

# Creating and Updating Alert Pages in OncPro

This document is intended to provide work instructions to Nursing and Pharmacy reviewers on how to revise alert page content and post alert pages to OncPro.

## Changes with Alert Page Generator v2.0 released 11/21/2022:

- New text editor simplifies the ability to format text and allows for the insertion of lists, tables, symbols and images.
- Symbols display in the editor as they will appear in the resulting PDF.
- New functionality to mark items “Pending” when updates should occur with activation of an amendment or dose/cohort form.
- ODQ will be able to convert “Pending” items to “Active” and publish an updated alert page at activation.
- Columns on the main screen have been re-ordered to decrease scrolling and improve user interaction.
- Users will authenticate using the same single sign on process as other DF/HCC systems.

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## Locating a Protocol in the Alert Page Generator tool

1. A link to the Alert Page Generator is available on the [Clinical Trials Portal](#). The use of Google Chrome is recommended.
2. Log in with the same MGB/Partners username and password that you use to access OncPro.

3. Enter the protocol number for the appropriate study and click “Search”.



Protocol No:

4. On the next page, confirm that you have the correct protocol by reviewing the protocol number, protocol title, and core site PI name. Additional information about the protocol is shown for reference (e.g., links to view participating sites, study staff, and active arms/dose levels).
5. Once a protocol is located, the main page will show action buttons and a table of any existing alert page log items. If this table is blank, it means no information has been entered for this study in the alert page generator yet.
  - a. Note: A blank table does not necessarily mean that an alert page does not exist for the study. For existing protocols, please always check to see what is currently posted to OncPro first. Alert page documents that existed prior to the use of the Alert Page Generator are not automatically converted into log entries in this table.
  - b. The action buttons are used to perform the following actions:



- **Activate/Deactivate:** Change the status of an existing alert log item to make it active or inactive. Only active items will appear on the PDF alert page generated for posting to OncPro.
- **Add New Log Item:** Create a new entry in the alert log table. This is used to add new content to the alert page.
- **Reorder:** Use this button to change the order in which alert log items appear on the PDF alert page.
- **Generate Alert Page:** Once all updates to the table have been made, click this button to generate, preview, and post a new PDF alert page to OncPro.

## Adding New Content to the Alert Page

1. Click on the “Add New Log Item” action button. This will bring you to a new screen as shown below:

All DF/HCC Sites:    
 DFCI:    
 BWH:    
 BCH:    
 MGH:    
 BIDMC:

APGenLogID:    
 Ver:    
 Submission Reference Number:    
 Category: SAFETY

Alert Title:

Alert Text:

Item Order:    
 IRB Notified:  (Checked for Yes)   
 Pending Activation:    
    

2. Indicate the sites that the new alert log entry applies to. By default, this will be all DF/HCC sites. However, if the content only applies to specific DF/HCC institutions, indicate this using the checkboxes shown.

All DF/HCC Sites:    
 DFCI:    
 BWH:    
 BCH:    
 MGH:    
 BIDMC:

3. The Log ID and version fields are not editable. These will be filled in automatically and are part of the audit trail generated automatically by the tool.

**APGenLogID :**    
**Ver :**

4. Enter the “Submission Reference Number” as appropriate for this entry. This is a free text field that is typically used to identify the iRIS reference number that triggered the need to add information to the alert page. This is useful in the event one wishes to trace the information back to a specific submission in IRIS. If there is no iRIS submission related to the content, free text is allowed and a comment should be entered to indicate the source of this information (e.g., “SIV on 3/3/2022”)

**Submission Reference Number :**

5. Choose and appropriate category for this item using the drop down. The category determines the section within the alert page where this information will appear. For example, the Safety

section appears first.

Category :

- SAFETY
- ELIGIBILITY
- PROCEDURE
- TREATMENT
- SPECIMEN
- OTHER

6. Enter a title or name for the information in the “Alert Title” field. For example, this is frequently used to identify the specific topic or section of a protocol that is being clarified, such as “Protocol Section 7.1.2 Schedule of Events”.
7. Enter the detailed information in the “Alert Text” box. This is the specific clarification or other language that should appear on the alert page.
  - a. See below for guidance on adding formatting, tables or images.
8. If desired, enter a numerical value in the “Item Order” field. This optional field allows users to control the order in which information appears on the PDF alert page. Lower number items will appear prior to higher number items within a given section. For example, enter 1 if you want an item to appear at the top of the section.

