FAQ Guidance:
DF/HCC Alert Page Policy and Process

As of May 26, 2022, there is a new process for creating, updating, and posting alert pages. Please be sure the review the updated OHRS Policy – Use of Alert Pages, as well as the Office Hours Webinar from May 19, 2022, explaining the rationale, specific changes, and how this new process affects study teams and reviewers.

What is changing with the alert page process?

Briefly:

- Alert Pages will no longer be submitted in iRIS or require IRB review.
- Designated Nursing and Pharmacy reviewers will post alert page updates/changes to OncPro using the Alert Page Generator.
- Sponsor correspondence that requires IRB review, per the updated OHRS policy, can be submitted separately as an administrative modification.

Will existing alert pages remain on OncPro?

Yes, existing Alert Pages will remain posted unless/until they are replaced with an updated version created in the Alert Page Generator.

How are we handling alert pages within iRIS submissions that were submitted prior to May 26?

After May 26, please do not attach an alert page to any submissions that do not already include alert page changes.

- If an alert page is already attached to a pending submission, it will still be approved and posted by ODQ activation. Please continue to revised/update the alert page in iRIS, as necessary, in response to conditions.
- If a draft submission was started prior to May 26, but will not be submitted until after May 26, please remove any alert page documents prior to submitting. The rest of the amendment can be submitted as usual.
- Otherwise, if you receive or are responding to alert page-related conditions, please provide the requested information/correspondence and remind reviewers to use the Alert Page generator to make updates.

What types of information can be added to the alert page?

- The IRB expects that changes or additions to the protocol be revised via a formal amendment. For example, changes to eligibility that are only communicated by the sponsor in a memo cannot be added to the alert page and used without an eligibility exception.

- Immediate changes needed to ensure the safety of research participants (such as Dear Investigator Letters memos) may be submitted to the IRB prior to a formal amendment. The alert page may be used to capture and communicate such information temporarily after the IRB has been notified.
- Alert pages can also be used to communicate operational details specific to DF/HCC institutions and/or clarifications received from the sponsor that don't require IRB review.
- Alert pages should not be used on DF/HCC investigator-sponsored protocols. The protocol itself should be amended instead.

What sponsor correspondence needs to be submitted to the IRB?

Please refer to the updated OHRS policy posted on the DF/HCC website.

How do we submit sponsor correspondence to the IRB if it's not part of a larger submission?

Sponsor correspondence can be submitted separately as an administrative modification.

How does information from sponsor correspondence in an administrative modification get added to the alert page?

Sponsor correspondence submitted separately as an administrative modification will route to the IRB. If the information may need to be placed on the alert page, the IRB will route the submission to core site's Nursing and/or Pharmacy for review. The designated reviewer can then update the alert page if necessary.

Who is notified when a new/revised alert page is posted to OncPro?

Alert page changes are usually the result of an iRIS submission or other communication with Nursing and Pharmacy. The Alert Page Generator does not send email notifications automatically when a new document is posted.

Do study teams need to file alert pages in the regulatory file?

No. Alert Pages are an internal communication tool. They are not regulatory documents and are no longer approved by the IRB. Therefore, there is no DF/HCC requirement to file Alert Pages in the regulatory file. However, any sponsor correspondence supporting the information on the alert page is considered a significant protocol communication that must be maintained in the regulatory file.

Can alert pages be posted for studies under a single IRB?

Yes. Alert pages may be used to communicate operational details specific to DF/HCC institutions and/or clarifications received from the sponsor that don't require IRB review. Alert pages may also be used to communicate immediate changes needed to ensure the safety of research participants provided that the IRB of record has been notified.

Can the Alert Page Generator be used for new protocols that are pending activation?

Yes. The Alert Page Generator will be available for Nursing and Pharmacy in case they need to add information during their feasibility reviews.

Will alert page updates be published to OncPro at activation / at the same time other documents in the submission are posted?

The alert page can be updated and published to OncPro at any time. In many cases, updates can be made prior to activation. When updates need to coincide with activation of an amendment, the designated Nursing/Pharmacy reviewer should alert ODQ per the Alert Page Generator work instructions.

How can regulatory staff obtain previous versions of the alert page?

DF/HCC does not require that alert pages be filed in the regulatory binder, so it usually will not be necessary to request prior versions. Instead, regulatory staff should ensure that they file all sponsor correspondence supporting any information that we choose to communicate via an alert page. Please email ODQActivation@dfci.harvard.edu if an older version of a document previously posted to OncPro is needed.

Who do I contact if I still have questions?

For questions regarding what requires IRB review and how to make submissions to the IRB in iRIS, please email OHRS@dfci.harvard.edu.

For questions regarding the posting of documents to OncPro, please email ODQActivation@dfci.harvard.edu.