iStar

***I**RB **S**ubmission **T**racking **A**nd **R**eview System*

University of Southern California

Childrens Hospital LA

User Guide for Investigators and Study Personnel

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Contents

Welcome to iStar

iStar stands for the **I**RB **S**ubmission **T**racking **A**nd **R**eview system. The development of iStar is a collaborative effort between the University of Southern California Institutional Review Boards (IRBs) and the Committee on Clinical Investigations (CCI) office at Childrens Hospital LA (CHLA). The project was funded by two NIH grants awarded to the USC and CHLA IRBs.

The iStar system is a web-based application created to standardize and computerize the application submission, routing, and tracking of research projects involving human subjects. The system allows us to serve investigators more efficiently and ensure better protection of research participants.

This user guide was developed specifically for investigators and study personnel using the iStar system. This booklet includes the following topics to get you started:

- iStar requirements
- Examples and an overview of the submission and review process
- Some basic methods you need to know to create and submit electronic IRB applications
- Where to get help if you have a problem

Frequently Asked Questions

Listed below are some commonly asked questions and their answers. This list is only a small portion of the questions we have written and prepared answers for. The entire list of frequently asked questions, or FAQ, is available at https://istar-chla.usc.edu/istar/Rooms/DisplayPages/LayoutInitial?PageID=FAQ

Q: The system won't let me submit my study.

A: There are several possible reasons for this problem.

1. You must be the Principal Investigator. If you do not see the **Submit Application to ____** activity, you are not the Principal Investigator. You must be the assigned principal investigator for the specific campus to be allowed to submit the application.
2. The application is not complete. If after clicking the **Submit Application to ____** activity, it displays a list of errors, you must complete the specified sections to be allowed to submit the application.
3. Co-Investigators have not agreed to participate in the study. All assigned co-investigators must login to the study and use the **Agree to Participate** activity.
4. You have not agreed to the assurances. You must indicate agreement to the PI's assurances by checking the **I agree** box. If you are a student, you must agree to the student's assurances.

Q: I made a mistake and clicked OK on an activity when I didn't mean to.

A: Once you click **OK** on an activity, there is not much that can be done. Please make sure you are truly ready to submit the application or response before clicking the **OK** button. If this happens, contact the help desk.

Q: My study is stuck and nothing is happening.

A: In the study workspace, look at the current state. Some sections of the review process may take longer than others. If you think there is a problem, contact the help desk or the assigned IRB administrator.

Convert a paper-submission study to the iStar system

Studies that have been previously prepared and approved in the paper system can only be converted into an iStar study at time of continuing review. Conversion of paper studies is a two phase process consisting of submitting a **Conversion Amendment** and then submitting a **Continuing Review**. Both submissions must be approved in sequence for approved continuation of the study past the end of the IRB or CCI approval period.

1. Notify the IRB or CCI office of your intent to convert a paper submission study into an iStar study. Office personnel will then create an entry in the iStar system for the study and will complete certain required fields, such as study title and personnel. If possible, the study will maintain the same IRB or CCI number. Office personnel will notify the Principal Investigator and Study Coordinator upon completion of this step.

TIP: *It is suggested that you notify the IRB or CCI office at least a week before you wish to begin working on the conversion amendment.*

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2. The study team will begin the application process by clicking on the **New Conversion Amendment** icon in the study workspace. All applicable sections of the abbreviated smart forms must be completed, in the same fashion as a new study proposal.
3. When the conversion amendment is completed, click on the **Submit to IRB** activity on the left hand side of the study workspace.
4. The conversion amendment will then be checked for accuracy and validity by IRB or CCI office personnel. When the iStar study is the same as the paper-submission study, office personnel will issue an approval of the conversion amendment.
5. Upon receipt of approval for the conversion amendment, the study team may begin the normal process of creation and submission of an iStar Continuing Review.

iStar requirements and access

Requirements

There are no particular hardware or operating system requirements for use of the iStar website. You are only required to have one of the following standard internet browsers:

- Microsoft Internet Explorer 6 or higher (*preferred*)
- Mozilla 1.5x or higher
- Firefox 1.5x or higher

***PLEASE NOTE: Macintosh users should use Firefox 1.5 or greater. Safari is not supported at this time.*

For all internet browsers, you must have client-side JavaScript enabled. To use the document upload feature and some reporting features, you may be asked to allow Java applets or Active X to run in your browser. All items are certified by Click Commerce Incorporated. Please make sure that your computer is kept up to date with patches and upgrades, especially Operating System and Java patches. This will help ensure that iStar works properly on your computer.

