Cycle 1 2021 Funding Cycle

PCORI Funding Announcement:
Optimizing Infrastructure for Conducting Patient-Centered Outcomes Research

PCORnet®, the National Patient-Centered Clinical Research Network – Phase 3

Published February 9, 2021; Updated March 19, 2021

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes April 6, 2021, at 5 pm ET. Submission Instructions, templates, and other resources are available at https://www.pcori.org/funding-opportunities/announcement/optimizing-infrastructure-conducting-patient-centered-outcomes-research-cycle-1-2021.
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by our authorizing legislation, is to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions” and by promoting the dissemination and uptake of this evidence.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients and other stakeholders.

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## Overview

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### Key Dates

- **PFA Posted:** February 9, 2021
- **Online System Opens:** February 17, 2021
- **Town Hall:** March 2, 2021, noon ET
- **Application Deadline:** April 6, 2021, by 5 pm ET
- **Merit Review:** May 2021
- **Awards Announced:** September 2021
- **Earliest Project Start Date:** January 2022

### Maximum Project Budget (Total Costs)

- $6.5 million for CRNs with up to 7 data contributing sites
- $7.5 million for CRNs with greater than 7 data contributing sites

At the time of contract execution, PCORI sets aside all funds associated with an awarded project to be made available throughout the contract’s period of performance. This PFA may consider budgets greater than outlined above. Any budget exception requests must be approved by PCORI prior to submission. To submit a budget greater than the limits above, email pfa@pcori.org

### Maximum Research Project Period

3 years

This PFA does not consider exceptions to period-of-performance limits. PCORI will not review submissions exceeding the stated period of performance.

### Funds Available Up To

$60 million

### Eligibility

For this limited competition PFA, PCORI is soliciting applications from Prime organizations of Clinical Research Networks (CRNs) currently funded to participate in PCORNet. The Internal Revenue Service (IRS) must recognize all applicant organizations. Individuals are not permitted to apply.

### Review Criteria

1. PCORNet governance, collaboration, and operations to facilitate multi-network PCORNet research of definitive studies of national scope
2. Highly engaged patients, researchers, clinicians, health systems, and health plans
3. High quality, analysis-ready standardized data, use of the PCORNet Common Data Model, and preserving strong privacy and data-security protections
4. Investigators and environment
5. Dissemination and Resource Sharing

### Contact Us

**Programmatic Inquiries:** sciencequestions@pcori.org, phone (202-627-1884), or online ([http://www.pcori.org/PFA/inquiry](http://www.pcori.org/PFA/inquiry)).

**Administrative, Financial, or Technical Inquiries:** pfa@pcori.org or phone (202-627-1885).

PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days prior to a deadline. Applicants are asked to plan accordingly; it is the applicant’s responsibility to submit the application on or before the application deadline.

### Other

Deadlines are at 5 pm (ET). If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.
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I. **Introduction**

Beginning in 2014, the Patient-Centered Outcomes Research Institute (PCORI) provided $105 million in initial infrastructure development funds (Phase 1) for PCORnet, the National Patient-Centered Clinical Research Network. Funds were awarded for the planning and design of data and research infrastructure development for 11 clinical data research networks (now known as Clinical Research Networks, or CRNs), 18 patient-powered research networks (PPRNs), and one coordinating center. In 2016, PCORI provided an additional $175 million for PCORnet infrastructure expansion, implementation, demonstration, and continued capacity building (Phase 2) for 13 CRNs, 20 PPRNs, and one coordinating center. A central goal during this expansion and capacity-building phase was to increase the availability of complete, longitudinal data on populations receiving health care within the institutions that comprise the CRNs. PCORI recognized the importance of linkage of complementary data from CRNs and health plans to optimize the PCORnet infrastructure and enhance the ability of PCORnet to serve as a national resource to support multi-network patient-centered observational and interventional research. Therefore, during Phase 2, PCORI also provided $8.9 million in funding for 2 Health Plan Research Networks (HPRNs).

