IRB #2057285 MU

Amendment Form #386541

Submission date: **01/23/2023**
Submitted by: **Song, Xing**

1. Application Revisions

1. **Revisions to the Application**

   Instructions:

   Click the “Revise Application Form” below to review your approved application and make proposed changes. All changes you make to the application will be tracked.

   *It is possible you will not need to edit the application for certain changes to your study, but you must review the application in its entirety to ensure all information is still accurate and current.

   After making your changes (or no changes), go to the submit section within the application to save your changes. The application revision status below will switch to “complete”, and you will proceed with the next section of the amendment by hitting “Save & Continue” below.

   See: Application Revision No. 10

2. Revisions

1. Provide a summary of the proposed changes.

   A summary of changes is required to be provided here unless you have a sponsor-provided Summary of Changes document. Be sure to upload a tracked changes and clean copies of revised documents. Also, if ancillary units are affected by the proposed change, please be sure to communicate directly with them, if applicable.

   1. we expand the study scope/aims to explicitly call out the following aims:
   (4) To support comparisons among Medicare/Medicaid-insured, commercially-insured and uninsured population.
   (5) To evaluate and enhance data quality derived from electronic health records (EHR) and claims.
   (6) To 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.
   2. we further clarify the inclusion criteria as: all observable patients included within the GPC network OR all Medicare/Medicaid beneficiaries residing within GPC catchment area

2. Describe why these changes are necessary.

   Two of our partner sites questioned that the current IRB scope looks restricted to only Medicare/Medicaid beneficiaries. We would like to make it clear in the Master IRB protocol that we will need to also compare against non-Medicare/non-Medicaid population. However, this amendment may not be required by all of our participating sites.

3. Do you have adequate resources to support this amendment?

Consider adequate time for the researchers to conduct and complete the research; adequate qualified number of staff; adequate facilities and equipment; access to a population that will allow recruitment of the necessary number of participants; and availability of medical or psychological resources that participants may need as a consequence of the research.

● Yes ○ No

4. Are there new risks to subjects associated with these changes, or an increase in the frequency/severity of risks?

   Often times in revised sponsored protocols or CIDBs, you will find a table or list of adverse events that must be compared in order to make an accurate decision.

   ○ Yes ● No

5. Are you requesting a revision to a HIPAA waiver/alteration, or do you need a new one?

   If yes, a subform will generate. The HIPAA waiver/alteration is no longer submitted on an attached file/Word document. It is embedded within the amendment form.

   ○ Yes ● No

6. Are you revising your consent documents?

   ○ Yes ● No

7. Would you like to request for this study to be advertised on the MU Division of Research, Innovation, and Impact (RII) website created for recruitment purposes?

   If yes, you will be asked additional questions creating information to pull to the website about your study as soon as this amendment is approved. The information below is what will be included on the website. Please ensure what you include here is succinct, clear of typos, and in alignment with what you have included in your recruitment materials. You will need to notify the IRB when this should be removed, and it will not stay on the website if your project is closed to enrollment or expires. [This is in the process of being finalized on the RII website]

   ○ Yes ● No

3. Enrollment/Re-Consent

1. How many subjects are currently on active study?

   Subjects that are continuing to receive study-related treatment/interventions, or actively participating in research activities.

   N/A, this is retrospective study

2. How many subjects are currently in long-term follow-up?

   Subjects that have completed all study-related treatment/interventions, but are being followed per study protocol to monitor study-related outcomes. This includes interactions that involve no more than minimal risk (i.e. quality of life questionnaires), and collection of follow-up data from procedures or interventions that would have been done regardless of the research (i.e routine clinical or non-clinical activities to further monitor a subject).

   N/A, this is retrospective study

3. Do the changes include significant new findings that may affect subject willingness to continue participation?

This could be changes in potential or actual risks or benefits to subjects, addition or deletion of study procedures or number of visits required, alteration to their study treatment, changes to subject costs, etc. Mark NA if no subjects are enrolled.

○ Yes ○ No ● N/A

4. Do you plan to re-consent subjects?

   Mark NA if no subjects are enrolled.

   ○ Yes ○ No ● N/A

5. For treatment/intervention studies, when was the last time a subject was on active treatment? Leave blank if this is not a treatment/intervention study.

   Depending on the proposed revisions, this information will help the IRB determine whether re-consent or notification is required.

Application Revision No. 10

1. Project Title/Investigators

1. **Project Title**

   If the study is externally funded or internally grant funded, this title should match the title on the grant/ contract.

   Greater Plains Collaborative PCORnet Cohort Characterization for Breast Cancer, ALS, and Obesity (GROUSE)

2. **Key Personnel - List all investigators engaged in the research by clicking on the "Add an Investigator" button.** This includes individuals interacting or intervening with subjects, collecting or accessing identifiable data, or consenting subjects. Please note, if individuals are performing services that are typically performed for non-research purposes, and they are only providing a service for this project, they do not need to be listed. Do not add external investigators from another institution/ organization who have their own IRB unless you are specifically asked by our office to add them to our application.