The iStar website was designed using a screen resolution of 1024 x 768. It is suggested you use this screen resolution for the optimal display of the iStar website.

Access

The iStar website is available at the internet address http://*istar-chla.usc.edu*. The website is available via any internet connection made by one of the supported browsers above. iStar is accessible 24 hours a day, 7 days a week.

Login access to the system is limited to employees, students, and authorized associations of USC and CHLA. Information on obtaining an iStar account is available on the website. Please note that all fields with a red asterisk are mandatory; and you must submit a valid email address to be granted access to the system. It is highly recommended that you use a USC/CHLA email address as the primary form of contact for all email notifications generated by the iStar system.

What is in iStar?

Using the iStar website, you can do the following:

- Create and edit an electronic application for submission of studies and grants to your Institutional Review Board.
- Add other investigators and study personnel to assist in editing the application.
- Prepare the application via “smart forms” that present only those sections that are applicable and relevant to your study.
- Attach electronic or scanned documents to the study (.pdf, .doc and .xls documents are allowed).
- Print out the application in a printer-friendly version.
- Use context-specific guidance to assist in answering questions consistent with guidelines and regulations.
- Validate the application before submission to catch common mistakes and reduce the number of changes required after submission.
- Submit a single application electronically to any of the three participating IRBs.
- Track the progress of the application as it is automatically routed for review and signoff to the appropriate organizations (i.e., faculty advisor, division and department reviewers) before being received by the IRB.
- Receive email notifications any time the application is sent back for requested changes by a reviewer.
- Receive the approval letter via email once the study is approved. A copy of the approval letter and approved consent forms will be posted online with the study and available for download at any time.
- View a time stamped log of all changes made to the application and any correspondence sent between the study team and the IRB.

Submit a continuing review for the study

You should begin preparing an application for continuing review before your IRB approval ends. If the study is currently approved in the paper system, you must complete a **Conversion Amendment** before submitting a continuing review in the iStar system. For directions on converting paper-submission studies, see the section on the next page.

Create a new continuing review

1. In the approved study’s workspace, click the 

button to start the application for a continuing review.
2. Complete the first page of the application and select the status of the study.
3. Click the **Continue** button and complete the rest of the application.

TIP: *If this continuing review requires you to also submit an amendment to the study, click the **Create Related Amendment** activity in the continuing review workspace.*

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4. When the continuing review is complete, any member of the study team may submit the continuing review to the IRB using the **Submit to IRB** activity.

Submit an amendment to the study

When you need to make a change to an approved study, you must submit an amendment to the IRB for approval. When making changes, the approved study application is the working document and all required changes must be made in the **Modified Study**, a copy of the approved study.

When the IRB approves the amendment, the **Modified Study**, becomes the approved version of the study. All previously approved versions of the study are stored in the system for record keeping and audit purposes.

Create a new amendment

1. In the approved study's workspace, click the 

button to start the application for a new amendment. Complete the first page and click the **Continue** button.

NOTE: *The iStar system only allows one amendment to be in process at a time. All amendments must be approved, rejected, or withdrawn before a new one is created.*

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2. Provide justification for any changes that need to be made in the study application.
3. When finished explaining the changes, save and exit to the amendment workspace.
4. All changes to the study **MUST** be made in the modified study.

Edit the modified study

1. In the amendment workspace, click the 

button to open the study smart forms. Note this is a copy of the approved study that can be used to make your changes.
2. Make all the changes you detailed in the amendment application.
3. To return to the amendment workspace, click the **Exit** button.

