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| Template PCORnet Welcome Guide for Participating Site |
| Purpose: This guide is designed to give researchers who plan to or already have joined a PCORnet project an overview of PCORnet and the steps required to initiate a PCORnet project. |

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# **PCORnet at [Your site] Welcome Guide | Participating Site**

Thank you for your interest in participating in PCORnet at [your site]. If you are a site PI for a recently funded project, congratulations. If you are working on a proposal, we wish you the best of luck. The goal of this document is to outline key tasks and expectations for our faculty serving, or considering serving, as site principal investigators for PCORnet projects.

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## Understanding 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 now receives funding support from the People-Centered Research Foundation. Multiple trials, cohort studies and observational data analyses are underway using these resources.

### What is [CRN Name]?

*[*Provide a description of your CRN *Sample text: 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.]*

[CRN name] is one of nine CRNs comprising PCORnet. While there are commonalities among CRNs, there are often differences in how each CRN operates. [Provide description of how your CRN operates then offer an example of how a contrasting CRN may operate. *Sample text: For example, STAR is a distributed network: each site maintains its own datamart, 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 in 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.

### [If applicable] How does [CTSA name] fit in?

[If your CRN activities are housed in a CTSA or other department with researchers may be familiar, use this section to describe how they are connected. *Sample text: UNC’s participation in PCORnet is managed through the Informatics and Data Science service at the NC TraCS Institute, UNC’s home for the Clinical and Translational Science Award. The TraCS Clinical Data Research Network (CDRN) team manages the data infrastructure central to PCORnet; liaises with network analysts and project managers at other sites; consults with UNC investigators participating in PCORnet; and completes data extractions necessary for PCORnet.*

*While you may interface with STAR and PCORnet from time-to-time, the TraCS CDRN team will likely be your main point of contact for data extraction. ]*

## 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](https://pcornet.org/data-driven-common-model/).

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 TraCS CDRN team about your data needs so we can be sure we have the data required for your project.

#### 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 TraCS staff know early on so we can assess data availability and budget needed.

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| Image result for info icon | Learn more about the PCORnet CDM, distributed queries, and sidecars, in our *PCORnet Common Data Model Overview* slide deck, available in the [TraCS ShareHub](https://tracs.unc.edu/index.php/tracs-resources/sharehub/category/2-informatics). |

#### PCORnet Coordinating Center

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

#### Computable Phenotype

A computable phenotype is a clinical condition, characteristic, or set of clinical features that can be determined solely from the data in 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.

Here’s 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 plans, please plan to budget substantial time and effort toward this process. Computable phenotype validation efforts may take months or longer.

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| Image result for info icon | Watch our *Computable Phenotypes* lecture to learn more. It is available in the [TraCS ShareHub](https://tracs.unc.edu/index.php/tracs-resources/sharehub/category/2-informatics).  |

## 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 TraCS Analyst and/or CDRN Project Manager*
* *Contract/Sub-Contract*
* *IRB*
* *CDW Data Request*
* *Data Use Agreement*

## Consult

[Provide instructions for submitting a consult and what the consult includes. *Sample text: 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, while for others this may be as you are joining an already funded projects. You can request a consult by submitting a TraCS Consultation request:* [*https://tracs.unc.edu/consultation*](https://tracs.unc.edu/consultation)*. 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.* ]

## Contract and Budgeting

### Scope of Work

As you begin conversations with the lead site, you should request a scope of work for the project. The scope of work should outline tasks and expectations for the site principal investigator, research staff, and data analysts. It should also provide some information about the data needs for the project and how queries will be written (i.e., distributed or written locally).

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| Image result for question icon | What department should the project be routed through? Generally, contracts are routed through the site Principal Investigator’s (PI) department. |

### What should I budget for?

This varies greatly depending on the nature of the study. The lead site typically provides budgeting guidance to 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 submission; review charts and data; and participating in publications, among other things. We usually recommend 5-10% FTE for this work.
* Project Coordinator or Project Manager – Some studies choose to budget for a project coordinator or project manager to coordinate the regulatory paperwork, milestone tracking, reporting etc.
* 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 Analyst - A local CRN 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, and other times the analyst may have a deeper, consultative role. Please reach out to [appropriate contact for estimates] early in the budgeting process for an estimate of the effort required to support your project. **Please note [add billing information here].**

Projects that require patient recruitment likely will 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 recruited.

