

Office for Human Research Studies

New OHRS Information Sheet & Related Changes

As of March 1, 2009 the Dana-Farber Cancer Institute (DFCI) Institutional Review Board (IRB) will no longer accept IND/IDE Safety Reports reporting events that take place outside of the DF/HCC by sponsors unless they meet the reporting criteria outlined in the new policy. Because these reports seldom contain sufficient information to allow the Principal Investigator or the IRB to make a meaningful judgment about the reported event the IRB has instituted this new policy. The following additional documents have all been revised as a result of this new policy.

1. [OHRS Information Sheet: DFCI IRB Policy on Receipt and Review of IND/IDE Safety Reports](#): **NEW**

This new policy is effective as of 3/1/2009.

2. [OHRS Information Sheet: DFCI IRB Adverse Event Reporting Policy](#): **REVISED**

Revisions include:

1. Removed previous IND/IDE reporting information and incorporating the information into the new policy above.

3. [Continuing Review Form](#): **REVISED**

Revisions include:

1. Part H, question 2 was split into two questions, one addressing SAE's and the new question requests verification from the PI of review of any IND/IDE reports received and not submitted to the IRB.

Please note: The current version of the Continuing Review form posted for use with this communication is dated 2/20/2009. After 3/20/2009 Continuing Reviews submitted on an earlier version of this form will not be accepted by OHRS.

4. [Sponsor Letter](#): **REVISED**

Revisions include:

1. Information pertaining to the new IND/IDE policy included for sponsors.
2. Information pertaining to the IRBs reconsenting of subjects policy included for

sponsors.

If you have any questions, please do not hesitate to contact us.

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