Context-specific guidance while you work

iStar includes new help/guidance links that give you quick access to context-specific information while you work. You can use these buttons to get technical help on any activity or process or access IRB guidance on any question or topic in the application – all within iStar.

iStar includes the following buttons and links to help you:

Quickly open technical help describing the actions you may take on this screen.

Get detailed, up-to-date guidance on any state/federal regulations or guidelines applicable to this application question.

Access information on the current state of the application in the review process and available actions you may take.

iStar Help and other sources of information

Details and how-to information about working in iStar are just a click away in the iStar application.

Context-specific help/guidance screens

Question specific guidance screens are available via the "Guidance" link on most application questions. Each question subject has a brief description, guidance from the IRB, and links to all the relevant regulations and guidelines. Technical help screens, available through the Help button, give instructions for website procedures, such as uploading documents and searching studies. In addition, because the processes and applications of three IRBs are combined, there is a list of common terms with agreed upon definitions. This list is available at https://istar-chla.usc.edu/istar/Rooms/DisplayPages/LayoutInitial?PageID=Defininitions. Each IRB also provides form templates on how to begin a protocol. The templates could be slightly different depending on the campus. They can be found at:

For HSIRB: http://www.usc.edu/admin/provost/oprs/hsirb/forms/

For UPIRB: http://www.usc.edu/admin/provost/oprs/upirb/forms/

For CCI: http://www.childrenshospitalla.org/body.cfm?id=213

Downloadable User Guides

User guides provide detailed documentation for all procedures and activities necessary for a particular user role. The guides can be downloaded by navigating to the **Training Resources** section of the website. Manuals for the following user roles are available:

- Investigators and Study Personnel (*This manual*)
- Organizational Approvers – In Development
- IRB Staff Personnel – In Development
- IRB Committee Members – In Development

The remainder of the **Documents** tab displays any question in the application that allows you to upload a document or file. Use the tab to quickly locate any document in the application.

Submit a reportable event for the study

Reportable events are used to report any of the following to the IRB:

- Internal Serious Adverse Event (SAE) - Initial Report
- Internal Serious Adverse Event (SAE) - Follow-up Report
- External Serious Adverse Event (SAE) - Initial Report
- External Serious Adverse Event (SAE) - Follow-up Report
- Data Safety Monitoring Report
- Protocol Deviation or Error

Create a new reportable event

1. In the approved study's workspace, click the New Reportable Event button to start the application for a new reportable event.
2. Complete the first page of the application and select the type of reportable event.
3. Click the **Continue** button and complete the rest of the application.

TIP: *If this reportable event requires you to also submit an amendment to the study, click the **Create Related Amendment** activity in the reportable event workspace.*

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4. The principal investigator or the co-investigator must submit the reportable event to the IRB using the **Submit to IRB** activity.

Reportable events versus non-reportable events

When completing the application for serious adverse events, you will be asked several questions classifying the nature of the event. If the event does not meet the requirements for a reportable event, you may still submit the event to the IRB.

When you submit a non-reportable event, you will receive an email confirming the event has been filed and does not require further review by the IRB.

View the approval letter and approved consent forms

When your study has been approved by the IRB or CCI, you will receive an email notification containing the approval letter. The approval letter will also be posted in the study workspace and will be available for download at anytime.

View the IRB approval letter

1. From your PI & Staff personal folder, select the **Studies** tab and click on the title of the approved study.
2. In the study workspace, the summary panel will now have an item for **Letter of Approval**. Click on the **[View]** link to the right.
3. The approval letter will open in a new window. You can then print the letter by selecting **File → Print…** form the menu bar.

TIP: *The approval letter will also be saved for recordkeeping in the history log under the activity **Study Approved.** You can view the letter by clicking on the link **See Approval Letter**.*

Access approved consent forms

Once your study has been approved, the consent forms, with the IRB approval stamp, will be accessible from the study workspace under the **Documents** tab. All documents from the approved application will be available under this tab.

