**MEMORANDUM**

**TO:** Randolph W. Hall, PhD

Vice President of Research

Office of Research

**FROM:** Martin Koning-Bastiaan,

Director of Research Technology

Office of Research

**DATE:**  August 27, 2013

**SUBJECT:** 21 CFR Part 11 Compliance Statement

The University of Southern California Institutional Review Boards maintain and require use of an electronic system for the submission and approval of human subjects research (iStar). This system is a closed system, and thus possible applicability of Part 11 would be under section 11.10 “Controls for Closed Systems.” While recent FDA guidance suggests that IRB documents may not fall under Part 11, we have proceeded under the assumption that it does. The IRB system does conform to the Part 11 requirements put forth in section 11.10. The iStar system used by USC is:

1. Validated (ensuring accuracy, reliability, consistency and ability to discern altered records)
   * The iStar system tracks all changes made by any individual in the system. Any change is date/time stamped with the author of the change and a complete account of what changes were made.
   * All changes to the software follow best practice software development practices to ensure that the changes are appropriate, reliable, and correct.
2. Auditable (ability to generate accurate and complete copies of records and activities)
   * iStar includes an ability to generate a complete version of the study, in addition to the history of changes being able to be displayed and printed.
   * All changes indicate who made the change with a date/time stamp. No change can be made without a record of the change.
3. Protected (records retention and limited access)
   * All IRB records are retained within the system and change is strictly controlled.
   * Access to data and abilities are controlled by individual user accounts, user roles, and the status of application in the system.
   * The application’s status strictly enforces what actions or changes can be made to it.
   * All accounts are password protected.
   * Significant actions (such as the submission of a study for review) include a comprehensive set of assurances including a personalized stamp with date and time.
4. Documented (written policies defining proper use and responsibility)
   * All users must agree to a written policy that they agree that the electronic signature has the same force as a written one and prohibits use of an account by someone other than the person whose account it is.