In Phase 3 of PCORnet, this “network of networks” is intended to optimize its capacity to serve as a national resource for conducting rapid, efficient, patient-centered comparative clinical effectiveness research (CER) that improves healthcare delivery and health outcomes. PCORI is launching this funding initiative to support CRN execution of Phase 3 of PCORnet. CRNs comprise entire populations receiving health care within specified healthcare delivery systems. These populations must be at least one million persons in size. During Phase 1 and 2 of the program, the CRNs worked to capture complete, longitudinal healthcare data on this population, including electronic health record (EHR) data from both ambulatory and inpatient care in the delivery system, and claims information or other records representing care received outside the delivery system. In Phase 3 of PCORnet, CRNs will ensure the continuity and optimization of critical CRN resources and operations developed in prior phases to facilitate implementation of definitive research studies that are national in scope and align with PCORI’s Strategic Research Priorities and other priorities stemming from PCORI’s ongoing strategic planning efforts (e.g., intellectual and developmental disabilities, maternal morbidity and mortality, and COVID-19).

**Summary of Program**

As outlined in the [PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet](#), the network has three defining characteristics that make it a unique and powerful national resource for patient-centered clinical research:

- **The Network Is National in Scope**: PCORnet is a federated network of networks representing a large array of healthcare systems, a range of care settings and a large segment of the American population. Participating networks have developed a high level of trust and a shared commitment to patient-centered clinical research. The breadth permits PCORnet to be a valuable resource for large, impactful studies, national in scope, not easily implemented without pre-existing infrastructure.
• *The Patient Is at the Center:* A culture of patient centeredness permeates PCORnet at every level, through every participating network and at all stages of the research process. The culture advances PCORI’s core mission to transform clinical research throughout the nation by integrating patients as essential partners. Its influence extends well beyond the impact of a project-by-project approach.

• *Data Can Be Linked to the Patient:* PCORnet’s Common Data Model is unique in that its distributed structure permits direct connections to patients and providers and re-access of primary data with appropriate privacy and confidentiality protections, consistent with legal requirements. The connectedness is possible because of the established trust between participating network partners within this federated network. PCORnet’s unique data model connected to patients and providers and their data facilitates studies that are national in scope and enables direct recruitment of study participants.

This announcement describes the scope of work for the PCORnet CRNs for Phase 3 and available funding to allow for Phase 3’s execution. CRNs are system-based networks that include hospitals and community based-practices, and that may include health plans, all of which routinely and securely collect individual patient-level data. Characteristics that all successful CRNs must demonstrate include:

1. Coverage of large, diverse, defined populations unselected for a particular disease, condition, or procedure; ability to capture complete clinical information on this population over time, including longitudinal information on clinical care, changes in clinical characteristics and conditions, and the occurrence of clinical care or outcomes, within or outside the system.

2. Involvement of multiple (two or more) health systems, with data interoperability and data standardization to allow efficient, valid sharing of individual or aggregate data across systems for purposes of data analysis.

3. The ability to efficiently contact patients for the purposes of recruitment; collecting patient-reported information; and maintaining consistently high levels of participation of a population of participants representative of the CRN’s overall population in research studies, including sustained randomization, participation, and follow-up over time.

4. Demonstrated ability to partner with patients and other stakeholders, both within and outside their systems, for purposes of generating research questions, participating in network governance, and throughout the research process.

5. Involvement of the healthcare system leadership in governance and use of the network to enhance network efficiency, utility, and sustainability and facilitate implementation of research results into practice.

6. Willingness to serve as a national data infrastructure resource for the conduct of patient-centered CER by researchers outside the network.

7. Capacity to support large-scale multi-network comparative effectiveness trials, as well as observational studies of research questions aligned with PCORI’s Strategic Research Priorities, including prevention, treatment, and care delivery, at low marginal cost, with substantive patient involvement throughout, including formulation of research questions and essential study characteristics, study participation, and dissemination of study findings.
8. Capacity to embed research activity within functioning healthcare systems without disrupting the business of providing health care; alignment of human subjects oversight, IRB review and approval, and informed consent procedures with the level of risk in proposed comparative effectiveness studies, including plans to obtain buy-in from all organizations to accept review of specific projects under auspices of a central IRB.

9. Clear, proven policies to maintain data security, patient privacy, and confidentiality; ability to collect, store, retrieve, process, or ship biological specimens for research purposes, with appropriate consent, for use by qualified researchers.

10. Ability to advance the quality and availability of complete and comprehensive data sets, including through linkages of disparate sources of complementary data and strong partnerships with entities with health payment records.