   Principal Investigator Assurance: After you hit submit on this application, the PI will be sent an email from the system requesting the completion of the PI Assurance Form. This application will not officially be submitted to the IRB until this step is complete.

   Primary Contact(s): Whoever you would like to be copied on IRB correspondence, including reminders and approvals, please be sure to add them as primary contacts when prompted under the "Add an Investigator" button. There must be at least one primary contact on this application.

   Fellows and Residents: Must have a faculty member listed as a co-investigator.

   Student-Initiated Projects: Students must list themselves as Principal Investigator and also include an Advisor on the project. After you hit submit on this application, the Advisor will be sent an email from the system requesting the completion of the Advisor Approval Form. This application will not officially be submitted to the IRB until this step is complete.

Medical Procedures and/or Treatment Studies: For activities that require consent to be obtained by a licensed physician outside the scope of research, only a physician, advanced practitioner, or appropriately licensed provider may have the consent role as "authorized to obtain consent". Review our Informed Consent Requirements SOP for additional information.

Expedited and Full Board Studies: Please be sure the Principal Investigator has uploaded their Curriculum Vitae (CV) or resume to their personal document storage in eCompliance. When the PI logs into eCompliance, this will be uploaded under the "Prerequisites" column. This only needs to be uploaded once for all studies.

Registered Nurses as PI or Co-I: If you are a Registered Nurse and Employee of MU Health Care, please contact Sean Pridgeon, Coordinator of EBP and Nursing, for additional information regarding MU Health Care project tracking at pridgeons@health.missouri.edu.

Role	Investigator	Department	CITI IRB Training	Primary contact	Consent personnel role	Truman VA Hospital personnel
Principal Investigator	Waitman, Lemuel Russell	Health Mgmt & Informatics	07/24/2021	☑	Non-Consenting Personnel	☐
Co-Investigator	Mosa, Abu Saleh Mohammad	Health Mgmt & Informatics	12/09/2022	☐	Non-Consenting Personnel	☐
Co-Investigator	Song, Xing	Health Mgmt & Informatics	12/21/2020	☑	Non-Consenting Personnel	☐
Research Staff	Hossain, Md Saber	Health Mgmt & Informatics	07/01/2021	☐	Non-Consenting Personnel	☐
Research Staff	Khan, Mirza Samiuddin	School of Medicine Residency	08/23/2022	☐	Non-Consenting Personnel	☐
Research Staff	Mandhadi, Vasanthi	Health Mgmt & Informatics	04/14/2022	☐	Non-Consenting Personnel	☐
Research Staff	McMahon, Tamara Jo Misenor	Biomedical/ Health Informatics	06/01/2021	☐	Non-Consenting Personnel	☐
Research Staff	Powell, William James	Biomedical/ Health Informatics	06/06/2022	☐	Non-Consenting Personnel	☐
Research Staff	Rana, Md Kamruz Zaman	Health Mgmt & Informatics	06/13/2022	☐	Non-Consenting Personnel	☐
Research Staff	Safipour Afshar, Askar	Inst for Data Sci & Informatic	08/22/2021	☐	Non-Consenting Personnel	☐
Research Staff	Spinka, Christine Marie	Health Mgmt & Informatics	02/14/2022	☐	Non-Consenting Personnel	☐
Research Staff	Turabieh, Hamza Ibrahim	Health Mgmt & Informatics	10/11/2022	☐	Non-Consenting Personnel	☐
Student Investigator	Khan, Huzaifa	Health Mgmt & Informatics	09/06/2022	☐	Non-Consenting Personnel	☐

	Role	Investigator	Department	CITI IRB Training	Primary contact	Consent personnel role	Truman VA Hospital personnel
+	Research Staff	Gaddam, Rakesh Indivar Will be **added** to this project	Health Mgmt & Informatics	03/07/2023	☐	Non-Consenting Personnel	☐
+	Research Staff	Paka, Vyshnavi Will be **added** to this project	Health Mgmt & Informatics	06/08/2022	☐	Non-Consenting Personnel	☐

3. Contact Information (Read-Only)

Principal investigator

Waitman, Lemuel Russell

Job title	ASSOCIATE DEAN & DIRECTOR OF MEDICAL INFORMATICS IN PRECISION HEALTH INSTITUTE & PROFESSOR
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

Primary contact

Waitman, Lemuel Russell

Job title	ASSOCIATE DEAN & DIRECTOR OF MEDICAL INFORMATICS IN PRECISION HEALTH INSTITUTE & PROFESSOR
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

Song, Xing

Job title	PROF, AST
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

4. VA Research

A. Is the research going to be conducted by investigators serving on VA compensated, VA without compensation, or Intergovernmental Personnel Act appointments?

