Human Research Protections Program
Medical College of Wisconsin and Froedtert Memorial Lutheran Hospital

To Whom It May Concern:

The Medical College of Wisconsin (MCW) has an approved **Federal Wide Assurance** (FWA-FWA00000820) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). The MCW IRB Organization number is IORG0000056.

Froedtert Hospital (FH) of Milwaukee, WI has an approved **Federal Wide Assurance** (FWA-FWA00002157) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, FMLH cedes responsibility for IRB review to the six MCW IRB Committees.

Community Memorial Hospital (CMH) of Menomonee Falls, WI has an approved **Federal Wide Assurance** (FWA-FWA00006858) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, CMH cedes responsibility for IRB review to the six MCW IRB Committees.

St. Joseph's Community Hospital of West Bend (SJH), WI has an approved Federal Wide Assurance (FWA-00016986) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, SJH cedes responsibility for IRB review to the six MCW IRB Committees.

West Bend Clinic (WBC) of West Bend, WI, **has** an approved **Federal Wide Assurance** (FWA- FWA-00017021) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, WBC cedes responsibility for IRB review to the six MCW IRB Committees.

Blood Center of Wisconsin (BCW) has an approved Federal Wide Assurance (FWA-00005505) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, BCW cedes responsibility for IRB review to the six MCW IRB Committees.

FWA information and IRB Organization numbers including the expiration dates can be found on the MCW HRPP website, under the Resources tab.

The following MCW Institutional Review Boards (MCW IRBs) are registered with OHRP and are designated in the MCW FWA to conduct reviews of research involving human subjects for the Medical College of Wisconsin, Froedtert Hospital, and the other institutions that cede IRB review:

- IRB00001395-Committee #1
- IRB00001396-Committee #2
- IRB00001564-Committee #3
- IRB00000078-Committee #4
- IRB00006380-Committee #5
- IRB00011716-Committee #6

The MCW IRBs are also registered in compliance with the Food and Drug Administration (FDA) regulations at 21 CRF Part 56. Additionally, the MCW IRBs serve as the IRBs of record for affiliated institutions pursuant to inter-institutional agreements.

The Medical College of Wisconsin Inc., Froedtert Health, Inc. and Versiti, Inc. earned Full Accreditation from the Association for the Accreditation of Human Research Protection Programs on June 10, 2011. The Medical College of Wisconsin Inc., Froedtert Health, Inc. and Versiti, Inc. were re-accredited as of June 15, 2014 and June 17, 2019. The current accreditation period extends for 5 years.

All research involving human subjects reviewed by the MCW IRBs is guided by the ethical principles in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The MCW IRBs are duly constituted, fulfilling Federal requirements for membership; have written policies procedures for initial and continuing review for human subjects research which are available to investigators; prepare written minutes of convened meetings; and retain records pertaining to the review and approval process all in compliance with the requirements for IRBs defined in DHHS 45 Code of Federal Regulations (CFR) Parts 46 and 164 and Food and Drug Administration (FDA) 21 CFR Parts 50 and 56. Whenever required by contract, the MCW IRB is compliant with the Guidelines of the International Conference on Harmonization relating to Good Clinical Practices (GCPs) to the extent required by the FDA.

IRB membership rosters are posted on the IRB website, but the names of IRB Reviewers for specific studies are not released. Any IRB member who is an investigator, co-investigator or has any other conflict of interest with a protocol under review by the MCW IRBs will not participate in the deliberation or vote of that protocol although he or she may be called upon to answer questions during the review.

MCW IRB has a policy to manage genuine or perceived conflicts of interest of IRB members. All members who serve as either co-Investigator or as Key Personnel for a research project must recuse themselves. However the policy does not require hospital based pharmacists in general or Froedtert Pharmacists to declare a conflict of interest or recuse them unless they are listed as co-investigators or Key Personnel for a specific study or clinical trial. The IRB recognizes that as part of their routine clinical duties, Froedtert Pharmacy staff often has a role (as hospital pharmacist) in studies and clinical trials. Since the MCW IRB has one member of the Froedtert Pharmacy staff serving on each of the four IRB full committees, these pharmacists often participate in the IRB review of studies and clinical trials that are managed by their office. Since they are salaried hospital employees, and as they are recused whenever they have a co-investigator or key personnel role for a particular study or clinical trial, the MCW IRB and its policies do not define a hospital pharmacist's peripheral involvement in a study/trial as "conflicted".

The MCW IRBs do not require the IRB Chairs or any other member of the IRB to sign approval letters. There is no regulatory requirement for such signatures. Final IRB approval occurs when the IRB votes to approve a research protocol and that approval is reflected in the IRB's electronic record. With respect to a conditional approval, an IRB member signs off in the IRB's electronic record to confirm that the investigator has met all of the IRB conditions before a final approval letter is sent to the investigator.

