



knowledge changing life

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November 11, 2021

To: Whom it may concern

Re: FDA Title 21 CFR Part 11 and HIPAA Compliance Summary for Florence eBinders

Please accept this memo as documentation that Florence eBinders has been authorized for use with HIPAA-protected data and for research requiring Title 21 CFR Part 11 compliance at the Medical College of Wisconsin (MCW). MCW has a Master Software and Services Agreement in place with the vendor, Florence Healthcare, Inc.

An Electronic Signature Certificate Statement was previously sent to the FDA on June 1, 2020, certifying the intent to use electronic signatures at MCW. A copy is available for your review.

MCW Corporate Compliance, MCW Information Security, and our affiliate hospital, Froedtert Health completed a security review of Florence eBinders. A review of the Florence vendor documentation confirmed extensive validation testing materials, a full traceability matrix to the Part 11 regulations, and an independent third-party audit certification for FDA 21 CFR Part 11 compliance. A copy of the certificate is available for your review.

MCW completed initial validation of Florence eBinders Title 21 Code of Federal Regulations (CFR) Part 11 compliance in August 2021. The validation process included reviewing vendor validation materials, developing and executing functional tests, and documenting standard operating procedures. All research investigators, staff and monitors are required to complete training before gaining access to the eBinders system.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann B. Nattinger".

Ann B. Nattinger, MD, MPH
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