IRB Online Submission and Review System
# Table of Contents

*Click the page number to jump to the section.*

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Login Instructions</td>
<td>2</td>
</tr>
<tr>
<td>Home Page Overview</td>
<td>3</td>
</tr>
<tr>
<td>Protocol History Overview</td>
<td>6</td>
</tr>
<tr>
<td>Creating a New Protocol</td>
<td>8</td>
</tr>
<tr>
<td>A. Starting a New Full Application or Initial Query</td>
<td>8</td>
</tr>
<tr>
<td>B. Adding Other Investigators and Partner Organizations</td>
<td>9</td>
</tr>
<tr>
<td>C. Filling Out the Application</td>
<td>11</td>
</tr>
<tr>
<td>D. Generating the Informed Consent Document</td>
<td>12</td>
</tr>
<tr>
<td>E. Certification and Submission</td>
<td>14</td>
</tr>
<tr>
<td>Adding Attachments</td>
<td>15</td>
</tr>
<tr>
<td>Creating a Renewal Application</td>
<td>18</td>
</tr>
<tr>
<td>Creating an Amendment Application</td>
<td>21</td>
</tr>
<tr>
<td>Comparing Protocol Versions</td>
<td>24</td>
</tr>
<tr>
<td>Contact Information</td>
<td>25</td>
</tr>
</tbody>
</table>
**Introduction**

**Summary**

The IRB Online Submission and Review System is a browser based application that allows Caltech researchers to prepare and submit research protocols to Caltech’s Institutional Review Board (IRB). IRB members can use the system to review and comment on protocols prior to Board meetings. Research compliance administrators can pre-review protocol applications, organize meetings, and process meeting decisions and related correspondence with the researchers.

**Key Definitions and Concepts**

**Protocol**

- **Definition:** a detailed plan for and description of a scientific research project or study involving human subjects. Throughout the system and this guide, “protocol” refers to the entire research project rather than any single application.
- **An active protocol may include multiple associated applications, such as an inquiry, full application, renewals and amendments; however, only one application can be “current” at a time within a protocol (see details under Protocol Applications below).**
- **Protocol Number:**
  1. The naming convention for protocol numbers is YY-NNNN. YY is the last two digits of the year the initial inquiry or full application was submitted, such as 14 for Year 2014. This remains unchanged throughout the protocol’s life, regardless of current year, until a de Novo submission is made after five years of research activity. NNNN is a unique continuous number incremented by 1.
  2. For de Novo resubmission, only YY changes to the current year: NNNN will stay the same. For example: for original Protocol Number 10-0005, the de novo resubmission protocol number is 14-0005 if submitted in 2014.
- **Options for creating new protocols:**
  1. Create a brand new initial query or full application.
  2. Create a full (usually de Novo) application by copying from any existing protocol application.

**Protocol Applications**

- **There are four application types:**
  1. Initial Query (Request for exemption or for initial guidance from the IRB)
  2. Full Application
  3. Amendment 1st, 2nd, 3rd, 4th, etc. (Request to change protocol in some way)
  4. Renewal 1st, 2nd, 3rd, 4th (Protocols are renewed at least annually, and study information is provided. Renewals can include requests to change the protocol)

**Informed Consent**

- **The Informed Consent (IC) must be completed and included in full applications, amendments, and renewals, unless a waiver is requested.**
- **The text in the IC is derived from protocol application responses and can be edited by the researcher.**
- **Options for creating IC:**
  1. Create brand new by filling out the Informed Consent section.
  2. Create a modified version based on an existing version in an earlier application within the same protocol.
Login Instructions

To log into the system, use your regular username and password on access.caltech.edu and scroll down to the Academic Services section, then click on IRB Submission and Review:

* We recommend adding this link to your favorites by selecting the star icon 🌟 to access it more easily from the top of your access.caltech.edu home page.

Your access to the IRB Online Submission System requires that you meet certain criteria within Caltech’s HR database. If you are submitting to the Caltech IRB but do not have access to the IRB Submission and Review link, contact the IRB administrator at 626-395-8448.

If you are an employee of another institution, including JPL, you will be required to complete specific forms to be added to the database as a guest and gain access to IOSS.
Home Page Overview

Your home page will appear when you log in. This page will allow you to create a new protocol and display all protocols on which you are listed as a PI, Co-PI, or member of personnel. You can return to this page at any time by clicking Home in the upper right-hand area of the screen.

A) This feature allows you to create a new protocol by filling out an Initial Query or Full Application. To create a protocol, select the application type and click Create New Protocol. For further instructions, see Creating a New Protocol on page 8.

