

INSTRUCTIONS FOR RESEARCHERS



California Health and Human Services Agency

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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I. Introduction

a. CPHS:

CPHS is the institutional review board (IRB) for all of the departments under the California Health and Human Services Agency (CHHSA). CPHS is also the IRB required to review all research-related requests for state personally identifiable information from the University of California and non-profit educational institutions. CPHS must approve research requests for Death-Data from the California Department of Public Health.

The 13 CPHS members are volunteers who are appointed by the Secretary of the California Health and Human Services Agency (CHHSA). Members are chosen for their expertise in differing fields of research and abilities to represent and understand the needs of diverse research subjects, particularly those who may be vulnerable due to factors such as age, socio-economic status, ethnicity, or medical conditions. Detailed information about current CPHS members is available on the [CPHS Members page](#).

For assistance, you may contact CPHS staff by email at: CPHS-Mail@oshpd.ca.gov or call (916) 326-3660. Our business hours are Monday through Friday, 8:00 a.m. through 5:00 p.m. (Pacific Standard Time). If you need assistance outside of these hours, you may send us an email or leave a voicemail. CPHS staff will contact you.

b. CalProtects:

CPHS has implemented an electronic protocol submission and approval system, California PROTOCOL Electronic Communication and Tracking System (CalProtects)

[CalProtects](#) can be accessed through an internet browser under the following address:

<https://cphs.keyusa.net/>

The system allows researchers to:

- ❖ Submit [requests for determination](#) and [new projects for review](#)
- ❖ File for [amendments](#) and [continuing reviews](#) for existing CPHS projects
- ❖ [Notify CPHS staff](#) of breaches of security, adverse events, protocol deviations, and unanticipated problems
- ❖ [Complete](#) and [withdraw](#) active CPHS projects

II. Access to CalProtects

a. Registration:

To access CalProtects, researchers must register for a user account with CalProtects. CPHS staff reviews all requests for registration and will approve acceptable requests within one business day of request.

All project personnel are required to register individually prior to gaining access to their projects on CalProtects. Each protocol requires a minimum of two registered users – a Principal Investigator (PI) and Responsible Official (RO). If there are multiple PIs, researchers, and/or administrative staff on the project, they must register individually.

STEP-BY-STEP: CalProtects User Account Registration

1. Using a browser, navigate to CalProtects: <https://cphs.keyusa.net/> (Firefox is recommended)
2. Click the “Register” button found on the right hand side of the screen
3. The “New User Registration” page will load, complete accordingly
4. Answer the “Word Verification” at the bottom of the page – click the “Try a new code” button if you need a different image
5. Upon completion, click the “Submit” button at the bottom of the page
6. You will immediately receive an email notification regarding the request
7. Within one business day, you will receive an email notification stating your registration was approved by CPHS staff
8. In a separate email, you will receive a default password for your account – use it once to log in
9. In your initial login, the system will prompt you to create a new password

b. **User Roles:**

There is a maximum of five personnel allowed listed for each protocol. All personnel listed on a protocol have access to view and submit that protocol to CPHS. In addition, all personnel listed on a protocol receive email notifications regarding all activity on that protocol. A Principal Investigator and Responsible Official are **required** to be listed for each protocol. A third Co-PI can be listed as an Other Contact. Personnel listed on approved protocols can be edited via an Amendment ([see page 17](#)) or with a Continuing Review ([see page 16](#)).

Definitions of roles are as follows:

***Principal Investigator (PI):** Directly responsible for the research, hands on with research, main representative of research

****Co-Principal Investigator (Co-PI):** May be equal to PI or assistant to PI

***Responsible Official (RO):** An individual who is above the PI in the line of authority, hands off with research

Administrative Contact: A project representative for CPHS staff to contact for administrative concerns

Other Contact: Additional project representative, administrative contact, or additional investigator

* Required for every protocol

** Required if applicable

III. Application Types

There are two different applications on CalProtects: 1) for requesting a determination of whether a protocol is considered not research or exempt from review; and 2) for projects requesting CPHS approval in order to conduct research.

a. Research Type Definitions:

1. **Research:** According to CFR 46.102, research is defined as a "systematic investigation, including research development, testing and evaluation, designed to develop contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Therefore, this project will require CPHS' review.

If a project falls under any of these parameters, it will require CPHS' review and approval.

2. **Non-research:** An exemption for non-research can be approved based on the following: FDA evaluation, public health practice/surveillance, program evaluation, research utilization.
3. **Exempt Research:** An exemption for research can be approved based on the following: research involving analysis/study of existing data, research involving data which is publically available, no identifiable data is being requested from any of the CHHSA departments.

b. Determination for Exempt Research/Not Research:

If a researcher is unsure whether their project requires CPHS approval, a request for determination must be submitted. CPHS will determine whether the protocol falls under its purview.

Researchers requesting a determination from CPHS must complete and submit a "Determination for Exempt Research/Not Research" application via CalProtects. This application **requires** a Principal Investigator and a Responsible Official be listed on the protocol. A Co-Principal Investigator, Administrative Contact, and an Other Contact are optional.

Determination requests are reviewed on an expedited basis and are assigned to one reviewer. Once a determination is made, all personnel listed on the protocol are notified immediately via email.

