

The logo for Dana-Farber / Harvard Cancer Center (DF/HCC) is located at the top left of the page. It features the text "DF/HCC" in a large, bold, red font, with "DANA-FARBER / HARVARD CANCER CENTER" in a smaller, white font below it, all set against a dark red background. The background of the entire page is light blue with a pattern of white, wavy lines.

DANA-FARBER / HARVARD CANCER CENTER

Office for Human Research Studies

Notice of Revised OHS Forms Posted for Use

DFCI Serious Adverse Event Reporting Form:

1. Multi-Center Site Reporting

The revised SAE Form updated and posted for use in August 2008 incorporated the reporting of DF/HCC PI - Initiated Multi-Center SAEs to the DFCI IRB. Please ensure all reportable SAEs experienced by either (1) local DF/HCC participants or (2) outside Multi-Center Site participants where a DF/HCC Investigator is the overall PI are now reported to the DFCI IRB via the DFCI Serious Adverse Event Reporting Form.

2. Minor administrative and formatting changes made

Please note: The current version of the SAE form posted for use with this communication is dated 12/31/2008. After 1/31/2009 SAEs submitted on an earlier version of this form will not be accepted by OHS.

DFCI Major Deviation/Violation/Exception - Other Event Reporting Form:

1. Multi-Center Site Reporting

The revised Major Deviation/Violation/Exception - Other Event Form updated and posted for use in December 2008 incorporated the reporting of DF/HCC PI - Initiated Multi-Center Other Events to the DFCI IRB. Please ensure all reportable other events experienced by either (1) local DF/HCC participants or (2) outside Multi-Center Site participants where a DF/HCC Investigator is the overall PI are now reported to the DFCI IRB via the DFCI Major Deviation/Violation/Exception - Other Event Reporting Form.

2. Minor administrative and formatting changes made

Please note: The current version of the Other Event form posted for use with this communication is dated 12/31/2008. After 1/31/2009 Other Events submitted on an earlier version of this form will not be accepted by OHS.

DFCI Application for Continuing Review:

1. Summary of Amendments

Part H, question 6 was revised to request a summary of only the major amendments made to the study since the last continuing review submission or the initial review if this is the first continuing review submission.

Please note: The current version of the Continuing Review form posted for use with this communication is dated 12/31/2008. After 1/31/2009 Continuing Reviews submitted on an earlier version of this form will not be accepted by OHRS.

Please do not hesitate to contact OHRS if you have any questions or require additional information.

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(Please note: OPRS is now the Office for Human Research Studies.)

DF/HCC
Member
Institutions

Beth Israel Deaconess Medical Center / Brigham and Women's Hospital / Children's Hospital Boston /
Dana-Farber Cancer Institute / Harvard Medical School / Harvard School of Public Health /
Massachusetts General Hospital



A Comprehensive Cancer
Center Designated by the
National Cancer Institute