



THE UNIVERSITY OF MICHIGAN

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July 15, 2008

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

Michael Fauntleroy
Office of the Director (HFM-25)
Center for Biologics Evaluation and Research
Food and Drug Administration
11400 Rockville Pike, Room 4119
Rockville, MD 20857

Re: Electronic Signature Certificate Statement

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 Regents of the University of Michigan consider that all electronic signatures executed in our on-line human research application system, or *eResearch*, by our officers, directors, employees, students or contractors, located anywhere in the world, are the legally binding equivalent of traditional hand-written signatures, subject to applicable University policies including SPG 601.24: Delegation of Authority to Bind the University.

Sincerely yours,

Stephen R. Forrest
Vice President for Research

Timothy P. Slottow
Executive Vice President and CFO