Governance of the Patient Outcomes Research to Advance Learning (PORTAL) Network

Version 2
(August 2015)

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Prepared by the Patient Outcomes Research to Advance Learning Network, a consortium of 4 integrated delivery systems (Kaiser Permanente, Group Health Cooperative, HealthPartners, and Denver Health) and their affiliated research centers, with funding support from a contract awarded by the Patient-Centered Outcomes Research Institute (PCORI). The content is solely the responsibility of the authors and does not necessarily represent the official views of the PCORI.
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TABLE OF CONTENTS

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PORTAL: APPENDIX TOOLKIT

Patient Outcomes Research to Advance Learning (PORTAL) Network:

Governance Plan
Version 2
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I. INTRODUCTION TO THE PORTAL NETWORK

Summary
This section provides an introduction to the governance structure and process of the PORTAL Network. It describes the guiding principles; the scope of the work to be undertaken; and PORTAL's relationship with PCORnet.

The Patient Outcomes Research to Advance Learning (PORTAL) Network is a collaboration of researchers from eleven research departments "embedded" in integrated health care delivery systems across the US. PORTAL is organized as a distributed research network (DRN) that includes health data from these organizations while ensuring patient/member privacy and confidentiality and addressing proprietary concerns. The PORTAL DRN benefits from the pioneering work of multiple scientific networks over the last 20 years, including the Vaccine Data Link, Cancer Research Network (CRN), DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Network, Scalable Partnering Network (SPAN), Surveillance, Prevention, and Management of Diabetes Mellitus (SUPREME-DM), MiniSentinel Network, the Kaiser Permanente Center for Effectiveness and Safety Research (CESR), the Health Care Systems Research Network (HCSRN) and other topic- and funder-specific research networks.

The PORTAL Network views governance as **the high level policies, guidance and strategies that define how the Network collaborates and makes decisions**. By specifying such engagement governance practices proactively, we intend to establish trust and transparency to promote high-quality and efficient scientific collaboration. Governance is never complete, and this Governance document is a "living" document – a work in progress.

The bedrock principle of PORTAL governance is preservation of the privacy and security of personal medical/health information and the legitimate proprietary interests of our sponsoring health care delivery systems. The PORTAL Network honors the willingness of its patients, members, and care delivery and health plan colleagues to share their information and to develop knowledge jointly with us. We will reward that trust with exemplary stewardship.

This document provides an overview of the governance process for the PORTAL Network. It describes the organizational structure of PORTAL, including the Steering Committee and Cores. It also addresses decision-making within PORTAL; the approach to data governance, data privacy and confidentiality; conflicts of interest, and scientific misconduct. This governance plan incorporates relevant regulations and policies at the institution, network, state and federal levels,

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building on the rich experience of other networks and evolving national standards.[1,2] A glossary and list of acronyms is provided to assist the reader in using this document.

The PORTAL Steering Committee will approve and administer this Governance Plan and ongoing revisions. Standard operating procedures and specific activities to carry out the governance policies, guidance or strategies will be developed and implemented by the PORTAL Science Core, Cohort Development Cores, and Data Core in partnership with PCORnet. A set of appendices is being developed containing resources and tools to help implement various aspects of the Governance Plan. PORTAL Advisory Councils will provide input and guidance.

A. Guiding Principles and Purpose

The Patient Outcomes Research to Advance Learning (PORTAL) research network brings together four health care delivery systems: Kaiser Permanente, Group Health Cooperative, HealthPartners, and Denver Health. The eleven research centers affiliated with these systems will collaborate with patients, clinicians, and operational leaders to develop a high-functioning clinical data research network. Project investigators will create cohorts of patients with Colorectal Cancer (CRC); adolescents and adults with severe Congenital Heart Disease (CHD); and adults who are overweight or obese, including those who have pre-diabetes or diabetes. These scientifically sound cohorts can support specific comparative effectiveness research (CER) studies and future observational and interventional CER and patient-centered outcomes research (PCOR) studies, including pragmatic clinical trials. The PORTAL Network emphasizes the engagement of patients, clinicians, and operational leaders in network governance and commits to consistent communication with these stakeholders by methods (webinars, email, etc.) and with a frequency they determine.

B. PORTAL Guiding Principles

I. Research activities will:
- A. Arise from transparent decision-making
- B. Develop novel research infrastructure and methods
- C. Contribute generalizable knowledge to the public domain
- D. Encompass diverse populations, health care delivery systems, and perspectives

II. Organizations will:
- A. Retain autonomy in decision-making
- B. Promote appropriate use and stewardship of data resources, including those of PCORnet
- C. Collaborate effectively within the distributed network
- D. Ensure compliance with site, local, state and federal policies and regulations

III. PORTAL Network investigators will:
- A. Protect patient confidentiality and privacy
- B. Conduct priority, high-quality CER to improve health outcomes and inform clinical practice and public health policy
- C. Engage operational and patient stakeholders throughout the research process

IV. PORTAL Network governance will:
- A. Ensure fairness and transparency in all PORTAL decision-making
- B. Specify procedures for access to intellectual, technical and organizational resources
- C. Promote relevance, efficiency, and sustainability through strategic prioritization
- D. Continually update to reflect the learnings of the PORTAL Network and PCORnet
- E. Create and foster avenues of meaningful engagement for patients, patient advocacy representatives, and online advisors

Based on the values described above, the PORTAL Network has adopted the guiding principles listed in Table 1 above, which will be reviewed by the Patient Engagement Council and revised if necessary.

C. Scope of the PORTAL Project

The Patient Centered Outcomes Research Institute (PCORI) has contracted with the PORTAL Network to develop an infrastructure for CER projects over an 18-month time frame. PORTAL will satisfy 14 criteria that PCORI has established to determine whether an adequate infrastructure exists and specific milestones to judge the progress and completion of these aims:

1. Enroll at least 1 million persons in the network
2. Standardize data through the use of a common data model
3. Develop comprehensive, complete capture of data over time on enrolled population
4. Develop and implement appropriate governance policies
5. Actively engage patients and clinicians
6. Actively engage system and operational leaders
7. Develop a capacity for conducting clinical trials
8. Create three cohorts of patients to demonstrate utility of network
9. Enhance the ability to collect patient-reported outcomes

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10. Develop the capacity to imbed research in routine clinical care delivery
11. Align human subjects protection oversight with levels of risk
12. Ensure appropriate data security, privacy, and confidentiality
13. Develop the capacity to use biological specimens in research
14. Develop an effective and efficient management structure

D. PCORnet: The National Patient-Centered Clinical Research Network

PCORI funded 10 other Clinical Data Research Networks (CDRNs), 18 Patient Powered Research Networks (PPRNs), and a Coordinating Center (CC). Together the "network of networks" is known as PCORnet, the National Patient-Centered Clinical Research Network. PORTAL will participate in PCORnet through 11 Task Forces and the Steering Committee.

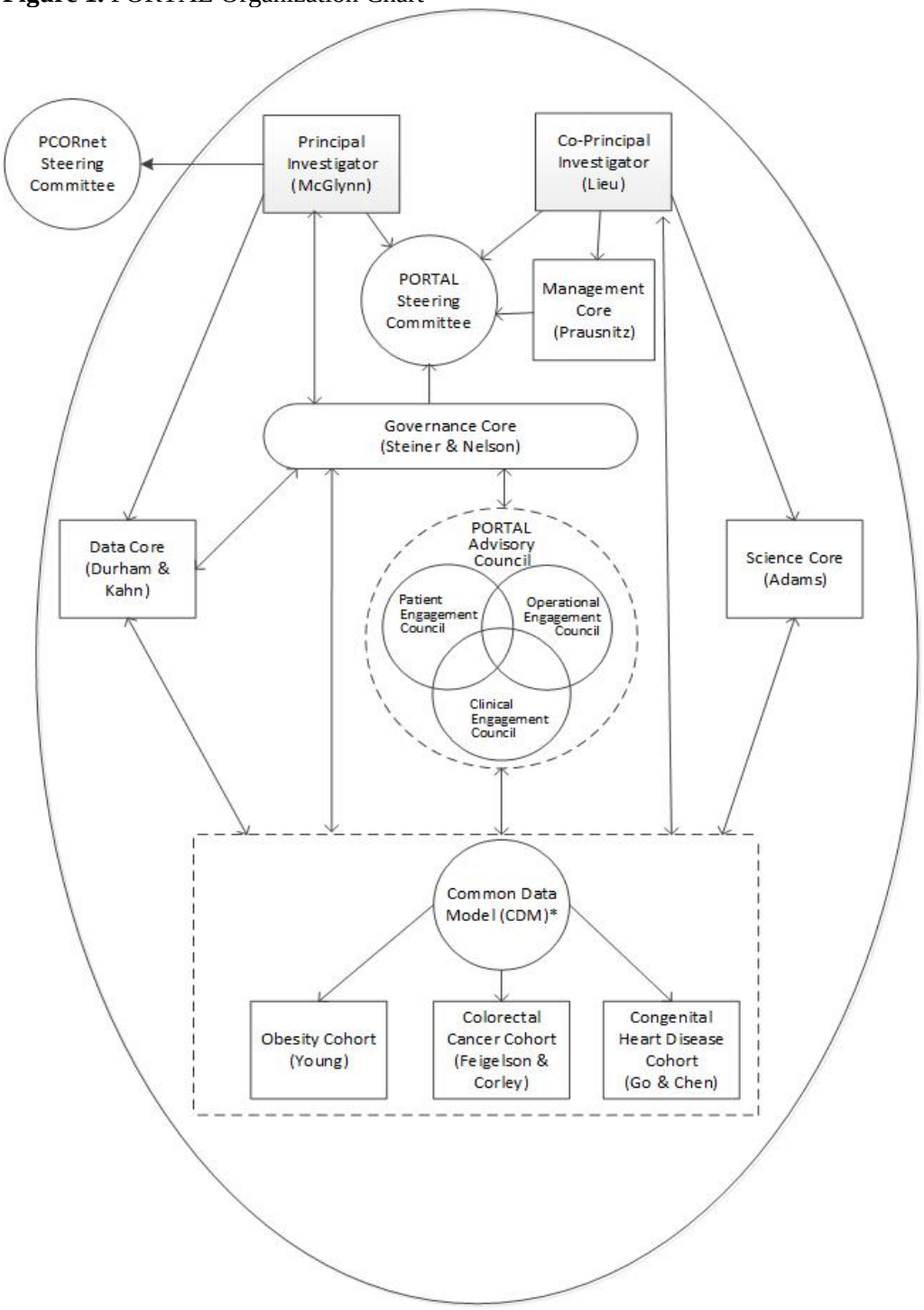
The purpose of PCORnet is to create a large, highly representative, national network for conducting patient-centered outcomes research. The PORTAL Governance Plan will be reviewed by the PCORnet Governance and Collaboration Task Force to assure consistency and harmonization of policies and goals within PCORnet. Elements of the PCORnet governance plan will be adopted or adapted for PORTAL as recommended by the PORTAL PIs, Steering Committee, Advisory Councils, and/or Governance Core. PCORnet guiding principles can be found here: PCORnet: A Commitment to Patient Privacy and Data Security.

II. ORGANIZATIONAL STRUCTURE

Summary
This section describes the structure of the PORTAL Network and the Network's Committees, Cores, Councils and Cohorts and the relationships between the PORTAL Network and PCORnet and other Clinical Data Research Networks (CDRNs).

Figure 1 depicts the organizational structure for the PORTAL Network, the major groups within the Network, and the ways in which they work together.

