MCW Guidance: Guidelines for Documentation of Human Subject Research

This document was created to provide guidance to the investigator and research team regarding the expectations for documentation of Human Subject Research Related Activities. The guidance document provides an overview of the Human Research Protection Program's (HRPP) expectations regarding the documentation of research related activities for studies regulated by FDA regulatory requirements, studies regulated by HHS regulatory requirements, and for those studies not subject to FDA or HHS regulatory requirements. The HRPP's expectations are based upon regulatory requirements, state law, Medical College of Wisconsin's policies and the HRPP SOPs.

In the table the left column lists various examples of research related documentation and in the subsequent columns to the right are the HRPP's expectations for documentation to be included in the research records for FDA governed studies with and without ICH GCP E6, HHS regulated studies and finally studies that are not governed by FDA or HHS regulatory requirements but are subject to MCW policies and SOPs.

These guidelines were reviewed and are supported by the MCW Human Research Advisory Committee in the efforts of promoting transparent information regarding the conduct of human research projects.

Documentation	FDA governed studies with ICH GCP E6	FDA governed studies	HHS governed studies (federally funded)	No federal regulatory oversight, subject to MCW policies and SOPs
Regulatory file	**X**	**X**	**X**	**X**
Signed consent forms (Unless IRB waived documentation or process)	**X**	**X**	**X**	**X**
In the event of documented or waived documentation of informed consent - document whether informed consent was obtained prior to initiation of research related activities	**X** Consenter signature in addition to the study subject	**X**	**X**	**X**
Screening (Required for FDA governed studies. Recommended for other studies if study involves a screening process to determine basic eligibility)	**X**	**X**	Recommended – if applicable	Recommended – if applicable
Determination of eligibility criteria (How inclusion & exclusion criteria was met)	**X**	**X**	**X**	**X**
Notification to the study participant's primary physician of the participant's involvement in the research project - must have participant's permission prior to notification	Recommended			
Research Related activities which include, but are not limited, to the conduct, observation and outcome of the activity	**X**	**X**	**X**	**X**
Pertinent information that demonstrates how individual met eligibility, tolerated research related activities, exposure to investigational product/activity and outcome; adverse and unforeseeable events.	**X**	**X**	**X** – if applicable	**X** – if applicable
Omitted/excluded research procedures	**X**	**X**	**X**	**X**
Relevant communication with study participant	**X**	**X**	**X**	**X**
Withdrawal from research (By PI or study participant)	**X**	**X**	**X**	**X**
Lost to follow up	**X**	**X**	**X**	**X**