The approved consent forms for your study will be accessible in two different formats:

- The **Approved Consent Forms** section will list all of the consent forms approved for use in the consent process. These MS Word documents will contain the IRB approval stamp and will be locked in read-only mode.
- The **Clean and Strikethrough Copies of Consent Forms** section will contain unstamped versions of the approved consent form. These documents will be editable in MS Word and should be used if there is a future need to amend the consent forms.

"Sandbox" Mode

For training purposes, a second iStar website is available at the internet address http://*istartraining-chla.usc.edu*. This sandbox website is a copy of the main iStar website and it is available for you to practice creating and submitting "fake" applications. **NOTE: THE SANDBOX WEBSITE WILL NOT BE USED TO PROCESS ACTUAL IRB SUBMISSIONS.**

Help Desk

Phone: (323) 276-2238

Email: istar@usc.edu

Hours: 8:30 AM – 4:30 PM

Office: IRD #404 (USC - Health Sciences Campus)

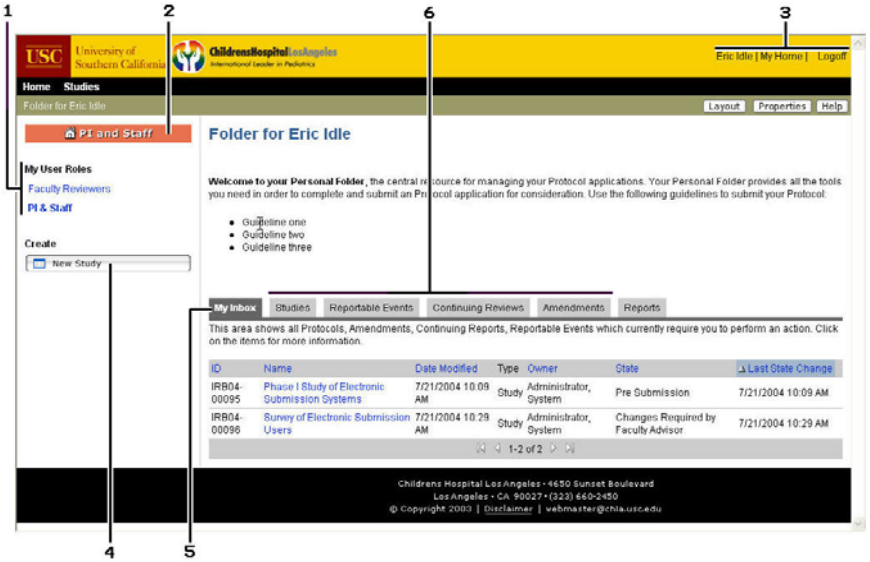
The help desk is available to answer any technical problems you may have. During non-business hours, you may email the help desk and you will receive a response by the next business day.

Workshop Classes

Instructional classes for iStar will be scheduled on an as-needed basis. Consult the **Training Resources** section of the iStar website to view upcoming classes or submit a request for a new class.

Personalized iStar experience

Your iStar experience is personalized to make working in iStar comfortable for you. When you log in to iStar you are taken to your personal folder which displays and has links to most items applicable to you as an investigator.



1. My User Roles allows you to select between user roles if you have more than one. This component will only display if you have multiple user roles.
2. The user role icon displays your currently selected user role.
3. The Top Navigator is available on almost all screens and has links to your Name (to change personal information), My Home (always brings you back to this page, your personal folder), and Logoff (ends your session and logs you out of the system).
4. The Create New Study button allows you to start a new study application from scratch.
5. The My Inbox tab displays all studies you are a part of that require some task to be done by the study team.
6. Tabs for Studies, Reportable Events, Continuing Reviews, and Amendments allow you to search through all of the respective items that you are part of, regardless of where it is in the submission and review process.

The Study History Log

Every study has a detailed history log. For auditing purposes, every action performed on the study is recorded in the history log. This information is viewable under the **History** tab. The history log is sorted in chronological order and displays only the actions you have permission to see. Each activity, when performed, is recorded in the history log with a data/time stamp and the name of the person performing the activity. You can click on the name of the activity to view the system details. A new interface is being developed to make these system details more user-friendly.

