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PCORnet at MUSC Welcome Guide

Purpose: This guide provides an outline of procedures and resources available for engaging in PCORnet multisite research collaborations. This document is intended for MUSC faculty, students, staff and affiliates planning to use the PCORnet Common Data Model for obtaining research data or seeking to lead an MUSC multisite PCORnet research project.

MUSC Medical University of South Carolina
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pcornet
The National Patient-Centered Clinical Research Network

STAR Stakeholders, Technology, and Research CRN

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Table of Contents

PCORnet at MUSC Guide | STAR CRN Participating Site

Overview of PCORnet

What is PCORnet?

PCORnet, the National Patient-Centered Clinical Research Network, is a large, highly representative, "network of networks" that enables access to data routinely gathered in a variety of healthcare settings, including hospitals, doctors' offices, and community clinics. Its mission is to support patient-centered and data enabled clinical research. With access to information on 76 million patients for observational studies and 37 million for clinical trials (patients seen in past year)—in addition to research capabilities, patient partnerships, and broad array of health services researchers—PCORnet is a transformative resource to support the conduct of reliable, meaningful, people-centered research. PCORnet was established via funding from the Patient-Centered Outcomes Research Institute (PCORI) and continues to receive infrastructure funding from PCORI. Multiple trials, cohort studies and observational data analyses are underway using these resources.

What is the STAR CRN?

The Stakeholders Technology and Research Clinical Research Network (STAR CRN) is one of the nine clinical research networks that comprise PCORnet. The STAR CRN includes Vanderbilt Health System (lead site); Meharry Medical College; Vanderbilt Healthcare Affiliated Network; Health Sciences South Carolina (includes Medical University of South Carolina); UNC-Chapel Hill; Duke University; Wake Forest Baptist Health, and Mayo Clinic. The STAR CRN was formerly known as the Mid-South CDRN.

STAR is one of nine CRNs comprising PCORnet. While there are commonalities among CRNs, there are often differences in how each CRN operates. For example, STAR is a distributed network: each site maintains its own data mart, has its own governance processes, and requires a site-level budget for all projects. In contrast, some CRNs are centralized. This means the data may be housed at a single site, resulting in different budgetary needs than STAR. Whatever CRNs you are working with will be able to guide you – the only thing to keep in mind is that the way something works at one CRN, may not work the same way at another.

How do the Biomedical Informatics Center and Health Sciences South Carolina fit in?

MUSC's participation in PCORnet is managed through the Biomedical Informatics Center (BMIC) in collaboration with Health Sciences South Carolina (HSSC). The BMIC HSSC team works to identify new investigators with interest in PCORnet STAR CRN multisite research collaborations. The BMIC HSSC team manages the data infrastructure central to PCORnet; liaises with network analysts and project managers at other sites; consults with MUSC investigators participating in PCORnet; and completes data extractions necessary for PCORnet participation.

While you may interface with STAR and PCORnet from time-to-time, the BMIC HSSC team will likely be your main point of contact (POC) for data extraction and project management.

Clinical Data in PCORnet

Key Concepts

PCORnet Common Data Model

The PCORnet Common Data Model (PCDM or PCORnet CDM) is a specification that defines how data is stored, structured, and labeled for all PCORnet sites. All PCORnet sites use the PCDM to store clinical data for the network, which enables us to compare "apples to apples" across sites. The full data dictionary can be found here.

Important Note: Although the PCDM provides a common format for data, there is some variability in supported data elements across sites, as well as variability in data quality. For this reason, it is important to have a conversation with the BMIC HSSC team about your data needs, so we can be sure we have the data required for your project. A consult can be requested on the SPARCRequest website under Biomedical Informatics Center (BMIC), EHR Network Data Beyond MUSC (PCORnet STAR CRN).

Distributed Query

A distributed query is written by one site and then sent to other sites, who can run the same query on their data, without modification. Distributed queries allow for harmonized data extractions and may reduce costs.

Sidecar

The term sidecar is used in reference to required data that is not available in the PCDM. A distributed query cannot be written for a sidecar. A sidecar may be necessary if your study requires data not currently available in the PCDM. One example of a sidecar would be extraction of device numbers on pacemakers from a local data warehouse. Use of side cars should be carefully considered and the costs/benefits should be carefully weighed; such data extractions will take additional time and resources. If the data outside of the PCDM is important to the research question, please let BMIC HSSC staff know early on so we can assess data availability and budget needed.

Learn more about the PCORnet CDM, distributed queries, and sidecars, in our *PCORnet Common Data Model Overview* slide deck, available in the PCORnet Resources Library.

PCORnet Coordinating Center

The PCORnet Coordinating Center (CC) is housed at the Duke Clinical Research Institute (DCRI) and Harvard Pilgrim. The PCORnet CC creates the standards for the PCDM and is able to write and run distributed queries across the network. Your study may or may not need PCORnet CC involvement.

