Human Research Protection Program
Medical College of Wisconsin

To Whom It May Concern:

The following document contains the most commonly questioned policies for conducting research at Medical College of Wisconsin (MCW), Froedtert Health, Versiti, Children's Wisconsin, or any other entity deferring IRB review to the MCW IRB. Please review the information carefully, as research conducted at the aforementioned institutions will be held to the standards detailed throughout this document.

The Medical College of Wisconsin (MCW) Human Research Protection Program (HRPP) and Institutional Review Board (IRB) is located at 8701 Watertown Plank Road Milwaukee, WI. 53226.

The Medical College of Wisconsin has an approved **Federal Wide Assurance** (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 Health has an approved **Federal Wide Assurance** (FWA00002157) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, Froedtert Health cedes responsibility for IRB review to the MCW IRB Committees.

Versiti, Inc. has an approved Federal Wide Assurance (FWA00005505) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, Versiti, Inc. cedes responsibility for IRB review to the MCW IRB Committees.

Children's Wisconsin has an approved Federal Wide Assurance (FWA00001809) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). Under this FWA, Children's Wisconsin cedes responsibility for IRB review to the 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 Health, Versiti, Inc., Children's Wisconsin, 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
- IRB00013550-Committee #7
- IRB00013551-Committee #8

Each of 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 (AAHRPP) on June 10, 2011. The Medical College of Wisconsin Inc., Froedtert Health, Inc. and Versiti, Inc. continue to maintain their Full Accreditation status with AAHRPP.

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 IRBs are 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 research projects are not released. Any IRB member who is an investigator, co-investigator or has any other conflict of interest with a research project under review by the MCW IRBs will not participate in the deliberation or vote of that research project although he or she may be called upon to answer questions during the review.

MCW IRBs have 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 research project. The IRB recognizes that as part of their routine clinical duties, Froedtert Pharmacy staff often has a role (as hospital pharmacist) in research projects.

Since the MCW IRBs have members of the Froedtert Pharmacy staff serving on the MCW IRB committees, these pharmacists often participate in the IRB review of research projects 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 research project, the MCW IRBs and their policies do not define a hospital pharmacist's peripheral involvement in a research project as "conflicted".

Consent documents and Clinical Trial contracts must be reviewed for consistency before any clinical trial can be issued final approval by the MCW IRB Committees. For every for-profit funded clinical trial, the HRPP Office must compare the proposed consent document and the final, executed clinical trial contract and confirm consistency on the following points of comparison before the IRB can issue its approval of the project.

1. Compensation and/or travel reimbursement for subjects
2. Additional costs of research activities which will be covered and who will be responsible for those costs
3. Coverage of any emergency treatment due to a research related injury or illness
4. Compensation available for any emergency treatment due to a research-related injury or illness

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).

The MCW IRBs do not require the IRB Chairs or any other member of the IRB to sign decision letters. There is no regulatory requirement for such signatures. Final IRB approval occurs when the IRB votes to approve a research project 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 the IRB conditions before a final approval letter is sent to the investigator.

No subject may be enrolled in a research project 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 IRBs require investigators to use one of several consent/assent/parental permission document templates that include necessary HIPAA authorization language as well as necessary language relating to the institution's compliance with the Common Rule. Investigators may enter salient information in the free-language fields of the template, but requests to alter or add to the mandatory-language paragraphs are rarely honored. A process for evaluating these requests does exist and requires a regulatory rationale to be provided prior to consideration. Sponsors should be aware of the institutional template requirements prior to site selection as these will not be waived on a Sponsor-by-Sponsor basis.

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

The MCW IRBs only use effective date stamps on approved consent/assent/parental permission forms that will be used and/or distributed at sites under MCW IRB purview. MCW IRBs do not stamp national advertising campaign brochures or other subject documents such as brochures, appointment cards, greeting cards, etc.

The MCW IRBs have 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. Research 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 do not include the language needed to obtain consent from a subject, then the research 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 IRBs 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 research protocol. These forms are intended to collect information about potential unanticipated problems. If a subject or the subject's partner were to become pregnant while participating in a research project where pregnancy is an exclusion criterion, the MCW IRBs will review and comment on the content of such forms and the components of the corrective action plan for this unanticipated problem.

Generally, the MCW IRBs review events arising during the research that may require a re- consenting of subjects. The MCW IRBs will determine the appropriate method of re-consenting based upon each individual situation. The MCW IRBs will consider an investigator or sponsor determination to re-consent a subject. The MCW IRBs will also consider whether a new signed consent document is required or whether verbal re-consent with accompanying documentation in the medical or research 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 than via a revised 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 or the IND holder for the IND, IDE, or HDE (or: guidance that none is necessary) is required to be included as part of the new research 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/Biologic
  - ☐ 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 external sites 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 research. 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 IRBoffice@mcw.edu or 414-955-8422 .

Sincerely,

Ryan Spellecy, PhD
Director, Human Research Protection Program
Medical College of Wisconsin

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