

# 1 - Study Application Smartform

## Study Smartform FAQ

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## **FAQ: Answers**

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**Q1: What does the red asterisk \* mean next to the items?**

- A. The asterisk means that it is a required item; it must be completed before you can submit the application to the IRB. **Tip:** If you want to skip the item and come back to it at a later time, use the **Jump To** menu to go to another application section. If you click **Continue**, you will get an error message reminding you to complete the item.

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**Q2: Where and what is the *Jump To* menu?**

- A. The **Jump To** menu is located at the very top and bottom of the application. It lists the pages that are currently required to complete your study. To use it, click on **Jump To**. When the list appears, click on the page that you want to go to. **Tips:** 1) The red page title indicates your current location. 2) As you work through the application, more pages may be added to the **Jump To** menu based on your answers.

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**Q3: How do I save my work?**

- A. webIRB saves your work anytime you click **Save** or **Continue**. These functions are located at the very top and bottom of the application screen. If you will be working on a page for 15 minutes or longer, remember to click **Save**. Otherwise webIRB will time-out and you will lose the unsaved work on **that page**. **Tip:** If you are using the **Jump To** menu to navigate through the smartform, click **Save** just before or after you jump.

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**Q4: How do I print the application?**

- A. To print a page: Click **Print** at the very top or bottom of the page. A form with a copy of the page will open. Click **Print** in the top right corner.

To print the entire application: **Exit** the application (save your work on the way out). Look

at the top left side of the study workspace. Click **Printer Version**. A form will open with copies of all the current required pages. Click **Print** in the top right corner.

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**Q5: How can I find out if I accidentally skipped some application items?**

- A. While the application is open: Click **Hide/Show Errors** at the top or bottom of the page. If you have more items to complete a list will appear at the bottom of the page. The **Jump To** links will take you directly each page. **Tips:** 1) When you complete an item, click **Save** at the top of the page and then **Refresh** in the top right corner of the **Error/Warning Messages** screen. This will update the list for you. 2) If you click **Hide/Show Errors** again, the **Error/Warning Messages** screen will disappear.
- B. From the study workspace: Under **My Activities**, click **Submit Response**. If you have more items to complete, the **Error/Warning Message** screen will open. If not, you will see the submit study screen. If you are not ready to submit the study, you can exit the screen.

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**Q6: Why did I get an error message for an item that did not have a red asterisk \*?**

- A. Some items are required based on how you answered a previous question. For example, if you choose “other” as an answer, you will likely be required to complete a text box to explain.

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**Q7: Where can I find help on specific application items?**

- A. There are several types of help available in the application:
- Brief guidance or links to additional guidance are often available in the gray column on the right side of the screen.
  - Icons are available in various areas of the application. Click on them for information about the associated item.
  - Some of the answers associated with checkboxes have blue links to definitions. You can click on these for more information.
  - Illustrated **Quick Reference Guides** are also available.

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**Q8: If I exit webIRB before I finish the application, how will I be able to find it again?**

- A. When you sign into webIRB, a link to the study will be listed in your Inbox. Click on the link to go to the study workspace. Then click on the **Edit Study** button (top left corner) to open the application smartform.

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**Q9: How can I find out my progress towards completing the form?**

- A. While you are in the smartform, click on the **Jump To** Menu. You will see a display of currently required smartform sections. Your current section will be **red**; the list of required sections will be **black**.

If you are in the study workspace, click **View Smartform Progress**. You will see a list of complete and incomplete sections.

**Note:** As you fill-out the smartform, additional sections may be added to the above lists.

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#### **Q10: Who can submit the application to the IRB?**

- A. PIs or PI Proxies can submit a completed study application to the IRB. The function **Submit Study** is available in the study workspace under **My Activities**. Other Study Staff can let the PI/PI Proxy know that the study is ready to submit by using the **Send Ready Notification** activity. After the study is submitted, look for the **PI Assurance** button under **My Activities**. The PI must click on this button and electronically sign the PI assurances before the IRB will approve the study. This activity is only available to the PI.

**Note:** If there is a Faculty Sponsor (FS) for the study, the FS must sign the FS assurances before the study can be submitted.

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#### **Q11: How do I let my Faculty Sponsor (FS) know that the study is ready for approval/assurances?**

- A. If you are the PI or PI Proxy, look for the **Send Notification to FS for FS Assurance** under **My Activities**. You can use this activity to send the Faculty Sponsor an e-mail that the study is ready for review. Once the FS reviews the study and completes the assurances, you will see the following on the study workspace: **FS Assurances: Completed**.