Item Order :

9. In the “IRB Notified” field, indicate whether the IRB has been notified of the new information, or if this is not applicable as the information does not require IRB review. This field is a prompt for the Nursing and Pharmacy reviewers to ensure that any new information that needs to be submitted to the IRB has been submitted appropriately. Checking this box does not send any information to the IRB.
10. If the changes should not be published until activation of a specific submission in IRIS, check the “Pending Activation” box. This will notify ODQ to update the alert page with the change(s) at activation.
  - a. This functionality should not be used during the initial submission of new protocols or sponsor correspondence. For new studies, alert page changes can be published immediately and will appear when the study goes live.
  - b. This functionality should not be used for sponsor correspondence submitted on the Administrative Modification form. Such submissions do not route to ODQ for an activation step.
  - c. **Important:** The correct iRIS number must be captured in the “Submission Reference Number” field. This is how ODQ will match your entries with the correct submission.
11. When finished, click “Add Log Item” to save this information and return to the main page. Otherwise, click “Cancel Entry” to return to the main page without saving.

Cancel Entry

Add Log Item

- Repeat the above steps to add additional items to the log. Once all items have been captured, proceed to the section on [Publishing the Alert Page to OncPro](#).

## Editing Existing Alert Page Content

- Existing alert items can be edited by clicking the Edit link in the first column of the table.
- Clicking Edit brings you to the same data entry screen as you use to create a new alert log item. Make the necessary changes to any of the fields and then click “Update Log Item” to save the changes. Otherwise, click “Cancel Entry” to return to the main page without saving.
- Once all changes have been made, proceed to the section on [Publishing the Alert Page to OncPro](#).

## Removing Items from the Alert Page

- Alert log items are removed from the posted alert page by inactivating the appropriate row in the table.
  - If removal of items needs to occur after activation of a submission, please add a **Take Note** in iRIS in the format of “ODQ Activation: Ref ##### please email [email address] at activation for removal of alert page items.” ODQ will then notify you at activation so the updates can be made.
- You can view previously inactivated items by selecting “Show Inactive Items” above the table.

Show Inactive Items

When this is checked, inactive items will appear at the bottom of the table shaded grey.

- To inactivate an alert log item, go to the “Active” column of the table and uncheck the checkbox for the rows that you want to hide. Depending on your screen resolution, you may need to use the scroll bar at the bottom of the table to scroll sideways.

Active
<input checked="" type="checkbox"/>

- After toggling the checkboxes appropriately, click the “Activate/Deactivate” button to apply the changes.

Activate/Deactivate

5. Similarly, items can be re-activated by checking the appropriate box in the “Active” column and clicking “Activate/Deactivate” to apply the changes.
6. Once all changes have been made, proceed to the section on [Publishing the Alert Page to OncPro](#). If all entries are now inactive for the protocol, please email [ODQActivation@dfci.harvard.edu](mailto:ODQActivation@dfci.harvard.edu) so they can entirely remove the previously posted alert page for you.

## Publishing the Alert Page to OncPro

Changes made to the log items in the table are not automatically published to OncPro. It is important for the Nurse/Pharmacist to confirm all changes, preview the generated PDF of the alert page, confirm accuracy, and determine it’s appropriate to publish the alert to OncPro.

1. After making changes to the log items in the table, click the “Generate Alert Page” button.

Generate Alert Page

2. On the next page, click the “Preview Alert Page” button. This will generate a PDF document of the active alert page log items to be viewed. **Please review this document carefully to ensure the information is accurate before publishing to OncPro.** If additional changes are needed, click the “Cancel Publish” button to return to the log table and make the changes.
  - a. Note: If a study has an existing alert page, publishing will completely replace the prior document. Therefore, be sure to verify that any pre-existing information on the alert page is carried over to the new version unless it is no longer relevant.
3. Once the alert page PDF is determined to be acceptable to publish, there are two different scenarios that may occur.
  - a. **If there is no previous alert page**, there will be an “Add to Index” button. Clicking this button will publish the alert page as a new document in the list of protocol documents in iRIS.
  - b. **If there is an existing alert page**, there will be a drop down to confirm the document you are replacing. Then, click the “Replace Existing” button to publish the new version.

### Option 2: Replace existing Alert Page - Choo

1 - Alert Page ▾

Replace Existing

4. Publishing a document to OncPro is immediate. Please access the study via OncPro and confirm the alert page published correctly.

