Human Subjects Protocol Application: Tips and Tricks

Quick Reference Guide

General Tips and Tricks
- Some special required fields will have a red asterisk: *.
- The General Checklist, Study Population, and Study Location sections drive what is asked for later.
- Check boxes - [ ] - mean that you may select more than one item from that group.
- Radio buttons - ☑ Yes  ☑ No - mean that you may select only one item from that group.

Tables
In some sections of the Protocol Application Form, you may one to add more than one item (investigational drugs, investigational devices, etc.). In these areas, you will see tables:

<table>
<thead>
<tr>
<th>Investigational Devices</th>
<th>Add</th>
<th>Delete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>Manufacturer Name</td>
<td>IDE #</td>
</tr>
<tr>
<td>☑ Wheelchair</td>
<td>Acme</td>
<td>1234567</td>
</tr>
</tbody>
</table>

To add an item to these tables, click the Add button. A popup window will appear with specific fields relating to that table. Complete each of the fields and click the Save button. In a moment, the popup box will disappear, and the main screen will refresh and display the added item:

To add another item, click the Add button, fill out the fields in the popup window, and click the Save button. The popup box will disappear and the main screen will refresh and display the additional item.

To edit an existing item, click on the hyperlinked field in the table (the word “Wheelchair” in the example above). A popup window will appear. Make any required changes, then click the Save button. The popup box will disappear and the main screen will refresh and display the revised item.

To delete an item, click the check box to the left of the item you wish to delete, then click the Delete button. A Confirmation popup window will appear. If you are sure you want to delete the item from the table, click the Yes button. The popup box will disappear and the main screen will refresh and display the table without that item.

Rollover Menus
On the Home Page, additional menu options appear when your mouse hovers over some menu items. For example, when you hover over Archived Protocols, shortcuts to Closed Protocols, Withdrawn Protocols, and Not Approved Protocols appear. You may click on the Archived Protocols section, or you may jump to any one of those categories by clicking on the rollover menu directly.
Check for Completeness

At any time during the creation of the protocol for submission, you may click the Check for Completeness menu item to see which other items the system will require you to complete prior to submitting the protocol. You may use this feature as often as you desire.

The Protocol Form Completeness Report pops up in a separate window. To jump to any section of the protocol application that the system feels still needs to be completed, click the hyperlink report item. This will automatically close the report and your original browser window will now show the section of the protocol you jumped to.

To exit the Protocol Form Completeness Report without jumping to a hyperlinked item, close the browser window. You will be returned to the Protocol Application Form in the same section you last worked on.

Submit Form

When you think you are ready to submit your Protocol to the IRB, click the Submit Form menu item. If you have any required items outstanding, you will be directed to the Protocol Form Completeness Report instead. If there are no additional system required items to complete, your protocol will be forwarded to the IRB Coordinator. The IRB Coordinator will assign your protocol to an IRB Panel Manager. The panel manager will manage your protocol through the review process.

Reviewer Comments

When you receive comments on your protocol, it will be listed on the Home page. Under the Protocol Events/Comments column, it will say Comments Received and will have a cycle number associated with it. Each protocol may go through one or more comment cycles before being approved.

To view the comments, click on the hyperlink that says Comments Received. This takes you to the Comments page. From here, you may view each comment individually by clicking on the hyperlinked Comment Title. Respond to each comment below the comment on the Comments page.

If your protocol needs to be updated as a result of changes requested by the reviewers, click the red Get Protocol button to launch the protocol. Any changes you make will be recorded. Reviewers will be able to see your previous and current entries to each question. Old versions of attachments will be saved and accessible in the Event History page.

Once you have made any requested changes and responded to each comment, press the Submit to Manager button to send your comments back to the IRB Manager and the Reviewers. Reviewers may then have new comments, or may recommend your protocol for approval.

Need Help?

Submit a HelpSU ticket online at http://helpsu.stanford.edu. In the Request Category field, select Administrative Applications. In the Request Type field, select E-Protocol Human Subjects from the drop down list. This will automatically email everyone on the support team.