○ Yes ● No

VA EXEMPT PROJECTS - Stop Here: The MU IRB does not review VA exempt projects. You must contact the Truman VA HRPP Specialist to obtain instructions for completing a VA exempt application since they utilize a separate online system. Her contact information is: Julie.Bauer2@va.gov or (573) 814 -6000 ext. 53691.

FORM INSTRUCTION: As you work through the form, you will be checking boxes that prompt additional questions. If you realize those additional questions do not pertain to your study, go back and uncheck the box that prompted those questions.

2. Exempt Determination

☑ **NOT EXEMPT: If you already know that your project is NOT exempt, please check this box to skip this entire section and additional sections will populate. If you are unsure, do not check this box and continue with #1.**

3. Basic Project Information

1. Select from the type of research this project would likely fall under:

☑ **Biomedical** - Research that is conducted to increase fundamental knowledge and understanding of the physical, chemical and functional mechanisms of human life processes and diseases.

☐ **Social/Behavioral/Educational** - Research that encompasses a range of methodologies and seeks to answer questions to improve our understanding of human behavior, attitudes, beliefs, and interactions as well as social and economic systems, organizations, and institutions.

2. Are there any conflicts of interests with this study?

Example: Financial, personal, institutional, or other, for any study team member. If none, please indicate no conflict. We will verify your responses with existing data on file.

○ Yes ● No

3. Is this study **limited to** the analysis of materials (data, documents, records, or specimens) that are collected solely for non-research purposes (such as medical treatment or diagnosis)?

Before selecting yes, refer to Exempt Category #4 (section 3 of the application) to ensure the project cannot be Exempt. Most activities fitting this limited analysis can be Exempt.

● Yes ○ No

4. Are you proposing to utilize or add information and/or biospecimens to an existing database/ biorepository ?

MU Health Care Policy: It is important to familiarize yourself with the policy outlining exempt specimens from routine pathologic examination. You will want to check on the availability of specimens for research before proceeding with IRB approval: https://muhealth.policytech.com/docview/?docid=38100&public=true

○ Yes ● No

5. Is this a multi-site collaborative study where MU is functioning as the lead site?

This means the MU investigator is (1) a PI on a grant with another site(s) as a sub-contracted site(s), and/or (2) taking on the role as the lead investigator/site overseeing/coordinating the conduct of the study.

● Yes ○ No

6. Select the appropriate option regarding the external site's involvement:

☐ **Responsible for a portion of the study** (for example: assisting MU investigators in data collection, data analysis, and/or recruitment and consent)

☑ **Conduct the entire protocol** (the external site will conduct this study at their site and requests MU IRB to be their Reviewing IRB)

Studies where external sites are conducting the entire protocol at their own site and using MU IRB as their IRB of Record/Central IRB:

You must secure local, MU approval first – prior to submitting external site specific information and documents. After you receive MU IRB approval for the MU site and model documents, you will then submit the **Amendment for External Sites** to add the external site information and documents for IRB approval.

7. If another site will have their own IRB review the study (no reliance), please list those institutions here.

8. Select from the committees or entities that will also be responsible for reviewing and approving this study:

☐ **Investigational Pharmacy** (Studies involving drug administration EXCEPT for approved, standard of care drugs that are part of a participant's standard clinical care within a clinical or home setting)

☐ **Radiation Safety** (Studies involving radiation therapy that is not considered standard of care and is protocol-driven, radioactive materials)
MU Radioactive Materials Website

☐ **VA Research and Development** (Studies involving Harry S Truman Memorial Veteran's Hospital)
Harry S Truman Memorial Veterans' Hospital Research and Development Website
Phone: 573.814.6550

☐ **Institutional Biosafety** (Studies involving recombinant or synthetic nucleic acid molecules, including the creation and the use of organisms and viruses containing recombinant or synthetic nucleic acid molecules, biohazardous materials; gene therapy studies)
Institutional Biosafety Committee Website

Other:

9. Select from the following to determine if HIPAA (Health Insurance Portability and Accountability Act) regulations apply to this study:

HIPAA Resource

☐ The study involves accessing/screening the medical record prior to contacting subjects and obtaining consent.

☑ Data are derived from a medical record or encounter

☐ Data are added to the hospital or clinical medical record

☐ Data are created or collected as part of health care

☐ Data are used to make health care decisions

☐ The research is being conducted in a covered entity or at a location where there is patient billing

☐ None Apply

A. If data are derived from the medical record, please identify the source here.

EHR systems used at participated GPC sites (e.g. Cerner Millennium used for MUHC). Medicare and Medicaid research identifiable files (RIF) are derived from Medicare and Medicaid claims provisioned by CMS and ResDAC (Research Data Assistant Center).