11. Ability to streamline subcontracting processes for research involving multiple sites.

A list of currently funded PCORnet Network Partners can be found at www.pcornet.org. PCORI expects that each Phase 3 PCORnet CRN will clearly demonstrate all of the above characteristics.

Eligibility

For this limited competition PFA, PCORI is soliciting applications from prime organizations of CRNs currently funded to participate in PCORnet. For this Phase 3 award, CRNs must propose a credible work plan describing utilization and optimization of the data and research infrastructure developed in prior phases of PCORnet to accomplish the scope of work for Phase 3 with a focus on optimizing infrastructure to increase diversity of populations and care settings, efficiently implement research studies addressing PCORI’s Strategic Research Priorities, strengthen patient and stakeholder engagement, and deliver high-fidelity, high integrity data.

II. Guidance for CRNs Responding to this PFA

Phase 3 Awards

PCORI anticipates funding up to 9 CRNs. Research networks will apply for Phase 3 continuation funding through this PFA. Applicants should ensure their local network partnerships are optimal to meet overall PCORnet goals. Research networks are not required to bring in all partners from Phase 2, however, no new partners or data contributing sites are eligible without prior approval from PCORI. While preference will be given to new data contributing partners that add diversity to the overall CRN patient population, it is expected that any new data contributing partner will meet all data requirements by the first quarterly data refresh for continuation in the program.

PCORI intends to provide funding to ensure the continuity and optimization of critical CRN resources and operations. It is also expected that CRNs—individually and in collaboration with other PCORnet CRNs—will attract an increasing amount of research funding from competitive awards funded by PCORI and other funding organizations during this three-year period. A fundamental requirement for PCORnet CRNs is their ability and willingness to participate in multi-network PCORnet research (i.e., research projects involving collaboration among two or more networks) with a particular emphasis on addressing PCORI’s Strategic Research Priorities. Thus, strong relationships with an array of clinical researchers,
patients, clinicians, and health system leaders within PCORnet-participating institutions is essential. It is also important that CRNs demonstrate an openness to respond to external requests for collaborative partnerships, especially with Federal Health Agencies.

Applicants should be aware that the milestones and deliverables agreed upon for this contract are subject to PCORI’s request for changes during the period of the award in order to ensure continued network optimization with a focus on data quality and alignment with PCORI’s Strategic Research Priorities and other priorities stemming from PCORI’s ongoing strategic planning efforts (e.g., intellectual and developmental disabilities, maternal morbidity and mortality, and COVID-19). Applicants should therefore make sure that they have the operational flexibility to make changes to their proposed work plans, deliverables, and timelines during the award period.

**CRN Scope of Work for Phase 3**

PCORI has supported the development of a large, highly representative, national network to improve the nation’s capacity to conduct comparative effectiveness research and conduct accurate and efficient large-scale research by learning from the healthcare experiences of millions of Americans.

The conduct of the CRN and participation in PCORnet for Phase 3 must be consistent with the core principles for PCORnet as described below:

1. Maintenance of governance and operational mechanisms for the meaningful engagement of patients and other stakeholders, including community members, families, caregivers, clinicians, delivery systems, payors and researchers, in all phases of the research process
2. Implementation through a distributed research network model that is committed to building a national resource that is accessible via a central gateway to researchers within and outside of the network
3. Commitment to a network model that encourages and facilitates the sharing of resources and tools, including through an online “commons” that is available to the networks and public
4. Use of a common data model that standardizes the definition, format, and content of data across participating data networks so that standardized applications, tools, and methods can be applied to advance quality and consistency
5. Use of streamlined and standardized mechanisms, including centralized IRB models (e.g., SMART IRB) and standardized data use agreements, for the efficient and rapid conduct of research in the network
6. Advancement of a network model that advances the quality and availability of complete and comprehensive data sets, including through linkages of disparate sources of complementary data
7. Compliance with applicable laws, regulations, and legal requirements, including but not limited to those governing privacy, security, data, research, and human subjects

**PCORnet governance, collaboration, and operations to facilitate multi-network PCORnet research of definitive studies of national scope. (Criterion 1)**

The implementation of PCORnet is an innovative effort, the success of which depends on high levels of cooperation and commitment of its participants. This includes partnership with patients, researchers,
clinicians, and health systems in CRN-level governance to facilitate decision making and administrative operational streamlining (e.g., centralized IRB) to facilitate CRN participation in multi-network PCORnet research aligned with PCORI’s Strategic Research Priorities. This also includes active participation in PCORnet-level governance, including committees, work groups, meetings and calls, and contributing to the optimization and implementation of operational frameworks, policies, practices, and systems for PCORnet.