STEP-BY-STEP: Determination Request Submission

1. Navigate to CalProtects: <https://cphs.keyusa.net/>
2. Instruct all necessary personnel to register for CalProtects user accounts ([see page 5](#))
3. Either the project's PI or RO must log into own account
4. On the Researcher Dashboard, click the "Create Protocol" button
5. The Create Protocol page will load, complete accordingly (do not click "Create" button until all the questions have been completed)
6. Select the IRB option "Determination for Exempt Research/Not Research"
7. The Principal Investigator field will appear with the current user signed in – if not PI, click the "Clear" button to erase this information and reselect IRB type
8. To add personnel, click the small binoculars image to the right of a role's name field
9. A pop-up window will appear – search for user by User ID or by First and Last Name, then click the "Find" button
10. A list is generated, select the user and click the "OK" button - the selected user's information will appear in the role's fields
11. Upon completion, click the "Create" button found on either top or bottom of the page
12. A new protocol will open in a separate window – complete accordingly.
13. To submit, click the "Submit Form" button on the left hand side of protocol
14. The protocol can be found under the "New" section header on the "Researcher Dashboard"
15. Check email daily for return notes, comments, or approval notifications regarding your protocol

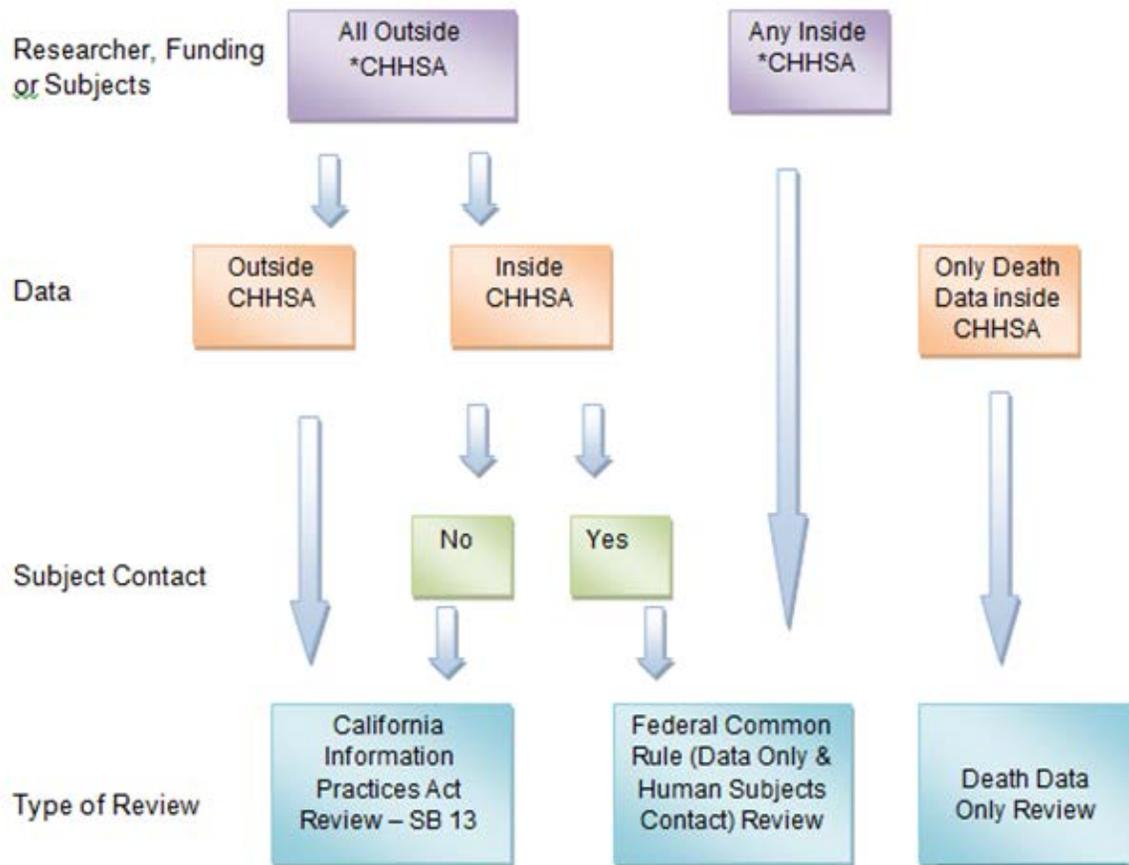
c. Request for CPHS Approval:

Projects that are under CPHS purview must obtain CPHS approval prior to beginning research. Projects that require CPHS approval are separated into three categories of review. These categories are based on the following four factors:

1. Does the proposed project involve research staff, funding, or subjects (e.g., State mental hospital patients) of any departments under the CHHSA?
2. Does the proposed project involve using protected data held by a CHHSA department?
3. Does the proposed research project involve contact with human subjects (not just use of data)?
4. Does the proposed research project only request state Death Data?

The flowchart provided below is to assist researchers in determining which type of CPHS review their proposed research project may require. However, CPHS makes all final determinations.

CPHS Review Pathways



*Departments under CHHSA are as follows:

Department of Aging
Department of Alcohol and Drug Programs
Department of Child Support Services
Department of Community Services and Development
Department of Developmental Services
Emergency Medical Services Authority
Department of Health Care Services
Department of Managed Health Care
Managed Risk Medical Insurance Board
Department of Public Health
Department of Rehabilitation
Department of Social Services
Department of State Hospitals
Office of Statewide Health Planning and Development

i. Death-Data Only:

Death-Data Only approval by CPHS is required by California Health and Safety Code Section 102231(a)(3) prior to the release of death data files containing personal identifying information to persons expressing a valid scientific interest. The full text of these and related statutes are contained in Sections 102175-102249. Projects exclusively using death data files (without living human subjects contact) may be evaluated through an expedited review. The death data review is focused on data security and privacy.

An approval from the California Department of Public Health's Vital Statistics Advisory Committee (VSAC) is required prior to CPHS review ([see page 13](#)). The VSAC approval must be attached to the protocol submission in the Attachments section.

ii. Information Practices Act (IPA):

The Information Practices Act (IPA), Civil Code 1798.24(t) (www.leginfo.ca.gov/cgi-bin/displaycode?section=civ&group=01001-02000&file=1798.24-1798.24b) is a state statute that requires CPHS to approve all of the research projects from the University of California and other educational institutions that are requesting personal information from any state department. The Information Practices Act requirements are narrower than the Common Rule review as it focuses on data privacy and security issues. All IPA projects are reviewed on an expedited basis.