B. If HIPAA regulations apply, select the form that will be used (this will need to be uploaded to the attached files section in a Word document). VA Studies must use the VA templates.

MU templates can be found here. VA templates can be found here

- ☐ HIPAA Authorization
  (Subjects will sign an authorization to allow the use of their personal health information (PHI) in research)
- ☑ HIPAA Waiver
  (Subjects will not sign an authorization to allow the use of their PHI)
- ☑ Data Use Agreement - Limited Data Set
  (Subjects will not sign an authorization to allow the use of their PHI. An agreement will instead be signed that allows the use of limited PHI without consent/authorization from the subject)

10. Is the research funded/supported?

Select "yes" for internal or external funding. If this proposal is associated with potential funding, please select "yes" and complete with the funding source you are seeking. When asked to submit the award information later in the application please indicate "pending". If funding is received, you will need to update your information in eCompliance.

● Yes ○ No

11. Sponsors

Sponsor #1
Patient-Centered Outcomes Research Institute

1. Select the sponsor from the drop-down menu:

Start typing the sponsor's name and the list will populate. If you do not see your sponsor in the drop-down menu, email irb@missouri.edu to add it to the list.

Patient-Centered Outcomes Research Institute

2. Select the appropriate funding types:

If your sponsor fits more than one type, please select all that apply.

- ☐ Internal Funding (departmental funding, research council grant, etc.)
- ☐ HHS funded (Department of Health and Human Services)
- ☑ Federally Funded
- ☐ Industry Sponsor (ex. Pharmaceutical company, device company, etc) * IRB fees apply
- ☐ Non-Federal, External Funding
- ☐ US Department of Education
- ☐ Department of Energy
- ☐ Department of Defense
- ☐ Environmental Protection Agency
- ☐ Department of Justice

3. Provide the NIH Project Number/Application ID (or Grant Award Reference Number for Federal, Non-NIH funders):

RI-CRN-2020-003-IC

4. Provide the MU Sponsored Program Grant Proposal Number, if applicable.

This number should start with two 0's. If you receive funding after IRB approval, you must update this information using the Requested Identification Form.

0070497, 0067314

5. What is your MOCode that will be associated with this project?

Select pending, if needed. If you receive your MoCode after IRB approval, you will need to submit the Requested Identification Form to add the MoCode. If this is not a sponsored study, a department MoCode will need to be provided.

☐ Pending

Enter MoCode Here:

DXH27

6. Select the fiscal manager who can approve the MOCode and MU Sponsored Program Grant Proposal Number listed above.

Cassone, Deandra Lynn

Job title	DIR RESEARCH ACTIVITIES
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

Sponsor #2
National Institute on Aging (NIA)(NIH)(PHS)

1. Select the sponsor from the drop-down menu:

Start typing the sponsor's name and the list will populate. If you do not see your sponsor in the drop-down menu, email irb@missouri.edu to add it to the list.

National Institute on Aging (NIA)(NIH)(PHS)

2. Select the appropriate funding types:

If your sponsor fits more than one type, please select all that apply.

☐ Internal Funding (departmental funding, research council grant, etc.)

☑ HHS funded (Department of Health and Human Services)

☑ Federally Funded

☐ Industry Sponsor (ex. Pharmaceutical company, device company, etc) * IRB fees apply

☐ Non-Federal, External Funding

☐ US Department of Education

☐ Department of Energy

☐ Department of Defense

☐ Environmental Protection Agency

☐ Department of Justice

3. Provide the NIH Project Number/Application ID (or Grant Award Reference Number for Federal, Non-NIH funders):

1R61AG068483-01

4. Provide the MU Sponsored Program Grant Proposal Number, if applicable.

This number should start with two 0's. If you receive funding after IRB approval, you must update this information using the Requested Identification Form.

5. What is your MOCode that will be associated with this project?

Select pending, if needed. If you receive your MoCode after IRB approval, you will need to submit the Requested Identification Form to add the MoCode. If this is not a sponsored study, a department MoCode will need to be provided.

- [x] Pending

Enter MoCode Here:

6. Select the fiscal manager who can approve the MOCode and MU Sponsored Program Grant Proposal Number listed above.

Cassone, Deandra Lynn

Job title	DIR RESEARCH ACTIVITIES
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

Sponsor #3
Centers for Disease Control and Prevention

1. Select the sponsor from the drop-down menu:

Start typing the sponsor's name and the list will populate. If you do not see your sponsor in the drop-down menu, email irb@missouri.edu to add it to the list.

Centers for Disease Control and Prevention

2. Select the appropriate funding types:

If your sponsor fits more than one type, please select all that apply.