The application should describe and document how the following will be optimized and maintained during the three-year award period:

- Specific CRN-level governance structures, policies, and processes that facilitate meaningful partnerships with patients and other CRN stakeholders in decision making, as well as governance that facilitates participation in multi-network studies while taking into account the CRN population and clinical expertise
- CRN data contributing sites have diversity in populations and care settings to meaningfully contribute to multi-network PCORnet research of definitive studies of national scope.
- CRN infrastructure to:
  - Implement and comply with PCORnet policies to use streamlined and standardized mechanisms, including centralized IRB models and standardized data use agreements, for the efficient and rapid conduct of multi-network research
  - Comply with PCORnet governing policies, procedures, and core principles for PCORnet for the scalable, secure, and streamlined conduct of patient-centered multi-network research
  - Implement and comply with all PCORnet data security, privacy, and other trust-building policies
  - Actively engage and collaborate in PCORnet-wide meetings, ad hoc work groups, and teams that support operations, management, improvement of network infrastructure in support of increased utilization of the PCORnet infrastructure for the conduct of multi-network research
  - Lead and participate in a variety of multi-network studies leveraging PCORnet innovative methods and infrastructure
  - Disseminate research opportunities shared by the PCORnet Front Door broadly within the network to facilitate participation in multi-network projects and studies
  - Respond to PCORnet Front Door requests for participation in multi-network studies within 10 business days
  - Facilitate collaborative relationships with other CRNs, the PCORnet Coordinating Center, and external research partners and Federal health agencies to support increased utilization of network infrastructure and the conduct of national-scope, multi-network research aligned with PCORI’s Strategic Research Priorities.
Highly engaged patients, researchers, clinicians, health systems, and health plans (Criterion 2)
The success of PCORnet depends on partnership with patients, researchers, clinicians, and health systems in decision making about the use of the network and its data and research infrastructure. Successful CRNs will have strong governance and operational processes to facilitate robust multi-stakeholder engagement to enable efficient study initiation, conduct, and dissemination of results to accelerate evidence into practice. The application should describe and document how the specific CRN-level governance and operational mechanisms will be optimized and maintained during the three-year award period:

- Meaningfully engage patients and other stakeholders, including community members, families, caregivers, clinicians, health systems administrators, payors and researchers, in all phases of the research process. CRN infrastructure should be optimized to strengthen the central role of patient and caregiver engagement to produce true partnerships in the full research process.
- Engage patients, clinicians, and health system stakeholders in network decision making and policy implementation
- Implement CRN-level policies and processes to strengthen partnerships and involvement of persons who reflect the diversity of the US population—including racial diversity and diversity in age, burden of disease, and socioeconomic status
- Actively identify and engage patients, caregivers, clinicians, or health system leaders to participate in the governance and conduct of multi-network PCORnet designated studies

High quality, analysis-ready standardized data, use of the PCORnet Common Data Model, and preserving strong privacy and data-security protections (Criterion 3)
A central expectation of all CRNs is analysis-ready standardized data of increasing richness, completeness, and quality extracted and stored in successive versions of PCORnet Common Data Model (CDM). All CRNs are expected to be able to carry out cohort identification and preliminary analysis by running standardized queries against analysis-ready, standardized data in the PCORnet CDM using PopMedNet query tool programmed in SAS. All CRN applicants must demonstrate a commitment to sharing high-quality, standardized data within a secure, distributed architecture that leverages the efficiencies of using a privacy-preserving linkage method for optimal ascertainment of outcomes in the conduct of patient-center research. The application should describe and document how the following will be optimized and maintained during the three-year award period.

