Institutional Review Board
University of Missouri-Columbia
FWA Number: 00002876
IRB Registration Numbers: 00000731, 00009014

310 Jesse Hall
Columbia, MO 65211
573-882-3181
irb@missouri.edu

April 04, 2023

Principal Investigator: Lemuel Russell Waitman
Department: Health Mgmt & Informatics

Your Amendment for External Sites to project entitled Greater Plains Collaborative PCORnet Cohort Characterization for Breast Cancer, ALS, and Obesity (GROUSE) was reviewed and approved by the MU Institutional Review Board according to the terms and conditions described below:

IRB Project Number	2057285
IRB Review Number	391624
Funding Source	Centers for Disease Control and Prevention National Institute on Aging (NIA)(NIH)(PHS) Patient-Centered Outcomes Research Institute
Initial Application Approval Date	May 05, 2021
Approval Date	April 03, 2023
IRB Expiration Date	May 05, 2024
Level of Review	Expedited
Application Status	Approved
Project Status	Active - Open to Enrollment
Risk Level	Minimal Risk
Type of Consent	Waiver of Consent
HIPAA Category	HIPAA Waiver HIPAA Data Use Agreement
Authorization Agreement	Allina Health Intermountain Healthcare Marshfield Clinic Medical College of Wisconsin University of Iowa University of Kansas Medical Center University of Nebraska Medical Center University of Texas Health Sciences Center at Houston University of Texas Health Sciences Center at San Antonio University of Texas Southwestern Medical Center (UT Southwestern) University of Utah Washington University

The principal investigator (PI) is responsible for all aspects and conduct of this study. The PI must comply with the following conditions of the approval:

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date.
2. All unanticipated problems must be reported to the IRB on the Event Report within 5 business days of becoming aware of the problem. Unanticipated problems are defined as events that are unexpected, related or possibly related to the research, and suggests the research places subjects or others at a greater risk of harm than was previously known or recognized. If the unanticipated problem was a death, this is reportable to the IRB within 24 hours on the Death Report.
3. On-site deaths that are not unanticipated problems must be reported within 5 days of awareness on the Death Report, unless the study is such that you have no way of knowing a death has occurred, or an individual dies more than 30 days after s/he has stopped or completed all study procedures/interventions and required follow-up.
4. Major noncompliance must be reported to the MU IRB on the Event Report within 5 business days of the research team becoming aware of the deviation. Major noncompliance are deviations that caused harm or have the potential to cause harm to research subjects or others, and have or may have affected subject's rights, safety, and/or welfare. Noncompliance not rising to the level of major noncompliance must be tracked and reported at the time of continuing review. Please refer to the MU IRB Noncompliance policy for additional details.
5. All study changes must be IRB approved prior to implementation unless they are intended to reduce immediate risk. All changes must be submitted on the Amendment Form.
6. All recruitment materials and methods must be approved by the IRB prior to being used.
7. The project-generated annual report must be submitted to the IRB for review and approval at least 30 days prior to the project expiration date. If the study is complete, the Completion/ Withdrawal Form may be submitted in lieu of the annual report.
8. Securely maintain all research records for a period of seven years from the project completion date or longer depending on the sponsor's record keeping requirements.
9. Utilize the IRB stamped consent documents and other approved research documents located within the document storage section of eCompliance. These documents are highlighted green.
10. For this research project, MU is the IRB of record. Each research site must comply with all decisions and determinations of the MU IRB. Specific reporting and other responsibilities are outlined in the executed agreement.

Please view the MU HRPP/IRB policies describing post IRB approval reporting and other IRB requirements.

If you have any questions, please contact the IRB Office at 573-882-3181 or muresearchirb@missouri.edu.

Thank you,
MU Institutional Review Board