The MCW IRB approval letters serve to document IRB approval of the entire submission including, but not limited to, the protocol, the informed consent document, and, if applicable, the Investigator Brochure. Although the investigator may submit other documents for the IRB to review, the IRB approval letter will list **only** the protocol, the informed consent document, the Investigator Brochure (if applicable), and advertising (if applicable).

No subject may be registered to a trial until IRB approval has been documented and the IRB has provided a consent document with the approval period displayed in the header and a stamped effective date.

The MCW IRB requires investigators to use one of several flexible consent document templates that include necessary HIPAA authorization language. Investigators may enter salient information in the free-language fields of the template, but requests to alter the mandatory-language paragraphs are rarely honored.

The MCW IRBs do not use version numbers on informed consent documents, but enter the most recent approval and expiration date in the header of the document. Consent forms are stamped only for studies that remain open to enrollment or in cases when an amendment is submitted to re-contact previously-enrolled subjects in a study closed to enrollment.

The MCW IRBs only use effective date stamps on approved consent forms and advertising materials that will be used, distributed, and or displayed at MCW institutions and affiliates. MCW IRBs do not stamp national advertising campaign brochures or other patient documents such as appointment cards, greeting cards, etc.

The MCW IRB has reviewed and approved the English 'short form' consent document posted to the HRPP website. The non-English 'short form' consent documents posted to the website are translations of the IRB-approved English version. Study teams may use the 'short form' versions of the informed consent documents posted on the MCW HRPP website for obtaining consent from occasional, unexpected examples of non-English speaking subjects. If the posted 'short form' consent documents does not include the language needed to obtain consent from a participant, then the study team must obtain a translation of the posted English version of the 'short form' and submit it to the IRB office prior to using it for obtaining informed consent.

The MCW IRB will not "approve" the use of pregnancy data collection consent forms or authorization forms for research projects where pregnancy is an exclusion criterion and/or may affect a person who is not enrolled in the research project (e.g., a male subject's partner) because they are not integral to the study protocol. These forms are intended to collect information about potential unanticipated problems. The MCW IRB will review and comment on the content of such forms if requested by the Sponsor but will not include them as an official part of the research project regulatory file.

Generally, the MCW IRBs review events arising during the course of the research that may require a re-consenting of subjects. The MCW IRB will determine the appropriate method of re-consenting based upon each individual situation. The MCW IRB will take into account an investigator or sponsor determination to re-consent a subject. The MCW IRB will also consider whether a new signed consent document is required or whether verbal re-consent with accompanying documentation in the medical or study record will be satisfactory given the circumstances. Re-consenting of subjects is often required when there is a new risk or event that impacts the risks/benefit ratio involved in participation in the research. Re-consenting is not required to inform of editorial or administrative changes, or, at the time of continuing review unless there are newly discovered risks or other critical information. Re-consenting is required where (1) the investigator proposes to re-consent subjects and the IRB confirms this; or (2) the IRB specifically requires re-consenting. While there may be situations in which re-consent occurs because of a sponsor requirement, the re-consent will not be viewed as an IRB requirement unless the IRB specifically so determines. Additionally, the IRB may require that new information be conveyed to subjects via written correspondence or verbally, rather that via a revised informed consent document.

Research projects involving the use of an unapproved drug or device, or off-label use of an approved drug or device, require that the Investigator or Sponsor contact and if necessary obtain an Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA in accordance with Federal regulations. See *IRB SOP: Use and Storage* of *Investigational Drugs or Biologics and IRB SOP: Use and Storage* of *Investigational Device.* Un-redacted documentation from the FDA for the IND, IDE, or HDE (or: guidance that none is necessary) is required to be included as part of the new research study application that is submitted to the MCW IRB for review and approval.

Documentation must include (at a minimum);

- Name of investigational article(s)
- Category that applies:

☐ Investigational Drug ☐ Combination investigational drug/device

☐ Investigational Device ☐ Humanitarian Use Device

- FDA-assigned number (IND, IDE, or HDE #)
- Month and year that IND/IDE/HDE first assigned
- FDA-assigned indication for this number
- Who manufactures this drug / biologic / device?

The MCW IRBs do not accept submissions from investigators of IND/IDE safety reports from outside sponsors detailing adverse events that have occurred at sites other than MCW or FH unless the report is of an incident that is: (1) associated with harm or risk of harm; (2) unexpected; (3) related to the research intervention; and, (4) has implications for the conduct of the study. If the incident falls within the guidelines above, investigators are required to submit the report as a Reportable Event.

If you require additional information please contact our office at the number listed above.

Sincerely,

David Clark, PhD
Director, Human Research Protections Program,
Medical College of Wisconsin and Froedtert Memorial Lutheran Hospital

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