Specific CRN-level governance and data infrastructure to ensure access to high quality, analysis-ready standardized data that consistently meets all requirements for research readiness designated by the PCORnet Steering Committee for each participating site within the CRN. This includes:

- Performing quarterly refreshes of the PCORnet CDM. As part of the quarterly update, data contributing partners may need to modify their extraction, transformation and loading (ETL) procedures to reflect changes to the CDM Implementation Guidance or Value Set Reference File, additions/modifications to the PCORnet Data Quality Checks, or to address quality issues identified by study teams based on the partner’s response to study-specific queries
• Generating data for quarterly updates with ≤90-day lag period

• Mapping at least 80% of medications (by frequency) to the appropriate Tier 1 Preferred RXNorm CUI codes as specified in the CDM Implementation Guidance within 3 months of release. The remaining medications should also be mapped to the most appropriate RXCUI as specified in the Implementation Guidance

• Mapping the top 80% (by frequency) of labs to LOINC within 3 months, fully specifying the result and result unit. Participating in network efforts to validate LOINC mappings, which will involve investigation of result unit, specimen source, and local values for the lab test name, result unit and specimen source. Resolving identified issues within 3 months. Populating values for lab normal ranges when present in record-level results. Providing information on normal ranges for tests where record-level entries are not available

• Maintaining data quality by investigating and aiding in remediation of data anomalies, fixing ETL procedures to remedy any failed required data checks, investigating the cause of any failed investigative data checks, and developing a plan to resolve any investigative check errors not caused by source data constraints within 3 months. This includes resolving recurring errors in the persistence data checks

• Advancing the quality and availability of complete and comprehensive data sets, including through linkages of disparate sources of complementary data

• For networks with centralized governance, providing site-specific results with all query responses. Site results must be submitted in the same fashion as distributed data marts

• Maintaining infrastructure to support query execution and return for 30 PCORnet-approved queries per year

• Responding to PCORnet-approved queries within five business days of receipt

• Complying with applicable laws, regulations, and legal requirements, including but not limited to those governing privacy, security, data, research, and human subjects

Investigators and Environment (Criterion 4)

Organizational capacity and the staffing plan for the CRN are critical to support a diverse portfolio of multi-network, patient-centered research aligned with PCORI’s Strategic Research Priorities led by a variety of internal and external PCORnet investigators. Applicants should provide a complete description of the staffing and management plan, organizational capacity, and roles and division of operational responsibilities for the CRN over the three-year funding period. In particular, the leadership team of the CRN, its expertise, level of effort, and organizational functioning must be described. This should include at least one senior project manager or project director with a significant track record in managing large multi-site projects of this nature, and he or she should be dedicated at minimum 50 percent effort.

The applicant must propose dual Principal Investigators (PIs) (one of which is the Contact PI named in the application and subsequent award contract). One of these two must have primary experience or expertise in clinical research, epidemiology, health services research, or comparative effectiveness
research, and one should have primary experience or expertise in clinical informatics, health system information technology, or large-scale database construction and linkage. Together, the dual PIs must contribute a minimum of 65 percent Full-Time Equivalent (FTE), with the Contact PI contributing 40 percent effort. The Contact PI must be a full-time employee of the prime applicant. In general, dual PIs should be physically co-located at one of the network sites. In some cases, PCORI will be amenable to considering a different set-up—for example, in cases where one of the dual PIs is a neutral convener not physically located at one of the constituent sites but able to play an important role in bringing disparate institutions together. Any application that proposes a different leadership plan than stated above must have approval from PCORI prior to submission, which may be requested via email to pfa@pcori.org.

The PopMedNet query tool uses SAS code to perform quality checks and develop queries. In addition, many analysis programs will use SAS code. Therefore, every CRN is expected to purchase or have in place a license and up-to-date SAS software and to budget for an analyst with SAS expertise.

PCORI is requesting networks to propose modest budgeted time for the network’s dual PIs, and patient partner to participate on or to lead one or more PCORnet work groups, or to lead other time-limited or highly focused activities in their areas of expertise.