- [ ] Internal Funding (departmental funding, research council grant, etc.)
- [x] HHS funded (Department of Health and Human Services)
- [x] Federally Funded
- [ ] Industry Sponsor (ex. Pharmaceutical company, device company, etc) * IRB fees apply
- [ ] Non-Federal, External Funding
- [ ] US Department of Education
- [ ] Department of Energy
- [ ] Department of Defense
- [ ] Environmental Protection Agency
- [ ] Department of Justice

3. Provide the NIH Project Number/Application ID (or Grant Award Reference Number for Federal, Non-NIH funders):

1 R01TS000336-01-00

4. Provide the MU Sponsored Program Grant Proposal Number, if applicable.

This number should start with two 0's. If you receive funding after IRB approval, you must update this information using the Requested Identification Form.

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5. What is your MOCode that will be associated with this project?

Select pending, if needed. If you receive your MoCode after IRB approval, you will need to submit the Requested Identification Form to add the MoCode. If this is not a sponsored study, a department MoCode will need to be provided.

☑ Pending

Enter MoCode Here:

6. Select the fiscal manager who can approve the MOCode and MU Sponsored Program Grant Proposal Number listed above.

Niu, Xiaofan

Job title	ASOC DIR PROGRAM/PROJECT OPS
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

12. Provide a description of your study, including the research objectives.

PCORnet was created in 2014 by the Patient Centered Outcomes Research Institute (PCORI) to further the goals of the Learning Health System and help to answer questions that are important to patient, clinician, and health system stakeholders. PCORnet now includes 13 clinical data research networks (CDRNs) and 22 patient-powered research networks (PPRNs). Each of the CDRNs is charged with aggregating longitudinal data on over 1 million individuals that is appropriate to inform all care that a patient receives, as well as creating 3 longitudinal cohorts — one rare disease, one common condition, and one to examine obesity.

For the Greater Plains Collaborative (GPC) CDRN, our rare disease is amyotrophic lateral sclerosis (ALS), our common disease is breast cancer, and we are tracking obesity in the context of all patients with healthy and unhealthy weights as specified by the PCORnet obesity task force. This obesity cohort is shared with the other CDRN PCORnet colleagues. Within the context of GPC and PCORnet, our study has six 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) To support comparisons among Medicare/Medicaid-insured, commercially-insured and uninsured population.
(5) To evaluate and enhance data quality derived from electronic health records (EHR) and claims.
(6) To 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.

13. Explain how the data to be used are reasonable and necessary to conduct the research.

This cohort will include only individuals residing in GPC regions supported by the GPC institutions NIH Clinical and Translational Science Award/Great Plains IDEA – Clinical and Translational Research, which includes the following states: Kansas, Missouri, Iowa, Wisconsin, Nebraska, Minnesota, Texas, Utah, North Dakota, South Dakota, Idaho, Nevada, Wyoming, portions of Illinois and Michigan. The geographic region described contains approximately 25 million beneficiaries. Because people may move between health systems, it is necessary to cover the regions, rather than the individuals, covered by the health systems. Therefore to accomplish all the aims in comparing our three studied conditions and their treatment patterns against the larger population within the states, it is necessary to obtain claims data for all patients residing in the eleven states. It is also important to be able to access EHR data of the study cohorts who are not Medicare/Medicaid insured, so that the comparisons against commercially-insured and uninsured population can be made possible

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. This activity will involve participating sites (including MU) sending PHI information (SSN, HIC, Birth_Date) to CMS's data warehouse contractor, New-Wave/GDIT.

14. Identify the source of the data and the purpose for which the data were originally collected, including whether they were collected for research purposes.

The source of EHR data from 13 GPC sites were originally collected for clinical use. The source of Medicare and Medicaid (CMS) claims data (i.e., the Research Identifiable Files) we requested from ResDAC were collected for research purposes (however, the raw Medicare and Medicaid claims were collected for administrative purposes).

For the purpose of this research, a key step is to properly link the EHR data with CMS claims data for data completeness. 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.

15. If data were collected for other research projects, is the reuse consistent with the consent under which they were collected?

○ Yes ○ No ● N/A

16. If the data were originally collected for non-research purposes (e.g. administrative, clinical), do the guidelines under which they were collected allow for reuse for research purposes?

● Yes ○ No ○ N/A

17. If the data are allowed for research purposes, select the level of access by the research team:

☐ Identified

☑ De-Identified

☐ Coded (the investigator has an identifying link and it can be traced back to the data/record)

18. Provide the date of the records to be reviewed.

The EHR data ranges from 2010 to 2022. Medicare and Medicaid claim data are currently between 2011 and 2020. We would refresh data of both sources on an annual basis when new data is available.

19. Will the study utilize the Clinical Research Center (CRC) within the School of Medicine?

Please upload the signed Protocol Intake Form from the CRC if you have it as this time.

