilities)". It contains the following text:

The Principal Investigator is ultimately responsible for the conduct of the project. Obligations of the Principal Investigator include:

Conduct the research involving human subjects as presented in the protocol, including modifications, as approved by the Department and Institutional Review Board. Changes in any aspect of the study (for example project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes (PI will submit the "Amendment/Revision" form);

Provide all subjects a copy of the signed consent form. If applicable. Investigators are required to retain signed consent documents for three (3) years after close of the study;

Submit either the "Protocol Deviation Form" or the "Report Form" to report protocol Deviations/Violations, Unanticipated Problems and Adverse Events that occur in the course of the protocol. Any of these events must be reported to the IRB as soon as possible, but not later than five (5) working days;

Submit the "Continuing Review" Form in order to maintain active status of the approved protocol. The form must be submitted annually at least four (4) weeks prior to expiration, five (5) weeks for protocols that require full review. If the protocol is not renewed before expiration, all activities must cease until the protocol has been re-reviewed;

Certify that all members of the study team have answered the financial interests question and only those individuals listed in section 8 above have disclosed any financial interest related to this study.

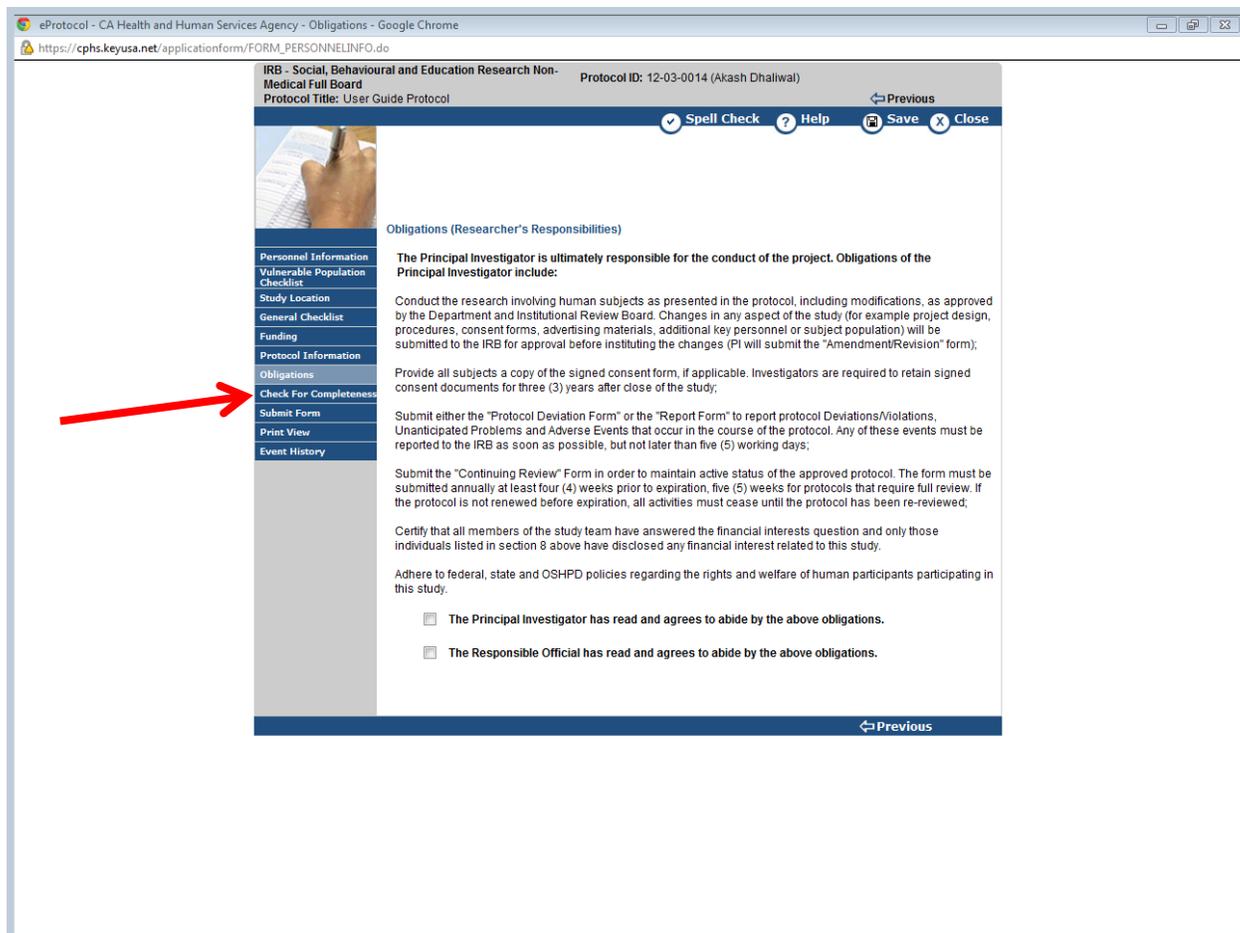
Adhere to federal, state and OSHPD policies regarding the rights and welfare of human participants participating in this study.

There are two checkboxes at the bottom of the page:

- The Principal Investigator has read and agrees to abide by the above obligations.
- The Responsible Official has read and agrees to abide by the above obligations.

A red arrow points to the "Obligations" menu item in the left sidebar.

16. Select **“Check for Completeness”** from the left column and a pop-up will indicate if you are missing any aspect of the protocol. Note, you must have pop-ups enabled for this feature to work successfully.



- a. The most common problem with checking for completeness is accidentally entering something as an attachment under the wrong heading. Ensure that attachments are labeled correctly.
17. After the protocol is complete, **“Submit”** your protocol for CPHS review. Once a protocol is submitted to CPHS it cannot be changed by the researcher . Unless it is returned by CPHS staff or reviewers (CPHS committee members) for amendments (revisions).
 - a. You can check the status of your project periodically on your dashboard (directly after logging in). Note if the reviewers need further clarification on your protocol. They may leave you a Comment on CalPROTECTS which will generate an automated email stating you have received Comments. You should have the ability to log into the system and click on the link under ‘Protocol Event’ to respond to any comments requiring attention.

Continuing Renewal Projects

For the first year of the online system, all projects are required to follow the steps for “New Protocols” above. Note you will be asked for your project’s “Original Protocol Number” . If you enter the “Original Protocol Number” will indicate that your project is a continuing renewal.

If you have any questions or comments, please contact CPHS at 916-326-3660 or by email at cphs-mail@oshpd.ca.gov.

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