**AGREEMENT OF INVESTIGATOR RESPONSIBILITES**

MCW Reliance on an External IRB

**Study Title:**

**MCW eBridge PRO:**

**MCW/FH/Versiti PI must sign the bottom of this document to verify that institutional requirements, regulations and policies have been/will be met.**

1. I have reviewed the proposal and will conduct the project in full compliance with the Federal Wide Assurances (FWA), institutional policies of the Medical College of Wisconsin and Froedtert Hospital, and applicable federal and state regulations.
2. I will not initiate any research involving humans until final documentation of reliance has been received and the project has been approved in writing by the Institutional Review Board (IRB) of record.
3. I will employ and assume the responsibility for the informed consent process in order to ensure that potential research subjects understand the purpose of the project, the procedures they are being asked to undergo, the potential risks, benefits, and alternatives of the project, their rights as a research subject, and have sufficient time to decide about participating. I will not enroll any subject in the project or conduct project procedures until such informed consent is obtained, unless waived by the IRB.
4. I will ensure that subjects are kept fully and promptly informed of any new information that may affect their willingness to continue to participate in the project.
5. I will maintain current and accurate records of data, outcomes and adverse events to permit an on-going assessment of the risks/benefits of participation. I will ensure the privacy of the subjects and maintain the confidentiality and security of the data in accordance with *IRB SOP: Privacy and Confidentiality.*
6. I will report to the **IRB of record and the MCW IRB**in a timely manner, all unanticipated problems involving risk to subjects or others (UPIRSOs), serious and/or continuing non-compliance, and suspensions or terminations.
7. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
8. I understand that it is my responsibility to provide site information to the Lead Principal Investigator (PI) so they can submit the project in a timely manner (minimally annually) for the "Continuing Progress Review" in order to obtain IRB renewal/approval from the IRB of Record. I am aware that failure to do so will result in a lapse of project approval, and all project activities must stop.
9. I agree to follow the protocol as approved by the IRB of record. All protocol deviations will be reported to the IRB of record. Documentation of protocol deviations will be kept in the project regulatory files, and if applicable, in the subject's research files.
10. I will ensure that the research coordinator(s), co-investigators and other research staff understand their association with and role in this project. I will provide access to a copy of the project protocol for the research coordinator (s), co-investigator (s) and other research staff. I will also ensure that all members of the research team have complied with the MCW Human Subject Research Protection training requirements.
11. I have identified and disclosed all actual or perceived conflicts of interest in accordance with MCW policies on conflicts of interest.

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| Signature of Incoming Principal Investigator |  | Date |
| Click or tap here to enter text. |  |  |
| Print Name |  |  |