

# **Audit Alert**

## **DF/HCC Audit Program**

### **Updated Internal Audit Subject Selection Procedure**

This audit alert is to inform you that a pilot procedure for selecting subjects is going into effect for internal audits scheduled on or after May 1, 2009.

The DF/HCC Audit Committee has noted that a larger number of violations are consistently being recorded on the minor violation log for audited subjects in the weeks prior to an audit. In order to promote stronger protocol compliance, the Audit Committee is instituting a four month pilot procedure, which includes the selection of unannounced subjects in internal audits.

- Beginning May 1, 2009 at least one subject per audit will be unannounced prior to the audit. For protocols with multiple participating DF/HCC sites, one unannounced subject may be audited from each site as accrual allows.
- Study teams will be informed of the unannounced subject on the first day of the scheduled audit at their site.
- External and Affiliate sites will not be affected by this policy at this time.

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