



OPRS NEWS Overview of Policy Change

OPRS NEWS Update 4-12-2007

Any SAE, IND/IDE Report or IDB that requires a change to a protocol or a consent document **must be submitted via an amendment**, which is the mechanism for making a request for any change to approved research. For example, if there is an IND safety report pursuant to which a change to the consent document is requested, this must now be submitted as an amendment for IRB review. The IND Report(s) is/are then submitted with the amendment request as back-up documentation for the request. Please note that the regulatory requirement is for submission of an IND safety report to the IRB, not necessarily IRB review, and that accordingly an IND that is submitted with a request for a consent change may not be processed in a timely fashion.

IND safety reports that do not require, at the outset, a change to the protocol or consent will be documented on the IND/IDE Reporting Form.

1. Revised DFCI IRB Adverse Event Reporting Guidelines and Related Forms

The new policy is attached and is effective as of today.

The following forms have been revised to meet the new reporting requirements and are posted on the [OPRS website](#):

[DFCI IRB - Serious Adverse Event Reporting Form](#)

[DFCI IRB - IND/IDE Reporting Form \(Excel Spreadsheet\)](#)

[DFCI IRB - Amendment Submission Form](#)

Thank you!

For further information, contact:

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