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

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

Your Amendment Form v.2 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	371200
Funding Source	National Institute on Aging (NIA)(NIH)(PHS) Patient-Centered Outcomes Research Institute
Initial Application Approval Date	May 05, 2021
Approval Date	March 03, 2022
IRB Expiration Date	May 05, 2022
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
HIPAA Waiver or Alteration Approval	The MU IRB determined the study meets the 3 criteria to approve a waiver of authorization under the Privacy Rule. 45 CFR 164.512 (i)(1)(i)
Authorization Agreement	Allina Health Indiana University 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 San Antonio University of Texas Southwestern (UT Southwestern) University of Utah Washington University in St. Louis

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:

- No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date.
- 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.
- 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.
- 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 resulting from investigators' failure to comply with the IRB approved protocol when these deviations caused harm or have the potential to cause harm to research subjects or others, and may have affected subject's rights, safety, and/or welfare. It also includes subjects' failure to comply with the protocol when these deviations caused harm. Minor noncompliance include deviations that had no harm to a research subject or others. Minor noncompliance should be reported at the time of continuing review. Please refer to the MU IRB Noncompliance policy for additional details.
- All 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.
- All recruitment materials and methods must be approved by the IRB prior to being used.
- 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.
- 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.
- Utilize the IRB stamped consent documents and other approved research documents located within the document storage section of eCompliance. These documents are highlighted green.
- 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.

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

Thank you,
MU Institutional Review Board

1. HIPAA Waiver for the Use and/or Disclosure of Protected Health Information (PHI) in Research

1. **Why do you need this waiver? Select all that apply:**

   ☐ **Pre-Screening** to review inclusion and exclusion criteria to determine if individual is eligible to participate in the study. Those meeting eligibility requirements will be contacted for authorization.

   ☑ **Records Research -** Researchers are unable to use de-identified information, and the research could not practicably be conducted if authorization were required.

2. **Sources of PHI**

   Select the source(s) of PHI

   ☑ Electronic Medical Record

   ☐ Electronic Databases in Ancillary Units (lab, pathology, radiology, pharmacy, etc.)

   ☐ Data being extracted from a Research Database

   ☐ Paper Record in Clinical Areas

   ☐ Other:

3. **PHI and Access**

   A. Identify the covered entity where data will be requested/pulled:

   ☑ MU Health

   ☑ Other Entity

   i. Identify entity:

   All participating GPC sites relying on this master IRB at MU

   B. Who will access/pull the PHI for this study?

   ☑ Research Team on the IRB Application with authorized access to PHI

   ☑ Third Party (non-research team member)

   i. Is it a necessity for the research team to access/pull the data?

   If no, for MU Health data, the School of Medicine utilizes the Show Me Portal for data requests. This could be an option for your team. For more information, click HERE.

   ● Yes ○ No

   ii. Identify the third party.

   New-Wave/GDIT, LLC. CMS's data warehouse contractor.

   iii. Have you already starting working with the third party on your data needs?

   If you are working with MU Health data and you have not started working with a third party, the MU School of Medicine utilizes the Show Me Portal for data requests. For more information, click HERE.

   ● Yes ○ No

   C. State the objective(s) of the research.

Within the context of GPC and PCORnet, our study has four overarching aims:
(1) To understand the development, treatment, and progression of breast cancer
(2) To understand the development, treatment, and progression of amyotrophic lateral sclerosis (ALS)
(3) To understand the development, treatment, progression, and consequences of healthy and unhealthy (overweight and obesity) weight
(4) Serve as a greater national resource to understand the development, treatment, progression, and consequences of acute and chronic disease cared for within the United States healthcare system and in support of quality care for the conditions championed by the Patient Powered Research Networks in PCORnet as well as the other conditions studied by our peer CDRNs.

To improve data completeness suitable for this study, a key step is to properly link the EHR data with CMS claims data. We will implement a privacy-preserving linkage technique through New-Wave/GDIT (CMS's data warehouse contractor) to create the patient mapping. This activity will involve participating sites (including MU) sending PHI information (SSN, HIC, Birth_Date) to New-Wave/GDIT, while only the patient mapping (in limited data set) will be shared with MU. In order to maintain an up-to-date linkage between the CMS and site EHR data, we seek to refresh the patient crosswalk file (i.e. a mapping between patients' local identifier to CMS beneficiary ID) on an annual basis until at least one year after the funding period (2025) if not further extended.

D. Approximately how many records do you anticipate will be needed to meet the objectives of the research?

There will be around 25 million medicare and medicaid beneficiaries, 30 million patients covered by GPC sites, it is estimated that the overlapping population will be about 20% of the medicare and medicaid beneficiaries.

