



February 6, 2018

RE: Emory University Compliance with Federal Regulations and ICH Guidelines

To Whom It May Concern:

The Emory Institutional Review Board (IRB), through its Federalwide Assurance and registered IRBs with the Office for Human Research Protections (OHRP), fulfills all federal requirements as a duly constituted IRB. The Emory IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the Emory University IRB complies with 45 CFR 46 Subparts A-D, 45 CFR 164.508-514, 21 CFR 50, 21 CFR 56, and applicable portions of 21 CFR 54, 21 CFR 312, 21 CFR 812, and 21 CFR 814.

Although the Emory University IRB has not officially adopted the ICH-GCP guidelines, its policies and procedures are in accordance with the ICH-GCP guidelines as published in the Federal Register, May 9, 1997, regarding Institutional Review Board/Independent Ethics Committee (IRB/IEC) criteria 3.1 through 3.4 of E-6.

The Emory University IRB's written policies and procedures are available online at:
<http://www.irb.emory.edu/documents/PoliciesandProcedures.pdf>

Thank you for your consideration.

Sincerely,

Rebecca Rousselle, CIP
IRB Director