See the Data Release Requirements section ([see page 13](#)) to see what your protocol may require for an IPA submission.

iii. Common Rule:

The Common Rule, 45 CFR 46, is the federal regulations for research protection compliance that CPHS and all institutional review boards throughout the United States must follow. The Common Rule applies to all projects that have an affiliation of research staff, funding, or subjects (such as individuals at State Hospitals and State Developmental Centers) with any of the 13* departments under the CHHSA. If a study is only requesting personal information and has no other affiliation with these departments, then a Common Rule review is not required. However, an Information Practices Act or a Death Data review may be required. Refer the Data Release Requirements section ([see page 13](#)) to see what your protocol may require for a Common Rule submission.

STEP-BY-STEP: CPHS Approval Request Submission

1. Navigate to CalProtects: <https://cphs.keyusa.net/>
2. Instruct all necessary personnel to register for CalProtects user accounts ([see page 5](#))
3. Each personnel listed on the protocol must log into their own account
4. While on the Researcher Dashboard, click the “Create Protocol” button
5. You will be taken to the Create Protocol page, complete accordingly (do not click “Create” button until whole page is answered)
6. Select the IRB option “Request for CPHS Approval”
7. The Principal Investigator field will appear with the current user signed in – click the “Clear” button to erase this information (reselect IRB type)
8. To add personnel, click the small binoculars image to the right of a role’s name field
9. A pop-up window will appear – search for user by User ID or by First and Last Name, then click the “Find” button
10. From the users generated, select correct user and click the “OK” button.
11. The selected user’s information will appear in the role’s fields
12. Once completed, click the “Create” button found on either top or bottom of page
13. A new protocol will open in a separate window –complete each field accordingly
14. Some fields may be grey. The shaded areas are not applicable to the type of project selected.
15. Using the appropriate document type heading (found in the drop down menu), attach the following required documents:
 - The Curriculum Vitae of the Principle Investigator (Co-PI and Translator if applicable).
 - A Project Budget
 - A Cover Letter
 - A signed Data Security Requirements Letter
 - New Project Application and Review Checklist
 - Current OSHPD Pre-Approval Letter, if requesting OSHPD data
other attachments may be necessary depending on project
16. Documents uploaded to CalProtects will adopt the same title they are stored under on the researcher’s desktop
17. Click the “Check for Completeness” button on the left hand side of the screen to ensure all fields are answered
18. Upon completion, click the “Submit Form” button on the left hand side of the screen
19. After selecting the “Yes” option, the window will close
20. The protocol can be found under the “NEW” section header on the “Researcher Dashboard”
21. Check your email daily for return notes, comments, or approval notifications regarding your protocol

• Levels of Review

Depending on the type of research being executed, the review of a protocol may be conducted at a scheduled public CPHS meeting or on an expedited basis.

A. Full Committee Review:

Protocols may require review by the committee at one of their scheduled public meetings. CPHS staff will notify researchers if their protocol requires full committee review.

Most projects that have any contact with human subjects, such as a survey or collection of specimens, must be initially approved at a scheduled public meeting. If they are deemed to be minimal risk, all subsequent reviews may be reviewed on an expedited basis.

If a protocol is to be heard at a scheduled public meeting, the researcher is to provide CPHS with 14 front-and-back hardcopies of their project's protocol and all of its attachments, including any consent/assent forms and tests or surveys, that were submitted via CalProtects. **Do not mail any copies until contacted by CPHS staff.**

CPHS meetings are held on the first Friday of even-numbered months (February, April, June, August, October, and December) from 8:30 a.m. to 5:00 p.m. Meetings are held in Sacramento at 400 R Street, Room 300, Sacramento, CA. Agendas are posted on the [OSHPD's Public Meeting page](#) at least 10 calendar days before a meeting. Researchers are encouraged to appear in person, but may attend by telephone via teleconference. Researchers must notify CPHS staff on how they plan on having their protocol represented at the meeting. A hearing schedule will be emailed within a week of the meeting to all interested parties. All meetings are open to the public and conducted in compliance with the [Bagley-Keene Open Meeting Act](#). All researchers are required to provide a brief oral summary of their project to the entire committee when requested by a committee member.

B. Expedited Review

Expedited Review protocols are reviewed on an expedited basis by one or two reviewers, as opposed to the entire committee at a scheduled public meeting. Unless otherwise notified by CPHS, your project will be reviewed as expedited.

C. Facilitated Review



This section is currently being revised. For information regarding this subject, contact CPHS staff at (916) 326-3660 or at CPHS-Mail@oshpd.ca.gov.

• Data Release Requirements

Different data sets may require pre-approval before being reviewed by CPHS. Information on the most common data requests are provided below. Contact your protocol's data department directly to ensure you are meeting all of their requirements.

A. Pre-Approval Requirements:

i. Office of Statewide Health Planning and Development (OSHPD) Data:

If a project utilizes Office of Statewide Health Planning and Development's (OSHPD) data, the draft CPHS protocol must be submitted to OSHPD's Healthcare Information Resource Center (HIRC) along with the OSHPD required paperwork prior to submitting the protocol to CPHS. Contact HIRC staff, Louise Hand at (916) 326-3813 or louise.hand@oshpd.ca.gov, to arrange this review. Subsequently, a copy of HIRC's preliminary pre-approval letter must be uploaded in the Attachments section of the protocol in CalProtects when submitting your project to CPHS for review.

ii. Vital Statistic Advisory Committee (VSAC) Data Files:

California birth, death, fetal death, still birth, marriage and divorce records are maintained by the California Department of Public Health Vital Records. For additional information on the services offered by VSAC, please visit their website:
<http://www.cdph.ca.gov/certlic/birthdeathmar/Pages/default.aspx>

B. IRB Reliance:



This section is currently being revised. For information regarding this subject, contact CPHS staff at (916) 326-3660 or at CPHS-Mail@oshpd.ca.gov.