E. Provide a description of the health information that will be accessed and minimum necessary to fulfill or satisfy the intended purpose described above.

This field must be completed in detail. Blank or limited descriptions will be returned. Details will need to include information about specific types of reports, exams, images, notes, summaries, demographics, diagnostic or billing codes, recordings, etc. as well as location/specialty area since vague information such as clinic notes or lab results will not be specific enough for the Privacy Office review of minimum necessary. If dates are being requested, details need to include reference regarding which dates such as discharge date, visit date, etc.

The minimum necessary standard, a key protection of the HIPAA Privacy Rule, is derived from confidentiality codes and practices in common use today. It is based on sound current practice that protected health information should not be used or disclosed when it is not necessary to satisfy a particular purpose or carry out a function. Although a covered entity may rely on the determination provided by the MU IRB, the covered entity always retains discretion to make its own minimum necessary determination for disclosures to which the standard applies. More information can be found here.

Social security number (SSN) or Medicare Health Insurance Claim (HIC) number will be needed to uniquely identify a patient and used for generating the patient mapping between EHR and CMS data. Birth_date and sex will also be provided as validators to evaluate linkage accuracy.

F. Select the identifiers that will be used in this study:

☐ Names

☐ Address - All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent codes

☑ Dates - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of

dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

i. Specify what dates are needed:

birth date

- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Email Addresses
- ☑ Social Security Numbers
- ☐ Medical Record Numbers
- ☐ Health Plan Beneficiary Numbers
- ☐ Account Numbers
- ☐ Certificate/License Numbers
- ☐ Vehicle Identifiers and Serial Numbers, including License Plate Numbers
- ☐ Device Identifiers and Serial Numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) Address Numbers
- ☐ Biometric Identifiers, Including Fingerprints and Voiceprints
- ☐ Full-Face Photographic Images and any Comparable Images
- ☐ Any other Unique Identifying Number, Characteristic, or Code, unless otherwise permitted by the Privacy Rule for Re-Identification

4. Justification for Waiver

The use or disclosure of protected health information must involve no more than minimal risk to the privacy of individuals. The following justification is required to determine whether this requirement is met.

A. Select from the following regarding the **storage** of PHI for this study to ensure proper use and disclosure:

Check all that apply:

- ☑ Hard Copy Information - Institutionally authorized secure physical location only accessible to research members listed on the IRB application.
- ☐ Electronic Information - Institutionally authorized secure online location only accessible to research members listed on the IRB application.

i. Describe other storage features if applicable:

The aforementioned PHI information will be stored as a "finder file" in an encrypted hard drive.

B. Select who will have **access** to the PHI to ensure proper use and disclosure:

Select all that apply:

- ☐ Members of the research team listed on the IRB application.
- ☑ Third party with institutionally authorized access assisting the research team.

i. Identify other parties if applicable:

The hard copy (i.e., finder file) will only be accessible by New-Wave/GDIT authorized personnel (New-Wave/GDIT is the CMS data warehouse contractor).

C. Select from the following describing the plan to destroy **identifiers** at the earliest opportunity to ensure proper use and disclosure:

This should only address the destruction of identifiers – not the research data required to be kept according to institutional policy.

- ☐ Promptly - As soon as data are coded in a de-identified manner.
- ☐ After all subjects have completed the study.
- ☑ At the conclusion of the study.
- ☐ There is a health or research justification for retaining identifiers or retention is required by law.

i. Provide any additional information regarding the timing of destruction if applicable.

D. Choose from the following options describing how the research could not practicably be conducted **without the waiver.**

Check all that apply:

- ☑ The research focuses directly on improving the source(s) containing PHI and not the PHI itself.
- ☑ The research does NOT include a requirement to interact or intervene with individuals AND the potential for improved, future treatment or health care operations outweighs any potential risk included in this study.
- ☐ Other:

E. Choose from the following options describing how the research could not practicably be conducted **without access to and use of PHI.**

Check all that apply:

- ☐ PHI will be used to track what records have already been accessed for the research to avoid repeat access to the same record.
- ☑ PHI will be used to conduct a longitudinal study which involves continuous or repeated observations of risk factors and/or health outcomes.
- ☐ PHI will be used because it is required to answer the research question(s) and potentially improve future treatment and health care.
- ☐ Other:

5. Attestation on the Use and Disclosure of Protected Health Information

Both must be checked below:

- ☑ I attest the research team and I will only use protected health information minimally necessary in this study.
- ☑ I attest the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or other research for which the use and disclosure of PHI would be permitted.