

## Legal Department

Mail code: L585 3181 S.W. Sam Jackson Park Rd. Portland, Oregon 97239-3098 tel 503 494-5222 fax 503 494-0917 November 27, 2007

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 CFR 21 Part 11

Dear Sirs,

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this letter hereby certifies that

Oregon Health & Science University (OHSU)

intends that all OHSU 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 individuals' official OHSU authority, responsibility and duties.

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

Sincerely,

, Mr. Hay -

Amy M. Wayson Vice President and General Counsel