### 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. Usually, you will need to get much of this information from the lead site. Key pieces of information that are helpful to us are:

* Scope of Work including study aims
* Inclusion/Exclusion criteria
* Data elements requested
* Special needs (e.g., data linkages, My Chart recruitment messages)

For grant proposals, we generally can provide preliminary 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 those changes will affect your estimated costs.

## IRB

All PCORnet research projects require an IRB submission at [your site]. The IRB submission should be prepared in coordination with the lead site.

Often times 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 in order to complete the paperwork locally. More information about reliance IRBs can be found here: [link to site or CRN info about reliance agreements].

In some cases, a reliance is not possible, so you will need to submit a full IRB application at [your site]. We suggest you request a protocol from the lead site, which you can use to complete the IRB forms locally.

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| Image result for alert icon | Please do not include CRN data analysts project managers as study personnel in your IRB submission, as we are not members of the study team. Our analysts act as honest brokers and our project managers act as liaisons between the analyst and the study team.  |

## CRN Data Request

[Provide any instructions about site or CRN level data requests required. Include how to submit, where a PI may be able to get the needed information (e.g., ask lead PI), and what data are needed].

### 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?

[Add relevant text for your network. *Sample text: After a request is submitted and approved, it enters our “queue” where it awaits assignment to an 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 with you to try and meet your needs as best we can. Regardless, when requests are received, they are assigned points according to the scheme* [*available here*](https://tracs.unc.edu/index.php/services/informatics-and-data-science/cdw-h/cdw-h-faq#time)*, and worked in order from highest total point value to lowest total point value.* ]

## Data Sharing and Data Use Agreements

Most PCORnet projects require us to share patient-level data that 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.” Usually these all refer to the same thing.

The site sending data is referred to as the “Covered Entity,” while the site receiving data is known as the “Recipient.”

### 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, studies complete study specific DUAs. It is very important to talk to the team about your DUA early on. This will allow us to provide you with guidance and avoid redundant work. [Add info about existing templates if applicable]

### 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’s 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: 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?

The answers to these questions will guide how the DUA is processed. [Add example of DUA steps if desired]

## Understanding CRN Staff Role

The 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, completing data extractions, and giving guidance on the DUA process, among others.

However, the CRN team are not usually members of the study team. We do not process IRB and contracts on behalf of studies or otherwise take on traditional study team tasks. For complex projects, a TraCS project manager may be assigned to your request. Their role is “request management,” meaning they work with the analyst to ensure your requested informatics work is on track. We do not, however, manage all activities – informatics related or otherwise – for the project. That being said, if you need support or guidance, just ask. If we can’t help you, we will try to connect you to someone who can.

## Stakeholder Engagement

PCORnet and [CRN name] 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 talk to depends on the nature of your project.

[List stakeholder resources available within your network. *Example text: The STAR Stakeholder Advisory Committee 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 TraCS CDRN 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 TraCS Community and Stakeholder Engagement (CaSE) service provides a variety of resources and services, including general consultations, guidance for multilingual research, and qualitative research support. Learn more at:* [*https://tracs.unc.edu/index.php/services/engagement*](https://tracs.unc.edu/index.php/services/engagement) ]

## Publications

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 [list appropriate contacts for publication reporting].

### Acknowledgments

PCORnet infrastructure is supported by the Patient-Centered Outcomes Research Institute (PCORI) and the People-Centered Research Foundation (PCRF). 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 [CRN Name] was initiated and funded by Patient-Centered Outcomes Research Institute (PCORI) through the contract [contact number], [additional funding source, such as CTSA, if applicable], 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).*

*[additional disclaimers required by other funding sources]*

*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, it probably is not.