

Drug Safety Notifications

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Introduction

The NCI Cancer Trials Support Unit (CTSU) distributes drug safety notices for all ETCTN studies. The lead DF/HCC investigator must review the safety notifications and determine if they meet the requirements for reporting to the DFCI IRB.

Procedure

- 1) Designated study team member prepares safety notifications for review by the lead DF/HCC investigator.
 - a) Safety notifications are posted in the Drug Safety Notification sub-folder under the appropriate protocol folder on the CTSU website and they are announced via the CTSU bi-monthly broadcast emails.
 - b) Any notification that requires a 24-hour response or will result in an immediate closure of a study (whether temporary or permanent) is distributed to all sites via a special targeted email from the CTSU.
- 2) The lead DF/HCC investigator follows the DFCI IRB Policy on Receipt and Review of IND/IDE Safety Reports.

Links

CTSU Member Website: <https://www.ctsu.org/public/Default.aspx>