knowledge changing life

Office of Research

MCW Use of Florence eBinders™

The Medical College of Wisconsin, Inc. (MCW) is a proven leader in the conduct of clinical research and development of innovative treatments. As a part of MCW's mission and values, we strive to deliver excellence and quality while emphasizing the creation and implementation of new knowledge and cutting-edge technologies. As such, we are implementing the use of Florence eBinders™ to further support and advance our clinical trials program. Florence eBinders™, including e-Signatures, is an FDA CFR Part 11 and HIPAA compliant service that manages both regulatory and source documents. This cloud-based system has audit trails, is backed up three times per day, and is a validated and compliance tested program.

The implementation of eBinders provides a streamlined approach to documentation of clinical trials. Roles and permissions allow for remote monitoring and improved oversight of documents. The electronic format allows for forwarding correspondence directly into eBinders via email, collaborating in the tool for electronic signatures, training, setting expiration of documents, and linking documents to improve efficiency and reduce duplication. Florence eBinders™ contains the full format of the paper regulatory binders and will be accessible to monitors and sponsor auditors for review during either remote or on-site visits.

Effective, beginning in July 2021, MCW is implementing Florence eBinders™ for all new externally sponsored, industry-funded clinical research trials. Existing active trials will be handled on an individual basis and will either be migrated fully into the eBinders software, split, and managed with eBinders based on a certain date, or not migrated at all. The decision will be made based on the current status of the trial, and the bandwidth of the research team to migrate older trials.

In order to utilize this technology, a standard one-time, non-negotiable, regulatory Florence eBinders™ Usage Fee of $1,500.00 plus F&A is incorporated into all externally sponsored, industry-funded budgets to permit access to protocol-specific regulatory documents stored in a 21 CFR Part 11-compliant digital format, allowing sponsor delegates to have remote review of all regulatory site files. The MCW Florence eBinders™ Fee does not include the effort and resources required by the Investigator or study team delegates to prepare, negotiate, submit, or execute any of the documents or processes required for clinical trial initiation, maintenance, or closure.

Please refer to MCW's Standard Operating Procedure for detailed information regarding the use for Florence eBinders®. Documents detailing Florence e-Binders' CFR Part 11 and HIPAA compliance are available upon request.

Clarifications and questions to the content of this document are to be directed to the MCW Office of Research at florence@mcw.edu.

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