Figure 1. PORTAL Organization Chart



*Participating sites: Kaiser Permanente regions (Colorado, Georgia, Hawaii, Mid-Atlantic States, Northwest, Northern California, and Southern California); KP Centers for Effectiveness and Safety Research [KP CESR], Denver Health and Hospital Authority, Group Health Cooperative, and HealthPartners.

The Principal Investigator (Elizabeth A. McGlynn, PhD) and Co-Principal Investigator (Tracy A. Lieu, MD, MPH) operate in partnership. Each takes primary leadership for specific areas and both make decisions in consultation with the PORTAL Steering Committee (PORTAL SC). Dr. McGlynn will serve as the PORTAL representative to the PCORI CDRN Steering Committee and will oversee all external-facing interactions. She will also provide oversight for the Governance and Data Cores. Dr. Lieu will provide oversight for the Management and Science Cores and all three Cohorts.

The PORTAL SC is responsible for scientific and strategic management of the PORTAL Network. Members of the SC include the PORTAL PI and Co-PI, the Co-Chairs of the Cores, leaders of the three cohorts, site PIs, patient engagement leaders, and the representative from SmartPatients. The SC evaluates recommendations from the Cores and Councils. The SC coordinates work at the sites by: integrating policies, guidance, and processes developed by the Cores; monitoring the timeline for project activities; overseeing cohort construction; and ensuring communication between sites, Cores, and all other Network participants. The SC also works closely with the Cores to refine data and network development, evaluate network usability, address scientific concerns and barriers to collaboration, obtain input and representation from stakeholders, and identify priorities for expansion. Matters that require dispute resolution will be addressed as described in Section III. H. The SC will evaluate requests for new collaborative research studies from internal and external investigators and other groups (such as other CDRN and PPRN awardees), make recommendations for Network participation, and bring new study requests to Site Principal Investigators (PIs) for a formal vote on participating as a Network. If the Network decides to participate, PORTAL sites retain the right to opt in or opt out of these research studies.

1. Management Core

The Management Core will report to the PORTAL Co-PI. Management Core activities will include:

- Assisting PORTAL sites with the Institutional Review Board (IRB) approval process or ceding arrangements
- Securing Data Use Agreements (DUAs) and Business Associate Agreement (BAAs)
  - If sharing limited data sets is required for cohort work, the Management Core will work to minimize the regulatory burden on network data partners by executing the minimum number of DUAs required.
- Setting and monitoring timelines and budget parameters
- Executing and overseeing subcontracts
- Coordinating conversations between PORTAL sites and the PORTAL DCC to address data storage, quality, and security
- Coordinating the work required to meet the milestones described in Section IB above
- Filing required reports to PCORI
- Managing the prime PORTAL contract

2. Governance Core

The Governance Core will develop, initiate, and monitor policies and procedures for PORTAL decision-making and the use of PORTAL resources. Two Co-chairs (Andrew F. Nelson, MPH, and John F. Steiner, MD, MPH) lead this Core, which advises and makes recommendations to the SC and other Cores and Councils as appropriate. At least one co-chair attends SC meetings to ensure that issues related to network and data governance are addressed, and to identify barriers to collaboration that can be managed by modifying the governance structure or process. The Governance Core will meet no less than once per month. Members of the Governance Core are listed in Appendix A.

3. Science Core

The Science Core includes researchers from participating PORTAL sites. This core is led by John Adams, PhD. The Science Core advises on cohort development, potential CER questions, study designs, and patient-reported outcomes data collection. When future CER/PCOR investigations are proposed, this core will review protocols and research plans for projects that propose use of PORTAL resources (e.g., data network, cohorts) and provide recommendations to the SC and Site PIs for approval. Training and mentoring for junior investigators will also be integrated into the work of this Core.

4. Data Core

The Data Core advises, with the SC and participating sites, to develop, implement, and expand the PORTAL Network on system architecture, data management, and site integration. This core is co-led by Mary Durham, PhD, and Michael Kahn, MD, PhD. The Data Core includes investigators and technical data experts in health informatics, system architecture, data development and storage, distributed network development, and data quality assessment. The Data Core will implement the PCORnet common data model (CDM) and the PopMedNet (PMN) query distribution environment. The Data Core will support the sites in the development of the PCORnet's CDM by providing standardizing ETL programs. Table creation will be streamlined by the use of a standardized CDM already implemented at the data partner sites, based on KP CESR. In addition, the DCC will help each PORTAL site implement the PCORnet's PMN system as needed. They will also serve as a resource to each cohort for questions about the CESR CDM tables, standardizing table shell creation and QA processes.

5. Cohort Development Cores

PORTAL will develop three cohorts of patient/members from the 10 participating clinical sites. A lead investigator or investigators and participating site investigators are responsible for defining and developing the cohorts. These cohorts will include individuals with (1) colorectal cancer; (2) adolescents and adults with congenital heart disease; and (3) adults with body mass index values placing them in the overweight or obese classifications. Work in all three cohorts will follow four general steps:

- Frame the key outcomes and research questions through engaging with patients and investigators from the participating clinical sites and the Councils. The Patient Engagement Council in particular will review research questions, surveys, and other relevant decisions in cohort development.
- Define the criteria for cohort inclusion and implement initial data extracts
- Survey cohort-eligible members in PORTAL sites
- Conduct descriptive analyses and document the methods used to construct the cohorts to inform future research

Each cohort will have scientific representation from all participating PORTAL sites. These scientific groups will meet regularly via conference call to develop cohort definitions and content for the patient survey, assess data quality, and ensure that unique characteristics of each site are taken into consideration. The groups will provide recommendations for future research studies that can be performed with their cohort.

B. Site Principal Investigators (PIs) and their Participating Sites

Each organization contributing data to the PORTAL Network has one Site PI. The Site PI is responsible for assuring that the local site contributes to the development of cohorts in which it participates. The Site PI and staff at each site are responsible for obtaining local IRB approval and/or ceding, and executing DUAs and/or BAAs. Each site is responsible for meeting all local site compliance requirements including (but not limited) to secure data storage and transfer in accordance with local, state, and federal regulations as well as institutional policies and procedures. The sites will work with the DCC on the development of any new content areas for cohort development.

Site PIs are part of the PORTAL SC and meet twice per month by teleconference with other Steering Committee members. Site PIs are expected to evaluate and vote on ancillary research ideas put forth by PORTAL investigators and other potential research partners. The Site PI has ultimate authority about whether or not the local site will participate in these ancillary efforts.

C. PORTAL Advisory Councils

Three Councils are at the heart of the PORTAL organizational structure to emphasize the centrality of key stakeholders to the proposed work.

1. Patient Engagement Council and Online Advisors

The Patient Engagement Council will include representatives from patient advocacy organizations aligned with the PORTAL cohorts (Fight Colorectal Cancer, the Adult Congenital Heart Association, and the African American Health Coalition to advocate on behalf of the obesity cohort) as well as Roni Zeiger from SmartPatients (an online community where patients and caregivers learn from each other about treatments, clinical trials, the latest science, and how it fits into their experience)[3], and 3 patients from each cohort who receive health care from

PORTAL delivery systems. One parent-young adult dyad may be included to represent the congenital heart disease cohort, resulting in 4 council members representing that condition. Patient Engagement Council members will be paid collaborators.

The Patient Engagement Council will meet face-to-face twice during the 18 month project and will have ten monthly webinars between September 2014 and July 2015. Council members will review materials before webinars and gather feedback from others in their community in preparation of the webinars (as applicable). The Council will operate on a "hub and spokes" model where the Council members provide input individually but also work with PORTAL staff to engage larger communities of patients in key discussions. They will provide guidance and build consensus about decisions during the webinars; as well as interacting through email and telephone with project staff to advance specific tasks. Members of the patient engagement council will also join task-specific or cohort-specific meetings. However, most of their work on behalf of PORTAL will be conducted in the context of the monthly webinars. The Patient Engagement Council will facilitate key early tasks for the cohorts. It will provide input on the outcomes that matter to patients in each of these cohorts as well as in identifying key research questions for the cohorts. In collaboration with Roni Zeiger, it will also recruit a group of "Online Advisors" who will help to establish three cohort-specific patient communities hosted by the SmartPatients. These online communities will promote communication and transparency throughout the project and will include mobile device accessibility.

To enable individual patients to fully contribute their insights and experiences to the work, we have recruited Fight Colorectal Cancer to help train Patient Engagement Council members in research concepts, principles, and challenges; and in how integrating a patient perspective improves research. Each monthly webinar will include a discussion of key skills and knowledge that can enable PEC members to serve on the PEC most effectively. Members of the Patient Engagement Council will have access to the PORTAL SharePoint website giving them the same access to project information as the research team.

Although PORTAL will not conduct research studies during this first 18-month period, these advisory groups will help identify research priorities and plans for engaging patients throughout the course of research conducted using our cohorts. The Patient Engagement Council will help develop the following aspects of PORTAL governance: guiding principles, network governance, data governance, and privacy and confidentiality. The Council will also post inquiries and receive summaries of discussions held on the SmartPatients online communities to obtain guidance and work with the patient advocacy organizations to seek input from their broader membership.

The charter for the Patient Engagement Council is attached as Appendix B.

2. Operational Engagement Council

The Operational Engagement Council will guide PORTAL leadership in evaluating the operational value of proposed research projects for the delivery of care within the participating

delivery systems, and the likelihood of potential improvements in care. The Operational Engagement Council will include at least one operational leader from each participating site, as well as KP Program Office. The Operational Engagement Council, which will be co-chaired by Raymond Baxter, PhD (Senior Vice President for Community Benefit, Research, and Health Policy at KP), will integrate the disciplines (e.g., analysis, administrative, web design) and expertise (e.g., information technology, social media, innovation, communications, clinical work flow), and will guide and respond to inquiries from the Core Leaders and Cohort Leaders. As appropriate, the Operational Engagement Council will convene *ad hoc* working groups of its members and other organizational experts to resolve specific technical problems, such as developing processes and tools to integrate collection of patient-reported information into clinical data systems and improving capacity for conducting pragmatic trials. These leaders will also provide advice to the PORTAL leadership about strategies for resolving organizational roadblocks to developing, conducting and disseminating research and aligning PORTAL research with operational needs and long-term operational objectives. The Operational Engagement Council will meet face-to-face twice during the project period and will meet by webinar or teleconference at least quarterly. Work Groups will meet as needed to complete specific tasks.

The Operational Engagement Council charter can be found in Appendix C.

3. Clinical Engagement Council

The Clinician Engagement Council will provide input on governance as well as on research-related activities. The Council will include both system and research leaders. Parallel to the Patient Engagement Council, the Clinician Engagement Council will be utilized in a "hub and spokes" manner in which we obtain individual input from Council members who will in turn engage the larger community of clinicians. During the first six months of the project, we will engage the Council in identifying research questions for each of our cohorts. For example, the Kaiser Permanente National Guidelines Program maintains a list of more than 180 clinical and care delivery questions that require answers to inform guidelines. The Guidelines Program uses a very structured approach to developing questions using the PICO (Population/ Intervention/ Comparator/ Outcomes) method and we plan to use that structure as we engage clinicians in developing research questions for the cohorts. The Clinician Engagement and Patient Engagement Councils will have a joint meeting about the research questions proposed for consideration by each group. They will meet twice face-to-face during the 18 month project period and will meet at least quarterly by webinar or telephone.

The Clinician Engagement Council will also interact with the Operational Engagement Council to enhance the process of integrating research into care delivery and taking successful interventions to scale. Each PORTAL site has well-established mechanisms for working with clinicians and delivery system staff, which. PORTAL will leverage in conducting its work.

