Language for SmartForm allowing for use of the Florence eBinders Software System

Section 34.3

All study-related regulatory and participant source documents (also known as the Master Study File or Regulatory Binder), with exceptions noted below,* will be digitally maintained in the cloud-based, 21 CFR Part 11 and HIPAA compliant Florence eBinders software system.

Servers for this cloud-based system will be under the oversight of Florence Healthcare Inc.

The following individuals will be provided permission-based access to individual study eBinder records to complete appropriate research-related activities:

- Study team members
- MCW employees (MCW Quality Assurance / Quality Improvement Program, MCW Corporate Compliance)
- Affiliated healthcare partners (Froedtert Office Clinical Research & Innovative Care Compliance-OCRICC, Froedtert Investigational Drug Services-IDS, Clinical Unit Managers)
- Sponsor delegates

Individual access will only be provided after completion of all required Florence training activities, completion of an attestation form, and as appropriate an individual signature log.

*Participant records maintained in the electronic medical record; Investigational Pharmacy records maintained in Vestigo.

Section 44.2

All information included in the Florence eBinder Master Study File will be removed upon the approval of the sponsor, which will be no sooner than 10 years after approval of the study agent for marketing and until there are no pending or contemplated marketing applications or 10 years have elapsed since the formal discontinuation of clinical development of the investigational product.

Language for Consent allowing for use of the Florence eBinders Software System

E2 of consent

- Florence Healthcare Inc.