

OFFICE OF HUMAN RESEARCH ETHICS

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STATEMENT OF COMPLIANCE

This certifies that the Institutional Review Boards (IRB) at the University of North Carolina at Chapel Hill, administered by the Office of Human Research Ethics, are organized and operate according to the 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 IRB conforms, when applicable, to the Good Clinical Practice (GCP) guidelines of the International Conference of Harmonization (ICH), to the extent that these do not contradict DHHS and FDA regulations.

The University of North Carolina at Chapel Hill Holds a Federalwide Assurance, FWA00004801, approved by the Office for Human Research Protections (OHRP).

Director Office of Human Research Ethics

1/21/14