Computable Phenotype

A computable phenotype is a clinical condition, characteristic, or set of clinical features that can be determined solely from the data in Electronic Health Records (EHRs) and ancillary data sources and does not require chart review or interpretation by a clinician. These can also be referred to as EHR condition definitions, EHR-based phenotype definitions, or simply phenotypes.

An example framework for a computable phenotype:

> Can you pull data from our EHR that will show me all patients between ages _____ and _____, who have been diagnosed with _____, but haven't had a _____ in the last 6 months, but have had ___ visits in the _____ clinic over the past year? I also need to know if they're taking _____, or have had any ___, ___, or ___ lab values over ___ mg/ml in the past year.

Many projects seek to validate computable phenotypes through iterative chart reviews. If this is in your scope of work (SOW), please plan to budget substantial time and effort toward this process. Computable phenotype validation efforts may take months or longer.

Beginning a PCORnet Project: A Checklist

The following items are required for most PCORnet projects. Completion of these tasks can take several months, especially because some key components of the study workflow and design will need to be decided on before some of these items can be completed.

Tasks are not always completed in the order presented below, although we do strongly recommend a consult early in the process. Note that the IRB must be completed and approved before a data request can be submitted. This document provides guidance on each of these items.

Key Start Up Tasks

- ☐ *Consult with STAR CRN Project Manager and Data Analyst*
- ☐ *Budgeting & Contracting/Sub-Contracting*
- ☐ *IRB Submission*
- ☐ *Data Request*
- ☐ *Data Use Agreement*

BMIC Consult

We **strongly advise** study teams to reach out to us early on to begin discussing their project. For some, this may be when you are developing a proposal engaging PCORnet, while for others this may be as you are joining an already funded PCORnet study. You can request a consult by submitting a BMIC EHR Network Data Beyond MUSC (PCORnet STAR CRN) request: https://sparc.musc.edu/services/47410. Please be sure to note in your request that you are working on a PCORnet-related project.

During the consultation process, we can work with you to gain an understanding of your data needs; provide information on available data and nuances in our data; and help you scope your project.

For some projects, the consult is a "one and done" meeting and for others it is an ongoing process. During the consult, the MUSC STAR CRN Project Manager and Data Analyst will assist with finalizing your computable phenotype and discuss the process for obtaining local and multisite feasibility counts from other STAR CRN or PCORnet sites.

Contract and Budgeting

Scope of Work

If MUSC is the lead site, then the principal investigator (PI) should work with the MUSC STAR CRN Project Manager to develop a scope of work (SOW) to share with other potentially interested PCORnet sites prior to completion of the STAR CRN Request Intake Form, which can be located here. The SOW should outline tasks and expectations for the collaborating site PI, research staff, and data analysts. It should also provide some information about the data needs of the project and how queries will be written (i.e., distributed or written locally).

What department should the project be routed through?

Generally, contracts are routed through the site Principal Investigator's department. Additional details can be found on the MUSC Office of Research & Sponsored Programs website, located here.

What should I budget for?

This varies greatly depending on the nature of the study. The lead site typically provides budgeting guidance to collaborating sites.

For studies that do not involve patient recruitment (sometimes referred to as "data only" studies), we recommend considering the following when budgeting:

- Principal Investigator – The PI's responsibilities may include attending study team consults; coordinating sub-contract, IRB, and DUA submissions; reviewing charts and data; and participating in publications, among other things. We usually recommend 5-10% FTE for this work.
- Project Coordinator and/or Project Manager – Some studies choose to budget for a project coordinator or project manager to coordinate the regulatory paperwork, milestone tracking, reporting etc. Please reach out to the MUSC STAR CRN Project Manager through a consult early in the budgeting process for an estimate of the effort required to support your project.
- Chart Reviewer – Some studies require chart review. Usually, the site PI participates in the chart review, but many also include fellows or residents on their team to complete the reviews.
- Local CRN Data Analyst - A local CRN data analyst will be involved in nearly all PCORnet projects. The degree of their involvement varies depending on the project: sometimes the analyst will only be involved in extracting data, while other times the analyst may have a deeper consultative role. Through a consult, the MUSC STAR CRN Project Manager can obtain an estimate of the effort required to support your project.

Projects that require patient recruitment will likely require several start-up and pre-recruitment tasks, including IRB, DUA, and contract submission; chart reviews; engagement with providers, clinics, and patients; and more. A study project manager or coordinator is especially important for these studies. Often these studies reimburse at a rate per patient enrolled.

MUSC's Research Coordination & Management (RCM) within the South Carolina Clinical and Translational Research (SCTR) Institute provides professional, experienced study coordinators equipped to perform a wide range of study coordination services to investigators across the large academic medical center.

