

 Washington University Physicians

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Washington University School of Medicine in St. Louis

Associate Vice Chancellor for Clinical Affairs  
Chief Executive Officer, Faculty Practice Plan

November 5, 2010

U.S. Food and Drug Administration  
Office of Regional Operations (HFC-100)  
5600 Fishers Lane  
Rockville, MD 20857

Re: Certification of Intent to Comply with 21 CFR Part 11

Dear Sir or Madam:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this letter hereby certifies that Washington University in St. Louis (WU) intends that all electronic signatures executed by our employees, agents, or representatives located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures when such electronic signatures are executed within the scope of the stated individual's official WU authority, responsibility and duties.

We have reviewed the electronic clinical systems owned and controlled by WU for compliance with 21 CFR Part 11 and certify that they meet all of the system, process and policy requirements of 21 CFR Part 11.

This certification applies exclusively to the electronic signature requirements of 21 CFR Part 11. This certification does not certify or imply WU intent for WU electronic signatures to satisfy any other legal or contractual requirements, nor does it certify or imply that WU electronic signatures are appropriate for use on records outside the scope specified in 21 CFR Part 11.

Sincerely,



James P. Crane, M.D.  
Associate Vice Chancellor for Clinical Affairs  
CEO, Faculty Practice Plan