The Clinician Engagement Council charter can be found in Appendix D.

III. DECISION-MAKING: DEVELOPMENT OF GOVERNANCE STRATEGIES AND POLICIES AND REVIEW OF RESEARCH REQUESTS

A. Decision-making for the PORTAL Network

PORTAL governance involves both development of broad strategies to achieve the goals of the Network, and specific policies or procedures to guide Network investigators and staff. Potential governance strategies and policies are likely to arise from multiple sources within the PORTAL Network (Figure 1). Since many of these policies will have ramifications for multiple Cores, Councils, individual sites, or the three cohorts, the PORTAL Steering Committee will serve as the focal point for review and discussion of strategies and policies. The Steering Committee will consider and refine suggestions from any source, develop the policy, and vote on a recommendation to adopt it (using the voting procedures described in Section III.F.). In all such discussions, the voice and perspective of patient/members, operational leaders, and clinicians should receive special consideration, as discussed in Section III.I. These recommendations will be presented to the PI and co-PI, who will make the final decision.

B. Decision-making within PORTAL Cores, Councils, and Cohorts

PORTAL Cores and Councils may use a similar deliberation process in developing recommendations for strategies or policies to be considered by the Steering Committee. They may also develop their own approaches. The cohorts may also use a similar approach, although the responsibility for scientific decisions ultimately should reside with the Principal Investigator for that cohort, consistent with the governance of other scientific projects.

C. PORTAL review of PCORnet policies

Governance policies developed by PCORnet nationally will be reviewed using a similar process. Any concerns expressed by the Steering Committee (such as inconsistencies between PORTAL and PCORnet governance policies) will be conveyed to the PI and co-PI, as well as the PORTAL representative on the PCORnet Governance and Collaboration Task Force (Steiner). These individuals will convey these concerns to the PCORnet Coordinating Center. At present, it is not clear whether PCORnet governance decisions will be viewed as binding on participating Networks; this issue requires resolution.

D. Decision-making for scientific projects or requests for collaboration

Suggestions for research projects or requests for collaboration are also likely to arise from multiple sources inside and outside the PORTAL Network. These sources include PORTAL investigators, other researchers from departments in the PORTAL Network, patients, operational leaders, clinicians from the participating delivery systems, other PCORnet investigators and networks, funding agencies, and external researchers not affiliated with PORTAL or PCORnet. These suggestions may come initially to anyone participating in PORTAL. Individuals receiving

such a request may either forward it directly to the PI and co-PI, or have preliminary discussions within the appropriate cohort, Core, Council etc. to refine the request or develop a preliminary review of its potential before forwarding it to the PI and co-PI.

E. Selection of principal investigators and sites for participation in scientific proposals and projects

For scientific projects and proposals, each organization participating in the PORTAL Network reserves the right to request to participate or to opt out. The PORTAL Network approved two processes: one for disseminating opportunities to find collaborators, and another for selecting the PI for a PORTAL-branded application (when there are multiple investigators interested in the PI role). These processes establish two key criteria:

1) Expertise – the PORTAL Network aims to identify the PI with the optimal chance of succeeding in obtaining funding
2) Balance – the PORTAL Network seeks to offer leadership opportunities to investigators from a range of sites. The PI and Co-PI will give special consideration to the capabilities of the proposed lead center/site; and to proposed plans for how the network's assets, both intellectual and data, will be used both within and following the project.

The general process for disseminating opportunities will ensure that PCORI RFAs related to PCORnet-specific opportunities will be routinely distributed to all Steering Committee members for local distribution to their faculty. For each PCORnet-specific RFA, the PI and Co-PI will establish a due date for expressing interest in (a) leading a response and (b) collaborating in a response. Similarly, if PORTAL is approached by another network to develop and/or participate in a PCORnet application, the request will be circulated to the Steering Committee for local distribution and identification of interested PORTAL PIs. Details regarding these processes are in Appendix E.

The Site PI is responsible for internal review of potential projects with local researchers, patients/members, operational leaders and clinicians (as appropriate), and for leading any internal deliberations. Reasons for the decision of a site to opt out should generally be disclosed. If a site repeatedly opts out of PORTAL proposals and projects, the PORTAL PI and co-PI will discuss the rationale with the site PI and determine the suitability of that site for continued membership in the Network.

F. Voting procedure

At any level of deliberation (Steering Committee, Core, Council, etc.), the group should decide whether to seek consensus-based decisions or to use a voting process. When a consensus based approach does not result in a decision, any SC member can call for a vote. If votes are taken, each member of the group should have the opportunity to vote to support a particular decision, not to support that decision, to abstain, or to recuse themselves (on the basis of concerns such as conflict of interest). Formal votes require a quorum of group members. A quorum is reached

when a simple majority (50% or more) of the group is represented. Each group member (or their representative) is entitled to one vote. A motion carries when a simple majority (50% of those present) has been achieved. Members abstaining count in establishing the quorum, but not in determining whether a majority of votes has been achieved. Votes may be taken either be in person or using web-based voting software. Except in special circumstances, an individual's vote should be publicly disclosed rather than anonymous, recognizing the importance of overt dissent and debate in the culture of scientific research. The results of votes should be tallied and reported to the group taking the vote, as well as other groups (such as the Steering Committee) that will consider the recommendations of the group.

G. Policy enforcement

The PORTAL PI and co-PI are responsible for enforcement of PORTAL policies (as well as other relevant policies of federal agencies, health care delivery systems, funders, and PCORnet). They are encouraged to include the PORTAL Steering Committee in discussions about policy enforcement, and may make use of ad hoc advisors (including individuals outside the PORTAL Network) as appropriate. The PORTAL PI and co-PI, assisted by the Steering Committee and others, should develop and apply appropriate and publicly disclosed metrics for adherence to policies. Emphasis should be placed on prevention or early detection of non-adherence to Network policies, with prompt and confidential communication with individuals or groups that are not adhering to policies or are at risk.

H. Dispute resolution

As a general principle, efforts to resolve disputes between individuals (investigators, staff) or entities (cores, councils, etc.) that affect PORTAL activities should begin at the most decentralized level. For example, a scientific debate about development of a cohort should be resolved within the cohort investigators wherever possible. The leader of that group (cohort PI, core leader, etc.) should lead the dispute resolution process unless they are a party to that dispute. Consensual processes for dispute resolution such as negotiation or mediation should be employed; guidance is available from standard references (Fisher, Ury, and Patton, 2011).

Disputes that cannot be resolved at the first level or that involve the leader of that entity should be discussed with the PORTAL PI and co-PI, who can advise or take a more active role in the process. They may also be able to determine whether involvement of a neutral third party would be helpful. If a consensual resolution to the dispute is not achievable, the PORTAL PI and co-PI will make the final decision.

I. Stakeholder role in policy development and decision-making

Consistent with the principles of stakeholder engagement in research, patients/members, operational leaders, and clinicians should be involved throughout the process of policy development and decision-making. The Patient Engagement Council, Operational Engagement Council, and Clinician Engagement Council, or individuals within those groups, are important

resources to consider issues or identify concerns, and should be included in deliberations wherever possible.

IV. DATA INFRASTRUCTURE AND GOVERNANCE

Summary
This section describes the common data model used in the PORTAL Network. It describes the distributed data approach, the process for data queries and data exchange and procedures for ensuring data consistency and quality. The rights and responsibilities of participating sites are also described. Processes for data access from both inside and outside of the Network are summarized.

The four healthcare systems in the PORTAL Network use different electronic health record (EHR) vendors and different clinical, administrative, and patient-access applications to support clinical care and to collect patient-entered data. Institutional differences in configurations, workflows, and codes prevent sharing data directly from existing systems, even among partners with the same EHR product.

One approach to resolving this barrier to multi-institutional data sharing is a Common Data Model (CDM). A CDM provides unambiguous definitions for structuring each data element and assigning codes to data values. The PORTAL Data Core will adapt its data model and data governance principles from prior scientific networks established through the HCSRN. Governance principles are most immediately based on the extensive work in data governance completed through the SPAN grant, funded by AHRQ from 2010-2013.

A. Distributed Data Approach

PORTAL uses a distributed data approach Under which, the participating institutions, the PORTAL DCC, lead sites for analysis of PORTAL cohort data, and the PORTAL SC are each responsible for the stewardship of PORTAL data in their possession.

Core governance principles for distributed data include:

1. Data partners retain full physical and operational control over the content and availability of their patient-level and institutional data
2. Fully identified data are not shared outside the data partner's institution. Where patient-level limited data sets are required, full IRB approval is required and HIPAA regulations will be observed.
3. Data partners have the right to determine if they will participate in a specific data request.
4. Data partners are accountable to a minimum level of participation in PORTAL or PCORnet requests to be considered active contributors, however. Data partners who do not maintain active participation will be evaluated as described in section III.F.

B. Common Data Model

The PORTAL Network will implement, and maintain the PCORnet Common Data Model (CDM). One of the key CDMs used in multiple national networks is the HCSRN Virtual Data Warehouse (VDW). The KP Center for Effectiveness and Safety Research (CESR) CDM is an *expansion* of the current HCSRN VDW. The PCORnet CDM will be based on the CESR CDM. In transforming data from local systems into the CESR CDM, differences in data structure and codes across PORTAL sites will be eliminated so that a single common view of shared data is available. Over a 20-year period, the HCSRN has developed detailed definitions, documentation, and implementation guides for the structure of each table and the allowed codes used in each field. CESR has extended those definitions, and the relevant components needed by the cohorts to support the PCORnet CDM will be used by PORTAL. This documentation is available on the HCSRN website[4] and the CESR website.

Governance principles regarding the CESR CDM include:

1. All PORTAL data partners will implement the tables and attributes required to support the data query needs of approved cohorts and studies, and the PCORnet CDM.
2. The PORTAL Steering Committee will determine the required network-wide CESR data elements with the approval of the Site PIs.
3. Each PORTAL data partner will implement new elements requested into the PCORnet CDM to the best of their ability, balancing timeline and budget constraints.
4. Data partners are responsible for maintaining and updating institutional CESR CDM data extracts with data refreshes at the frequency required by PORTAL SC governance (which may also be driven by PCORnet requirements for data refreshes), as their budgets allow.
5. Data partners, in collaboration with the PORTAL Data Core and Data Coordinating Center, are responsible for data quality assessment and resolution of data quality issues (See Appendix F).
6. Analytic data sets used for PORTAL will be retained by the participating institution for at least three years from the completion of PORTAL funding, or longer if required by institutional policies. The SC will instruct participating institutions regarding retention requirements for all data activities.

C. Data Queries and Data Exchange

PCORnet Data Queries and Data Exchange will be managed using the PopMedNet™ (PMN) technology, which is used by multiple national networks such as the FDA Mini-Sentinel Network. PMN provides security, authentication, and auditing required to ensure that only approved data requests are made.[5] All PORTAL sites will set up an instance of the PCORnet PMN for responding to network queries

Principles for PORTAL data queries and data exchange include:

1. All data requests must identify the requesting organization, responsible individual and contact information.
2. Data partners will identify a technical contact who is responsible for ensuring rapid site-level approval and execution of PORTAL and PCORnet approved query requests.