Responding to requested changes

The study team will receive automated notification when the study is sent back to them for requested changes.

1. In the study workspace, click on the most recent item in the history log. The link will be named **Changes Requested by ____** where the blank indicates the reviewer requesting the changes. The requested changes will be listed in the **Notes** section. Click the web browser's back button to return to the study workspace.

NOTE: *A preview of the requested changes will be shown in the history log along with any attached documents. It is suggested you click on the history log to see the requested changes in their entirety.*

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2. Navigate to the smart form application and make any needed changes. Remember to save the changes before exiting the application.

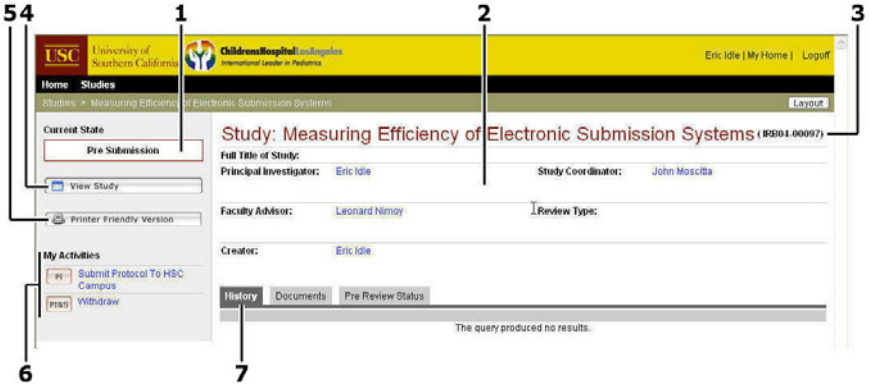
3. When you are ready to submit your response, click the requested changes link in the history log and copy the entire **Notes** section, listing all the requested changes.

4. Navigate back to the study workspace and click the **Submit Response to ____** activity.

5. Paste the requested changes you copied into the multi-line text box. Write your response after each requested change, detailing the change made or your reason for disputing it. When finished, click the **OK** button.

The Study Workspace

Every study created in the iStar system is assigned a folder or workspace. When you click on a study to view it, the study's workspace is opened. The workspace displays important information about the study and contains links to help navigate to any information contained in the study.



1. The current state displays the progress of this study in the review process.
2. The panel displays summary information about the study. The amount of information will change depending on the study's progress through the review process.
3. IRB/CCI number. The system will assign a temporary ID number during Pre Submission. Once the study is submitted, the system will assign the official IRB/CCI number.
4. The **View Study** icon will open the application smart forms.
5. The **Printer Friendly Version** icon will open all of the relevant smart form screens in one easy to print window.
6. **My Activities** lists all of the available actions you can perform on the study. Click on them and complete the opened screen to perform the action.
7. The **History** tab records all actions performed on the study. Each action is recorded with the date, time, and person performing the action. You may click on the name of the activity to see the system details.

iStar basics

This section begins with an overview of the basic iStar submission and review process, and then explains the following tasks that will get you started in creating and submitting your application:

- Create a new application and specify personnel
- Edit an application
- Submit the application
- Check the status of the application and respond to requested changes
- View the approval letter and approved consent forms
- Submit a reportable event for the study
- Submit an amendment to the study
- Submit a continuing review for the study

Overview of the iStar submission and review process

The following steps illustrate the basic application review process:

Step 1 **PI & Study Team**
Prepare and submit application.

Step 2 **Pre-Reviewers**
If applicable, the application is routed to the following people/organizations for approval and sign-off:
Faculty Advisor
Cancer Center Approval Committee
Division and Department Heads

Step 3 **IRB Staff Review**
An IRB Administrator will be assigned to the study. The IRB Administrator will conduct a staff review and manage the scheduling of the study. This is the person you will be in touch with throughout the study.

Step 4 **IRB Review**
The IRB committees or a chairperson (for expedited/exempt studies) will review the application and provide an approval. Committee decisions and approval letter are recorded by the IRB Administrator in iStar and sent to the PI & Study Team.