The budget and its justification should clearly specify the following:

- Time commitment: together, the dual PIs must contribute a minimum of 65 percent FTE, with the lead PI at 40 percent effort
- Affiliation requirements: The Contact PI must be a full-time employee of the prime applicant. Dual-PIs should be physically co-located at one of the network sites, although other arrangements will be considered if they provide critical advantages to the network or to PCORnet
- A detailed, specific, and credible staffing and management plan, including budgeted amounts for research staff with expertise in Natural Language Processing (NLP) and SAS data management and analysis
- How qualified, experienced, and matched proposed personnel are in relation to their described responsibilities and activities

**Dissemination and Resource Sharing (Criterion 5)**

A commitment by CRNs to a network model that encourages and facilitates the sharing of resources and tools, including through an online “commons” that is available to the networks and public is critical to the success of PCORnet. In Phase 3 of PCORnet, CRNs should also develop educational and outreach plans to build a community of interested investigators partnering with health system leaders, patients, and other stakeholders to expand the use of PCORnet infrastructure resources. The application should describe and document how the following will be optimized and maintained during the three-year award period including:

- Specific CRN-level governance and operational mechanisms to:
  - Share new clinical research, data, and engagement resources, methods, and lessons
with other PCORnet members and the public through PCORnet webinars, forums, websites, and other appropriate process or venues
  o Contribute to an online “commons” for a national, patient-centered, distributed, clinical research resource that encourages and facilitates the sharing of resources, tools, and results of research across PCORnet and with the public
  o Return results to study participants and clinicians as well as participating health systems and health plans

III. General Requirements for PCORI Funding

This section includes language that is specific to PCORI’s requirements for programmatic responsiveness under this funding announcement. Applicants should use this section as guidance when preparing their applications. For information related to administrative and technical requirements for application submission, please consult the PCORI Submission Instructions.

Methodological Considerations

The PCORI Methodology Standards represent minimal requirements for the design, conduct, analysis, and reporting of scientifically valid, patient-centered outcomes research. Regardless of study design, applications must adhere to all relevant PCORI Methodology Standards, and all deviations need to be justified. Applicants should address additional best practices—including relevant guidelines for conducting clinical trials developed by other organizations—in the application for PCORI funding.

Protection of Human Subjects

PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5, titled “Human Subjects Research Policy,” in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, which is issued by the US Department of Health and Human Services (HHS). In referencing the HHS Supplemental Grant Application Instructions, note that PCORI does not require that applicants comply with sections of that policy that refer to requirements for federal-wide assurance and the inclusion of women, minorities, and children in the proposed studies. Instead, PCORI expects applicants to address diversity in study participants in the research plan, through a focus on subpopulations, as described in the above section on Populations Studied. Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

PCORI requires awardees to ensure that there is a Data and Safety Monitoring Plan, which may include the need to appoint a Data and Safety Monitoring Board, as provided in the PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research.

PCORI merit reviewers will examine plans for protection of human subjects in all applications and may provide comments regarding the plans (see How To Evaluate Human Subjects Protections). Reviewers’
comments on human subject research are not reflected in the overall application score, but PCORI staff might use them during potential funding negotiations. Final determinations about the adequacy of human subject protections rest with the Institutional Review Board or international equivalent that have jurisdiction for the study.

The Awardee Institution, whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in PCORI-supported activities.

**Required Education of Key Personnel on the Protection of Human Subject Participants**

PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and FAQs are available on the [NIH website](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html).

### IV. Merit Review

PCORI’s merit review process is designed to support the following goals:

- Identify applications that have the strongest potential to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make informed decisions to improve patient outcomes
- Implement a transparent, fair, objective, and consistent process to identify these applications
- Elicit high-quality feedback that reflects a diversity of perspectives to ensure that the PCORI-funded research reflects the interests and views of patients, those who care for them, and other stakeholders, and that it meets the criteria for scientific rigor
- Fund projects that fill important evidence gaps and have strong implementation potential
- Regularly evaluate and continually improve the merit review process and policies in support of PCORI’s mission

PCORI merit review is a multiphase process that includes the review panel’s preliminary review of full applications and an in-person panel discussion of a subset of applications (identified by PCORI’s Program staff and based on the preliminary review and program priorities). After merit review, key steps include post-panel review of application by PCORI staff, the Selection Committee’s recommendation of applications for funding, and, finally, Board award approval.

**Preliminary Review**

PCORI conducts rigorous merit review of the full applications it receives. Note that PCORI may eliminate applications from the review process for administrative or programmatic reasons (e.g., nonResponsiveness). An application may be administratively withdrawn if it is incomplete; submitted past the stated due date and time; or does not meet the formatting criteria outlined in the Submission Instructions, in the PCORI templates, and in PCORI Online. An application may be programmatically withdrawn if it is not responsive to the guidelines described in this PFA or otherwise does not meet

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PCORI programmatic requirements.

