

## DFCI Institutional Review Board Adverse Event Reporting Policy

### The DFCI IRB requires the following events be reported:

- **Grade 2 (moderate) and Grade 3 (severe) Events** – Only events that are Unexpected and Possibly, Probably or Definitely Related/Associated with the Intervention.
- **ALL Grade 4 (life threatening or disabling) Events** – Unless expected AND specifically listed in protocol as not requiring reporting.
- **ALL Grade 5 (fatal) Events** – When subject is enrolled and actively participating in the trial OR when event occurs within 30 days of the last study intervention.

### **Notes:**

- If subject is in Long Term Follow Up, death is reported at continuing review.
- See protocol for additional reporting requirements (to sponsor, FDA, etc.).

### DFCI IRB Reporting Forms:

*When reporting adverse events to the DFCI IRB, one of the following forms MUST be used.*

#### **1. Serious Adverse Event Reporting Form:**

[http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/OPRS/Forms\\_Instructions/Post\\_Activation/SAE\\_Reporting.doc](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/Post_Activation/SAE_Reporting.doc)

The SAE Reporting Form must be used to report SAEs experienced by DF/HCC participants enrolled in a DF/HCC study including any serious adverse events on DF/HCC led Multi-Center trials where the event occurs at a non-DF/HCC site.

Full written SAE report must be submitted to OHRS as soon as possible, but no later than **10 working days** from notification of event. Reports must be submitted via OHRS Submit. No interoffice submissions, faxes or e-mail notifications of SAEs will be accepted.

**a. Follow Up SAE Reports:**

When submitting follow up reports to previously reported SAEs, **attach a copy of the original report and any prior IRB determinations to the follow up report.** This gives the reviewer all the information required to conduct a thorough review and eliminates questions that might otherwise be raised.

**2. AdEERS Reporting Form:**

[https://webapps.ctep.nci.nih.gov/openapps/plsql/gadeers\\_main\\$.startup](https://webapps.ctep.nci.nih.gov/openapps/plsql/gadeers_main$.startup)

The NCI AdEERS form may be used in place of the DFCI IRB SAE Reporting Form for NCI or Cooperative Group studies only. AdEERS will automatically file the report with the respective cooperative group. If the AdEERS form is used, the OHRS must be included on the e-mail ([ohrs@dfci.harvard.edu](mailto:ohrs@dfci.harvard.edu)) to the NCI. AdEERS reports must be submitted to OHRS as soon as possible, but no later than 10 working days from notification of event.

The following information **MUST** be included in the e-mail and within the description section of the AdEERS form:

1. DF/HCC Protocol Number
2. DF/HCC Overall Principal Investigator's Full Name

If the PI determines that the adverse event warrants a change to the protocol and/or consent form document(s) the completed AdEERS report must be submitted via OHRS Submit along with an amendment form. The AdEERS report must be attached to the amendment form as supporting documentation for the IRB to review.

**a. Follow Up AdEERS Reports:**

When submitting follow up reports to previously reported AdEERS, **attach a copy of the original report and any prior IRB determinations to the follow up report.** This gives the reviewer all the information required to conduct a thorough review and eliminates questions that might otherwise be raised.

## **Other Reporting Requirements:**

### **PI-Initiated/Sponsor holds IND**

The sponsor-investigator, as the holder of the IND/IDE, is responsible for reporting serious adverse events directly to the FDA. In addition to the FDA Form #3500a (Mandatory Medwatch Form), the DF/HCC PI may also be required to complete a form supplied by the sponsor. The DFCI IRB reporting requirements may differ from the sponsors. DF/HCC investigators must comply with both.

### **Industry Sponsored (Investigational)**

In addition to the DFCI IRB SAE reporting form, the DF/HCC PI may also be required to complete a form supplied by the sponsor. The DFCI IRB reporting requirements may differ from the sponsor. DF/HCC investigators must comply with both.

### **Industry Sponsored (Commercial)**

The FDA's MedWatch Online form, #3500, may be used to voluntarily report serious adverse events, potential and actual medical product errors, and product quality problems associated with the use of FDA-regulated drugs, biologics, devices and dietary supplements. The sponsor of the trial, however, may have its own form.

### **Human Gene-Transfer Studies**

The PI must report all applicable adverse events to the NIH/OBA per the OBA Guidelines outlined in Appendix M-I-C-4:

[http://www4.od.nih.gov/oba/RAC/guidelines\\_02/Appendix\\_M.htm](http://www4.od.nih.gov/oba/RAC/guidelines_02/Appendix_M.htm)

Additional information about Human Gene-Transfer Reporting requirements can be found in section 25.9 of the DF/HCC Guide to Human Research Activities (Revised August 2006).

## **Additional Resources:**

Common Toxicity Criteria for Adverse Events v.3.0 (CTCAE):

<http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx>