November 29, 2011

RE: Part 11 Compliance (Electronic Signatures)

The University of South Alabama is compliant with FDA’s regulations on electronic signatures at 21 CFR 21. The IRBNet System is fully compliant with the technology requirements for Electronic Records per CFR 21, Part 11, Section 11.10 - Controls for Closed Systems, and the technology requirements for Electronic Signatures per CFR 21, Part 11 Subpart C - Electronic Signatures. Correspondence to the investigator related to the acknowledgment or approval of an action are generated by the IRB staff utilizing the IRBNet management system. The University of South Alabama IRB, as of November 1, 2011, considers electronically generated documents as official notice to sponsors and others who seek IRB determinations.