CUNY HRPP Procedures: How to Use Ideate

Revising an Application: Response to IRB Request for Modifications

Applications that are returned to the Principal Investigator for revisions are displayed in the To Do List area.

To Begin Revising the Application:

Click on the text within the task located in the To Do List.

TYPES OF COMMENTS FROM A REVIEWER

Summary of Changes and Comments

A summary of the changes and comments provided by the reviewer are displayed for the investigator. Each tab that has a suggested change or a comment is identified with an asterisk.
**Revise Initial Application Submission**

**Location** – Provides a link to quickly navigate to the location of the suggested change and/or comment.

**Field** – Identifies the field that has the suggested change and/or comment.

**Original Value** – Displays the previous value that was submitted in the application.

**Suggested Value** – Displays the suggested value for the field.

**Comment** – Displays the comments provided by the reviewer.

**Action(s)** – Displays the actions taken by the principal investigator in their response.

**Field Level Review Comments:**

The reviewer may provide a comment only for a field. These are identified as a **Review Comment** link to the right of the field. Mouse over the link to display the reviewer comment.

**Lay Summary**

The purpose of this study is to determine whether treatment with the OPTIMIZER System is safe and effective in patients with moderate to severe heart failure symptoms.
General Review Comments

General comments from the reviewer are displayed on the left hand side of the page.

ADDRESSING COMMENTS FROM A REVIEWER

Addressing Suggested Changes:

Suggested changes can be made for most fields in the application. When the reviewer makes a suggested change, the field is identified and the suggested change is applied. The investigator may take one of three actions. Accept the change, restore the prior value or provide a new value.
**Prior Value** – To restore the original value, mouse over the Using Suggested Change and click on Prior Value; you will be asked to justify why you are not using the suggested change.

**Using Suggested Change** – The default for any suggested change. There is no action required to accept the suggested change.

**Using New Value** – To provide a brand new value for the field, simply enter the value in the field.

**Addressing Field Level and General Comments:**

The investigator can address these by revising the content of the application, where applicable, and/or including general comments in the “Investigator Response” box.

**Summary of Principal Investigator Actions:**

Once the investigator has completed their revisions to the application, the Changes tab summarizes all actions taken. The page is separated into two sections, the first section displays the actions for each field that had a suggested change or comment by the reviewer and the second section that displays each field that is altered by the investigator that was not suggested by the reviewer.
### Summary of Suggested Changes and Comments:

<table>
<thead>
<tr>
<th>Location</th>
<th>Field</th>
<th>Original Value</th>
<th>Suggested Value</th>
<th>Comment</th>
<th>Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary</td>
<td>Protocol Title</td>
<td>Evaluation of the Safety and Effectiveness of the OPTIMIZER System in Subjects With Heart Failure: FIX-HF 5</td>
<td>Evaluation of the Safety and Effectiveness of the OPTIMIZER System in Subjects With Heart Failure: FIX-HF 5 with a change from the Department Head</td>
<td>Change and a comment</td>
<td>Suggestion Ignored</td>
</tr>
<tr>
<td>Summary</td>
<td>Lay Summary</td>
<td>The purpose of this study is to determine whether treatment with the OPTIMIZER System is safe and effective in patients with moderate to severe heart failure symptoms.</td>
<td></td>
<td>Comment</td>
<td>New Value Entered</td>
</tr>
<tr>
<td>Research Design &gt;&gt; Overview</td>
<td>Research Purpose and Hypothesis</td>
<td>The purpose of this study is to determine whether treatment with the OPTIMIZER System is safe and effective in patients with moderate to severe heart failure symptoms.</td>
<td>Just a comment.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### New Modifications:

<table>
<thead>
<tr>
<th>Location</th>
<th>Field</th>
<th>Original Value</th>
<th>New Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Design &gt;&gt; Overview</td>
<td>Methodology</td>
<td>The purpose of this study is to determine whether treatment with the OPTIMIZER System is safe and effective in patients with moderate to severe heart failure symptoms.</td>
<td>A change that was not requested.</td>
</tr>
</tbody>
</table>

### To Submit the Revised Application:

1. Click the **Submit** tab.
2. Enter any desired **Submission Notes** in the field provided.
3. Check the **I Agree** checkbox to agree to the certification statement.
4. Click **Send for Review**.