○ Yes ● No

20. Qualifications

☑ I attest that all members of the study team have appropriate training, qualifications, and credentials to perform study related procedures/activities.

A. Does the study involve any study related procedures that require specialized training or certification?

● Yes ○ No

☑ I attest that all members of the study team will have the required training prior to performing the study related procedure.

21. Does your study include presenting photographs or other potentially identifiable media to the participants in your study?

As a reminder, just because pictures and other items are available on the internet does not mean they are approved to use in your research.

○ Yes ● No

4. Subject Recruitment

1. Does the study involve in-person interaction?

If yes, an additional subform will populate for completion regarding COVID-19 subject protections.

○ Yes ● No

2. List your inclusion criteria.

This would be a description of your subject population, who you will be targeting for recruitment. If all of this information is clearly stated in your protocol, you may refer to a specific page/section in your protocol.

Inclusion criteria: all observable patients included within the GPC network OR all Medicare/Medicaid beneficiaries residing within GPC catchment area

3. List your exclusion criteria.

This would be a description of who cannot participate in your research, who you are not targeting for recruitment. If all of this information is clearly stated in your protocol, you may refer to a specific page/section in your protocol.

N/A

4. Select if your inclusion criteria (target population) includes the following populations:

Do not check if the research is aimed at involving a broader population that may only incidentally include one or more of the following:

☐ Students

☐

Employees

☐ Community Veterans (do not check this if this study engages the Truman VA Hospital as a research site)

☐ MU Student-Athletes

5. Will you be processing (i.e. using, accessing, collecting, recording, storing, or transmitting) any personal data about individuals physically located in the European Union, or be involved with any transfer of personal information from the EU to an non-EU country?

○ Yes ● No

6. Explain how you will have access to this population and what method will be used to identify and recruit subjects.

If you are using medical records to identify potential subjects, you must describe the providers or group of providers that have treating relationships with the patients, and describe your plan to consult the providers before contacting patients.

We will access this population by extracting their electronic medical records and/or Medicare/Medicaid claims, which will be properly transformed and de-identified before being made accessible to research team.

You must upload all recruitment materials for review, including but not limited to, letters, emails, verbal scripts, advertisements, etc. All recruitment materials must receive IRB approval before use.

7. At all sites (multi-sites), how many people do you expect to complete the study?

An Amendment Form is required if your enrollment is going to exceed your target enrollment by more than 20%.

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about 40,000,000

8. At all sites (multi-sites), how many will be enrolled (sign the consent) to reach the number listed in the previous questions.

For some studies, this number may be the same, for other studies there may be a high rate of screen failures, so you will want to account for those screen failures.

N/A

Policy Regarding Recruitment Materials:

The recruitment should be limited to:

- The name and address of the investigator or research facility
- The condition under study or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information

The recruitment cannot:

- State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
- Make claims, either explicitly or implicitly, that the drug, biologic or device was safe or effective for the purposes under investigation
- Make claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic or device
- Use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article was investigational
- Promise “free medical treatment,” when the intent was only to say participants will not be charged for taking part in the investigation
- Include exculpatory language
- Emphasize the payment or the amount to be paid, by such means as larger or bold type

5. Subject Consent

1. Select what type(s) of consent will be obtained (there may be more than one):

☐ **Written (or the electronic equivalent)** - Templates can be found here

☐ **Waiver of Documentation (no signature requirement) -** Templates can be found here.
Example:
Telephone or online survey/interview
Note: A waiver of documentation of consent is no longer required for screening, recruiting, or determining eligibility, if you are obtaining information through oral or written communication with the subject or LAR UNLESS you are asking subjects to do something required by the protocol (i.e. fast, withhold medications, etc.). HIPAA regulations still apply to protected health information, and an authorization or waiver/alteration may still be required.

☑ **Waiver or Alteration of Consent**
Examples:
1. No consent will be obtained for the entire study (i.e. record review or observational only study)
2. The study involves deception (this would be an alteration of consent since certain elements of consent are being altered)
Note: A waiver of consent is no longer required for screening, recruiting, or determining eligibility, if you are (i) obtaining information through oral or written communication with the subject or LAR; or (ii) obtaining identifiable private information or identifiable biospecimens by accessing record or stored identifiable biospecimens. A HIPAA waiver is still required for access and use of protected health information.

2. Will the consent document be placed in the medical record?

The consent will need to be placed in the medical record if the study interventions/procedures may affect their current or future health care. Mark NA if written consent is being waived in this study.