3. Data partners may decline to respond to specific PORTAL SC-approved queries or PCORI-sponsored PCORnet queries, with written justification.
4. Data partners may review data queries prior to execution and review data query results prior to release to PORTAL and/or PCORnet. Data partners may elect to automate approval for accepting queries and/or releasing query results at their discretion.
5. Data queries and data exchange will never include direct patient identifiers. Queries that require patient-level limited data sets (actual dates) will require full IRB and HIPAA oversight and site-level review or ceding.
6. PORTAL will use secure data transfer technologies. Where PORTAL uses PopMedNet™ those security specifications are described in Appendix G.
7. Data exchange between PORTAL data partners will employ existing national terminology standards when applicable. PORTAL will encourage the use of terminologies targeted for ONC Meaningful Use compliance to better align PORTAL data exchange standards with their delivery systems. PORTAL will encourage PCORnet to adopt similar national terminology standards for data exchange.

D. Ensuring Data Consistency and Quality

The HCSRN has developed extensive policies, procedures, and technologies for evaluating and improving data validation, quality, and consistency. These will be incorporated into the PORTAL Network data operational structure. Bauck et al. developed a conceptual model for a consistent Data Quality Assessment (DQA) framework (see Appendix F) that is being implemented across the HCSRN/CESR sites and that proposes standardized data quality assessment reporting measures. These activities illustrate the attention to data consistency and quality by PORTAL sites.

Governance Principles regarding PORTAL data consistency and quality include:

1. Data quality assessment and improvement is a shared responsibility. The data partner has the lead role and the PORTAL DCC has a supportive role. The data partner will take primary responsibility for executing data quality assessment programs and for investigating data quality issues that are detected at the site and network levels. The PORTAL DCC will provide data quality assessment programs to be shared across PORTAL sites and will develop cross-site data quality assessment programs.
2. Each PORTAL data partner is responsible for completing site specific QA checks after each data refresh.
3. When a significant data quality issue is discovered, the data partner will take the primary role in identifying the source and developing a solution to the anomaly.
4. The PORTAL Steering Committee will provide guidance on resource allocation to data quality assessment and improvement activities.
5. PORTAL data partners will be identified in internal data quality reports
6. PORTAL data partners will resolve data issues that impact cohort research

E. Standardizing the development and distribution of SAS®programs

An Analytic Plan Procedure (APP) has been developed for the PORTAL Network. It describes a framework to develop, pilot test, refine, and submit SAS® programs to participating sites in the PORTAL Network. This procedure highlights procedures to help reduce the possibility of sharing PHI that is not allowable through data sharing agreements. Please see Appendix H for the PORTAL APP.

F. Data access

In the PORTAL Network, data may be accessed by:

1. submitting a query through PopMedNet™ (request is reviewed at each site and with local approval, is executed; results are consolidated and aggregated; deidentified results are returned to the requestor)
2. distributing SAS® programs (programs are reviewed and with local approval, are executed; results are consolidated and returned to the requestor); results can return limited data sets, de-identified data sets, or aggregate data sets

First priority for data access will be given to data requests from the PORTAL authorized investigators and staff (staff who are listed on IRB documentation as participating in PORTAL activities). Authorized individuals are encouraged to inform the Data Core of progress and anticipated data requests. Please submit data requests using the PORTAL Analytic Plan Procedures (APP) found in Appendix H.

While responding to data requests outside of the PORTAL scope of work may be feasible, and is desirable, the PORTAL SC will determine how these requests are submitted, evaluated, and executed. Such requests require staff time to process and therefore can affect both the funded scope of work and timelines. Therefore, the SC is obliged to balance these requests with the need to achieve the specific aims and goals of the PORTAL project.

Principles for data access:

1. PORTAL recognizes several categories of investigators who might require or request data access:
    - PORTAL investigators
    - Investigators from PORTAL sites who are not associated with PORTAL
    - PCORnet investigators (includes those from CDRNs and PPRNs)
    - Funding agency staff
    - Collaborating investigators from a other research institutions
    - Investigators from health systems not involved in PORTAL
    - Health care delivery system staff who request access for operations or for other than research or publication purposes
    - Patients

Other categories may be added in the future. Unique roles, responsibilities, and data access rights exist for each category.

2. The Steering Committee is the final authority for determining appropriate data access policies. When there is any doubt regarding a specific data access request, approval by the SC is required. The SC may appoint a Data Access Subcommittee (composed of members of the SC, Data Core and institutional data privacy experts) to review these requests at its discretion.
3. Across all data access categories, the regulatory requirements of HIPAA and the Common Rule will be enforced by technology where possible and by policy and standard operating procedures when technology cannot ensure compliance.
4. All data requests, queries, and responses will be audited and archived. Inappropriate use of the PORTAL Network will result in immediate loss of data access privileges.

Process for requesting data access:

1. Entities or individuals interested in becoming authorized users will submit a request to gain access to the Query Tool. The SC will review all requests from external investigators to become authorized users.
2. All requestors will complete the PORTAL: Data Access Request Form (to be developed). Responses should clearly describe the purpose of the data request, how and if the request is funded, and provide details about the intended use of the results. The completed form will be submitted to the Management Core Project Manager.
3. The request will be sent to the SC for consideration. In order to conduct funded work and to plan for the sustainability of the Network, priority is given to investigators in the PORTAL Network, PCORnet investigators (CDRN/PPRN), and representatives of funding agencies. The SC will arrive at its decision in consultation with the Data Core to determine whether other requests can be accommodated without jeopardizing existing workflows and project goals.
4. In all cases, results returned will adhere to minimum necessary standards as stipulated in the HIPAA Privacy Rule.
5. Once permission is granted, individual sites will decide whether or not to participate in a data request. The DCC will initiate the query or distribute the SAS® program. Participating sites will review and execute the query or program. The DCC will compile results and return them to the requestor.
6. Requestors may use PORTAL data only for agreed-upon purpose or purposes. The responsibility requestor must comply with federal and state regulations as well as any requirements from their local institution.

Please see Appendix I for the data sharing matrix.

G. Data Use Limitations

Participating institutions may use their own source data transformed into the PORTAL CDM for other purposes, including research, as long as they comply with applicable state and federal laws and regulations, including HIPAA and the Common Rule, and undergo local review processes.

PORTAL participating institutions and the PORTAL DCC may only use data obtained from sources other than their own institution in the conduct of PORTAL or PCORnet-sponsored activities. Such data may not be reused, re-disclosed, altered, or sold for any purposes other than those defined in the contracts. Collaborators external to the PORTAL Network may only use data for uses approved by the Steering Committee.

A list of authorized users of PORTAL data sets will be provided at least yearly from the SC to each PORTAL site. A participating institution that receives a request for use of PORTAL data sets from an unauthorized user should report the unauthorized request to the SC.

Consistent with PCORnet policies, any PORTAL data partner that receives a request to gain access to the Query Tool from a user not previously identified as an authorized user, or identifies unauthorized use, should report that request to the PORTAL SC and the PCORnet Coordinating Center. At the PORTAL SC's and PCORI's discretion, unauthorized use leads to revocation of access to the Query Tool.

V. DATA PRIVACY AND CONFIDENTIALITY

Summary
All members of the PORTAL Network must act as responsible stewards of patient data by maintaining, and whenever possible, strengthening the privacy and confidentiality of patient data used in this collaboration. This section describes how electronic data are accessed, shared, and protected according to relevant human subject protection and HIPAA regulations.

The HIPAA Privacy and Security Rules establish minimum federal standards for protecting privacy and maintaining confidentiality of Protected Health Information (PHI). In the context of the PORTAL Network, the participating sites have the authority and responsibility for ensuring the privacy and confidentiality of their respective data.

Each participating site must use and/or disclose PHI for the purposes of research in accordance with federal, state and other applicable regulations as well as following institutional policies and requirements in order to ensure the privacy and confidentiality of the individuals' PHI. The use and/or disclosure of PHI should be done in a manner that protects the privacy and maintains the confidentiality of the data. This includes securing the appropriate institutional approvals and permissions for use and/or disclosure of PHI (e.g. IRB/Privacy board approvals or waivers/alterations, applicable HIPAA agreements, etc.).

If PORTAL data are released, shared, and/or accessed in a way that is inconsistent with processes approved by the KPNC Institutional Review Board (IRB of record) and the PORTAL Reciprocal Data Use Agreement that has been executed by all participating sites, the procedures in Appendix J, Data Incident Response Plan, will be followed. These procedures include timely and transparent communication regarding the disclosure with: the local site's IRB, the lead IRB, PORTAL Co-PIs, and the SC.

A. Privacy

The Privacy Rule permits assigning to, and retaining with, the health information a code or other means of record identification if that code is not derived from or related to the information about the individual and could not be translated to identify the individual. The site may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

As a measure to protect privacy of data, each PORTAL site will assign a unique study identifier to each Cohort member. The sites are responsible for maintaining the linking file resident at each site and securely stored in order to maintain the privacy of the data. All data transfers between sites or vendors/contractors are done pursuant to the execution of applicable HIPAA or other institution specific agreements (e.g. Data Use and/or Business Associate agreements, etc.) to maintain confidentiality of the data.

B. Confidentiality

The Security Rule operationalizes the protections afforded in the Privacy Rule by establishing standards for addressing the technical and non-technical safeguards that organizations must have in place to protect the privacy of individuals' PHI. It allows for organizations to adopt new technologies to improve the quality and efficiency of patient care. Organizations must implement policies, procedures, and technologies that are appropriate for their particular size, structure, and identified risks to PHI.

VI. PUBLICATION AND PRESENTATIONS GUIDELINES

Summary
These guidelines refer to any publication, presentation, letter, press release or interview that arises from PORTAL activities. This purpose of these guidelines is to proactively encourage the quantity and quality of publications, to provide an overall approach to publications and presentations, and to facilitate and resolve disputes.

The goal of the Publications and Presentations guidelines is to foster a high volume of high quality scientific publications and presentations. Another guideline goal is to use this process as a way to notify the PORTAL Network about the intent to submit a manuscript or develop a presentation to coordinate efforts and avoid duplication. The PORTAL Publications Committee (PC) is comprised of the Co-PIs, a patient, and three Site PIs.

The guidelines are located in Appendix K. Important principles are summarized here.

A. Lead authors should complete the "Publications and Presentations Submission Request" form as early in the process as possible. The PC commits to responding to requests within 10 business days.

B. Lead authors are expected to extend a co-author invitation to every site PI to help ensure each site is represented.
C. Each site has complete control over the use and confidentiality of its data in any PORTAL publication or presentation. Each site must proactively agree to include site's data. Approval is garnered by including a co-author from each site or by contacting the Site PI for approval.
D. The participating investigator(s) from each site is/are responsible for the integrity of data from that site and for obtaining any necessary approvals for research use of those data.

VII. CONFLICTS OF INTEREST

Summary
This section describes PORTAL's Conflicts of Interest (COI) policies. These rely mainly on the COI policies at participating institutions.

In order to maintain public trust in the appropriate use of PCORI funds while maintaining respect for participating sites' autonomy, project data will only be accessible to PORTAL investigators and SC-approved non-PORTAL investigators whose home institutions maintain and enforce Conflict of Interest (COI) policies for staff investigators. These policies must address employees and their immediate family members.

In accordance with Federal Regulation 42 CFR 50 Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought[5], PORTAL relies on the investigator's home institution to maintain an appropriate written, enforced policy on COI that complies with the current version of this regulation. Participating institutions are expected to have COI policies that meet these minimum standards. Further, it is expected that PORTAL investigators and SC-approved non-PORTAL investigators who have access to project data, abide by the policies of their home institution. These must include, at a minimum:

- Processes to determine COI
- Requirements to disclose financial interests (including those of immediate family members) that might pose COI or perceived COI
- Requirements to disclose COI that might affect the research process or study participants including situations in which the investigator may have a real or perceived undue influence over the research process
- Remedies to manage, reduce or eliminate the COI
- Remedies to manage, reduce or eliminate the appearance of COI
- Establishes adequate enforcement mechanisms that impose sanctions when appropriate

VIII. SCIENTIFIC MISCONDUCT

The PORTAL Steering Committee must be informed of any instances of scientific misconduct by the site PI from which the misconduct originated. These instances are expected to be addressed by the investigator's home institution.