C. Distribution of Social Security Numbers to Researchers:

i. Title 42 > Chapter 7 > Subchapter II > §405 (3) (C) (ii)

In the administration of any law involving the issuance of a birth certificate, each State shall require each parent to furnish to such State (or political subdivision thereof) or any agency thereof having administrative responsibility for the law involved, the social security account number (or numbers, if the parent has more than one such number) issued to the parent unless the State (in accordance with regulations prescribed by the Commissioner of Social Security) finds good cause for not requiring the furnishing of such number. The State shall make numbers furnished under this subclause available to the Commissioner of Social Security and the agency administering the State's plan under part D of subchapter IV of this chapter in accordance with Federal or State law and regulation. Such numbers

shall not be recorded on the birth certificate. A State shall not use any social security account number, obtained with respect to the issuance by the State of a birth certificate, for any purpose other than for the enforcement of child support orders in effect in the State, unless section 7(a) of the Privacy Act of 1974 does not prohibit the State from requiring the disclosure of such number, by reason of the State having adopted, before January 1, 1975, a statute or regulation requiring such disclosure.

• Approval Receipt

A. Availability

Approval letters are released to researchers at different points of time depending on a protocol's application type and the review it is receiving.

- ❖ Researchers requesting Determinations for Exempt Research/Not Research receive immediate notification upon reviewer recommendation
- ❖ Researchers submitting New Protocols are notified on or after the committee's next scheduled public meeting
- ❖ Researchers requesting Continuing Reviews are notified on or after their protocol's expiration date
- ❖ Researchers submitting Amendments receive immediate notification upon reviewer recommendation
- ❖ Researchers submitting Final Reports receive immediate notification upon reviewer recommendation
- ❖ Researchers submitting Reports receive immediate notification upon reviewer recommendation or after a possible hearing at a scheduled public meeting.

B. Retrieval

Past and current approval letters can be found within a protocol's Event History. The letter will open in PDF format. Follow the instructions below to retrieve your protocol's approval letter.

STEP-BY STEP: Approval Letter Retrieval

1. Log into [CalProtects](#)
2. While on the "Researcher Dashboard", locate the project listed under the "Approved Protocols" section header
3. Click on the project's "Protocol ID" number
4. Open the protocol in "View Mode"
5. The protocol will open in a separate window
6. Click the "Event History" button on the left hand side of screen
7. All the protocol's past and current events will be listed in chronological order (with the most recent events on the bottom)
8. Click on the "Approval Letter" link to view an approval letter for the protocol
9. The letter will open in PDF format

C. Submission Deadline and Expiration Dates

Current deadlines for protocol submission dates are found on the CPHS homepage (<http://oshpd.ca.gov/Boards/CPHS/meetingsdeadlines.html>).

Submission Deadline Dates are set about a month before a project's Expiration Date. The Expiration Date is the date on which a project's approval ends. If a protocol's Continuing Review is not submitted by its Expiration Date, its CPHS' approval expires and all research must cease.

To find a protocol's Submission Deadline and Expiration Date, view its most recent approval letter ([see pervious page](#)).

- **Approval Maintenance**

A. Protocol Renewals:

Pursuant to 45 CFR 46.109(e), CPHS cannot approve a project for more than one year at a time. Therefore, project's requiring CPHS approval must be renewed at least once a year to continue conducting their research. Renewal reminder emails are sent to researchers 60, 45 and 30 days before the protocol expires. **Protocol personnel are given access to start a Continuing Review within 60 days of their protocol's expiration date.** Changes can be proposed along with a Continuing Review submission. Protocols reviewed as expedited but propose major changes may require review from the committee's scheduled public meeting.

STEP-BY STEP: Protocol Renewal

1. Log into [CalProtects](#)
2. While on the "Researcher Dashboard", locate the project listed under the "Approved Protocols" section header
3. Click on the project's "Protocol ID" number
4. A small pop-up window will appear, choose the "Start Continuing Review" option
5. The "Continuing Review" form will open in a separate window
6. Complete the form and proceed to the appropriate sections to make any changes
7. Navigate to the "Obligations" section and check all appropriate digital signature boxes
8. Upon completion, click the blue "Submit Form" button on the left hand side of the screen
9. A small pop-up window will appear confirming your submission
10. After choosing the "Yes" option, the window will close
11. The protocol can be found under the "Continuing Review" section header on the "Researcher Dashboard"
12. Check your email daily for return notes, comments, or approval notifications

If any of the following categories apply to the protocol, follow the instructions below.

i. Determinations of Exempt Research/Not Research:

When a protocol is found to be exempt/not research, it will remain with that determination indefinitely and no annual review is necessary. However, committee review is required when major protocol altering changes are proposed. Changes must be reviewed by CPHS staff via an Amendment submission ([see next page](#)).

ii: Facilitated Review Protocols:

Facilitated Reviews must be renewed annually via CalProtects. Follow the steps below to submit a Continuing Review for your protocol on CalProtects. When completing a Continuing Review for a Facilitated Review protocol, **enter "N/A: Facilitated Review" in all text boxes that do not apply.**

If a protocol is not renewed, it expires. To obtain approval for expired protocols, complete the steps outlined below:

STEP-BY STEP: Expired Protocol Renewal

1. Log onto [CalProtects](#)
2. While on the “Researcher Dashboard”, locate the expired protocol
3. Click on the “Clone Protocol” button and select the expired protocol to clone. Cloning the protocol will create a new Protocol ID.
4. In tab 1-3 of the Protocol Information section, input the Original Protocol ID number.
5. Complete the Obligations section in the new protocol.
6. Attach all documents from the expired protocol into the new protocol. Documents will not transfer automatically through the cloning process.
7. Complete and attach an expiration memo explaining the lapse in the protocol’s approval.
8. Ensure the protocol is complete by clicking on the “Check for Completeness” button found on the left side of the page.
9. Submit the protocol.