RCM services are offered at an hourly recharge rate. Depending on the needs of your PCORnet project, you may find that a coordinator from RCM can provide the support you need. Learn more here.

What do I need to know in order to get a cost estimate for informatics support for a PCORnet request?

The more information we have the more accurate of an estimate we will be able to provide. However, we understand that detailed information may not be available, especially during the grant proposal phase. Key pieces of information that are helpful to have are:

- Scope of Work (SOW), including study aims
- Inclusion/Exclusion criteria
- Data elements requested
- Special needs (e.g., data linkages, MyChart recruitment messages)
- Number of queries and timeframe for distribution and return
- Format of queries (e.g. SAS) and how they will be received (e.g. PopMedNet)

For grant proposals, we generally provide preliminary estimates. Please reach out to the MUSC STAR CRN Project Manager, through a consult, for budget/cost estimates. As more information is known about the data request, we can provide more detailed and specific estimates. Changes to the request or project scope may require additional effort, thus requiring additional funding. If you need to make changes, please discuss those with us and we can advise how the changes will affect your estimated costs.

IRB

All PCORnet research projects require an IRB submission at MUSC. The IRB submission should be prepared in coordination with the lead site by the study coordinator. IRB approval is not necessary for the overall sharing of MUSC data with HSSC, which is covered under an active Data Sharing Agreement (DSA) maintained by BMIC. Please enter an EHR Network Data Beyond MUSC (PCORnet STAR CRN) consult request to receive additional information on the MUSC DSA with HSSC.

Often PCORnet projects use reliance agreements (sometimes called SMART IRB). This means that another site is responsible for the detailed review of the IRB, and our site only needs to collect limited information about the project. You will need a copy of the lead site's protocol and approval letter, along with a general idea of the study plan and data flow to complete the paperwork locally. More information about reliance IRBs can be found here. In some cases, a reliance is not possible, so you will need to submit a full IRB application at MUSC. We suggest you request a protocol from the lead site, which you can use to complete the IRB forms locally.

Please do not include BMIC HSSC Data Analysts as study personnel in your IRB submission, as they are not members of the study team. MUSC analysts act as honest brokers.

Data Request

To request data the lead project PI should contact the MUSC STAR CRN Project Manager and BMIC HSSC Data Analyst through a consult. The Project Manager and Data Analyst will ensure the appropriate data request is entered based on the key details provided by the lead PI (e.g., what data is needed, timelines, etc.).

How much data can I request?

HIPAA requires that only the minimum necessary data be disclosed. Therefore, the more data one requests, the greater the justification one will need. What is the minimum amount of data needed to answer the research question? Consider both the scope of your patient population and the breadth of the data you are requesting.

The 'minimum necessary' standard should also be considered as the study team discusses data sharing. For example, the local study team may need medical record numbers to complete chart reviews, but an external partner conducting analyses would not.

How long will it take to get my data?

After a request is submitted and approved, it enters our "queue" where it awaits assignment to the BMIC HSSC Data Analyst. How long a given request takes depends on our current backlog, as well as the specifics of your request. Requests can be completed in days, weeks, or months, depending heavily on the size and scope of the project. We will always work to meet your needs as best we can.

Data Sharing and Data Use Agreements

Most PCORnet projects require sharing of patient-level data, which may or may not include identifiers. Regardless of whether identifiers are included, a data use agreement (DUA) is required to cover any data sharing. DUAs are contractual documents used for the transfer of nonpublic data that is subject to some restriction on its use. DUAs serve to outline the terms and conditions of the transfer. Specifically, DUAs address important issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. DUAs must be signed by an institutional official who has the appropriate delegated signature authority. You may also hear the terms "data transfer agreement" or "data sharing agreement." These typically all refer to the same thing. DUAs are often separate documents but can sometimes be a part of the study contract. Furthermore, it is also possible to leverage existing agreements for some projects.

The site sending data is referred to as the "Covered Entity," while the site receiving data is known as the "Recipient." Additional information can be found here.

PCORnet Data Sharing Agreement

The PCORnet Data Sharing Agreement (DSA) is an overarching agreement signed by all PCORnet sites and the PCORnet Coordinating Centers. If a project is transferring data via the PCORnet Coordinating Center, it may be eligible to use the PCORnet DSA. The PCORnet DSA allows the Coordinating Center to execute an agreement with the recipient site, rather than every site individually executing and agreement with the recipient site. If the lead site for your project has not brought up the PCORnet DSA, you likely will be completing a study specific DUA.

Study Specific DUAs

In many cases, research teams complete study specific DUAs. It is very important to talk to the BMIC HSSC team about your DUA early on. This will allow us to provide you with guidance and avoid unnecessary work.

