



TERRY PICKERING, RN, MSN
*Interim Chief Information Officer for USC Health
Associate Administrator for Nursing and Clinical Informatics
Chief of Clinical Applications
Information Services, Keck Medicine of USC*

March 31, 2016

FDA Office of Regional Operations (HFC-100)
5600 Fishers Lane
Rockville, MD 20857

Re: Electronic Medical Record Certification for the Keck Medical
Center of USC

To Whom It May Concern:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that the Keck Medical Center of USC, part of the University of Southern California, intends that all electronic signatures executed within the Cerner Millennium (KeckCare) by our employees, agents, or representatives, located anywhere in the world, are legally binding equivalent of traditional handwritten signatures. Insofar as the electronic signature is derived from user controlled access, this letter also certifies that the record in question meets the requirements of a "closed system" as defined by the aforementioned section. All appropriate procedures for the validation of a "closed system" are in place jointly between the University of Southern California as the client of the system, and by Cerner Corporation as the software vendor.

Further, with this letter, I certify that during the software development and implementation processes, Cerner Millennium (KeckCare) was validated to perform in a reliable, accurate and consistent manner, in accordance with the requirements of Part 11.

Thank you,

A handwritten signature in cursive script that reads "Terry Pickering".

Terry Pickering, RN, MSN
Interim Chief Information Officer
Keck Medicine of USC