B) The protocol numbers refer to the main protocol under which the current application was submitted (see Introduction on page 1 for a definition of “protocol” and the naming convention). When you hover on a protocol number, you will see a list of the applications associated with the protocol:
Clicking a protocol number will open the protocol history (see Protocol History Overview on page 6), where you can access all applications associated with the given protocol.

The Application Type indicates the most recent application in a particular protocol.

List of application types:

<table>
<thead>
<tr>
<th>Application Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Query</td>
<td>for classroom studies and studies believed exempt under 45 CFR 46.101</td>
</tr>
<tr>
<td>Full Application</td>
<td>for studies requiring IRB Review</td>
</tr>
<tr>
<td>Renewal</td>
<td>for renewal of previously approved IRB applications</td>
</tr>
<tr>
<td>Amendment</td>
<td>for changes to previously approved IRB applications</td>
</tr>
</tbody>
</table>

C) A protocol may include one Initial Query, one Full Application, up to four Renewals (a De Novo Full Application must be submitted after four renewals), and any number of Amendments.

D) The Status column allows the research team to see the point in the review process at which the application currently stands. Items in red indicate action needed from the PI.

List of statuses:

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work in Progress</td>
<td>The PI is working on completing the application and it has not been submitted for review.</td>
</tr>
<tr>
<td>Pending IRB Review</td>
<td>The application has been submitted and a review type has yet to be determined.</td>
</tr>
<tr>
<td>Pending IRB Decision</td>
<td>The review type has been determined and the application is awaiting a decision.</td>
</tr>
<tr>
<td>Modification Required</td>
<td>The review committee or subcommittee has requested that modifications be made by the PI.</td>
</tr>
<tr>
<td>Pending IRB Ratification</td>
<td>A decision made by the subcommittee is awaiting ratification at the full committee meeting.</td>
</tr>
<tr>
<td>IRB Decision Made</td>
<td>A full committee has made a decision or ratified a decision made by a subcommittee.</td>
</tr>
<tr>
<td>Closed</td>
<td>The study is closed and all enrollment, procedures, and analysis of identifiable data must cease.</td>
</tr>
</tbody>
</table>

E) The IRB Review Type is determined during pre-review and dictates who will review the application and make the decision.
List of IRB Review Types:

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair/Admin Review</td>
<td>Review only by the chair and IRB administrator (often the case for exempt and non-human subject applications).</td>
</tr>
<tr>
<td>Subcommittee Expedited Review</td>
<td>Review by a selected group of IRB members. Their decision is to be ratified by the full committee at the IRB meeting.</td>
</tr>
<tr>
<td>Full Committee Review</td>
<td>Review by the full committee convened at an IRB meeting.</td>
</tr>
</tbody>
</table>

F) The *IRB Decision* column indicates what decision was made by the full committee, subcommittee, or Chair and administrator (depending on IRB Review Type). Clicking a decision will allow you to open the official Status Memo PDF.

List of IRB Decisions:

<table>
<thead>
<tr>
<th>Decision</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Human Subject Research</td>
<td>The project does not constitute human subjects research and does not require IRB review.</td>
</tr>
<tr>
<td>Exempt</td>
<td>The project qualifies as Exempt under one of the statutory exemptions found at 45 CFR 46 101.</td>
</tr>
<tr>
<td>Full Application Needed</td>
<td>A decision made only for Initial Queries when a full application is required.</td>
</tr>
<tr>
<td>Approved</td>
<td>The application is approved and the study team may begin enrollment and procedures.</td>
</tr>
<tr>
<td>Not Approved</td>
<td>The application was not approved because the proposed procedures do not meet the ethical principles and HHS regulations by which Caltech abides.</td>
</tr>
<tr>
<td>Pending Admin</td>
<td>The application requires a provision of materials or clarifications by the PI to be reviewed by the IRB administrator.</td>
</tr>
<tr>
<td>Pending Subcommittee</td>
<td>The application requires a provision of materials or clarifications by the PI to be reviewed by an IRB subcommittee.</td>
</tr>
<tr>
<td>Closed</td>
<td>The study is closed and all enrollment, procedures, and analysis of identifiable data must cease.</td>
</tr>
</tbody>
</table>

G) The *Attachment* column allows you to easily view or attach documents in an application (for more information, see *Adding Attachments* on page 15). Hovering on the attachment icon will display the name(s) of the attachment(s) currently in the application or – if there are no attachments – indicate that you can attach documents by clicking the icon:
Protocol History Overview

Clicking a protocol number on your home page will display all the applications associated with the protocol, with the most recent on top. Depending on your submissions, it may include only the initial query and/or full application or also list your renewals and amendments.