B. Protocol Amendments:

Proposed amendments must be reviewed and approved by CPHS before being implemented. If project changes must be made without prior CPHS approval for protection of subject safety and welfare, a Report Form must be submitted to CPHS within 48 hours of the occurrence ([see page 20](#)).

If a protocol is within 60 days of its Expiration Date, changes can be proposed along with a Continuing Review, and a separate Amendment is **not** needed.

When a researcher is required to make changes to their protocol or their protocol’s personnel, an Amendment must be submitted via CalProtects. (Note: There is a track changes feature built into CalProtects).

When amendments for a protocol are approved, the researcher and all project personnel will receive notification via email. **The protocol’s submission deadline date and expiration date will not change.** Reference the protocol’s most recent approval letter to see the protocol’s Submission Deadline Date and Expiration Date.

STEP-BY-STEP: Protocol Amendments

1. Log into [CalProtects](#)
2. While on the “Researcher Dashboard”, locate the project listed under the “Approved Protocols” section header
3. Click on the project’s “Protocol ID” number
4. A small pop-up window will appear, select the “Start Amendment” option
5. The “Amendment” form will open in a separate window
6. Complete form and proceed to the appropriate sections to make your changes.
7. Navigate to the “Obligations” section and check all appropriate digital signature boxes
8. Upon completion, click the blue “Submit Form” button on the left hand side of the screen
9. A small pop-up window will appear to confirm your submission
10. Select the “Yes” option, the window will close
11. The protocol can be found under the “Amendments” section header on the “Researcher Dashboard”
12. Check your email daily for return notes, comments, or approval notifications regarding the protocols

• Protocol Closure

A. Protocol Completion:

When a protocol's data collection, data analysis, and publications are completed, a Final Report Form must be submitted to CPHS. Personally identified data must be destroyed or returned as required in the original protocol. Projects may be considered completed if they are in the publication stage, as long as there will be **no** further data analysis. However, it is recommended that a protocol be filed for completion after its findings have been published (if applicable).

Follow the steps below to submit a Final Report Form on CalProtects.

STEP-BY-STEP: Protocol Completion

1. Log into [CalProtects](#)
2. While on the "Researcher Dashboard", locate the project listed under the "Approved Protocols" section header
3. Select the project's "Protocol ID" number
4. A small pop-up window will appear, choose the "Start Final Report Form" option
5. After you answer a set of questions, the "Final Report Form" will open in a separate window
6. Once completed, click the "Submit Form" button on the left hand side of the screen
7. A small pop-up window will appear to confirm submission.
8. Select the "Yes" option, the window will close
9. The protocol can be found under the "Final Report" section header on the "Researcher Dashboard"
10. Check your email daily for return notes, comments, or approval notifications regarding the protocol

B. Protocol Withdrawal:

Protocols that will not be completed must be withdrawn from CalProtects. [Contact CPHS staff](#) to notify them of the protocol's withdrawal. CPHS staff will remove it from CalProtects manually.

C. Protocol Expiration:

If a protocol is not renewed, it will expire. All personnel listed on the protocol receive an email notification of the expiration. All data collection, data analysis, and research related to the project must cease until approval is restored. To continue the expired protocol's research, a new protocol must be created and submitted via CalProtects.

• Reporting Events to CPHS

A. Reporting Adverse Events, Unanticipated Problems, Security Breaches, and Protocol Deviations:

Adverse events, unanticipated problems, security breaches, and protocol deviations must be reported to CPHS immediately (within 48 hours of the event). A researcher must complete and submit a Report Form for the protocol on CalProtects. After submitting the Report, the researcher [must call](#) CPHS staff to notify them of the submission.

1. An Unanticipated Problem occurs when any incident, experience, or outcome meets all of the following criteria:
 - a. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
 - b. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
 - c. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
2. An Adverse Event occurs when any event meets the following definition:
 - a. Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).
 - b. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion they can occur in the context of social and behavioral research.
3. A Security Breach occurs when there has been a breach in the security of the project's data. This includes, but is not limited to, the breaking of any

administrative, physical, or electronic safeguards as stated within the protocol, such as improper encryption of data, unauthorized/wrong recipient of data, lost or stolen equipment involving research/data, improper release or disposal of data, and data storage left unlocked, unsupervised, or unattended.

4. A Protocol Deviation occurs when there is any departure or change from the protocol that has not been approved by the IRB. A Protocol Violation is a deviation that MAY AFFECT a subject's rights, safety or well-being and/or the completeness, accuracy and reliability of the study data.

Examples of a Protocol Deviation may be scheduling a required procedure outside of the time frame specified in the protocol, or a higher rate of response to a survey than had been expected or approved. A protocol deviation that DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data, is considered a minor deviation.

Examples of a Protocol Violation are:

1. enrolling subjects who did not meet entry criteria without prior permission
2. failing to obtain informed consent prior to any study-related procedures
3. failure to treat subjects according to protocol procedures that specifically relate to primary safety or efficacy endpoints

Follow the steps below to file a Report Form for a protocol on CalProtects.

