

# **Audit Alert**

## **DF/HCC Audit Program**

### **Updated DF/HCC Clinical Trials Audit Manual**

This audit alert is to inform you that the DF/HCC Clinical Trial Audit Manual has been updated.

These updates include:

- The organizational and reporting restructuring which occurred as a result of the formation of the Clinical Investigations Leadership Committee (CLC) and independence of the Audit Committee
- The requirement for protocol amendments proposed as a result of the audit findings to be reviewed by the Audit Committee prior to submission to the DFCI IRB.
- The addition of the new DF/HCC SOPs regarding audit requirements for new clinical researchers and overall PI's (QA- 723 & QA-722)
- Administrative and typographical revisions

The Clinical Trial Audit Manual can be located on the DF/HCC Clinical Research Support website under the Quality Assurance Office for Clinical Trials, Policies and Procedures section.

[http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/QACT/Policies\\_and\\_Procedures/Audit\\_Manual\\_Jan\\_2009.doc](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/QACT/Policies_and_Procedures/Audit_Manual_Jan_2009.doc)

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