A) This area is known as “breadcrumbs” and allows you to navigate the system more easily. You can trace the pages you clicked through to drill down to your current screen and return to a previous screen by clicking it in the sequence.

B) The pencil icon symbolizes an edit or view action throughout the system. Clicking this icon will allow you to view applications that have been submitted or edit applications that are still in progress or were returned to you for modifications.

C) The Informed Consent icon is a quick way to open the Informed Consent section of the application (for more information, see Generating the Informed Consent Document on page 12).

D) If you would like to create a protocol that is similar to a protocol that you have already submitted (for example, in a de Novo application), you can choose to copy an existing application to create a new protocol. Clicking the copy icon will bring up the following pop-up window:

![Pop-up Window]

Clicking “OK” will open a new “Full Application” (for more instructions, see Creating a New Protocol on page 8).
E) The *Delete* option, displayed as a trashcan icon, is available only for applications with the status, “Work in Progress.” Clicking the trashcan icon will bring up the following pop-up window:

![Image of delete confirmation dialog]

Clicking “OK” will delete the application you selected. Deleting renewals and amendments will keep the rest of your protocol (i.e. protocol number) intact. However, deleting the main application (Initial Query and/or Full Application) will remove your current protocol number and assign you a new number when you start a new application.

F) The *Reliance IRB Expiration Date* and *Other IRB Expiration Date* columns apply only to applications that are relying on or include another institution’s IRB review and approval. If the date is in red, an updated approval document from the institution must be provided (for instructions, see *Adding Attachments* on page 15). You can customize your view and remove these columns if they do not apply by using the *Actions* button.

G) The check box below the application list allows you to request to close the entire protocol when you are ready to complete or stop the study:

![Image of protocol closure dialog]

*Are you sure you want to close this protocol? Clicking “OK” will send a closure request to the IRB Administrator.*

Click “OK” to confirm that you want to send a closure request to the IRB Administrator.
Creating a New Protocol

A. Starting a New Full Application or Initial Query

Every protocol starts with the submission of an Initial Query or a Full Application. To create a new protocol:

1) Select the application type and click [Create New Protocol] on your home page. Alternatively, a current protocol can be copied to create a new application (see item D under Protocol History Overview on page 6).

2) A new application will appear. Enter the Principal Investigator’s name, typing in the last name first. This is an auto-complete field that uses the Caltech database (see Login Instructions on page 2 for details). Select the “PI Type” from the drop-down: if the PI is not one of the three PI Types listed, the Faculty Member field will become required and only the faculty member will have access to the “Submit” button. Add training information for the PI.

3) Click “Save” to create the new protocol application and be assigned a protocol number.
B. Adding Other Investigators and Partner Organizations

The buttons to add “Other Investigators” (personnel) and “Partner Organizations” become available when the steps above for starting a new application are completed (i.e., the PI’s information and training is entered and saved):

To add personnel:

1) Click Add Personnel.
2) Enter the name and training information of the personnel member. * If the member is not in the Caltech database, select the “Non-Caltech Person” check box before entering his or her information. Note that non-Caltech personnel will not have access to the online application. ** If the member’s role is strictly administrative and will not involve contact with study participants, select “Administrative Contact” and the Training filed will no longer be required.
3) Click to include the personnel member in the application.

4) Click to return to the main application. Repeat steps 1-4 for each member of personnel.

To add Partner Organization(s):

1) Click Add Organization.

2) Enter the name of the organization and a brief description of its role in the research.

3) If you are not relying on another institution’s IRB review, click “Add Org” to include the partner organization in your application.

4) Click “Back” to return to the main application. Repeat steps 1-4 for each partner organization you want to add.

* If you are relying on another institution’s review, select the “IRB Reliance Agreement” check box and provide information in the fields that will appear as a result of your selection:

   ![IRB Reliance Agreement](image)

   ** Reliance Institution:

   Reliance Expiration Date: [MM/DD/YYYY]

** If you are obtaining approval from another IRB, select the “Approval Obtained from Other IRB” box, provide the date that the other approval expires, and attach a copy of the approval (see Adding Attachments on page 15).
C. Filling Out the Application
The section links to the left of the main application allow you to keep track of your progress through the application:

A check mark indicates that the required items in a particular section are complete.

A red flag indicates that some or all of the required items in a particular section are incomplete.
CAPITAL LETTERS indicate that you are currently viewing or editing this section.

