

Holden Comprehensive Cancer Center Clinical Research Services

Subject: Electronic Signatures compliance with Part 11 of Title 21 of the Code of Federal Regulations

This document is intended to certify that electronic signatures obtained and stored using the electronic regulatory management system eREG at Holden Comprehensive Cancer Center Clinical Research Services are fully compliant with part 11 of Title 21 of the Code of Federal Regulations.

These signatures and documents in the eREG system are intended to be used in place of paper format and electronic signatures are intended to be the equivalent of handwritten signatures.

Clinical Research Services retains documented evidence of validation, to demonstrate compliance with CFR Title 21 Part 11 and any other applicable regulations, and this documentation is available for review upon request.

The FDA certification letter, per U.S. CFR Title 21 Part 11 is on file with the FDA

The system has adequate controls for user identifiers and passwords to verify the identity of signatories, as well as written procedures for operation and maintenance of the electronic signature system. This documentation is available for review upon request.