PCORI Merit Review Officers (MROs) recruit each review panel based on the number and topic areas of invited applications. MROs recruit the panel chair, scientist reviewers who are subject matter experts, patient representatives, and representatives of other stakeholder groups. All panel members receive training during the review cycle to ensure that they understand the programmatic and organizational goals of review.

Below are PCORI’s merit review criteria. PCORI’s merit review panel will use these criteria during the preliminary and in-person review phases to evaluate and score all submitted applications, and to ensure consistency and fairness in how applications are evaluated.

**Criterion 1. PCORnet governance, collaboration, and operations to facilitate multi-network PCORnet research of definitive studies of national scope**

The application should address the following questions:

- Has the applicant demonstrated its ability and provided credible work plans consistent with a network governance structure to:
  - Facilitate meaningful partnerships with patients and other CRN stakeholders in decisions about network participation in multi-network studies
  - Comply with PCORnet governing policies, procedures, and core principles for the scalable, secure, and streamlined conduct of patient-centered multi-network research
  - Implement all PCORnet data security, privacy, and other trust-building policies
  - Actively engage and collaborate in PCORnet activities to support operations, management, and improvement of network infrastructure in support of increased utilization of the PCORnet infrastructure for the conduct of multi-network research
  - Lead and participate in a variety of multi-network studies leveraging PCORnet innovative methods and infrastructure
  - Facilitate collaborative relationships with other CRNs, the PCORnet Coordinating Center(s), and external research partners and federal health agencies to support increased utilization of network infrastructure and the conduct of national-scope, multi-network research aligned with PCORI’s Strategic Research Priorities

- Has the applicant described the demographics of the CRN site populations, site care settings, and prior contributions to PCORnet-enabled research including rapid response to COVID-19 data and research needs that would facilitate participation in future multi-network PCORnet research of definitive studies of national scope aligned with PCORI’s Strategic Research Priorities?

**Criterion 2. Highly engaged patients, researchers, clinicians, health systems, and health plans**

The application should address the following questions:

- Has the applicant demonstrated its ability and provided credible work plans consistent with a network governance structure to:
Meaningfully engage patients and other stakeholders, including community members, families, caregivers, clinicians, delivery systems, payors and researchers, in all phases of the research process. CRN infrastructure should be optimized to strengthen the central role of patient and caregiver engagement to produce true partnerships in the full research process.

Engage patients, clinicians, and health system stakeholders in network decision making and policy implementation

Involve healthcare system leadership in governance and use of the network to enhance network efficiency, utility, and sustainability, and facilitate implementation of research results into practice

Strengthen partnerships and involvement of persons who reflect the diversity of the US population—including racial diversity and diversity in age, burden of disease, and socioeconomic status

Actively identify and engage patients, caregivers, clinicians, or health system leaders to participate in the governance and conduct of multi-network PCORnet designated studies

Criterion 3. High quality, analysis-ready standardized data, use of the PCORnet Common Data Model, and preserving strong privacy and data-security protections

The application should address the following questions:

- Has the applicant demonstrated its ability and provided credible work plans consistent with a data infrastructure committed to:
  
  - Sharing high quality, analysis-ready, standardized data using the PCORnet Common Data Model within a secure, distributed architecture that leverages the efficiencies of using a privacy-preserving linkage method for optimal ascertainment of outcomes in the conduct of patient-centered research
  
  - Providing access to high quality, analysis-ready standardized data that consistently meets all requirements for research readiness designated by PCORnet Steering Committee

Criterion 4. Investigators and environment

This criterion should assess the appropriateness (e.g., qualifications and experience) of the investigator(s)/team and the environment's capacity (e.g., resources, facilities, and equipment) to support the proposed project. It should not be an assessment of the institution's quality.

The application should also address the following questions:

- Has the applicant provided evidence of a detailed and diverse staffing and management plan consistent with the diverse expertise and skill set needed to oversee and manage an infrastructure committed to contributing to a national, patient-centered, distributed, clinical research resource?

- Does the PI leadership plan demonstrate adequate support for the lead PI at 40% including...
expertise in clinical research, epidemiology, health services research, or comparative effectiveness research; and the co-I with expertise in clinical informatics, health system information technology, or large-scale database construction and linkage and at least 25% effort?

