National Cancer Institute (NCI)
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

Adverse Event Reporting

Contents

Introduction

Adverse events that occur at DF/HCC must be reported to the NCI Cancer Therapy Evaluation Program (CTEP). Events requiring expedited reporting are submitted using the CTEP Adverse Event Reporting System (CTEP-AERS) in addition to routine reporting in the Medidata Rave system.

In addition, the DFCI IRB retains responsibility for the oversight of all events occurring at participating DF/HCC sites. The study team is required to follow all DFCI IRB adverse event reporting policies.

Procedure

1. Review the CTEP Adverse Event Reporting Guidelines and CTEP-AERS training material on the CTEP website.
2. Follow the instructions within the protocol document for expedited and routine adverse event reporting to CTEP.
3. Follow OHRS requirements to determine when events require reporting to the DFCI IRB.

Links

ETCTN Serious Adverse Event Reporting (SAE) Information Sheet:
https://ctep.cancer.gov/initiativesPrograms/etctn_information_checklists.htm

CTEP Adverse Event Reporting Information:
https://ctep.cancer.gov/protocolDevelopment/adverse_effects.htm

CTEP-AERS application: https://eapps-ctep.nci.nih.gov/ctepaers