Use of Alert Pages

As of 5/26/2022, Alert pages are generated and posted to OncPro by the appropriate research nurse and/or research pharmacist feasibility reviewers. Most Alert Page additions will not require IRB review.

1. PURPOSE

The Alert Page on OncPro is used to communicate operational details specific to DF/HCC institutions and/or clarifications received from the sponsor during and after the protocol approval. The alert page may also be used to alert research staff to information that impacts patient safety but is communicated outside of, or prior to, a formal amendment.

2. PROTOCOL CHANGES

If the investigator or sponsor requests changes or additions to the current protocol, the IRB generally expects the protocol to be revised with an amendment. However, clarifications to protocol requirements, or immediate changes related to the safety of participants (such as Dear Investigator Letters memos) may be submitted to the IRB prior to the submission of a full amendment.

A sponsor may request modifications to the IRB approved study outside of a formal amendment (e.g., via a memo or other sponsor communication); this communication must be submitted to the IRB via an administrative modification in iRIS. The IRB may acknowledge receipt of minor clarifications, approve as an amendment, and/or request a formal protocol amendment for these modifications. The alert page may be used to capture and communicate such information temporarily after the IRB has been notified.

Alert pages for immediate changes to the protocol should not be used for DF/HCC Investigator-sponsored protocols when an amendment to the protocol should be submitted.. The pertinent information should be added to the protocol and other study documents as appropriate and submitted for full amendment review. Please reach out to the OHRS Inbox for potential exceptions to this requirement.

3. CREATION AND MAINTENANCE

Alert Pages are created, updated, and posted to OncPro by nursing and/or pharmacy feasibility reviewers at the Consortium sites.

Alert page content is added or updated by a reviewer as the result of a submission in iRIS. In the case of new protocols and amendments, nursing and pharmacy reviewers may request information that is needed for the alert page via a condition in iRIS. The research team will obtain the requested information and provide it to the reviewer in the submission response. Once approved by the relevant feasibility reviewer, that reviewer will add it to the alert page.

If the feasibility reviewer determines that the additional information may require IRB review, OHRS will be notified by the feasibility committee through the OHRS email Inbox regarding the content. OHRS will follow up with a determination of next steps and notify the feasibility reviewer.

4. OTHER USES FOR ALERT PAGES

In addition to new protocol and amendment submissions with feasibility reviews, there may be sponsor communication that may be reviewed through the administrative modification process.

The following are examples of types of sponsor correspondence that can be appropriately communicated via the alert page, once submitted to the IRB as an administrative modification:

- Safety Memos (e.g., Dear Investigator Letters)
- Memos that clarify or temporarily modify IRB approved documents (i.e.., local amendments, eligibility clarification of existing criteria, etc.).

Generally, changes to eligibility criteria require a formal amendment and approval. However, clarification of the criteria, and/or advance notice of forthcoming safety alterations of the criteria may be submitted in iRIS as an administrative modification, and can be added to the alert page. Changes to eligibility that are not safety related (e.g., expanding of criteria) that are only communicated by the sponsor in a memo and not a formal amendment may be acknowledged by the IRB and added to the alert page via an administrative modification submission in IRIS; however a patient specific eligibility exception must continue to be approved by the IRB prior to enrollment. The IRB may approve such an eligibility exception for a specific participant with sponsor approval included in the deviation submission.

5. DOCUMENTATION

Research teams must maintain any documentation they receive that supports the information added to the alert page. For example, if information is added to the alert page in response to a sponsor memo or other correspondence, said correspondence must be filed in the regulatory file for the protocol. The actual correspondence itself will not be posted to OncPro directly.