○ Yes ○ No ● N/A

3. Will the study involve accessing identifiable student educational records?

Written consent must be obtained from the subject or their legal guardian to allow the release of identifiable student educational records UNLESS the study meets an exception to written permission. Additional information can be found here: US Department of Education FAQ or MU Website

○ Yes ● No

4. Please select the option that you are requesting:

☑ A full waiver of consent

☐ An alteration of consent (example: deception studies)

A. Describe how the research involves no more than minimal risk to participants.

Data will be de-identified before made accessible to researchers

B. Describe how the waiver or alteration will not adversely affect the rights and welfare of the participants.

Data will be de-identified before made accessible to researchers. No patients can be re-identified.

C. Describe how the research could not practicably be carried out without the requested waiver or alteration.

Given the amount of observational cohort, it would not be practical or even feasible to request consent from each individual.

D. If the research involves identifiable private information or identifiable biospecimens, describe how the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

No identifiable private information will be directly accessed by researchers. No patients can be re-identified.

E. Whenever appropriate, describe how the subjects or legally authorized representatives will be provided with additional pertinent information after participation (debriefing).

No identifiable private information will be directly accessed by researchers. No patients can be re-identified.

F. **Research or demonstration projects that are conducted by or subject to the approval of state or local government officials**

*This is another waiver/alteration option infrequently used here, but available if needed.

☐ The research or demonstration project is designed to study, evaluate, or otherwise examine: (A) public benefit or service programs; (B) procedures for obtaining benefits or services under those programs; (C) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.

6. Risks and Benefits

1. Describe the potential risks associated with the research and identify the procedures that will be used to prevent and/or minimize any potential risks and discomforts.

For drug studies, please do not list all drug side effects (these will go on the drug sub-form). Some examples of potential risks may include, breach of confidentiality, invasion of privacy, psychological, physical, social, economic, legal, or other.

No risks or discomforts is expected, as this is a retrospective observational study. Data will be de-identified before made accessible to researchers. No patients can be re-identified or contacted.

2. What are the potential direct benefits to the subjects?

It is possible the study has no potential for direct benefit. If this is the case, please state this.

No direct benefits is expected for the subjects. However, this ultimate goal of this study is to understand the development, treatment, and progression of breast cancer, ALS and obesity, in order to improve overall patient outcomes.

3. What are the potential benefits to the community and society?

The integrated database (GROUSE) will 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 PPRNs in PCORnet as well as the other conditions studied by our peer CDRNs.

4. Does the study require a data and safety monitoring plan?

A plan is required if this is a clinical trial, treatment and/or intervention study, sensitive data are being collected, there is a potential for subjects to experience adverse events, etc.

○ Yes ● No

5. Do you have or plan to obtain a Certificate of Confidentiality? For more information on Certificates of Confidentiality, please go here.

Certificates of Confidentiality are issued to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. NIH funded researchers are automatically issued a CoC through their award. Other Department of Health and Human Services (HHS) agencies issue CoCs to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research.

○ Yes ● No

6. Describe your plan to protect subjects' privacy during and after the course of the data collection?

Privacy refers to a person, not the confidentiality of their data. Confidentiality is addressed in the next section.

Data will be de-identified before made accessible to researchers. No patients can be re-identified.

7. What are the consequences to subjects if a loss of privacy were to occur (e.g. risks to reputation, insurability, embarrassment, other social risks)?

Data will be de-identified before made accessible to researchers. No patients can be re-identified.

8. Mandated Reporting

If you anticipate obtaining information during the research study which might fall under mandated reporting guidelines, select the guidelines that will be followed:

☐ Missouri Department of Social Services (i.e. child abuse)

☐ Missouri Department of Health and Senior Services (i.e. elderly abuse)

- ☐ Title IX
- ☐ Other
- ☑ None apply

7. Confidentiality and Security

1. Select all identifiers that may be accessed and/or included in the research records for the study, check all that apply:
   - ☐ Names
   - ☑ Dates
   - ☐ Postal Address
   - ☐ Phone Numbers
   - ☐ Fax Numbers
   - ☐ E-Mail Addresses
   - ☐ Social Security Number
   - ☐ Medical Record Number
   - ☐ Health Plan Number
   - ☐ Account Numbers
   - ☐ License or Certificate Numbers
   - ☐ Vehicle ID Numbers
   - ☐ Web URLs
   - ☐ IP Address Numbers
   - ☐ Biometric Identifiers
   - ☐ Facial Photos or Images
   - ☐ Any Other Unique Identifier
2. If you plan to disclose any subject identifiers listed above as part of the study process with anyone outside of the research team, identify the individuals or entities that will have access.

   This must be disclosed in the consent document and HIPAA Authorization, if applicable.

   No subject identifiers will be disclosed.
3. Will any web/electronic applications be utilized for such purposes as recruiting subjects, completing questionnaires/surveys, conducting interviews/focus groups, or processing/storing data?

   ○ Yes ● No
4. If you are administering an anonymous online survey, have you checked the appropriate boxes on the survey tool to ensure that the data collected will be anonymous?