### Delaying Publication Until Activation of a Submission

In some situations, you may wish to add an alert entry to the generator during your review of a submission in iRIS, but the updates should not be published until the submission is active and posted to OncPro. Please consider whether it is necessary to delay publishing the alert page changes before using this functionality.

When necessary, please follow the steps below:

1. Add the new entry to the alert page generator per the [instructions above](#).
2. If the changes should not be published until activation of a specific submission in IRIS, check the “Pending Activation” box. This will notify ODQ to update the alert page with the change(s) at activation.
  - a. This functionality should not be used during the initial submission of new protocols or sponsor correspondence. For new studies, alert page changes can be published immediately and will appear when the study goes live.
  - b. This functionality should not be used for sponsor correspondence submitted on the Administrative Modification form. Such submissions do not route to ODQ for an activation step.
3. **Important:** The correct iRIS number must be captured in the “Submission Reference Number” field. This is how ODQ will match your entries with the correct submission.

### Changes Requiring IRB Review

Please refer to the [OHRS Information Sheet: Use of Alert Pages](#) for details on how alert pages are used and what information is appropriate to include on the alert page. Some types of changes outside of a formal protocol amendment may require IRB review.

Below are some examples of common alert page items that may or may not require IRB review.

No IRB Review Necessary	IRB Review Required
Approval to follow institutional standard practices (e.g., tubing, weight changes, formula calculations, pregnancy testing)	Immediate changes required due to safety concerns that must be implemented prior to a formal amendment
Windows for treatment or assessments when no windows are provided in the protocol	Eligibility exceptions and/or deviations from the dose modification procedures in the protocol
Guidance on treatment administration (e.g., order of administration, infusion rates, missed/vomited doses, take home drug dispensing, dose holds, supportive care) when not specified in the protocol and/or pharmacy manual	Whether treatment can begin while safety-related test results are pending; addition or removal of safety assessments
Guidance on stability, preparation, storage requirements and temperature excursions when not specified in the protocol and/or pharmacy manual	Change in investigational product or associated medication supply that impacts patient cost language in the ICF; use of biosimilars (impacts ICF language)
Clarifying whether cycle and day numbers will progress without interruption in the event of dose delays	Significant changes to the protocol that are communicated outside of a formal amendment.

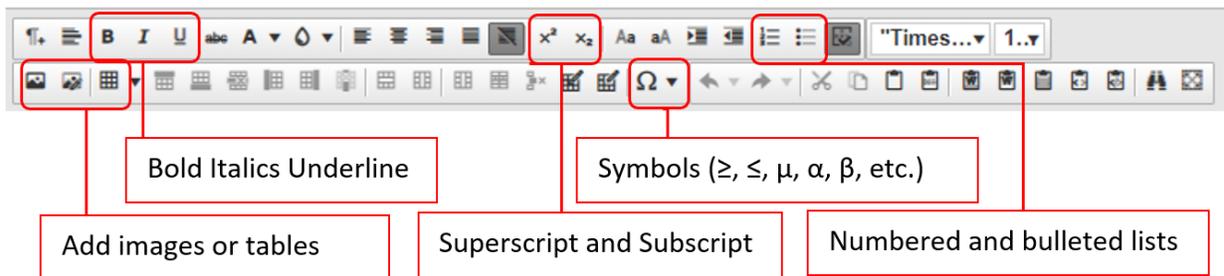
*\* In general, if the protocol is silent on an issue, we do not need to ask sponsors for additional requirements that are not specifically indicated in the protocol.*

## Tips for Formatting, Images, and Tables

### Formatting Text

The text editor allows users to copy and paste text from other sources (including Word) and will retain most of the formatting when this occurs. You can also use the toolbar in the editor to add/create formatting on the fly.

Some of the most commonly used functions are highlighted below:



### Adding Images

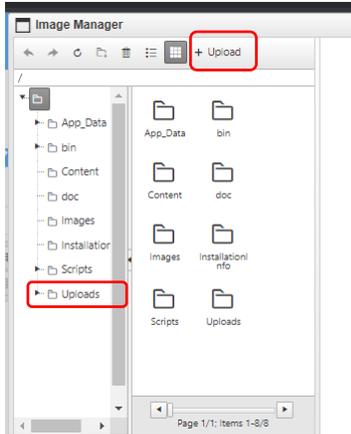
Copying and pasting images into the text editor may not produce the desired result when previewing and publishing the PDF alert page. Therefore, **users should always save images to the desktop and then upload the image file**. A simple way to accomplish this is to take a screenshot of the image and save the screenshot as a .gif or .jpeg file.