To complete an application, respond to each required and applicable item in each section, clicking “Save” as often as possible (note that all sections except Subject Participation will not allow saving until all required items are provided). In order to be able to submit the application, all sections must have a check mark:
D. Generating the Informed Consent Document

Many of your responses throughout the application are automatically imported into a draft of the Informed Consent (IC). When all preceding sections are completed, click the Informed Consent section to begin the process of editing and creating an Informed Consent form:

![Image of Informed Consent section]

The Informed Consent section will include several questions about the consent process:

1) Complete all items in the section.

2) Click “Save.”

3) Click to begin the process of creating your Informed Consent. This will open a draft of the consent form:
A) As is the case in the main application (see Filling Out the Application on page 11), all sections of the Informed Consent must be completed before generating a PDF of the document. Because IC sections get automatically populated by your application responses, they will be accompanied by check marks rather than red flags.

B) The black text in the IC template is static and cannot be changed. If elements of your study require modifications to the black text, you can request to change it by selecting the checkbox next to “Request Change in Fixed Text.” A text box asking for your justification of this request will appear. Enter your reasons for the request:

C) All red text in the template is populated directly from your responses in the main application. All red text must be reviewed and edited to ensure that the language is at an appropriate reading level for the IC, uses the pronoun “you” when referring to subjects, and is grammatically and syntactically correct.

D) The pencil icon allows you to edit the red text that was automatically inserted from the application. To edit, click the pencil icon. The red text will be converted into a text box where you can edit the entry:
When you are finished editing the entry, click the floppy disk icon to save the revised text. Repeat this process for all the red text that needs revisions in the IC draft form.

E) Click “Save” after each modification.

* If you would like to delete the entire IC draft and start over, click the “Delete” button. You will be able to start the IC over, with responses pulled from your application.

F) When you have finished reviewing, editing, and saving all the red text in the IC draft, click to create a PDF copy of the draft. This is the version that will be reviewed by the IRB and, if approved, used to consent the participants in your study. Once the PDF is generated, an “Informed Consent” button will appear at the top of your main application. Clicking this button will allow you and the reviewers to open the IC PDF at any time:

G) After generating the PDF, click “Back” to return to the application to complete the final submission steps (see Certification and Submission below).

E. Certification and Submission

Click Certification to complete the final section and add or remove attachments (see page 15 for attachment instructions). Once finished, click Save. When completed and saved, Submit to IRB will appear at the top of the application for qualified PIs or for the Faculty Member (for more information, see item 2 on page 8). Click this button to submit your protocol application for review.
Adding Attachments

There are four ways to add attachments to your application:

A) Clicking the attachment icon or for an application on your home page (see Home Page Overview on page 3) or under Protocol History (see Protocol History Overview on page 6).

B) Clicking at the top of your main application:

Using methods A and B will redirect you to the attachment manager:

1) Select the application type from the drop-down menu to specify which application should contain this attachment:
* If you select the check box next to “Check if shared by all applications within protocol,” the “Application” drop-down will disappear and your attachment will be accessible from all the applications under this protocol. If you open the attachment manager through any application and un-check the “shared by all applications within protocol” box, the attachment will no longer be shared and only be appended to the application you currently have open.

2) Select an attachment category from “Protocol Doc” or “Other IRB Approval.” If you select, “Other IRB Approval,” you will be asked to provide the name of the institution or organization providing the IRB approval.

3) Provide a title for the attachment and click Browse... to select the file from your hard drive.

4) Click Save Attachment.

5) Click Back to return to the application and repeat option B/steps 1-5 for additional attachments.

C) In the Partner Organizations sub-section in the main application (see Adding Partner Organizations on page 10). To attach partner organization documents:
1) Enter the name of the partner organization and the role it will play in your research.

2) Click \[\text{Add Org}\] to save the organization information. *Note: the next step is only available after clicking \[\text{Add Org}\].

3) Select the check box next to “Approval Obtained from Other IRB.” This will activate the attachment field.

4) Enter a title for the attachment.

5) Click \[\text{Browse...}\] to select the file to attach from your hard drive.

   * If you want this attachment to be shared by all the applications within this protocol, select the check box next to “shared by all applications within Protocol.”

6) Enter the approval expiration date on the partner IRB approval notice.

7) Click \[\text{Save Attachment}\].

8) Click \[\text{Back}\] to return to the application and repeat option C/ steps 1-8 for additional partner organization attachments.

D) Using the attachment area at the bottom of the Certification section:

1) Provide a title for the attachment and click \[\text{Browse...}\] to select the file from your hard drive.

2) Click \[\text{Save Attachment}\].

   * If you want this attachment to be shared by all the applications within this protocol, select the check box next to “Check if shared by all applications within Protocol.”
Creating a Renewal Application

Up to four renewals may be submitted for a protocol before a De Novo application (i.e. a new protocol) is required. A renewal may only be created for an approved protocol with no other “Work in Progress” applications. A renewal application can be created on the Protocol History screen (see Protocol History Overview, on page 6). To apply for renewal, select Renewal under “Application Type” and click Create.

