



OFFICE OF RESEARCH COMPLIANCE

Memorandum

FROM: Thomas A. Coggins, Director
Lisa Marie Johnson, IRB Manager

DATE: April 1, 2015

SUBJECT: Institutional Review Board Regulatory Authority and Assurance

This memorandum is being provided in response to requests from study sponsors for some or all of the points as described below:

The University of South Carolina has an approved Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP), (**FWA00000404**).

The University of South Carolina is a registered IRB Organization with OHRP, (**IORG0000142**).

The University of South Carolina IRB is registered with OHRP, (**IRB00000240**).

The University of South Carolina IRB is organized and operated in compliance with FDA regulations 21 CFR Parts 50 and 56 and DHHS regulations 45 CFR Part 46 as appropriate. The University of South Carolina IRB utilizes a 21 CFR Part 11 compliant, electronic IRB platform (eIRB) for protocol submissions.