

Audit Alert

DF/HCC Audit Program

Documenting Protocol Treatment Administration

This alert is to give feedback from findings from our internal auditing program and from audits conducted by external groups (i.e. FDA, CALGB, RTOG etc.).

Recently, internal and external audits have noted lack of documentation of protocol treatment administration and compliance. This is a reminder that all treatment administrations must be clearly documented in the medical record. For example, if a protocol dictates the duration of an infusion, the start and stop times of the infusion must be documented (in both inpatient and outpatient settings). It is not enough to only document the start time and the duration.

For documenting at home protocol medications, please refer to DF/HCC SOP PM 406: At Home Study Medication Compliance:

http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/CRO/Policies_and_Procedures-SOPs/PM-406_DFHCC_Policy_for_at_Home_Study_Medication_Compliance.pdf

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