



MCW Office of Research Guidance Document

Impact of Use of Florence eBinders on MCW IRB Applications

Unit: Human Research Protections Program; Florence Support Team; MCW Office of Research

Applies to: MCW Faculty/Staff/Students involved in human research who utilize Florence eBinders

Scope:

The MCW IRB has evaluated how to best review and document the changes needed to existing IRB-approved projects due to the implementation of the Florence eBinders platform. This document addresses both existing and new MCW IRB clinical trial applications.

Existing / Active Projects and Subjects:

Since the eBinders implementation does not change or modify the access to a subject's private health information or the use of this information or protection measures in place, the MCW IRB office has determined that currently enrolled subjects do **not** need to be re-consented for this change. Subjects **should be notified** of this change at their next visit (in-person or via phone or other virtual platform) after eBinders implementation and this should be documented.

Currently approved research studies should be amended (PRO SmartForm section 34.3 & 44.2 and E2 of the consent form) using the language provided by the Office of Research (see [Smartform & Consent Inclusions](#)) **at the time of the next amendment**. Changes to the PRO SmartForm and consent form (if applicable) can be made at the time of 6-year renewal continuing progress reports (CPRs). Changes to the consent form can be made at the time of CPR, but there is no ability to change the PRO SmartForm with CPRs.

New MCW Clinical Trial IRB Applications:

All new MCW clinical trial IRB applications are required to include language explaining the use of Florence eBinders. Impacted fields include SmartForm section 34.3 & 44.2 and Consent form E2.

See [Smartform & Consent Inclusions](#) for the approved language.

Long-Term Records Retention:

Use of Florence eBinders will not have no impact on the length of time research records are retained. Guidance on Long-Term research records retention is found in Tips for Using eBinders.

Questions should be directed to Florence@mcw.edu or irboffice@mcw.edu

Effective Date:	8/18/2021
Version number:	1.0
Previous Version/date:	Not Applicable
Responsible Office:	Office of Research – HRPP & Administrative Team