

TO: Whom It May Concern

FROM: Jennifer A. Graf

A handwritten signature in blue ink, appearing to read "Jennifer A. Graf", is written over the printed name.

Manager, Human Research Protections and Research Integrity

DATE: 26 August 2012

SUBJECT: Statement of Compliance for the Protection of Human Research Participants

The Cambridge Health Alliance (CHA) Institutional Review Board (IRB) is responsible for reviewing research involving human subjects to ensure that subjects' rights and welfare are protected in conformity with applicable regulations issued by the Department of Health and Human Services ("DHHS"), the US Food and Drug Administration (FDA), and other federal agencies, as applicable.

CHA abides by the ethical principles and guidelines for the protection of human research participants established in the Belmont Report, including respect for persons, beneficence, and justice.

The CHA IRB has been issued Federalwide Assurance (FWA) 00000014 by DHHS. CHA complies with the regulations of 45 Code of Federal Regulations (CFR) 46 and chooses to limit the assurance to federally funded research; however, the regulations at 45 CFR 46, including Subparts B, C, and D, inform for the review and approval of all research at CHA, irrespective of the funding source. The IRB is registered with DHHS as IRB00000760.

CHA participates in clinical research that is under the jurisdiction of the FDA. As a result, CHA complies with the regulations found at 21 CFR 50, 56, 312, and 812.

CHA also complies with International Conference on Harmonisation Guidelines on Good Clinical Practice where they are consistent with FDA and DHHS regulations.