- Is the level of effort for each team member appropriate for successfully conducting the proposed work?
- Does the application describe adequate availability of and access to facilities and resources to carry out the proposed scope of work?
- Is the institutional support appropriate for the proposed scope of work?
- What is the likelihood of successful completion of the proposed work based upon the experience and qualifications of key personnel and the project team, available resources and infrastructure, and activities proposed?

**Criterion 5. Dissemination and Resource Sharing**

The application should address the following questions:

- Has the applicant demonstrated its ability and provided credible work plans consistent with a network governance structure to:
  - Share new clinical research, data, and engagement resources, methods, and lessons with other PCORnet members and the public through PCORnet webinars, forums, websites, and other appropriate process or venues
  - Contribute to an online “commons” for a national, patient-centered, distributed, clinical research resource that encourages and facilitates the sharing of resources, tools and results of research across PCORnet and with the public

**In-Person Review**

During preliminary review, all administratively and scientifically compliant applications are evaluated and scored by panels of external reviewers based on PCORI’s merit review criteria, including evaluation of adherence to the PCORI Methodology Standards (e.g., Standards for Data Networks as Research-Facilitating Structures). After preliminary review, PCORI program staff members evaluate panel scores and critiques to identify a subset of applications for merit reviewers to discuss at the in-person review meeting. Not all submitted applications move forward to in-person review.

During the in-person review, merit reviewers meet to discuss applications and to clarify further the merits of the proposed research. They also identify areas for improvement. Each application is re-scored based on the content of discussion. The Panel Chair and PCORI MRO lead the in-person panel meeting and ensure that all applications receive a fair and thorough review according to the standards outlined in the PFA.

**Post-Panel Review**

After the in-person meeting, PCORI program staff evaluate final merit review panel scores and
comments, identify duplication or synergy among funded projects, consider the fit of applications within the programmatic vision, and evaluate past performance of the CRN and participating sites. PCORI’s evaluation will include assessment of site-level data quality and prior participation in multi-site research. Program staff members then recommend projects to a Selection Committee, which includes members of the Board. The Selection Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI’s strategic priorities. This slate is then proposed to the Board for consideration and approval.

In addition, PCORI evaluates applicant risk before issuing a PCORI award. Factors considered include financial stability, quality of management systems, audit findings, and past performance on PCORI awards (e.g., compliance with PCORI reporting requirements, conformance to PCORI terms and conditions on previous awards, and timely achievement of milestones). Based on the risk assessment, PCORI may impose special terms and conditions on awardees or withhold contract issuance until such business risks are mitigated. **PCORI will not award new contracts to current awardees with overdue reports (progress, interim, final, etc.) until the overdue reports have been submitted.**

**Summary Statements and Funding Recommendations**

Summary statements are provided to applicants approximately two weeks before funding decisions are announced. **If an application progresses to in-person discussion,** the applicant will receive a summary statement, which will include:

- In-person panel discussion notes
- Final average overall score
- Preliminary reviewer critiques

Summary statements for applications that do not progress to in-person discussion include only the preliminary reviewer critiques.

Funding recommendations are made by identifying meritorious applications that fit the programmatic needs and that satisfactorily address the merit review criteria while adhering to the PCORI Methodology Standards. Programs also consider the funds allotted for the current funding announcement when deciding which applications to recommend to the Board for approval. Applicants to this current cycle’s PCORnet PFA will receive summary statements and notification of the funding status of their application no later than September 2021.

**V. PCORI Policies that Govern Awardees Related to Data Access, Privacy, and Public Reporting**

Applicants should be aware that all PCORI awardees are required to comply with the following requirements:

**PCORI Public Access Policy**

PCORI requires all awardees to adhere strictly to PCORI’s publication policies, which will be shared with awardees within the research contract.
Standards for Privacy of Individually Identifiable Health Information

On August 14, 2002, the Department of Health and Human Services issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the “Privacy Rule.” The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the Department of HHS Office for Civil Rights.

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The Office for Civil Rights\(^5\) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools related to “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding and progress monitoring of grants, cooperative agreements, and research contracts is available from NIH.\(^6\)

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\(^5\) Available at [http://www.hhs.gov/ocr/](http://www.hhs.gov/ocr/).