Image files can be uploaded to the alert page generator by clicking the add image button on the toolbar:



Next, make sure to select the "Uploads" folder first. Then, either find the folder associated with this protocol or create a new subfolder using the protocol number as the name. It's helpful to organize images by protocol number to avoid confusion later. (Note: If images are not placed in the correct folder, they may not appear in the posted alert page.)

Then click the "Upload" button in the Image Manager.



Then, click the “Select” button to locate and select the image file on your PC.

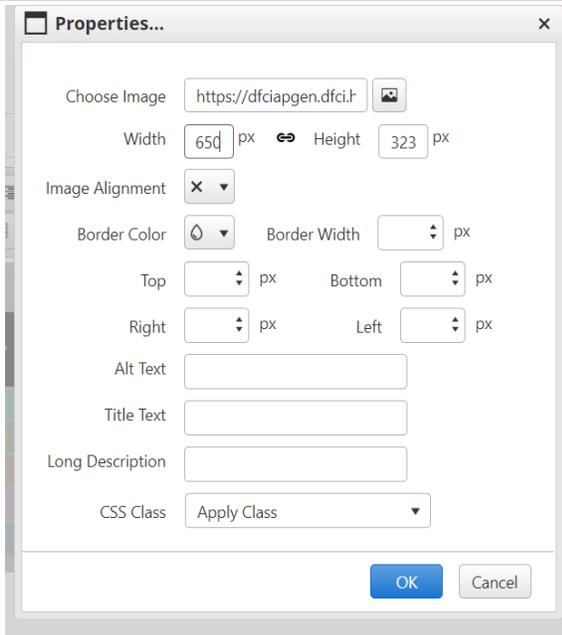


Once the correct image file is selected, click Upload.

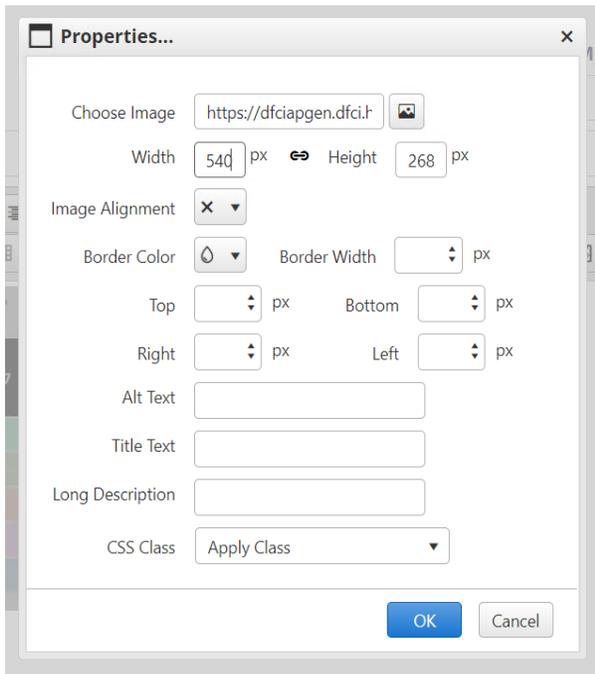
In order to fit on the alert page, **images must have a width of 540 pixels or less**. To resize an image, please select the second image icon on the tool bar. This is the image property tool.



This will bring up the following dialog window:



As with images, tables must have a width of 540 pixels or less. To resize an image, please select the second image icon on the tool bar. Please adjust the width to be 540 px or less. The height will automatically proportionally.



### Adding Tables

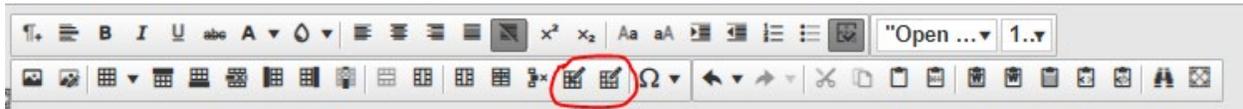
We do not recommend that users copy and paste tables into the alert page editor. The formatting may not always carry over correctly. **It is usually better to take a screenshot of the table and add it as an image** (see above).