STEP-BY-STEP: Protocol Report Forms

1. Log into [CalProtects](#)
2. While on the "Researcher Dashboard", locate the project listed under the "Approved Protocols" section header
3. Select the project's "Protocol ID" number
4. A small pop-up window will appear, choose the "Start Report Form" option
5. After you answer a set of questions, the "Report Form" separate window will open
6. Upon completion, click the blue "Submit Form" button on the left hand side of the screen
7. A small pop-up window will appear confirming your submission
8. Select the "Yes" option to close the window
9. The protocol can be found under the "Report" section header on the "Researcher Dashboard"
10. Check your email daily for return notes, comments, or approval notifications regarding the protocol

B. Reporting Abuse:

If at any time research staff becomes aware of any type of abusive behavior, including but not limited to child abuse or domestic violence, they must immediately report it to the appropriate authorities, as well as placing a call to CPHS. A Report Form must be filed with CPHS within 48 hours of the event ([see page 20](#)).

• Communication Tools

A. Return Notes:

Every protocol submitted for any type of review is screened by CPHS staff. The staff reviews every submission for completeness and accuracy. If the staff finds an issue with the submission, they will write Return Notes describing said issue(s). All personnel listed with the protocol will receive an email notification when Return Notes are written. The protocol is no longer considered submitted and opens to the researcher for editing. The Return Notes must be addressed and the protocol **resubmitted** after corrections and/or clarifications are made. If the items on the Return Notes are not corrected, the protocol will not pass staff screening and will be returned until addressed. Researchers cannot reply back with their own notes. Screening approval from CPHS staff is required before a protocol can be considered for committee approval.

To locate your protocol's Return Notes, follow the steps below. [Contact CPHS](#) staff for clarity on a Return Note or if you believe you were sent a Return Note incorrectly.

STEP-BY-STEP: Return Notes

1. Log into [CalProtects](#)
2. While on the "Researcher Dashboard", locate the project listed under its corresponding header
3. Click on the project's "Protocol ID" number
4. A small pop-up window will appear, choose either the "View" or "Edit" mode option
5. The protocol will open in a separate window
6. Click on the "Return Notes" button on the left hand side of the protocol
7. A separate pop-up window will appear with the protocol's current Return Notes (you cannot reply back)
8. Navigate back to the protocol window and proceed to make necessary changes
9. Upon completion, click on the "Submit Form" button on the left hand side of the protocol

B. Commenting:

If a reviewer has any questions or concerns regarding a protocol, they may send the researcher a comment via CalProtects. All personnel listed with the protocol will receive an email notification when comments have been sent. The protocol associated with the comment remains submitted for review. The protocol is now unlocked for the researcher to edit. Once the researcher has made all necessary changes, the researcher must **reply** back to the reviewer's comment. After the reply is sent, the protocol is no longer available for the researcher to edit. Please note: A researcher cannot initiate the first comment. If

the researcher realizes that a correction needs to be made, the researcher may [contact CPHS](#) staff directly. The project may be returned to the researcher for editing.

Comments are broken down into “Cycles”. A cycle is started when a reviewer sends one or more comments. That cycle is completed when a researcher replies back to those comments

To locate your protocol’s Comments, follow the steps below.

STEP-BY-STEP: Replying to Reviewer Comments

1. Log into [CalProtects](#)
2. While on the “Researcher Dashboard”, locate the project listed under its corresponding header
3. Click on the project’s “Protocol Event” text (i.e. “Comments Received (Cycle 1)”)
4. You will be taken to a page with all of your protocol’s current comments
5. To view different sets of comments, choose a different Cycle number
6. Your protocol is unlocked for editing, proceed to make necessary changes
7. Upon completion of changes, click the “Write Comment(s)” button found on the Protocol Event page
8. Save your comment(s) and click the “Submit to IRB” button
9. Once your comment(s) are sent, the protocol will lock and you will no longer be able to edit it

• Managing Protocols and User Accounts

A. Researcher Dashboard:

The Researcher Dashboard is where researchers manage their protocols within CalProtects. Here researchers have access to create, delete, clone, view, or edit protocols. The Researcher Dashboard is the first page that opens after logging into your account. Important dates and announcements are posted at the top of the dashboard.

1. Clicking the Create Protocol button brings you to the starting point of beginning a new protocol.
2. Clicking the Clone Protocol button brings you to a page listing all of your active and non-active protocols. Here you choose a protocol and create an identical copy of it with a different assigned Protocol ID number. However, the Obligations section of a cloned protocol will need to be re-answered.
3. Clicking the Delete Protocol button brings you to a page listing all of your active protocols. Here you can delete whole protocols or specific reviews (e.g., Amendments, Reports). **Deleted protocols cannot be reinstated or accessed for viewing.**

The Researcher Dashboard displays protocols by the following categories: Protocols (In-Preparation/Submitted), Approved Protocols, and Non-Active Protocols.

1. Under the Protocols (In Preparation/Submitted) section header, protocols that are not yet submitted and protocols awaiting approval by CPHS are displayed
2. Under the Active Protocols section header, protocols that are currently approved by CPHS are displayed
3. Under the Non-Active Protocols section header, protocols that are Closed, Not Approved, Withdrawn, and Expired are displayed. These protocols can be viewed; they cannot be reactivated.

The Information Resources section is found at the bottom of the Researcher Dashboard. The Information Resources section is a list of webpage links to assist researchers in their submission process.

B. User Account:

Users can change their password by navigating to their Researcher Dashboard and clicking the Change Password option at the top right of the page. Researchers can also [contact CPHS](#) staff to reset their password.

Researchers must contact CPHS staff in order to change any user account information (i.e., address, phone, organization). User IDs cannot be changed once created. Researchers must contact CPHS staff in order to inactivate their account.

• Appendix

a. Informed Consent and Assent:

This appendix provides background information and instructions for the CalProtects protocol sections #12 Informed Consent and #13 Informed Assent. In these sections of CalProtects, describe the procedures to be used in obtaining and documenting prior informed consent and assent. Any non-English versions of the consent form must also be attached, along with the documented qualifications of the translators (e.g., CVs, certifications).