This will open a Renewal Application:
A) The renewal application will automatically include all information from the last approved application under the selected protocol. Therefore, all sections of the application, except Renewal, Informed Consent, and Certification will have check marks. The flagged Renewal section allows you to summarize the study’s progress, report unanticipated events, and indicate changes in application.

B) This set of check boxes allows you to modify the other sections of the protocol by selecting the box next to the section you want to change. You will be automatically redirected to the section you selected, where you can make the change. When you have updated your response, click “Save” to be automatically redirected back to the Renewal section. The box next to the section you modified will remain checked, along with a summary of the change:
Note that un-checking a box will revert your application back to its original responses. If you want to make further changes in the same section, simply click the section, make the modifications, then click “Save” to return to the renewal section again.

When you have provided and saved all responses and made the appropriate modifications, click Informed Consent on the left hand side to go to the IC section, then click [Edit Consent Form]. You will be given the option to open the most recently approved IC form or a brand new form that pulls information from the current application:

If you have made no changes or minimal changes, we recommend that you use the first option to open the previously approved application and modify the appropriate text. For instructions on creating and modifying a consent document, see page 12.

When you have generated the Informed Consent PDF for the renewal, click Certification to complete the final section and add or remove attachments (see page 15 for more information about attachments). Once finished, click “Save”. When completed and saved, [Submit to IRB] will appear at the top of the application for qualified PIs or for the Faculty Member (for more information, see item 2 on page 8). Click this button to submit.
Creating an Amendment Application

In addition to indicating changes to the protocol during renewal, separate amendment applications can be submitted to modify the protocol during its approval period. An amendment application can be created on the Protocol History screen (see Protocol History Overview on page 6). To apply for an amendment, select Amendment under “Application Type” and click the Create button:

This will open an amendment application:

i. The amendment application will automatically include all information from the last approved application under the selected protocol. Therefore, all sections of the application, except Amendment, Informed Consent, and
Certification will have check marks ✅. The flagged Amendment section allows you to indicate changes in application.

ii. If you are requesting changes to the protocol that are not sufficiently explained by selecting the options listed in the Amendment section, select the check box next to “Other Change(s)” to bring up a text entry field and enter a summary of your changes:

C) This set of checkboxes allows you to modify the other sections of the protocol by selecting the box next to the section you want to change. You will be automatically redirected to the section you selected, where you can make the change. When you have updated your response, click the “Save” to be automatically redirected back to the Amendment section. The box next to the section you modified will remain checked, along with a summary of the change – for example:

Note that un-checking a box will revert your application back to its original responses. If you want to make further changes in the same section, simply click the section, make the modifications, then click “Save” to return to the amendment section again.

When you have made all the appropriate modifications, click Informed Consent on the left hand side to go to the IC section, then click Edit Consent Form. You will be given the option to open the most recently approved IC form or a brand new form that pulls information from the current application:
If you have made minimal changes, we recommend that you use the first option to open the previously approved application and modify the appropriate text. For instructions on creating and modifying a consent document, see page 12.

When you have generated the Informed Consent PDF for the amendment, click **Certification** to complete the final section and add or remove attachments (see page 15 for more information about attachments). Once finished, click “Save”. When completed and saved, the button will appear at the top of the application for qualified PIs or for the Faculty Member (for more information, see item 2 on page 8). Click this button to submit your amendment application for review.
Comparing Protocol Versions

The Application Comparison feature is available only for protocols that include more than one application. The feature can be found at the bottom of the main sections of an application:

To compare two versions of a protocol, first go to the section in the application that you want to compare, then follow these steps:

1. Select two applications from the lists below to display the differences.
2. Application 1: Select - Application 2: Select -
3. Show Difference
1. Select an application from the “Application 1” drop-down list:

   ![Application 1 Dropdown]

2. Select a different application from the “Application 2” drop-down list:

   ![Application 2 Dropdown]

3. Click “Show Difference.”

   If there are differences between the two applications you selected (within the current section), a comparison table will be displayed:

   ![Comparison Table]

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Full Application</th>
<th>Renewal 4th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>Male and Female</td>
</tr>
</tbody>
</table>
Contact Us

If you have questions about the application or require assistance during the submission process, please contact the Office of Research Compliance at 626-395-6336 or 626-395-8448 or email us at irb@caltech.edu.

For more information about the Caltech Committee for the Protection of Human Subjects, visit https://irb.caltech.edu.