Step 5 **PI & Study Team**
Conduct research.
Report adverse events.
Submit requests for continuing reviews.
Submit amendments.

Check the status of the application and respond to requested changes

Once the application has been submitted to the IRB, the application is automatically routed to the required people in the review process. As part of the study team, you will receive notifications from the system indicating the completion of certain elements of the review process or requesting changes to be made to the application. You can also check the progress of your application by opening the study workspace in iStar.

Receiving Progress Notifications

The iStar system automatically generates email notifications and sends them to the study team when significant events have occurred in the review process. The study team will always receive a notification when a reviewer requests changes be made to the application. In addition, the study team will receive notifications at the following times:

- Confirmation that the application has been submitted.
- Receipt at the IRB office.
- Official action letter form the IRB.

NOTE: *It is important that your email address recorded in the iStar system is current, since the system uses this email address to send notifications about review progress. You can check your email address by clicking your name in the top navigator bar.*

Any member of the study team can use the activity **Send Correspondence to IRB** to send an email to the IRB Administrator assigned to the study. The correspondence will also be recorded in the study's history log.

Application validation and submission

1. The assigned Principal Investigator clicks on the title of the study from the PI & Staff personal folder.
2. In the study folder space, click the activity called **Submit Application to _____** , where the blank indicates the IRB name. The IRBs available for submission are selected in question 1.4. of the application.

NOTE: *The **Submit Application to ____** will only be displayed for the person that is assigned as the Principal Investigator for that campus in the study personnel section of the application.*

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3. The system will run a final validation check on the entire application before submission. If there are any errors, they will be displayed on the submission screen that opens up and your application will not be submitted.

   The application must be error-free and have all co-investigators agreed to participation before it can be submitted.
4. On the new screen that opens up, read the principal investigator's assurances and select Agree to Participate in Study and check **I agree** box. If the principal investigator is a student, he/she must also check **I agree** box for the student's assurance and the Faculty Advisor must approve the protocol for it to move forward.
5. Click the **OK** button at the bottom of the screen to submit the application for the new study.

Create a new application and specify personnel

With the PI & Staff user role, you can create a new study and grant proposal by using the New Study button on your personal folder. By clicking on this button, you will be taken to a new application and asked to fill in the identifying information for this study or grant.

Begin the study process by creating a new study

1. Log on to iStar. From your PI & Staff personal folder, click the New Study button on the left-hand side of the screen.

   The first application screen of the study appears. The Application # will be assigned once the first screen is saved.
2. Enter in the required fields (marked with a red asterisk *).

TIP: *You can answer the text questions by typing or using the clipboard. If it is easier to type a section in another application, such as Word, you can copy the appropriate section and then paste it into the text box.*

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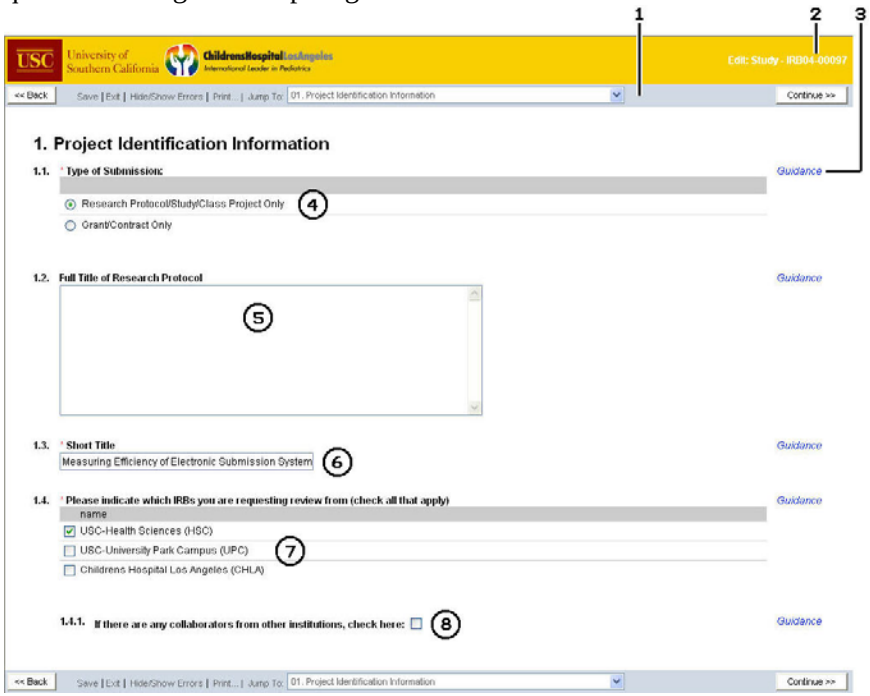
3. Click the **Continue** button in the navigator bar to save and move to the next screen.