IX. REFERENCES

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X. ACRONYMS

CDM: Common Data Model

CER: Comparative Effectiveness Research

COI: Conflict of Interest

DCC: Data Coordinating Center

DUA: Date Use Agreement

HIPAA: Health Insurance Portability and Accountability Act

HCSRN VDW: Health Care Systems Research Network Virtual Data Warehouse

IRB: Institutional Review Board

LDS: Limited Data Set

PCORnet: Patient Centered Outcomes Research Network

PHI: Protected Health Information

PI: Principal Investigator

PORTAL: Patient Outcomes Research to Advance Learning

PORTAL SC: PORTAL Steering Committee

XI. GLOSSARY

Business Associate's Agreement (BAA): An agreement that is required between an entity or person (Business Associate), who is not a member of the covered entity's workforce (data provider) in order to transfer data. The Business Associate is not acting as a researcher in the study, and performs research support services on behalf of the covered entity that involves the use or disclosure of PHI.

Common Data Model (CDM): The PCORnet Common Data Model (CDM) is a data structure that standardizes administrative and clinical information across PCORnet partners. Participation by the network partners in the creation, implementation, updating, maintenance, enhancement, and use of the CDM will be in accordance with guiding principles developed by the PCORnet Governance and Collaboration Task Force.

Data Use Agreement (DUA): An agreement into which the site enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

Limited Data Set: According to the Privacy Rule (see HIPAA), a data set that may be used for research when the data set recipient enters into a Data Use Agreement (DUA) with the site (data owner) providing the data set. A LDS can ***include*** dates, limited geographic information, and a link field (e.g., an encrypted identifier), such as:

- Dates (e.g., admission, discharge, and service dates; dates of birth and death) and ages of research participants;
- Certain general geographic information, including five or nine-digit zip codes and state, county, city, and precinct; and
- Links which may be used to identify individuals when the researcher maintains and holds confidential the key required for re-identification.

A LDS must ***exclude*** all other PHI identifiers, such as:

- Names and street or postal addresses;
- Telephone and fax numbers;
- E-mail and Internet Protocol (IP) addresses and web Universal Resource Locators (URL);
- Social Security, medical record, health plan beneficiary, and other account numbers;
- Certificate and license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Biometric identifiers, including finger and voice prints; and
- Full-face photos and any other comparable images.

Minimum Necessary Standard: The Privacy Rule imposes a minimum necessary requirement on all permitted uses and disclosures of PHI. It is the responsibility of each participating site to follow their respective policies and procedures to limit the use and disclosure of PHI to "the

information reasonably necessary to accomplish the purpose of the sought or requested use or disclosure".

Protected Health Information (PHI): PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

PCORnet: Supported by the Patient-Centered Outcomes Research Institute (PCORI), PCORnet is the National Patient-Centered Clinical Research Network whose purpose is to create a large, highly representative, national network for conducting clinical outcomes research. PCORnet's goal is to transform clinical research by engaging patients, care providers, and health systems in collaborative partnerships to improve healthcare and advance medical knowledge. By bringing research and patient care together, this innovative health data network will be able to explore the questions that matter most to patients and their families. Visit this website to learn more: http://pcornet.org/.

PORTAL Participating Institution: One of the four health systems that contribute data to achieve the goals of the PORTAL Network.

Privacy Rule: Federal regulations promulgated under HIPAA designed to protect the privacy of identifiable health information. The Privacy Rule establishes conditions under which Protected Health Information (PHI) may be used and disclosed by PORTAL sites as Covered Entities.

Security Rule: Federal regulations promulgated under HIPAA that set standards by which covered entities protect the confidentiality, integrity, and availability of electronic Protected Health Information (PHI) while permitting appropriate access and use by health care providers, clearinghouses, and health plans.

Scientific Misconduct: According to the NIH, scientific misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- *Fabrication* is making up data or results and recording or reporting them.
- *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- *Research misconduct* does not include honest error or difference of opinion.

Governance of the Patient Outcomes Research to Advance Learning (PORTAL) Network

APPENDIX TOOLKIT

PORTAL: APPENDIX TOOLKIT

This section is a companion to the PORTAL Governance Document available at: PORTAL Network Governance Page

TABLE OF CONTENTS

Appendix A: PORTAL Governance Core Members

PORTAL Governance Core Co-Chair
John F. Steiner, MD, MPH
Senior Director
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PORTAL Governance Core Co-Chair
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Appendix B: Patient Engagement Council Charter

PORTAL
PATIENT ENGAGEMENT COUNCIL
CHARTER
Draft: July 22, 2014

CHARTER OVERVIEW

This document will serve as a tool to guide the work of the Patient Engagement activities of the PORTAL Network, which include but not be limited to the Patient Engagement Council. It will be version-controlled and reviewed and approved by the Principal Investigator, the Co-Principal Investigator, the co-chairs of the Patient Engagement Council, and the Governance Core to ensure alignment with PORTAL and PCORnet goals.

GOAL/PURPOSE

The overarching goals of the Patient Engagement activities are to provide input to PORTAL leadership on the ways in which patients and advocacy groups can be effectively engaged in research including governance (providing feedback on important aspects of governing the network, such as privacy and confidentiality, informed consent) identifying outcomes and research questions that are important to patients; collaborating with PORTAL staff to include larger communities of patients in key discussions and facilitating communication between PORTAL and broader patient/community audiences; other strategies that will enhance the successful implementation of PORTAL goals in participating organizations.

MEMBERSHIP ROSTER

Co-Chairs	Carmit McMullen, PhD – Investigator, Center for Health Research KP Northwest; and Carol Somkin, PhD – Research Scientist, Division of Research, KPNC
Members:	**Congenital Heart Disease Cohort** Parent/Young Adult dyad and two adult patients Representative from the Adult Congenital Heart Association
	Colorectal Cancer Cohort Three patients Representative from Fight Colorectal Cancer
	Obesity Cohort Three patients

MEETING SCHEDULE

Two in-person meetings (Oakland) over the 18 month contract and ten monthly webinars from September 2014 and July 2015; and conference calls as needed.

SPECIFIC GOALS FOR COUNCIL

At the first meeting of the Patient Engagement Council we will bring together patients and advocacy group members representing the three PORTAL research cohorts to begin to create a diverse, cohesive body who can work collaboratively with researchers to shape future research that matters to patients and improves health

outcomes. In subsequent webinars, we will jointly explore topics of interest to patients, PORTAL Scientists and PCORI/PCORNET related to these goals.

COMMUNICATION AND MANAGEMENT

Co-Chairs	• Co-lead Council and provide overall direction • Co-lead webinars • Report progress and issues to PORTAL leaders • Serve as representative(s) to the PORTAL Governance Core
Council Members	• Attend Council in-person meetings and webinars • Advocate for the patient perspective within and across disease/condition • Work together as a group to reach consensus • Actively participate in decisions and contribute to deliverables

STAFFING

Patient Engagement Council activities will be led by Drs. McMullen at KPNW and Somkin at KPNC. Research assistants and project managers under their supervision will support PEC activities.

Appendix C: Operational Engagement Council Charter

PORTAL
OPERATIONAL ENGAGEMENT COUNCIL
CHARTER
Draft: April 29, 2014

CHARTER OVERVIEW

This document will serve as a tool to guide the work of the Operational Engagement Council of the PORTAL Network. It will be version-controlled and reviewed and approved by the Principal Investigator, Co-Principal Investigator, Chair of the Operational Engagement Council, and Governance Core Leaders to ensure alignment with PORTAL and PCORnet goals.

GOAL/PURPOSE

The overarching goals of the Operational Engagement Council are to: 1) guide PORTAL leadership in evaluating opportunities for collaboration, the operational value and likely impact of proposed research projects on the delivery of care and on the likelihood of potential improvements in care, 2) provide advice to PORTAL leadership about strategies for resolving organizational roadblocks to developing, conducting and disseminating research and aligning PORTAL research with operational needs; 3) champion change as needed to ensure the smooth functioning of the PORTAL network in participating organizations.

MANAGEMENT INFORMATION

Chair:	Raymond Baxter - KP, Senior Vice President for Community Benefit, Research and Health Policy
Co-Chair(s):	TBN
Members:	Karen Emmons, PhD – KFRI, Vice President, Research Jeffrey Braff, DrPH, MBA, CIP - KFRI, Director, Human Research Protections Tricia Zeller, RN, MHA – Group Health, Clinical Research Program Manager Kathy Scheirman – KP, Senior Vice President, Corporate Services for Information Technology Margo Gordon, PhD – KPSC, Director of Clinical Analysis Michael Johnson PhD - Kaiser Foundation Health Plan, Director, Utility for Care Data Analysis Hovannes Daniels – KPSC, Vice President, Information Management Bill Towner, MD - KPSC, Regional Medical Director, Clinical Trials Jeff Benabio, MD – KPSC, Physician Director of Healthcare Transformation Holly Potter - KP, Vice President, Public Relations, National Media and Stakeholder Management Marilyn Chow, RN, PhD, FAAN - KP, Vice President, National Patient Care Services Rep from KP Member Voice HealthConnect expert? NLP expert? Reps from HP, DH Implementation Science people?
Meeting Schedule	Webinar or telephone - Quarterly In person – Twice over 18 months (summer 2014, fall 2015)

SPECIFIC GOALS FOR COUNCIL

1. Informing the research process, including governance and implementation
2. Developing approaches to the efficient use of data sources and integration of new types of data (especially consumer reported)
3. Designing (or reviewing proposed) methods for efficiently implementing research in care delivery
4. Adapting research infrastructure to organizational needs
5. Contributing to discussions around sustainability of the PORTAL network
6. Guide and respond to inquiries from the Core Leaders and Cohort Leaders

COMMUNICATION AND MANAGEMENT

Chair	• Lead Council and provide overall direction • Lead meetings and calls • Report progress and issues to PORTAL leaders • Serve as representative to the PORTAL Governance Core • Convene ad hoc working groups of its members and other organizational experts, as needed
Co-Chair(s)	• Assist the Chair with overall leadership • Actively participate in decisions and contribute to deliverables • Attend Council meetings and calls lead selected calls
Team Members	• Attend Council calls and meetings • Actively participate in decisions and contribute to deliverables • Raise issues with Council chair • Participate in ad hoc working groups, as requested

Appendix D: Clinical Engagement Council Charter

PORTAL: CLINICIAN ENGAGEMENT COUNCIL

CHARTER

Draft: July 8, 2014

CHARTER OVERVIEW

This document will serve as a tool to guide the work of the Clinician Engagement Council of the PORTAL Network. It will be version-controlled and reviewed and approved by the Principal Investigator, the Co-Principal Investigator, the chair of the Clinician Engagement Council, and the Governance Core to ensure alignment with PORTAL and PCORnet goals.

GOAL/PURPOSE

The overarching goals of the Clinician Engagement Council are to provide input to PORTAL leadership on the ways in which physicians and other clinical leaders can be effectively engaged in research including governance, selection of research priorities, design and operation of pragmatic trials, conduct of observational studies, engagement with patients, and other strategies that will enhance the successful implementation of PORTAL goals in participating organizations.