Every potential research subject (or their legally authorized representative) has the right to be fully informed of the procedures, risks, and other aspects of the research before voluntarily choosing to participate. The potential research subject (or legally authorized representative) must be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The information provided for informed consent and assent must be in language that is fully understandable to the subject or the legally authorized representative. Informed consent may not include exculpatory language through which the subject or the representative waives or appears to waive any legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Children 7-17 years of age must provide informed assent (as distinguished from “consent”) to participate in research even if their parents or guardians have given permission for their participation through informed consent. The required elements of informed assent are very similar to the required elements of informed consent (see below).

1. Two Procedures for Written (Documented) Informed Consent and Assent

- a. Regular (or “long”) form. This is the usual type of informed consent or assent in which the subject is presented with a detailed, printed form to read and sign that provides complete information about all required elements of consent. Regular (or “long”) form consent is designed to be fully informative.
- b. Short” form. In this type of informed consent or assent, the required elements of consent are explained orally to the subject by the investigator and the subject is asked to sign a form that summarizes the elements of consent. A witness must be present for the oral presentation and sign a copy of the summary. The protocol must contain a verbatim transcript of the oral information to be presented to the subject (or legally authorized representative).

In general, the choice of “long” or “short” form consent or assent is to be decided by the Principal Investigator based upon the risk of the research, the methodology of the research, and the characteristics and needs of the human subjects. If “short” form consent is chosen, the principal investigator must provide solid justification in the protocol.

2. General Principles of Written (Documented) Informed Consent and Assent

- a. The informed consent form must begin with the official title of the research project.
- b. The title should reflect the purpose and intent of the study.

- c. The form should next identify the principal investigator and the institution conducting the research.
- d. The body of the form (elements 1-11) should be written using the pronoun "you", while the pronoun "I" should be used for the signed consent section (element 12). Because the purpose of the consent form is to obtain consent, as well as to confirm it, the body of the informed consent form must be written in conditional language that does not read as if the potential subject has already agreed to participate.
- e. The form must be written in language that is fully understandable to the potential subjects. Scientific and technical terms should be avoided if simple but equivalent words are available.

3. Required Elements of Informed Consent and Assent

An Informed Consent Form, which lists the required information and headings, is located on the CPHS Website at www.oshpd.ca.gov/Boards/CPHS/forms.html#consent.

1. Purpose, Participation, and Procedures

This section should provide: a statement that the study involves research; an explanation of the purposes of the research; an explanation of how the potential subject was selected; an approximate number of subjects to be involved; the expected duration of the subject's participation; a description of the procedures to be followed; and identification of any procedures which are experimental.

2. Description of Risks

This section should provide a description of any reasonably foreseeable risks or discomforts to the subject. Risks may be physical, psychological, social, or economic. An assessment should be provided of the likelihood, severity, and duration of such risks. Levels of potential risk or discomfort must be accurately and clearly represented to potential subjects, and should not be unduly minimized. Any risk described in the project protocol should be addressed clearly in the informed consent form. A description should be provided of any less risky methods that were considered along with an explanation of why they will not be used. Research projects that collect or analyze personal information involve some degree of risk of loss of confidentiality for subjects. As with other risks, this should be accurately described to potential subjects.

3. Confidentiality

This section should provide a description of any measures that will be undertaken to protect the confidentiality of human subjects involved in the research. In general, statements guaranteeing complete confidentiality should not be made to potential subjects. If records may be subject to legal challenges, or certain information must be reported to law enforcement officials, this should be stated. If a federal certificate of confidentiality will be obtained, it should be described in this section.

4. Description of Benefits

This section should provide a description of any benefits to the subject or others that may be reasonably expected to result from the research. Neither compensation for participation in the activity nor the absence of costs or charges to subjects may be portrayed as benefits. If no benefits for the subjects are expected, that should be clearly stated.

5. Alternative Procedures

This section should describe any similar or equivalent procedures or treatments that may be available to potential research subjects who do not choose to participate in the research. For example, potential subjects may be able to request a similar test or treatment from their personal physician. If no alternative procedures or treatments are available, that should be stated.

6. Compensation

This section should clearly describe the value and circumstances for receipt of any money or other compensation for participation in the study. If no compensation is to be received, this should be stated. The absence of costs or charges to the subject cannot be considered compensation.

7. Treatment for Injury

If the research is greater than minimal risk, describe any treatment that will be available if any injury occurs to the subject as a result of the research. Provide information about where treatment information may be obtained and who will be responsible for any costs related to the treatment. If treatment will not be available, this should be stated.

8. Potential Conflict of Interest and Funding

This section should describe any financial or other relationship interests the researcher may have that may potentially affect the performance of the research or how results of the research are interpreted. In addition, the funding source or sponsor of the research must be identified.

9. Questions

This section should provide information about: 1) who to contact with questions about the research (usually the principal investigator), and 2) who to contact with questions about research subjects' rights (usually an institutional review board, an ethics board, or other oversight panel). If another board or panel is not reviewing the project, the subjects may be instructed to contact: Administrator, Committee for the Protection of Human Subjects, California Health and Human Services Agency (916-326-3660 or cphs-mail@oshpd.ca.gov) for information about research subjects' rights.

10. Voluntary Participation

This section should provide a clear statement that participation in the research is voluntary and that refusal to participate or withdrawal from the research at any point will not result in any penalty or loss of benefits to which the subject is otherwise entitled.

11. Research Participant's Bill of Rights

This section should include a statement that the subject is being given a copy of the Research Participant's Bill of Rights in addition to the informed consent form. For medical experiments, California law (Health and Safety Code, Section 24172) requires that the "California Research Participant's Bill of Rights" be used. English and Spanish versions of these forms are available on the [CPHS Forms](#) page. Medical experiments are defined in Section 24174 as:

"(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

(b) The investigational use of a drug or device as provided in Sections 111590 and 111595.

