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Institutional Review Board

FWA # (FWA00000873) IRB# (IRB00000673)

To: Michael D Caldwell, MD, Principal Investigator

From: Stephanie Kohlbeck, PhD, Chair, Institutional Review Board

Signature applied by Stephanie L Kohlbeck on 10/08/2019 01:59:00 PM CDT

Date: October 08, 2019

Cc: Madalyn M Palmquist; Shicheng Guo

Re: **IRB#:** IRB-18-384
MCR Code: BRA20112

Study Title: Piloting Use of MicroRNA Expression Patterns to Predict Patients at Risk for Atrial Fibrillation Development Following Coronary Artery Bypass Grafting - Data and Tissue Bank

Item(s) Reviewed: - Submission Components		
Form Name	Version	Outcome
Change or Update to Original Submission	Version 1.0	Approved

Item(s) Submission Date: 09/30/2019 12:18:48 PM CDT

Additional Description of Item(s) Reviewed: The addition of Shicheng Guo as co-investigator as outlined in your submission

Type of Review Conducted: Expedited

Date Reviewed: October 7, 2019

Review Decision: Approved

Review of this change/update to original submission using Expedited review is in compliance with 45 CFR 46.110 (b)(2).

This change request submission does not alter the waiver of informed consent and/or waiver of authorization that was allowed at original review.

DATA OR MATERIAL SHARING

If your research involves the sharing of individual level data or specimens with any external party, an appropriate transfer agreement must be in place. To initiate an agreement, complete and submit a "Request to Transfer Data or Materials" form. Contact Marla Ripp Fischer with any questions regarding this process.

As principal investigator, you are ultimately responsible for all aspects of this research project. Co-investigators and research staff are expected to assist in maintaining these responsibilities. A list of such responsibilities is referenced below.

Principal Investigator Responsibilities Following IRB Approval

* Ensure that the dignity, rights, safety and well-being of subjects are considered and respected at all times.

* Ensure that all individuals engaged in your research are familiar with the following:

    a) The Belmont Report
    b) DHHS Regulations
    c) FDA Regulations
    d) The terms of Marshfield Clinic's Federal Wide Assurance (FWA)

* Ensure that all individuals engaged in your research follow all IRB policies.

* Ensure that all individuals engaged in your research are appropriately qualified and trained.

* Ensure the accuracy and completeness of all information provided to the IRB regarding this research.

* Adhere to the research plan reviewed and approved by the IRB. This includes the application, protocol, consent forms and other documents.

* Meet all prior approval and reporting requirements (see below).

* Ensure that your research undergoes continuing review by submitting a continuing review report prior to your research's expiration date.

* Ensure any investigational drugs used in this research are under the control of the Investigational Drug Program (IDP).

* Maintain all research records, including copies of signed consent documents (unless waived), for a period of six (6) years past the date the project is officially terminated with the IRB.

*Have these records available for audit as requested.

IRB Prior Approval and Reporting

IRB prior approval is required for any proposed changes or additions to the research activity such as:

a) protocol amendments
b) changes to the consent form or informed consent process
c) recruitment procedures and documents
d) new or different subject incentives per the "IRB Recruitment of Subjects" policy
e) any proposed increase in the total number of subjects to be enrolled on a multi-center study
f) any proposed increase in local accrual that changes a limit specifically stipulated by the protocol
g) addition of research sites
h) change of principal investigator or addition of co-investigators
i) plan to communicate with subjects regarding new findings that may impact their willingness to continue participating in the research

These changes may **not** be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

Reporting Requirements

The following table summarizes which types of events or information should be reported to the IRB or Research Compliance, along with the applicable policy and report form.

Please contact the IRB Office at 715-389-3022 or the Research Compliance Officer at 715-281-7040 if you have questions.

Event	Reporting Deadline (business days)	Applicable Policy	Applicable Forms
Unanticipated Problem	7	Reporting and Review of Unanticipated Problems	IRB Unanticipated Problem Involving Risks to Participants or Others Report
Non-Compliance	7	Non-Compliance with Federal Regulations, Institutional Policies, and IRB-Approved Applications and Protocols	Electronic Non-Compliance Reporting Tool
ICH-GCP Adverse Events (potential risk increase and/or provides new information)	7	International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines and IRB Review	IRB Unanticipated Problem Involving Risks to Participants or Others Report
ICH-GCP Adverse Events	30	International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines and IRB Review	ICH GCP Adverse Event Report
Expanded Access—Emergency Use with an Investigational New Drug (IND)/Investigational Device Exemption (IDE)	5	Expanded Access—Physician Initiation of Emergency Use of a Test Article	IRB Emergency Use Report Form
Unanticipated Problems with a Humanitarian Use Device (HUD)	7	Humanitarian Use Devices	IRB Unanticipated Problem Involving Risks to Participants or Others Report