MEMBERSHIP ROSTER

Chair	Philip Madvig, MD, Associate Executive Director, The Permanente Medical Group
Co-Chair(s):	TBN
Members:	Craig Robbins, MD, MPH– KPCO, Medical Director, Center for Clinical Information Services Michael Kanter, MD – KPSC, Medical Director, Quality and Clinical Analysis Michael McNamara MD – KPNW, Associate Medical Director, Department of Medical Informatics Alan Go, MD– KPNC, Regional Medical Director of Clinical Trials Michael Horberg, MD, MAS, FACP, FIDSA – KPMAS, Executive Director Research and Community Benefit Thomas Mackenzie, MD, MSPH– Denver Health, Chief Medical and Quality Officer Robert Reid, MD, PhD – Group Health, Associate Medical Director for Research Translation Amy Compton-Phillips, MD – The Permanente Federation, Associate Executive Director, Quality T.R. Levin, MD, Clinical Lead, Colorectal Cancer Screening, Physician Site Leader, Gastroenterology, Walnut Creek CA Joanne Schottinger, MD, Medical oncologist SCPMG, Care Management Institute Cancer Lead for Medical Oncology Steven Connelly, MD, CMO Care Delivery Systems, HealthPartners Patrick Courneya, MD – Executive Vice President & Chief Medical Officer, Kaiser Foundation Hospitals and Health Plan

MEETING SCHEDULE

Webinar or conference call quarterly

Two in-person meetings (Oakland) over the 18 month contract (summer 2014, fall 2015)

SPECIFIC GOALS FOR COUNCIL

1. For the first 6 months, develop a way to elicit research questions from key clinical leaders for each of the Cohorts. The Clinician Engagement and Patient Engagement Councils will have a joint meeting about the research questions proposed for consideration by each group.
2. Interact with the Operational Engagement Council on issues around imbedding research, particularly pragmatic trials, into care delivery and taking successful interventions to scale
3. Provide perspective on various patient outcomes, emphasizing potential utility in care delivery
4. Serve as advisors to the PORTAL leadership around effective partnering with clinicians across the participating organizations

COMMUNICATION AND MANAGEMENT

Chair	• Lead Council and provide overall direction • Lead meetings and calls • Report progress and issues to PORTAL leaders • Serve as representative to the PORTAL Governance Core • Convene ad hoc working groups of its members and other organizational experts, as needed
Co-Chair(s)	• Assist the Chair with overall leadership • Actively participate in decisions and contribute to deliverables • Attend Council meetings and calls, lead selected calls
Team Members	• Attend Council calls and meetings • Actively participate in decisions and contribute to deliverables • Raise issues with Council chair • Participate in ad hoc working groups, as requested • Identify other clinicians who should be engaged in specific tasks

STAFFING

Donna Woo (KPSC; project manager for Beth McGlynn and for the Obesity Cohort leader, Debbie Young) will provide primary staffing for the Council under the direction of Beth McGlynn.

Appendix E: Process for PI Selection

(approved 12/9/2014)

Process for PI selection

This process establishes two key criteria for PI selection for PORTAL Network studies:

3) Expertise – the PORTAL Network aims to identify the PI with the optimal chance of succeeding in obtaining funding
4) Balance – the PORTAL Network seeks to offer leadership opportunities to investigators from a range of sites. The PI and Co-PI will give special consideration to the capabilities of the proposed lead center/site; and to proposed plans for how the network's assets, both intellectual and data, will be used both within and following the project.

There are two processes: one for disseminating opportunities to find collaborators, and another for selecting the PI for a PORTAL-branded application (when there are multiple investigators interested in the PI role).

Disseminating opportunities

I. General process for disseminating opportunities:
   a. PCORI RFAs related to PCORnet-specific opportunities will be routinely distributed to all Steering Committee members for local distribution to their faculty.
   b. For each PCORnet-specific RFA, the PI and Co-PI will establish a due date for expressing interest in (a) leading a response and (b) collaborating in a response.

II. Similarly, if PORTAL is approached by another network to develop and/or participate in a PCORnet application, the request will be circulated to the Steering Committee for local distribution and identification of interested PORTAL PIs.

Leadership selection when competing for leadership on a single application submitted on behalf of PORTAL

I. The process seeks to allow investigators to express interest in leading and to gather appropriate input from the sites potentially involved. For each PCORnet RFA:
   a. An open call for a leader will be announced and a conference call scheduled to discuss the opportunity. Any PI who is associated with a research center in the PORTAL network may declare their interest or be nominated.
   b. The Steering Committee will review the nominees and make a recommendation to the PORTAL Network PI and Co-PI. In parallel, Steering Committee members will be expected to indicate whether their site plans to collaborate.
   c. The PI and Co-PI will make the final choice of candidate based on the criteria above.

Appendix F: Standards for Data Exchange and Quality Assurance (QA)

Data Exchange, both among PORTAL sites and between the PORTAL network, other PCORnet networks, and non-PCORnet data partners require both syntactic (structure) and semantic (meaning) harmonization. Within PORTAL, the PCORnet CDM satisfies both requirements. For sharing data between multiple networks, mappings between common data models can be constructed to provide syntactic harmonization. But semantic harmonization can be difficult if two networks use different terms, coding systems, and data definitions. While not a complete solution to full semantic harmonization, the use of widely adopted national and international coding systems as data elements and values in a data model can significantly reduce the barriers to information exchanged due to semantic differences across networks.

Internal (within PORTAL) Data Sharing

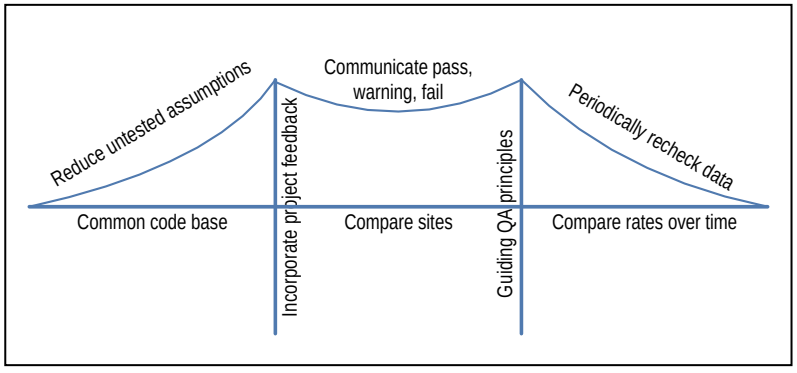
The PCORnet CDM contains all of the terminologies specified in the Meaningful Use Stage 2 regulations (http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html) except for SNOMED CT. As the 10 operational EHRs and other clinical systems at PORTAL sites transition to these new coding systems, our data extracts into the PCORnet data model will begin to receive data elements encoded in these new terminologies. Because the current PCORnet CDM has the ability to record data in multiple coding standards (e.g., diagnosis in both ICD and SNOMED-CT), adding SNOMED-CT codes will not require changes to the data model structure and will permit the co-existence of legacy data in legacy coding systems in addition to data captured using newer coding systems in operational EHRs.

External Data Sharing

As a member of the national PCORnet, the PORTAL Data Core will periodically map elements in the CESR CDM into the current PCORnet Common Data Model when new versions of the data model, detailed specifications, and data element definitions are updated.

Over the past 20 years, the HCSRN has developed extensive policies, procedures, and technologies for evaluating and investigating data validation, quality, and consistency. These will be incorporated into the PORTAL network data operational structure. Bauck et al. developed a conceptual model for a consistent Data Quality Assessment (DQA) framework (see Figure 1) that is being implemented across the HCSRN/CESR sites. These activities illustrate the attention to data consistency and quality by PORTAL sites.

Figure 1. Multiple components in a multi-institutional data quality and validation program by Bauck et al.



The PORTAL network will implement and extend the existing DQA methods. Figure 2 provides examples from the current library of data quality and validation macros that already are available to PORTAL. We will use the

current CESR DQA library and add new methods relevant to the PORTAL Cohorts and their data elements, create new data visualizations to display key data quality features, and make these tools and their documentation available to the PCORI CDRN community for adoption into their DQA processes. Figure 2 is a sample of some data quality assessment procedures implemented for CESR CDM. Similar data quality procedures will be followed in PORTAL.

Figure 2. Representative data quality assessment procedures implemented for CESR CDM.

Macro	Description
CESR_Exp_Frequency	Computes frequencies of all variable values
CESR_TLC_DatasetExist	Verifies that dataset exists and can be referenced with agreed on naming
CESR_TLC_Refresh	Identifies the date a dataset was last modified
CESR_VLC_Category	Identifies unexpected and expected values for categorical variables
CESR_VLC_Frequency	CESR_VLC_Frequency
CESR_VLC_IncludePHI	Determines if string variable contains values from a PHI variable
CESR_VLC_Linkage	Verifies that variable values are found in reference table
CESR_VLC_Missing	Determines frequency of missing values for one variable
CESR_VLC_Obsolete	Determines if obsolete values are present in a variable
CESR_VLC_Trend	Computes the change in the number of records across rolling consecutive time periods
CESR_VLC_Uniqueness_SV	Checks that one variable contains only unique values
CESR_VLC_Uniqueness_MV	Checks that a key defined by multiple variables is unique in dataset
CESR_VLC_VarExist	Verifies that variable exists in dataset
CESR_VLC_VarNotExist	Verifies that variable does not exist in dataset
CESR_Age	Computes age as a whole number
CESR_HideLowCount	Sets counts < &lowest_count. to 0

TLC is Table Level Check, VLC is Variable Level Check

A. Participation and Expected Response time: The time necessary to process a PCORnet query may vary based on the complexity of the query and the need for IRB review, among other factors. Each PORTAL site will review a query request and can either opt out or run and submit their query results via the PCORnet query tool to the PORTAL DCC for review. The DCC then will review, approve and upload the aggregated results to PCORnet. See data sharing matrix.
B. Standards for Data Refreshes: PORTAL sites will be expected to refresh the PCORnet CDM according to the PCORnet standards. Phase II will implement a bi-annual refresh in the first two years followed by a quarterly refresh in the last year. Each refresh will include a QA program that will be sent out by the PORTAL DCC.
C. Standards for Data Retention: PORTAL will follow the PCORnet standards for retention. The PCORnet approved data will remain locked until the next refresh. The current PCORnet standard is that they require sites to maintain access to the prior refresh to enable DSSNI to go back to the prior version if an error is identified after CDM approval. The data can be archived/zipped, it just needs to be available if needed.

Appendix G: PopMedNet™ Security Specifications

The PopMedNet™ (PMN) software system has undergone third-party security audit and passed a Harvard Pilgrim Health Care security audit and penetration test. As new software versions are released, Lincoln Peak Partners (LPP), the software developers of PMN, performs security testing and audits (https://popmednet.atlassian.net/wiki/display/DOC/PopMedNet+Security+Audit) as does Harvard Pilgrim. PORTAL leadership or KPNW DCC members can request copies of the most recent security testing results from LPP or Harvard Pilgrim at any time and share these results with PORTAL DCC and any requesting PORTAL data partner.