However, users can create a table from scratch by clicking the button on the toolbar and then selecting the appropriate table size:

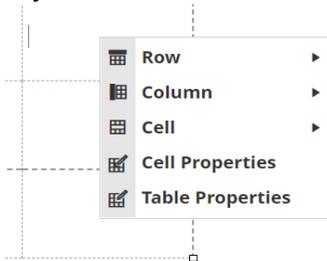


The table can re-sized by clicking and dragging any edge or corner. In order to fit on the alert page, **tables must have a width of 540 pixels or less.** To resize the table, use Table Properties.

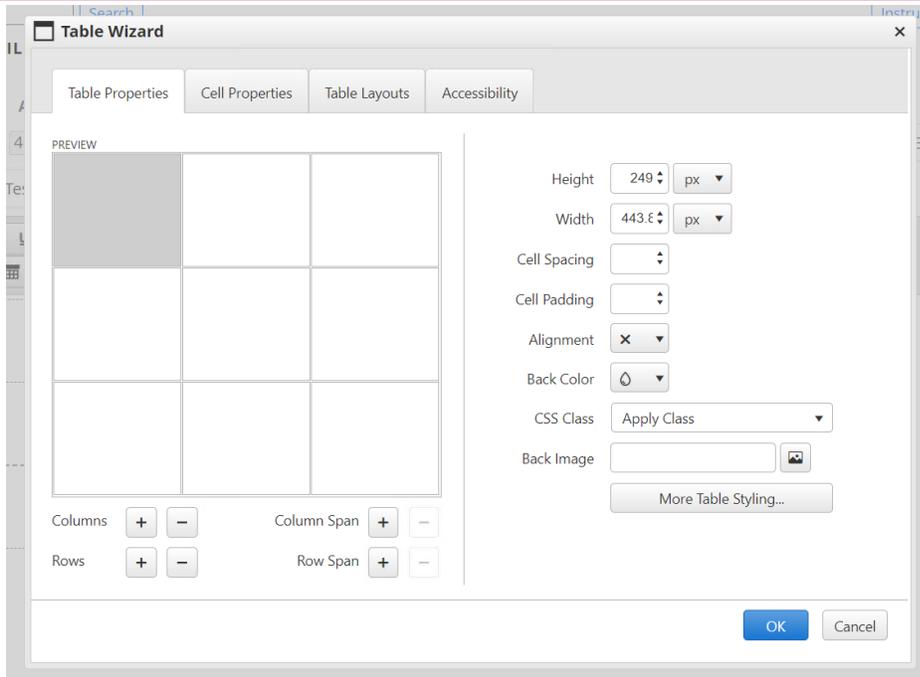
Users can either right-click on the table for options, or use the Cell Properties and Table Properties buttons on the toolbar:



Cell Properties allows users to adjust one or all cells within a table. Table Properties allows users to adjust the attributes of the table such as borders and size.



Here you would set properties like height, width, the layout, etc. Please set the maximum width to 540 px or less.



## Asking for Help

Please utilize your supervisor(s) and/or department leader(s) as a resource for common questions. Enhancement requests should be suggested to your department leadership and brought to the Nursing and/or Pharmacy Subcommittee Working Group(s) for consideration. Please do not submit helpdesk tickets to request changes to the system that have not been vetted and approved by appropriate DF/HCC Nursing and Pharmacy leadership.

**If an alert page document is published to OncPro in error**, there is no “unpublish” functionality available. Instead, the information in the alert log table must be updated and a correct version of the alert page re-published to replace the erroneous version.

**If you have inactivated all alerts for a protocol**, please email [ODQActivation@dfci.harvard.edu](mailto:ODQActivation@dfci.harvard.edu) so they can remove the previously posted alert page for you.

**If you experience technical issues**, such as an error message when trying to perform an action, please open a helpdesk ticket for the OncPro support team in RIO. Please do not send an email.

**To request granting/removal of access to the Alert Page Generator**, please open a helpdesk ticket for the OncPro support team in RIO. Please do not send an email.

**If you are unable to remove a prior alert page from OncPro** because it is bundled into a single PDF file with other documents, please email [ODQActivation@dfci.harvard.edu](mailto:ODQActivation@dfci.harvard.edu). The ODQ team can separate out the components into separate files and remove the old alert page.