How the DUA Process Works

The DUA process can take several months, so we advise beginning the process early. The first step in the DUA process is gaining an understanding of the data flow. Here is what we need to know:

- What institution is sending data?
- What institution is receiving data?
- What data will be shared with 3rd parties? Will it contain any identifiers? *Note: Age, dates and zip codes are considered identifiers; they may be shared as part of a HIPAA limited dataset.*
- What is the source of the data (e.g., EHR data, patient surveys)?
- Are patients consented and aware data about them will be shared?
- How will the data be transferred?

What department should the DUA be routed through?

Generally, agreements are routed through the site Principal Investigator's department. DUAs are routed for review via email by contacting the appropriate ORSP staff. ORSP contact information is located here.

The answers to these questions will guide how the DUA is processed. Once a DUA or DTA is received or you need to initiate the agreement process, please contact the MUSC STAR CRN Project Manager who will route the agreement(s) to the appropriate individuals for review and execution. Once the agreement is executed the MUSC STAR CRN Project Manager will provide a copy of the fully executed agreement to the study PI, coordinator, BMIC HSSC data analyst, and collaborating sites.

Understanding STAR CRN Staff Role

The STAR CRN staff team consists of data analysts and project managers. We can support PCORnet researchers in a variety of ways: provide insights on available data, complete data extractions, give guidance on the DUA process, assist department grant administrators with compiling grant proposal documents, route DUA and contract documents for review, attend ongoing project calls, and send out meeting minutes to study teams, among others.

The BMIC HSSC data analyst is not usually a member of the study team, as their role falls under their standard job responsibilities as honest brokers. Additionally, the MUSC STAR CRN Project Manager does not typically process IRB applications on behalf of studies or otherwise take on traditional study coordinator tasks. However, a BMIC project manager is often assigned to your study to address project barriers as they arise and act as the point of contact between the data analysts and study teams within MUSC and beyond. The project manager will work with the analyst to ensure your requested informatics work is on track. If you need support or guidance, please ask. If we cannot help you, we will try to connect you to someone who can.

Stakeholder Engagement

PCORnet and STAR are dedicated to patient-centered research and meaningful stakeholder engagement throughout the process. Stakeholders are broadly defined to include patients, clinic staff, community members, caregivers, and others. The stakeholders you will need to engage depends on the nature of your project.

The STAR Stakeholder Advisory Committee (SAC) conducts reviews of stakeholder engagement plans and can provide recommendations on the study's approach to recruitment, outcome measure choice, and future dissemination, among other areas. Additionally, the BMIC HSSC team works with a small group of stakeholders who may be able available to review materials or discuss some aspect of your stakeholder engagement plan. Finally, the SCTR Integrating Special Populations (ISP) service provides a variety of resources and services, including general consultations, guidance for multilingual research, and qualitative research support. An ISP consult can be requested in SPARCRequest under the MUSC SUCCESS Center. Learn more here.

PCORnet Quarterly Deliverables

Publications, Presentations, and Queries

PCORnet's longevity will be determined by the research outcomes that arise from PCORnet driven work, as such, it is important for us to be able to track publications and presentations and record PCORnet in publication and presentation acknowledgments.

Reporting

If you publish or present on work related to PCORnet, please share information about the publication/presentation with the MUSC STAR CRN Project Manager.

Acknowledgments

PCORnet infrastructure is supported by the Patient-Centered Outcomes Research Institute (PCORI). Publications and presentations that arise from PCORnet projects should cite PCORnet.

Sample citation text is below. When an acknowledgment statement is included, it must be accompanied by the disclaimer statement.

> *"The STAR CRN was initiated and funded by Patient-Centered Outcomes Research Institute (PCORI) through the contract [contact number] and institutional funding.*
>
> *The research reported in this [work, publication, article, report, presentation, etc.] was conducted using PCORnet®, the National Patient-Centered Clinical Research Network. PCORnet® has been developed with funding from the Patient-Centered Outcomes Research Institute (PCORI). The [views, statements, opinions] presented in this [work, publication, article, report, etc.] are solely the responsibility of the author(s) and do not necessarily represent the views of organizations participating in, collaborating with, or funding PCORnet® or of the Patient-Centered Outcomes Research Institute (PCORI)."*
>
> *Optional: Add simple statement referencing source of funding for the study.*

If the project you are participating in is designated as a PCORnet Study, there are different requirements for acknowledgements. PCORnet can advise you on these requirements. If your lead site does not know if your study is designated as a PCORnet Study, please reach out to the MUSC STAR CRN Project Manager.

Queries

Each participating site in PCORnet must complete a certain number of Front Door (FD) queries against the PCDM quarterly to maintain compliance with our standing PCORnet contract. The BMIC HSSC Data Analyst completes all the informatics work pertaining to the PCDM and ensures MUSC is running the appropriate number of queries to stay in contractual compliance and meet metric thresholds.