(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject."

For non-medical research, the "Research Participant's Bill of Rights for Non-Medical Research" (Appendix IV) should be used. The Spanish version of this document is also included in Appendix IV. The researcher may submit alternative versions of the bill of rights for non-medical research for CPHS approval.

A copy of the approved medical or non-medical bill of rights must be attached to the consent form given to the subject.

12. Consent Statement and Signature

This is a signed and dated statement that the subject gives consent to participate in the research study and has received a copy of the Research Participant's Bill of Rights. For this statement the pronoun "I" should be used. If applicable, space should be provided for the signature of a witness. In certain circumstances the signatures of both parents may be required for children who are involved in research (see CFR §46.408).

4. Additional Elements of Informed Consent and Assent

When appropriate, information on one or more of the following elements should be included in the consent form:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
6. For research involving subjects with severe psychiatric disorders: a statement regarding (a) whether the treating psychiatrists are also members of the research team, and (b) whether study medications are determined by clinical need or dictated by the research protocol.
7. For research involving test articles regulated by the Food and Drug Administration (FDA): a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article.
8. Specifics on the methods, amounts, and timing of any proposed taking of blood or any other human materials, and their subsequent disposal.
9. Details regarding authorization for access to the subject's personal records (school, university, hospital, and employment, or others).
10. Details regarding the use of tape recorders or other audio or visual recordings, and an explanation of the proposed uses and disposition of such materials.
11. Assurance that should the investigator discover any untoward medical condition or inheritable disorder in the subject, this will be brought, if possible, to the attention of the subject's own physician, or the subject will be informed of the condition and advised to seek proper assistance.

5. Additional Requirements for Informed Assent

The same *Required Elements of Informed Consent*, listed above, must be used for the Informed Assent form. Because some children cannot read through as long a form as an adult, assent forms may be shortened to facilitate reading and understanding by children. However, all of the required elements of the informed consent still must be adequately

addressed. Also, the informed assent form must be written at a level that is understandable to potential subjects who are children 7-17 years of age. Different informed assent forms may be needed if the study involves children of significantly different ages.

6. Waiver or Alteration of Informed Consent and Assent

The CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent if Criteria A or Criteria B (below) apply.

Criteria A

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

Criteria B

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration;
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Written Informed Consent and Assent

CPHS may grant a waiver of the requirement for written informed consent or written informed assent under carefully justified circumstances as follows:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Examples of projects for which the CPHS may consider requests for waivers of written consent or assent include: projects in which the research subjects are illiterate; projects in which the risks (usually psychological risks) inherent in asking subjects for their signatures outweigh the risks of not obtaining the signatures; projects in which requests for signatures demonstrably violate or distort the subjects' perceptions of the nature and the purpose of the investigation; and interview studies in which the subjects will read and keep the information contained in a consent document.

The waiver of written informed consent does not eliminate the investigator's ethical and legal obligation to obtain the prior consent of subjects for participation in the research activity. The protocol must explain how this consent will be obtained.

b. Guidance for Using Small Numbers or Small Cells:

1. Definition of a small cell or a small number

- (1) A *cell* is the intersection of a row and a column in a table, a spreadsheet, or in any matrix of numbers. For example, a table with four rows and three columns has twelve cells;
- (2) The CPHS considers a cell *small* when it contains 1 to 15 research subjects;
- (3) Some projects do not report data as tables but still might describe the characteristics of *small numbers* of subjects. Whenever a project describes 1 to 15 subjects, it is important to be especially careful that the identities of all subjects are protected from possible disclosure.

2. Why small numbers or small cells are potential problems

A *small number* of subjects in a descriptive report or *small cells* in a table could potentially lead to the unintended identification of a research subject's identity. With a small study population, or with a small subset of a larger population, researchers should be careful about possibly identifying subjects. For example, research subjects in a rural community might be easily identified because their community has only one or two instances of a particular disease. Similarly, multiple tables describing an urban community might allow for the deduction of a subject's identity through a process of subtraction involving cells if the numbers in them are sufficiently small.

3. Suggested methods for dealing with small cells or small numbers

1. Eliminate tables with *small cells* or data descriptions with *small numbers*: Within a table, combine (collapse) the row (or column) containing a *small cell* with another row (or column) to increase cell size;
2. Combine the different time periods, such as fiscal years, represented by two or more tables (or descriptions) into a single table (or description) to increase cell size (or number size);
3. Suppress a *small cell* with a non-numeric symbol that hides the number of subjects, for example {sc}. To prevent the identification of a small cell through subtraction, the

suppression symbol should appear at least twice in the row and column of each of its intersections, as in the following example.

	> 65 yrs.	18-64 yrs.	< 18 yrs.	TOTAL
Agree	{sc}	30	{sc}	60
Neutral	{sc}	60	{sc}	150
Disagree	70	90	80	240
Undecided	0	0		0
TOTAL	120	180	150	450

Use of these suggested methods is recommended but not required by the CPHS. Researchers may request approval from CPHS for using alternative methods to protect subject identity when using small cells or small numbers.

c. HIPAA Waiver or Alteration of Authorization

Researchers may request a waiver or alteration of patient authorization under the Health Insurance Portability and Accountability Act (HIPAA). HIPAA waivers or alterations of authorization are only required when protected health information is first being requested and when there are any changes to the study that affect the HIPAA waiver or alteration. Only one IRB approval of waiver or alteration of patient authorization is required. If another IRB has approved the waiver or alteration, indicate that in the protocol and include that documentation in the Attachment section.

A statement specifying that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA.

