

CHAPTER 20 SITE VISITS

20.1 Site Visits

Each clinical center and Core will be site-visited by NIH and DCC personnel during the study. These visits will enhance the working relationship between the DCC and each clinical center, and provide an opportunity for face-to-face questions and answers on any outstanding problems a clinical center is having with individual patients or with study procedures in general.

At the site visits, the DCC will monitor the clinical center's performance in following the protocol by observing HFM Study procedures. HFM Study patient files will be inspected, and a sample of HFM Study data forms will be checked against original source documents in the patients' medical records.

Throughout the course of the study, each clinical center's performance will be monitored by a series of data quality reports. These include reports of enrollment, number of missing forms, rates of invalid data, data quality, and numbers of missed visits. These reports will routinely be sent to the clinical centers, the Steering Committee, and the NIH Program Office.