# IRB #2094579 MU

## Human Subjects Research Determination Form (Including QI Projects) #385484

Submission date: **11/11/2022**
Submitted by: **Song, Xing**

## 1. Human Subjects Research Determination

**1.** Project Investigators

| Role | Investigator | Department | Consent personnel role | Primary contact | Truman VA Hospital personnel |
|---|---|---|---|---|---|
| Principal Investigator | Song, Xing | Health Mgmt & Informatics | Non-Consenting Personnel | ☑ | ☐ |

**2.** Contact Information

**Principal investigator**

**Song, Xing**

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

**Primary contact**

**Song, Xing**

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

**3.** Project Title:

PCORnet Phase III Milestone - GPC-VA Data Linkage Pilot Study

**4.** Describe the purpose of your project.

Note: If you are using an investigational invitro diagnostic device on biospecimens, you must complete the IRB application, even if the biospecimens are unidentified.

As one of the critical milestones for PCORnet Phase 3, GPC will advance Datavant tokenization of the Veterans Administration (VA) and Department of Defense (DoD) electronic health records to support linkage across PCORnet and the corresponding Governance processes. Leveraging existing inter-network resources and in support of the brain injury data sharing (BIDS) project, we propose a demonstration linkage project between GPC EHR data and DoD/VA EHR data to advance the understanding of treatment, progression and long-term outcomes of traumatic brain injury (TBI) for Servicemembers and Veterans, with the following 4 over-arching aims:

Aim 1: We will leverage DVINCI and GPC infrastructures and privacy-preserving linkage technique to link DoD, VHA and GPC EHR data, establish governance process and demonstrate feasibility.
Aim 2: We will combine structural modeling techniques and machine learning to rigorously evaluate potential causal associations between TBI and long-term outcomes (composite, individual and joint).
Aim 3: We will adopt our established Ensemble Embedded Feature Selection (EEFS) algorithm to identify a robust set of prognostic factors that are highly associated with the long-term outcomes of interests.
Aim 4: We will discover resilient clinical care pathway patterns by mining patients' visit sequences as discrete, time homogeneous, first-order, Markov chain. We will then further correlate the discovered pathways with long-term outcomes as well as with existing treatment plan guidelines to identify any potential gaps.

**5.** What do you intend to do with the data collected?

We will generate GPC-specific hash token using Datavant privacy-preserving linkage software in support of the proposed overlapping analysis and federate modeling. In addition, as the project hub, we will collect all de-identified hash tokens from participating GPC sites and submit the integrated finder file to our VA collaborator at University of Utah (a GPC partner) via secure transfer. No PHI information will be involved in the project.

**6. Quality Improvement Activities VS Human Subject Research Determination**

**A.** Do you consider the activities you will perform to be Quality Improvement instead of human subject research?

If yes, you will be prompted with additional questions.

○ Yes ● No

**7. De-Identified Biospecimens and/or Information**

**A.** Does this project involve analyzing de-identified, secondary information?

● Yes ○ No

**B.** Is this a restricted use dataset requiring a contract or other data use agreement to be in place (and potentially an IRB approval)?

Typically restricted use datasets have the ability to re-identify making the dataset not truly "de-identified".

If yes to this question, you will need to submit, at minimum, the IRB application for an exemption under category 4 if it applies. You can stop here and not submit this form. Go back to IRB Forms to complete the application.

○ Yes ● No

**C.** Does the project involve analyzing de-identified biospecimens (and possibly corresponding de-identified health information) obtained through pathology, an MU associated repository, or another source?

○ Yes ● No

D. Identifiers

Select all potential identifiers that may be accessed and/or included in the research records for the study.

☐ Names

☐ Dates

- ☐ Postal Addresses
- ☐ Phone Numbers
- ☐ Fax Numbers
- ☐ Email Addresses
- ☐ Social Security Numbers
- ☐ Medical Record Numbers
- ☐ Health Plan Numbers
- ☐ Account Numbers
- ☐ License or Certificate Numbers
- ☐ Vehicle ID Numbers
- ☐ Web URLs
- ☐ IP Addresses
- ☐ Biometric Identifiers
- ☐ Facial Photos or Images
- ☐ Any other unique identifier
- ☑ No identifiers (none of the above apply)

**E.** Does the study involve analyzing de-identified information that will be de-identified by a third party unrelated to the research?

○ Yes ● No

**F.** Describe the de-identification process including (a) information about how these data or biospecimens are already publicly or commercially available in de-identified form, OR (b) what process a third-party has available to provide the information or biospecimens in a de-identified form.

Only de-identified and encrypted hash token will be used for linkage and analysis will be performed on de-identified EHR data sharing by GPC partners

## 8. DHHS Human Subject Research

A project falls under DHHS regulations if it is research and involves human subjects. The questions below will assist in making this determination.

**A.** Is the project a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?

This is the DHHS definition of research. MU defines a “systematic investigation” as an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. MU defines “generalizable knowledge” as those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program.

○ Yes ● No

B. The following activities have been deemed NOT human subject research. Please select from any of the following if it applies to the proposed activities:

☐ **Publicly or commercially available information/data** with no restrictions on the use of the information.

☐ **Publicly or commercially available biospecimens** with no restrictions on the use of biospecimens.

☐ **Public health surveillance activities,** including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

☐ Collection and analysis of information, biospecimens, or records by or for **criminal justice agency** for activities authorized by law or court solely for criminal justice or criminal investigative purposes.

☐ Authorized operational activities (as determined by each federal agency) in support of **intelligence, homeland security, defense, or other national security missions**.

☐ **Scholarly and journalistic activities focused on a person/family/group** (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

**9. FDA Human Subject Research - Clinical Investigations**

A project falls under FDA regulations if it is research and involves human subjects. The questions below will assist in making this determination.

**A.** Does the project involve a test article regulated by the FDA?

A test article is any product that is regulated by the FDA, including: food, dietary supplements, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, or certain electronic products used for human health care.

○ Yes ● No

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

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