

Guidance on Alert Pages

The Alert Page is a document used to communicate essential protocol information relating to safety concerns, patient care, and current dose level information. Please note that Alert Pages do not include Status Pages. Status Pages are created by OHRS to communicate information such as temporary protocol closures or separate activation of sites.

The following information is intended to assist study teams in preparing Alert Pages accurately. If you have any questions, please contact OHRS at (617) 632-3029.

1. FORMAT

There can only be **one** Alert Page **document** per protocol. This document may be several pages in length. The font must be in 12 pt Arial unless otherwise noted on the Alert Page template. Please be concise and do not repeat information already contained in the protocol document.

2. DATES

Date Submitted: Please make sure the date submitted matches the date the materials were sent to the OHRS office.

Date Posted: This date will be filled in by the OHRS Online team to accurately reflect the date the document is posted on OncPro.

3. DF/HCC PROTOCOL NUMBER

Please include the DF/HCC protocol number if it has been assigned. If the Alert Page is submitted with a New Protocol Submission, this may be left blank and can be filled in prior to the posting of the Alert Page.

4. DOSE ESCALATION TABLE

Please include a dose escalation table only when the doses per cohort levels are not clearly defined in the protocol document, i.e. they are not pre-determined, or the protocol states that doses are "provisional" or "an example" or stated in percentage increments (e.g. a chemotherapy template cannot be built beforehand).

The dose escalation table must contain all dose levels **up to** the current dose level. This table may be copied if the protocol includes more than one dose escalation scheme. Please remember to clearly title each dose escalation table. The current dose level must be highlighted and bolded.

5. SUBMITTING A NEW ALERT PAGE

Before Activation: Alert Pages are often created during the SRC / IRB review process. In this case, the Alert Page is submitted to OHRS along with the point-by-point response to the SRC / IRB committee review.

After Activation: Alert Pages submitted after the protocol is enrolling are sent to the OHRS via an Amendment form.

6. AMENDING AN EXISTING ALERT PAGE

Please indicate on the Alert Page if an amendment is forthcoming. Remember to update or remove the Alert Page, as appropriate (e.g. when submitting a protocol amendment). Whenever an Alert Page needs to be changed, you must submit both a clean and tracked version of the Alert Page document with the amendment form.