   ○ Yes ○ No ● N/A
5. How and where will data be stored during data collection and analysis?

If utilizing subject identifiers, the MU policies regarding security measures for data classification "Data Classification System – Definitions" and subsequent policies and guidance must be reviewed to ensure all MU Data Classification Level (DCL) requirements have been met. Access the policies here: https://www.umsystem.edu/ums/is/infosec/classification and have conversations with IT professionals assigned to your research area.

We have established a secured AWS private cloud environment to store the data and support analysis.

6. How and where will the data be stored after the study is complete?

   Note: Retain records for seven (7) years after the final report on the research project has been submitted. If the research is being done under a contract that requires a specific retention time, the contract retention time will apply.

   The data will be stored in the secured AWS private cloud environment after the study is completed.

7. If data are coded and the data key will be destroyed, please provide the anticipated date of destruction:

   Leave blank if not applicable.

8. If you will retain identifiers with the data, explain the security measures you will take while the data is directly identifiable.

   Leave blank if not applicable.

9. If data will be de-identified, describe the method that will be used to de-identify the data and when this process will occur.

   Leave blank if not applicable.

8. Costs Associated with the Research

1. Are you conducting the study in a MU Health Care location?

   ● Yes ○ No

2. Will the subjects or their insurance bear any costs, including routine care (standard of care) costs, throughout the course of their participation in this study?

   The informed consent will need to accurately reflect the potential cost to the subject or their insurance.

   ○ Yes ● No

3. Do you have adequate resources to conduct the study?

   Consider adequate time for the researchers to conduct and complete the research; adequate qualified number of staff; adequate facilities and equipment; access to a population that will allow recruitment of the necessary number of participants; and availability of medical or psychological resources that participants may need as a consequence of the research.

   ● Yes ○ No

4. Coverage Analysis

Coverage analysis materials are required to be submitted to the Clinical Research Support Center. You must submit (if you haven't already) a completed coverage analysis as part of the preliminary budget packet to umhssomctproposals@health.missouri.edu.

A final version of the coverage analysis, if required, must be uploaded to this application prior to opening the study to enrollment.

A. Select from the items below regarding the status of the coverage analysis:

- [x] A coverage analysis has been determined to NOT be required.
- [ ] The coverage analysis is currently under review, and a copy of the final coverage analysis will be uploaded upon receipt and prior to subject enrollment.
- [ ] The final coverage analysis is complete and will be uploaded to this application submission.

9. Completion of Required Sub-Forms

1. **Select the items that are included as part of your study. For items marked, an additional form will be generated for your completion at the end of this application and is labeled "Additional Forms".**

FORM INSTRUCTION: As you work through the list and you check a box that generates a sub-form, then you realize those additional questions in the sub-form do not pertain to your study, go back to this page and uncheck the box that generated the sub-form to make it go away.

BIOMEDICAL SPECIFIC SUB-FORMS

- [ ] Collection of **biospecimens (i.e solid tissue, blood, saliva, urine, and other biospecimens)**
- [ ] Administration of a **drug or biologic** (investigational, unapproved use, or FDA approved administered for research-only)
- [ ] **Compassionate Use (Expanded Access)** Request
- [ ] Administration of a **supplement, food, or cosmetic**
- [ ] **Cold Isotopes** (non-radioactive isotopes)
- [ ] **Medical Device**, including **Humanitarian Use Devices** in a clinical investigation (investigational, unapproved use, or FDA approved (if the device is approved and is being used for research-only))
- [ ] **Radiological Procedures** (may or may not involve radiation - MRI, xray, ultrasound, DXA Scan, etc.)
- [ ] **Radiation Therapy**
- [ ] Involves an **Exception from Informed Consent for Planned Emergency Research**

SUBJECT POPULATION SUB-FORMS

- [ ] Participants with **impaired decision-making capacities** (unable to legally consent on their own behalf)
- [ ] **Pregnant women or fetuses** (This item is for studies that will target pregnant women, or is a treatment-intervention study (i.e. drug/device) that will not exclude pregnant women/fetus)
- [ ] **Children** (under 18 in Missouri, also dependent on State law)
- [ ] **Non-viable neonates or neonates of uncertain viability** (neonates=newborns)
- [ ]

Non-English speaking subjects (Select if it is known at this time that you will enroll non-English speaking subjects, and the study documents will need to be translated. You can always amend your study to add non-English speaking at any time)

☐ **Short Form Consent** (Enrollment of potential non-English speaking) - Do not check if the entire consent form will be translated.

☐ **Prisoners**

☐ **International Study** (data collection is taking place outside of the United States)

OTHER SUB-FORMS

☐ Establishing a Biorepository and/or Database for Research Uses

☐ HIPAA Waiver

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