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#### **Q12: What's a PI Proxy?**

- A. A PI proxy is a member of your study team whom you authorize to submit applications to the IRB. You can select up to two PI Proxies per study. The **Edit PI Proxy** activity is available to the PI in the study workspace under **My Activities**.

**Note:** If you have a Faculty Sponsor, s/he is automatically one of your PI Proxies.

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#### **Q13: When I click a button, such as *Continue*, why is there a couple seconds delay before the program responds?**

- A. During the delays webIRB is processing information. For example, when you click **Continue**, the webIRB is using your responses to compute which sections should appear next.

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**Q14: Why isn't the "PI Assurances" activity available?**

- A. The "PI Assurances" activity is available only to Principal Investigators and only after a study is submitted to the IRB. If a study is returned by the IRB with requests for changes, then the "PI Assurances" activity will become available again after the response is submitted to the IRB.

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**Q15: How are IRB numbers assigned?**

- A. The format is "IRB #xx-yyyyyy" where xx is the year the study was submitted to the IRB and yyyyyy represents the numerical order of submissions. For example, IRB #10-000025 is the 25<sup>th</sup> study submitted to the IRB in the year 2010.

Note: prior to submission, new studies are assigned a "pre-submission" number using the prefix **PRE**. The IRB number is assigned once a study is submitted to the IRB; it will not match the **PRE** number.

***Important Note about Studies Converted from Paper:*** When you convert a study from paper, it will be assigned a new IRB number, as described above. Please be sure to notify any campus departments that may be working with the old IRB number (e.g., Contracts and Grants, Pharmacy, etc).

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**Q16: Can I recall my study after submission to the IRB (for example, I forgot to attach the consent form to the application)?**

- A. Yes. Use the **Send Inquiry or Reply to IRB** activity to ask IRB staff to return your study to your inbox.

**Important Note:** do *not* use the **Withdraw** activity to recall your study unless you wish your study to be archived.

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**Q17: Does webIRB provide documentation of study submission?**

- A. Yes. webIRB generates an e-mail confirmation once a new study is submitted. E-mails are sent to the PI, PI proxies, and study contact as listed on page 1 of the smartform application.

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**Q18: Is the information in section 1.1, item 1.1 (Protocol Version Date and/or Number) included in the IRB Approval Notice?**

- A. No. Only information included in section 1.1, item 1.0 (Full Title of the Submission) is included in the IRB Approval Notice.

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**Q19: Why is the study application called a “smartform”?**

- A. Built-in branching logic gives the study application its “smartform” designation. The application will branch to items depending on the answers you provide to key questions. You won’t have to figure out which forms and supplements to fill out, or which items to skip—webIRB will do this for you.

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**Q20: Does the program signal when my webIRB session is about to time out?**

- A. Not currently. The program will be updated with a new release from the vendor later this summer. The new release will have a warning feature when the program is about to time out.

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**Q21: I have more than one affiliation. How do I add affiliations to the smartform application?**

- A. Click on the “Profile” tab in your homepage. Next, click on your name and then on “Edit Researcher Profile”. A profile smartform will open. Item 2 on the first page of the smartform will allow you to enter multiple affiliations. You also have the option of clicking on “Other” as your response and then filling in your other affiliations in item 2.1

Note: your affiliations will be displayed in section 1.1, item 3 of the new study smartform.

**Q22: What do I do to close a study?**

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- A. Use the Continuing Review smartform to close a study. The first item is, “Indicate the type of report you are submitting.” Click **Study Closure**. The smartform will then gather the information needed to close the study. When it is completed, you can submit the smartform to the IRB.

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**Q23: How can I add a person to a study as Key Personnel if they are from another institution (not UCLA)?**

- A. You can request an account for a colleague from another institution. The instructions are on the webIRB Homepage under the [How to get a webIRB account](#) tab. Once the person has a webIRB account, his/her name will be available to add to the study.

**Q24: I don't see my funding source in the drop down list in the application. How do I indicate "Other?"**

- A If you do not see your funding source in the drop down list in section 6.2/item 1.0, enter "other" as the name of the funding source, then click "Find." "Other" will appear as a choice for you to select. You can then type the name of the funding source in item 1.1.1.