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Office of Research

Justification Statement for Florence eBinders™ Usage Fee

Beginning in July 1, 2021

To facilitate efficient management and execution of this research project, please accept this Justification Statement for the Florence eBinders™ Usage Fee. Florence eBinders™, including e-Signatures, is an FDA 21 CFR Part 11 and HIPAA-compliant electronic regulatory binder software system that provides both the sponsor and the site with an efficient mechanism to manage and store site regulatory documents. The MCW Office of Research will assess a one-time, all-inclusive fee of \$1,500, plus F&A, on behalf of the Medical College of Wisconsin, Inc. The MCW Florence eBinders™ Fee is applied to all new externally sponsored, industry-funded clinical trials that are approved by the MCW IRB and conducted with support of MCW personnel, facilities and/or equipment. This fee is non-negotiable.

The Florence eBinders™ system is an institutional resource implemented by MCW to further support and advance our clinical trials program. Use of the e-Binders platform will provide the clinical trial sponsor remote access to the site regulatory documents during the initiation, maintenance, or closure of the clinical trial.

Florence eBinders™ system provides the user:

- Real-time, secure access to the MCW site regulatory documents from feasibility through the duration of the clinical research trial for sponsor and site research team.
- Easy to use e-Signature tool for execution of regulatory documents.
- Virtual and on-site access for monitoring and auditing activities.
- Secured, and easy to access long-term clinical trial storage capabilities for all clinical trial documents.
- FDA 21 CFR Part 11 and HIPAA compliant regulatory purpose-built digital software.

The MCW Florence eBinders™ system Usage Fee does not include the effort and resources required by the Investigator, or study team delegate to prepare, negotiate, submit, or execute any of the documents or processes required for clinical trial initiation, maintenance, or closure.

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