Medical College of Wisconsin /
Froedtert Hospital
Institutional Review Board

To: Sakti Chakrabarti, MD
CC: Bicky Thapa, MD
Ronald Cox

Date: **4/1/2021**

Re: **Project Title**: A retrospective review to study the spectrum of COVID-19 vaccine-related adverse events in cancer patients
PRO ID : PRO00040038

IRB Registration Date: 4/1/2021

The MCW/FH Institutional Review Board #5 has determined the above-referenced submission meets the criteria for registration in accordance with the MCW/FH IRB Policy: *Registration Projects: Human Subject Research Projects which Qualify for Flex Review,* Registration Category **8**.

This determination extends to the following institutions:

Froedtert & the Medical College of Wisconsin Hospitals and Health Partners
Froedtert Hospital (including all specialty clinics, the Cancer Center and the Eye Institute)
Medical College of Wisconsin - Milwaukee Campus

The items listed below were submitted and reviewed with this submission. Research must be conducted in accordance with the IRB's determination as described in the documents listed below:

Data collection tool
Study protocol

Given that the current project does not involve direct contact with subjects, an informed consent process is not required. The IRB has granted approval of a waiver of HIPAA authorization requirements at 45 CFR 164.

Decedent data may be accessed in accordance with 45 CFR 164.512.

Any and all proposed changes to this submission must be reviewed by the IRB prior to implementation. When it is necessary to eliminate hazards to subjects, changes may be made first. This should be followed promptly by contacting the MCW/FH IRB Office.

All Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) must be reported promptly to the MCW/FH IRB according to IRB Standard Operating Procedures (SOPs).

Category 8 Registration Projects no longer require Froedtert Office of Clinical Research and Innovative Care Compliance (OCRICC) review and approval.

In order to meet the requirement of accounting for all use and disclosures of Protected Health Information (PHI) for the purpose of research without patient authorization, research staff must complete an Accounting Log specific to that project's disclosure. This must be completed electronically via the web-based Accounting Log Form located here. Upon completion, this log will be submitted directly to Froedtert Health Information Management (HIM) and will be considered valid for the length of the IRB Approval of the study. At time of government audit or other administrative request, researchers must be able to produce their less than 50 screening list within 48 business hours, if requested. Principal Investigators are ultimately accountable for the conduct of their research.

Be advised:

1. MCW Researchers are required to use the Medical College of Wisconsin (MCW) Clinical Translational Science Institute (CTSI) Clinical Research Data Warehouse (CRDW) resources and tools for obtaining formal Reports of PHI data, images, etc.
2. Requests for financial, cost or other data not yet available through the CRDW: MCW researchers will need to complete an F&MCW Reports, Data & Analysis Request https://remedy.prod-smartit.a1.fchhome.com/ux/myitapp/#/catalog/home. Researchers must attach a copy of the project IRB Registration Letter & the Data Collection Form (DCF) to your Report Request. This process does require a Froedtert network account. To obtain Froedtert network access, work with your Department Administrative personnel.
3. Questions regarding access to FH data or OCRICC review and approval, please contact OCRICC office: ocricc@froedtert.com

If you have any questions, please contact the IRB Coordinator II for this IRB Committee, Cara Marzion, at 414-955-8601 or cmarzion@mcw.edu.

Sincerely,

Nevin Uysal Biggs, MD
Kathryn Gaudreau
IRB Chair
MCW/FH Institutional Review Board #5