

Use of Alert Pages

The following information is intended to assist study teams in preparing appropriate Alert Pages for submission. If you have any questions, please contact OHRS at OHRS@dfci.harvard.edu.

1. PURPOSE

The Alert Page is a document used to communicate local deviations/amendments to the protocol specific to DF/HCC institutions. The alert page may also be used to communicate corrections, clarification, or changes issued by the sponsor that impact patient safety but are communicated outside of a formal amendment.

Alert pages are not used to indicate the status of sites, cohorts, dose levels, etc. or provide operational details that are outside of the written protocol / study documents. Alert Pages may not be used to simply highlight information that otherwise exists in the protocol or other study documents.

2. FORMAT

Alert pages must be created on the [DFCI IRB Alert Page template](#). There can only be one Alert Page document per protocol. The font must be in 12 pt Arial unless otherwise noted on the Alert Page template. Please make sure the date submitted matches the date the materials were sent to the OHRS office and the version date entered in IRIS. Please include the DF/HCC protocol number once it has been assigned.

3. PROTOCOL CHANGES

If information in the current protocol is missing or incorrect, the IRB generally expects the protocol to be revised. For DF/HCC Investigator-Sponsored research, the protocol must be revised, and an alert page should not be used.

In some cases, an external sponsor may issue memos that make changes to the approved protocol without amending the protocol document itself. The IRB will determine whether this is appropriate and must approve such changes before they can be posted on an Alert Page.

Examples of appropriate alert page information include:

- a. Sponsor approval to follow institutional standard practices when they differ from the protocol or other approved study documents. The alert page may also be used to alert local study teams that the protocol differs from institutional policy only when the protocol explicitly conflicts with local policies.
- b. Sponsor approval to allow windows for eligibility, treatment, or assessments that are not defined in the protocol or other approved study documents.
- c. Specific dosing instructions (e.g., order of administration, how to handle missed/vomited doses) that are not included in the protocol or other approved study documents.
- d. Immediate changes to study conduct (e.g., for subject safety) requested by the sponsor while an amendment is pending.

4. SUBMITTING AN ALERT PAGE (DFCI IRB)

New Protocols: Alert Pages may be added to a submission prior to IRB review in response to feasibility reviewer conditions and requests.

After Activation: Alert Pages can be changed or added via an Amendment. Please remember to update or remove from the Alert Page any information that has since been revised in the protocol or other study document.

Sponsor correspondence indicating approval of the information on the Alert Page is required with the Alert Page submission.

5. SUBMITTING AN ALERT PAGE (External sIRB)

External IRBs usually will not approve the DF/HCC Alert Page document itself. The study team must submit a local protocol amendment or deviation to the IRB of record and include the sponsor approval for the changes. If the external IRB approves the changes as a local amendment/deviation, the study team will submit an sIRB amendment in iRIS with the sponsor approval, IRB of record approval, and a revised alert page. Only changes approved by the IRB of record can be added to the Alert Page.

6. SUBMITTING AN ALERT PAGE (NCI CIRB)

The NCI CIRB will not review or approve the DF/HCC Alert Page document, nor will it review or approve any local protocol deviation requests. To use an Alert Page for an NCI CIRB-reviewed study, submit a blanket deviation request to the Study Chair. Once approval is received, the study team may then submit an sIRB amendment in iRIS with the documented Study Chair approval and a revised alert page. Only deviations approved by the Study Chair may be added to the Alert Page.