All communications between the PMN DataMart Client application and the PMN portal use HTTP/SSL/TLS connections to securely transfer queries and results between the application and the portal. Once results are uploaded, they are hosted in a FISMA compliant data center.
The following list contains major system security governance specifications of the PMN system:

- Enhanced system procedures
    - Securely store credentials as Salted Hashes
    - Use cryptographically secure random values for session IDs (.Net Type 4 GUID)
    - Cookies marked as 'SECURE', 'SESSION' & 'HTTPONLY' and the cookie domain
- Transmission between PMN Portal and PMN Data Mart Client
    - Require/force Secure Socket layer (SSL) for all communications
    - Enable strongest cipher suites and Transport Layer Security (TLS) versions
- Web Service and Portal Authorization
    - Ensure all submissions are performed via POST method
    - Do not publish WSDL
    - Limit the number and size of file submissions
- Users are required to select strong passwords with the following rules: at least 8 characters, maximum length of 100, at least 1 number, at least one nonnumeric character, at least one capital letter, at least one lower case letter, and at least one special character.
- The system will force users to change their passwords every six months.
- A user's last five passwords cannot be re-used.
- The system will automatically log users off after thirty minutes of inactivity.
- The system will automatically delete all query results after one year.
- The system will automatically delete file transfers after 21 days.
- The system will backup files or deleted queries on the disaster recovery database for 4 days and will automatically delete on day 5.
- Site Network Administrators will verify user identities and email addresses before approving or creating new user accounts.
- Users must use corporate email addressed for network communication.
- Only Site Network Administrator shall modify user email from user administration page on the portal.
- The system will audit all network activity (e.g., access, user ID changes, query initiation, results upload, etc.) and will regularly review audit logs to look for inappropriate system use.
- Antivirus software will run regularly on all system servers.
- DataMart Administrators will be able to create audit logs of all activity related to their DataMart.

Appendix H: Analytic Plan Procedures (PORTAL APP)

Analytic Plan Procedure (APP) for Participating Sites

This Analytic Plan Procedure (APP) describes the general framework for sites to submit SAS® programs that operate on the PORTAL Network and provides expectations for resource use within PORTAL.

Definitions:

Cohorts: Three cohorts are being developed and analyzed in the PORTAL Network: Colorectal Cancer (CRC); adolescents and adults with severe Congenital Heart Disease (CHD); and adults who are overweight or obese, including those who have pre-diabetes or diabetes. Not all sites participate in all cohorts.

Common Data Model (CDM): The PCORnet Common Data Model (CDM) is a data structure that standardizes administrative and clinical information across PCORnet partners. Participation by the network partners in the creation, implementation, updating, maintenance, enhancement, and use of the CDM will be in accordance with guiding principles developed by the PCORnet Governance and Collaboration Task Force.

Data Coordinating Center (DCC) Lead Site: Kaiser Permanente Northwest (KPNW).

Data Coordinating Center Lead programmer: the DCC lead programmer is responsible for developing, testing and distributing SAS® programs and work plans for the development of the Common Data Model (CDM) and for all Quality Assurance (QA) programs for the CDM.

Lead cohort programmer: Working closely with the lead Investigator, the lead programmer is responsible for developing, testing, beta-testing (with the help of a participating site), and distributing a SAS® program and Work Plan for approved analyses. The lead programmer is also responsible for coordinating and consolidating results returned from a Work Plan as needed.

Participating programmer: Programmer at a participating PORTAL site who executes a SAS® program and Work Plan for approved analyses.

PORTAL Lead Site: Kaiser Permanente Northern California (KPNC).

Participating PORTAL Sites: All health care organizations and collaborators with investigators funded to contribute to the PORTAL Network that have signed the PORTAL data use agreement (DUA) and contribute data to the PORTAL Common Data Model and/or Cohorts. All participating PORTAL contribute data to refreshes and cohort projects.

Site SFT Location: Secure File Transfer site (or other secure site) for which access to data is granted to a single site.

Framework when SAS® Programs are submitted:

1. SAS® programs and Work Plans for cohort tasks will be written by the Site leading the PORTAL cohort activity. The DCC lead programmer writes the SAS® programs and Work Plans for all central PCORnet Common Data Model (CDM) and Quality Assurance (QA) tasks.
2. The Cohort PI or lead programmer from the site leading the activity should send a timeline to the DCC Lead Site Technical Research Program Manager: Reesa Laws at Reesa.Laws@kpchr.org with expected dates for site data requests. The DCC will contact the requestor if dates need to be altered to accommodate multiple requests. The Site writing the SAS® program will initiate the data request after it is beta-tested at the originating site and one additional site that agrees to test it.
3. All SAS® programs and Work Plans are expected to use the following naming convention: PORTAL_(insert requesting cohort group identifier such as: CDM, CRC, CHD, WT)_WP#_VersionDate (year_mo_day). For example: PORTAL_CRC_ETL_WP01V01.doc or PORTAL_CRC_QA_WP01V01.doc
4. Once the SAS® program and Work Plan have been written and tested, the site leading the activity is responsible for distributing the SAS® program and Work Plan to Participating Sites via the PORTAL internal project website. Work plans related to the CDM will be posted under the Data Core/_CDM. Work plans related to cohorts will be posted under Data Core/_Cohort Work plans and Documents/*Cohort name*. The Work Plan, the programs and all documentation should be contained in a zip file and posted to the appropriate folder on the PORTAL website.
5. In general, participating sites will be given at least two weeks to complete a Work Plan request. If the participating Site cannot meet the deadline requested, it is that Site's responsibility to contact the PI, Programmer, and Project Manager at the site leading the activity to arrange a new due date.
6. The Lead Site will notify Participating Sites and DCC before distributing a program. The notification utilizes the standard Work Plan format and provides relevant information such as the name of the core study, CDM building/refresh, or other analysis, the name and number of the Work Plan, a description of the objectives of the program, any potential issues or program specific issues, the deadline, contact information for the lead programmer, lead investigator, lead project manager, the PORTAL website link to the zip file containing all the Work Plan, programs and documentation and other relevant information.

   An example of a completed Work Plan from the CESR network is included as Attachment A. This document is intended to assist the programmer in determining what is to be included in a Standard Work Plan.
7. The Standard Work Plan document is written by the lead programmer and contains a summary of the information the output of the program is expected to return, and lists where the program needs to be edited when it calls CDM/VDW files. If applicable and if there are multiple programs, the Standard Work Plan should specify the order in which the programs are to be run. A completed Standard Work Plan document is expected to accompany all PORTAL SAS® program requests (see attachment A). All Work Plans, Programs, and Documentation should be zipped and posted to the PORTAL project website. The email request should contain the link to the website with an alert that everything has been posted.

8. SAS® programs will only be submitted after approval of the study activity by the Steering Committee and Cohort leads as per the PORTAL Publication, Presentation, and Proposed Studies Policy.
9. Work Plans and SAS® programs will be sent only to sites participating in the activity.
    a. For CDM refreshes, SAS® programs will be sent to all 11 participating health care organizations. All Work Plans related to the CDM will be distributed by the DCC.
    b. For cohort studies, the Lead Site programmer must document the sites participating in the cohort activity prior to distributing the SAS® programs so that only participating sites in the various cohort activities receive the programs.
10. SAS® programs will be sent only to designated PORTAL programmers/analysts at sites participating in the activity.
    a. The list of designated PORTAL programmers/analysts for each PORTAL site is to be maintained at both the DCC (KPNW) and the PORTAL Lead Site (KPNC) and updated quarterly.
    b. The PORTAL programmer/analyst list will be provided to any site leading a specific activity.
    c. When programmers/analysts change at any participating PORTAL site, both the DCC, Lead Site and PORTAL Lead Site should be immediately notified so that the list of designated PORTAL programmer/analysts is current.
11. To help avoid the possibility of sharing Protected Health Information (PHI), when developing the Work Plan, the lead programmer should:
    a. Use “keep” statements to ensure only the necessary variables are included in the output.
    b. Remove or comment out all “proc print” statements in the final version of the program.
    c. Perform a “proc contents” before opening sites’ data files.
    d. Use of local and share folders to avoid sending files that might contain PHI. Each site is responsible for verifying contents of these folders before sending the results back.
12. The following folders should be created and included in the zip file for all programmers who will be running distributed code:
    a. **DOCUMENT** – This folder contains the Work Plan, current data dictionary, data models, and effort documents.
    b. **DRAFT_VDW_TABLE** – After a successful program run, the folder will contain the datasets created for the VDW (if needed). Contents of this folder will not be shared with the requesting site.
    c. **INPUT** – This folder contains SAS® programs that are included in the main program and the following:
        - List programs
    d. **SAS** – This folder contains the program to be run. After a successful program run, the folder will still contain the program. If run in batch mode, it may also contain the first part of the log.

e. LOCAL_ONLY – This folder is sent empty. After a successful program run, the folder will contain the following: Contents of this file will not be shared with the requesting site.

- Log and list files

f. SHARE – This folder is sent empty. After a successful run, it will contain files to be returned as indicated in this document. This may include SAS® datasets, SAS® program lis files (reports), and effort tracking documentation.

13. Once the Participating Site programmer has completed running the requested SAS® programs, the programmer should review the output for errors and conduct within-site data quality checks (QC) prior to routing the SAS® output elsewhere. Whenever possible, QC should be incorporated directly into main SAS® programs. This approach requires investigator input up front to identify plausible, unlikely, impossible results (e.g., how the flags/variables relate). Internal site data QC should include a year-by-year descriptive review of variables, range checking, and other rudimentary checks (e.g., encounter type), that is standardized across Sites. The DCC will write a standard QC program to be routinely used for PORTAL CDM data requests. The lead cohort programmer is responsible for writing QC checks for all cohort specific programs. This standard QC program represents just one level of QC, however. Two additional levels of QC are required:
    a. Within-site QC -- activities/support from individual Site programmers is required
    b. QC necessary for specific analytic plans--QC leadership/support from Lead Site programmers is required.
14. Any problems with or questions about distributed SAS® programs should be addressed to the lead programmer listed on the Work Plan. Although most questions will be resolved through this communication, the DCC will assist if requested by the Lead Programmer for the activity and/or the Participating Site programmer.
15. After reviewing the output for quality issues and after checking the Work Plan to confirm which SAS® data files should be transferred, the participating programmer will route SAS data files, etc. to the lead programmer/analyst listed on the Work Plan.
    a. Participating programmer/analyst will post SAS® data files, etc. to the PORTAL SFT website, which is managed by the KPNW DCC and only after HIPAA concerns have been addressed. Participating programmers should do a “proc contents” to make sure only the required data fields are included and returned to the requesting site. He or She should check that the program did not produce PHI such as medical record numbers within log and output files. At the very least, “Proc Print” statements should be removed or commented out to reduce the chance of any PHI inadvertently being uploaded to the secure web site. If time and resources allow, sites might consider having another programmer double-check results that no PHI was generated before uploading results files. Code can – and generally should -- be written to mask cell sizes less than 6 by writing data frequencies to temporary SAS® files and then printing out after editing/censoring to remove small cell sizes. Individual sites are required to comply with their institutions’ policies regarding sharing data with small cell sizes. See item #12 above for a listing of which folders should be returned via the SFT.
    b. When a lead programmer is writing distributed code, files need to be classified as containing MRNs (or whatever may constitute PHI) vs. those that can be uploaded for the project. Then, in SAS®, the lead programmer should define

separate libraries (usually at least 2). One library will be for a folder that will contain files that may be uploaded, and the other folder will be for files that remain at the site since they contain PHI. It also helps to give the library an intuitive name, for example "outkpco" for files that may be uploaded. This reduces the chance that a recipient site will inadvertently grab the wrong files and upload them.

c. Site programmers/analysts should save output for archival and future review at the Site as per PORTAL or site-specific policies for research dataset retention and following instructions on the specific Work Plan.

d. Patient level datasets will generally not be shared across the sites. For example, the creation of the CDM and the QA programs will produce summary information that goes back to the DCC but it will not contain patient level data. However, cohort work plans may require sharing of patient level data if the lead site is conducting cross site analysis. If sharing patient-level data is required, appropriate DUAs must be in place before this can occur. It is the lead cohort's team responsibility to track that all DUA's are in place prior to sending these Work Plans.

e. Alternatively, the Site leading the analysis can conduct the review of individual Site output and merging across Sites.

f. The Lead Programmer from the Lead Site will contact a local Site Programmer if irregularities from the local site need to be addressed.

