

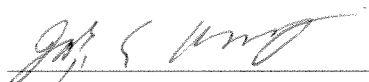
Office of Research
Institutional Review Board

STATEMENT OF COMPLIANCE


This will certify that the Institutional Review Boards (IRBs) at Wake Forest University Health Sciences, administered by the Office of Research, 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 on Harmonization (ICH), to the extent these do not contradict FDA and DHHS regulations.

Wake Forest University Health Sciences holds a Federalwide Assurance, FWA 1435, approved by the federal Office for Human Research Protections (OHRP).



Joseph E. Andrews, Jr.
Director, HRPP & IRB



Date