NOTE: *If you select "Grant/Contract only" as the type of submission, you will be presented with a different set of application screens that are only applicable to grant and contract submissions.*

The application screen

Each screen of the application is composed of different types of questions along with helpful guidance.



1. The Navigator Bar contains buttons to save, exit, and move throughout the application.
2. The assigned study number. This number will be set to the IRB Number once the study is submitted.
3. The guidance link allows you to access the online help associated with this question.
4. A single selection question. Only one option may be selected.
5. A multi-line text question. Multiple lines of text may be entered into this box. There is no limit to the number of characters.
6. A single-line text question. Up to 255 characters may be entered into this box.
7. A multiple selection question. Any number of the options that apply may be checked.
8. A single checkbox. Check the box to indicate “yes”, leave it blank for “no”.

Submit the application

Before the application is submitted, it will be validated to check for common errors. As part of the study team you can check the progress of the application writing process at any time by using the SmartForm calculator. The SmartForm progress calculator validates the study in its current version. The application is also validated when the Principal Investigator submits the application to the IRB.

Use the SmartForm progress calculator

1. From your PI & Staff personal folder, click on the title of the study you wish to select.
2. In the study folder space, click the **SmartForm Progress** link.

   A new window will be displayed, listing all of the sections of the new study application. On the right-hand side, the status for each section is displayed. The following icons and indicators are used:

Complete	This section is required and completed with no errors.
Incomplete	This section is required, but it is incomplete or has errors.
Not Required	This section is not required.

3. To go directly to a section in question, click the name of the section. The main window will go to the first application screen in the section. The SmartForm progress window may be closed.

Agree to Participate for Co-Investigators

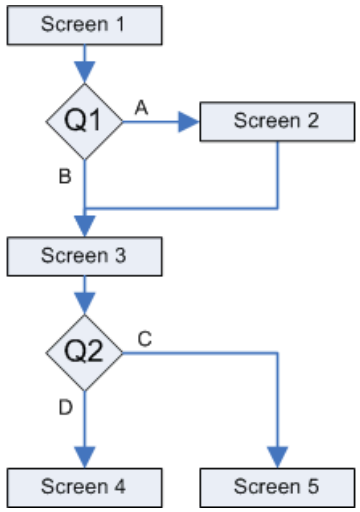
All co-investigators designated in the study personnel screens must agree to participate in the study before the application can be submitted. The co-investigators need to navigate to the study folder space and use the **Agree to Participate** activity. Their decision will be recorded in the history log.

If a co-investigator refuses to participate in the study, they must be removed from the study team in order for the application to be submitted.

Smart Form Flow and the Continue button

By using the **Continue** button on the navigator bar, you take advantage of Smart Form Flow, a behind-the-scenes feature that determines which form you see next based upon your responses to previous questions.

An example smart form flow is given to the right. Q1 denotes a question on screen 1 with possible answers "A" and "B". Q2 denotes a question on screen 3 with possible answers "C" and "D". When you click **Continue** on screen 1, the smart form looks at your answer for Q1. If you answered "A" you would go to screen 2 and click **Continue** again to go to screen 3. If you answered "B", you would skip screen 2 and go directly to screen 3. The following table lists the possible screen progressions depending on the answers specified for Q1 and Q2.



