


February 15, 2008

MEMORANDUM

TO: Medical University of South Carolina Research Sponsors

FROM: Dave Northrup, Director of Clinical Systems
Reece H. Smith, Academic Compliance Officer




RE: 21 CFR 11

The purpose of this memo is to provide information related to MUSC's compliance with 21 CFR 11. At this time MUSC's three primary clinical information systems, Access Anywhere, Practice Partner and Oacis, meet all of the mandatory requirements as specified by 21 CFR 11 except for one variance listed below. Please note that this statement of compliance applies to the three named/primary clinical information systems; not all source systems that provide information to these systems have been reviewed.

MUSC has not implemented the re-authentication requirement in 21 CFR 11.200(a)(1)(i). This section of the regulation specifies that "when an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual."

Our clinical information systems require the use of two passwords. One is required for initial access into the system. A second password is required prior to the initial electronic signature on a record. Once that signature password is used, the individual who is signing records can sign as many records as necessary during that period of controlled access without re-entering the second password for each record. It is our belief that our dual password requirement sufficiently protects the records without requiring a password to be entered prior each signing, a practice which we feel could create additional security risks.

This review was performed in January 2008 and represents the systems and practices that are currently in place.