



THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL  
Office of Human Research Ethics

Office of the Director  
(919) 966-1344  
Fax (919) 966-7879

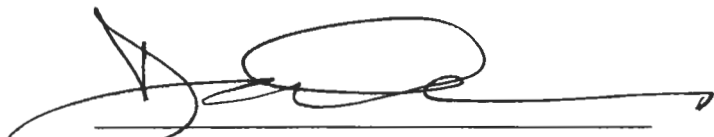
School of Medicine Bldg. 52, CB 7097  
University of North Carolina at Chapel Hill  
Chapel Hill, NC 27599-7097

## STATEMENT OF COMPLIANCE

This will certify that the Institutional Review Boards (IRBs) at the University of North Carolina at Chapel Hill, administered by the Office of Human Research Ethics, are organized and operate according to applicable laws and regulations governing research involving human subjects.

These include, when applicable, statutes of the State of North Carolina and regulations of the Food and Drug Administration (21 CFR 50 and 56) and Department of Health and Human Services [45 CFR 46 (the "Common Rule") and 45 CFR 164 (the Health Insurance Portability and Accountability Act, HIPAA)]. In addition, the IRBs conform, when applicable, to Good Clinical Practice (GCP) guidelines of the International Conference of Harmonization (ICH), to the extent these do not contradict DHHS and FDA regulations.

The University of North Carolina at Chapel Hill holds a Federalwide Assurance, FWA 4801, approved by the federal Office for Human Research Protections (OHRP).

  
Daniel K. Nelson, Director

April 7, 2004  
Date