Q1	Q2	Form Progression
A	C	Screen 1, 2, 3, and 5
A	D	Screen 1, 2, 3, and 4
B	C	Screen 1, 3, and 5
B	D	Screen 1, 3, and 4

TIP: *If you fill out the application in order and use the **Continue** button, you will be able to fully take advantage of the smart form flow. The smart forms will only present to you relevant screens of the application.*

Navigate to other screens in the application

1. Use the navigator bar to move to the screen that requires changes.
2. Make the specified changes.
3. Click the **Save** button or **Continue** button to save the changes.
4. Click the **Exit** button to return to the study folder space.

Assign study personnel

As the creator of a new study application, you will specify who has permissions to edit and view the study. You control these by whom you assign as the study team on screen 2 of the application.

1. From the first screen, Project Identification Information, press the **Continue** button.

   You will navigate to the study personnel screen for the campus(es) you selected in question 1.4.

2. Select the Principal Investigator for the study submission on this campus in question 1. by clicking the **Select** button. A search page will open that will allow you to search for the investigator by last name, first name, division/department, or their user ID.
3. In questions 2.1, 2.2, 2.3, and 2.4, specify the Study Coordinator/Contact Person, Co-Investigators, and other Study Personnel.

TIP: *Only the users specified in the first four questions of screen 2 will be able to edit and save the study application. If you would like to give a new person permission to edit the study later on, you will have to add them to one of these questions at that time.*

4. Answer if you require a faculty advisor in question 2.4 and if "yes", select the faculty advisor in question 2.6.
5. Press **Continue** to save and navigate to the next screen.

   The next screen will automatically list any division or department approvals needed for the study based upon the home departments of the principal investigator and co-investigators.

6. If additional division or department approvals are needed for your study, specify them in question 3.
7. Press the **Save** button to save the current screen.
8. Press the **Exit** button to leave the study application.

9. When you have completed the application, the last of the screens is a "finish" screen with instructions on next steps. ****PLEASE NOTE: your study will NOT be submitted for IRB review from this screen.* ***

   Exiting or pressing "finish" at the end of the application will bring you to the home page for this study. This screen will serve as the central place to interact with the study. From here you will be able to:

   - View summary information about the study and review process.
   - Access the log of all correspondence and actions taken on this study.
   - Use activities (bottom left side of the page) to do certain actions, such as **Submit Application to IRB**.
   - View all attached documentation including consent forms, recruitment materials, and drug brochures.
   - Once the study is approved, view and navigate to all reportable events, amendments, and continuing reviews for this study.

Edit an application

A study or grant application may be edited before it is submitted (during **Pre Submission**) or any time changes are requested by reviewers or the IRB. The study will appear under the "My Inbox" tab in all of these occasions.

To open a study to make changes

1. From your PI & Staff personal folder, click on the title of the study you wish to select.
2. In the study folder space, click the View Study button.

   The first study application screen appears in edit mode.

NOTE: *The View Study button is also available when changes are not required and will instead open the study or grant in read-only mode.*

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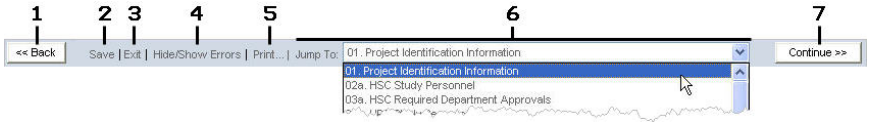
3. Make any necessary changes and save the study by clicking the save or continue button.

Use the application navigator bar

The navigation is displayed at both the top and bottom of the smart form screen for your convenience.



1. The back button will take you to the last form you were on.
2. Save allows you to save the information on the screen.
3. Exit takes you to the folder space for the study. If you didn't save the study manually, then by clicking on the Exit button, you will receive a prompt if you want to save changes or not.
4. Validates the current screen and displays any errors.
5. Assembles the entire application into a printer-friendly version.
6. Use the Jump To dropdown box to navigate directly to any screen in the application.
7. The continue button will save the current screen and navigate to the next screen in the smart form flow.