16. Sites will be identified using a short acronym (e.g., DH, GH, HP, KPCO, KPGA, KPHI, KPMA, KPNC, KPNW, and KPSC).

17. The PORTAL data are based on the HCSRN Virtual Data Warehouse (VDW). Programmers will find useful tips regarding VDW data and writing multi-site SAS® programs that operate on VDW data as well as a VDW Programmers' Guide and VDW standard macros at: http://www.hmoresearchnetwork.org/share/page/site/VDW/documentlibrary#filter=path%7C%2Fdata_documentation%2Fdata_specifications_and_guidelines&page=1

Resource Expectations and Use:

A fundamental principle of PORTAL is that the necessary resources must be available for research activities to be completed successfully. The Lead Investigator should have anticipated and articulated the analytic needs of his/her project at the time the project was proposed (in the PORTAL Publication, Presentation, and Proposed Ancillary Studies Application). In addition, the considerations listed below must be followed to facilitate efficient and timely completion of research activities.

1. Resources for analyses need to be clearly estimated and communicated to the PORTAL Principal Investigators (Beth McGlynn, PhD and Tracy Lieu, MD, MPH) and the DCC (Lead Investigator: Mary Durham, PhD and Technical Research Program Manager: Reesa Laws), as well as to all appropriate personnel across all Sites involved in programming and analysis.

2. The Lead Investigator for the research activity is expected to consult with the DCC (Lead Investigator: Mary Durham, PhD and Technical Research Program Manager: Reesa Laws) regarding programming and analytic resources needed.

    a. This discussion should occur well in advance of the date when the resources are needed.

b. It should include, at a minimum, discussion about data availability, quality, the scope of analytic resources needed, a review of the analytic plan, and a review of the available funding to identify/resolve any mismatch.

c. At the time of the discussion, the Lead Investigator is expected to provide a preliminary list of PORTAL variables needed for the specific analysis.

3. Biostatistician support from John L. Adams, PhD, MS, Research Scientist Biostatistician III, KPSC, is available if needed to assist in finalizing methods and with analysis. John.L.Adams@kp.org.

1.1.1.1.1.1.1 **APPENDIX A: (Example)** CESR_PRO_ETL_201409_V01 (Workplan 06 Version 01)
Date submitted: September 30, 2014

Project Name: CESR PRO (Patient Reported Outcome)

Overall Project Objective: This is an ETL program to create the PRO tables: PRO_TYPES, PRO_SURVEYS, PRO_SURVEY_RESPONSES.

Primary Contact Information		**Other Contacts:**	
Name:	Brenda Ackerson	Name:	Reesa Laws
Institution:	CESR	Institution:	CESR
Phone #:	503-335-6301	Phone #:	503-528-3976 (603976)
Email:	Brenda.B.Ackerson@kpchr.org	Email:	Reesa.Laws@kpchr.org

Programmer(s): Brenda Ackerson, Weiming Hu

Project Stage (feasibility, pilot data, funded, …): Site specialist time to run, review, and customize to match site requirements for the VDW database. Funded by CESR.

Workplan Timeline: Please run by **October 15, 2014**

Workplan Package Zip file:

- CESR_PRO_ETL_201409_V01.ZIP

Files included in Zip file:

- SAS\CESR_PRO_ETL_201409_V01.SAS
- INPUT\CESR_PRO_ETL_STATS_201409_V01.SAS
- INPUT\PRO_INCLUSIONS.SAS7BDAT
- INPUT\PRO_SURVEY_MODES_CROSSWALK.SAS7BDAT
- DOCUMENT \PRO_INCLUSIONS.XLSX
- DOCUMENT \PRO_SURVEY_MODES_CROSSWALK.XLSX
- DOCUMENT\CESR_PRO_ETL_WP06V01.DOC
- DOCUMENT\CESR_PRO_DD_draft_20140915.XLS
- DOCUMENT\CESR_PRO_ERD_20140911.VSD (MS VISIO)
- DOCUMENT\Effort_For_CESR_Request.XLSX
- DOCUMENT\EpicCare_Flowsheets_DataModel.jpg
- DOCUMENT\EpicCare_Questionnaries_DataModel_EditedBy_CESR_DCC.jpg

Number and type of files to be returned from the SHARE folder:

1. PRO_201409_**&_siteabbr.**_Effort.xlsx *
2. PRO_ETL_201409_**&_siteabbr.**_RUN_TIME.SAS7BDAT *
3. PRO_SURVEY_RESPONSE_SUMMARY_**&_siteabbr.**.XLM (Opens with MS Excel, No PHI)
4. PRO_SURVEY_RESPONSES_RETURN__**&_siteabbr.**.SAS7BDAT
5. PRO_SURVEYS_**&_siteabbr.**.SAS7BDAT
6. CESR_PRO_WP06V01_REPORTS_**<DATE>**.RTF

IMPORTANT: Uses 4 character site abbreviations for importing purposes. Otherwise, import programs fail.

Workplan purpose:
This program builds the initial tables for PRO: PRO_TYPES, PRO_SURVEYS, PRO_SURVEY_RESPONSES and executes the CESR_PRO_ETL_STATS_201409_V01.SAS program to create frequency reports on the PRO_SURVEYS and PRO_SURVEY_RESPONSES tables. This ETL is designed to extract data from Epic/Clarity using tables from the Questionnaires and Flowsheets data models. It currently does not include code for SmartData Element tables.

Storage:

Root – Please determine the location and name of this workplan's root folder. Consider including the date in the folder name, i.e. PRO_ETL_201409_BUILD. After expanding the zip file into the root folder, you will see the following folders:

1. **DOCUMENT –** This folder contains this workplan, current data dictionary, data models, and effort documents.
2. **DRAFT_VDW_TABLE –** After a successful program run, the folder will contain the datasets for each of the PRO tables that match the data dictionary with the exception of the site specific variable/column for encounter id.
3. **INPUT –** This folder contains SAS programs that are %included in the main program and the following:
    - PRO_INCLUSIONS dataset includes all surveys and questions by pro type that are to be included in the PRO_SURVEY and PRO_SURVEY_RESPONSES tables.
    - PRO_SURVEY_MODES_CROSSWALK dataset contains the mapping or crosswalk used to categorize all the various survey modes (i.e. encounter_types & other types) from the source tables.
4. **SAS –** This folder contains the program to be run. After a successful program run, the folder will still contain the program. If run in batch mode, it may also contain the first part of the log.
5. **LOCAL_ONLY** – This folder is sent empty. After a successful program run, the folder will contain the following:
    - CESR_PRO_ETL_V01_&_siteabbr..log
    - CESR_PRO_ETL_V01_&_siteabbr..lst
6. **SHARE** – This folder is sent empty. After a successful run, it will contain files to be returned as indicated in this document.

Program Dependencies:

Clarity Questionnaire Tables: (See EpicCare_Questionnaires_DataModel)

- CL_QFORM
- CL_QQUEST
- CL_QQUEST_OVTM
- CL_QANWSER
- CL_QANWSER_QA
- MYC_MESG
- MYC_MESG_QUESR
- MYC_MESG_QUESR_ANS

Clarity Flowsheet Tables: (See EpicCare_Flowsheets_DataModel)

- IP_FLO_GP_DATA
- IP_FLO_MEASURE
- IP_FLWSHT_MEAS
- IP_FLWSHT_REC
- PAT_ENC

Other Clarity tables used in the code not listed or missing from the EpicCare Data Models:

- IDENTITY_ID

- PAT_ENC_QUESR
- ZC_MYC_MSG_TYP
- IP_DATA_STORE
- IP_FLO_DESCRIPTION
- ZC_DISP_ENC_TYPE

Other Files:

- stdvars.sas

Running this workplan:

Program Edit Section: The workplan program has a clearly marked edit section near the top of the program. Please complete the following edits as directed by comments and examples in the program:

1. Edit the path to the Standard Variables program, i.e. StdVars.sas.
2. Edit the root location into which the ZIP file was extracted.
3. Edit the Identity_ID.Idenitity_Type that refers to the patient MRN without the hyphen
4. Edit the user login and password path and file.
5. Edit the data connection to Epic/Clarity.
6. Edit the ushare libname and macro variable.

Additional Program Edits:

- If your site does not use the health plan MRN extracted from Clarity as the VDW MRN, it is required that you modify the code to use VDW-compatible MRN values for MRN in the PRO_SURVEY_RESPONSES table. These must link to MRN in the VDW Demographic file. There are 3 areas of the code that will need edited under the section called: **EXTRACT DATA FROM EPIC/CLARITY.**
    - QUESTIONNAIRES - CLARITY FORMS - SURVEY RESPONSE DATA
    - QUESTIONNAIRES - MY CHART - SURVEY RESPONSE DATA
    - EVS FLOWSHEET - SURVEY RESPONSE DATA
- Please create ENC_ID, containing VDW linkable encounter IDs, in the PRO_SURVEY_RESPONSES table. If you are unable to edit and map the VDW encounter ID, create it but leave empty (null).
    - Do not remove **kp_pat_enc_csn_id**
- Review the log for errors and warnings. If there are problems and if you opt to send a log to the DCC, ensure the log is redacted of PHI and any site specific information that your site does not want released.
- Please note that depending on the operating system and submission method you may receive the following message(s): (NOTE: There should be NO warnings.)
    - **NONE**
- Please review the document in the SHARE folder called: CESR_PRO_WP06V01_REPORTS_**<DATE>**.RTF. This is a lengthy report produced by the CESR_PRO_ETL_STATS_201409_V01.SAS program that provides basic analysis of the response data for your resource who is participating in the PRO Workgroup.

- After the program has run successfully, review the draft VDW tables to verify that they match the current data dictionary.

- **ACTION REQUIRED**: Verify that there is NO PHI in the SHARE folder.

- **IMPORTANT**: The data in the PRO_INCLUSIONS and PRO_SURVEY_MODES_CROSSWALK files in the DOCUMENT and INPUT folder will need to be reviewed and edited on an annual basis and updated as needed.

- **IMPORTANT**: This program creates a temporary table to an alternate Epic/Clarity database that contains user tables and views. Please edit the libname ushare and %let clarityushare statements in the Edit section to go to the location of your user tables for Epic. The SCHEMA= option enables you to view or modify a different user's DBMS tables or views, assuming that you have the requisite Teradata privileges to that user's tables and views.

Next Steps:

- Zip the following files in the **SHARE** folder:

    - PRO_201409**_&_siteabbr.**_Effort.xlsx *
    - PRO_ETL_201409**_&_siteabbr.**_RUN_TIME.SAS7BDAT *
    - PRO_SURVEY_RESPONSES_SUMMARY__**&_siteabbr.**.XLM (No PHI)
    - PRO_SURVEY_RESPONSES_RETURN__**&_siteabbr.**.SAS7BDAT (No PHI)
    - PRO_SURVEYS_**&_siteabbr.**.SAS7BDAT
    - CESR_PRO_WP06V01_REPORTS_**<DATE>**.RTF

  IMPORTANT: Please use 4 character site abbreviations on these files. Otherwise, it causes import issues.

- Name the zip file **CESR_PRO_ETL_WP06V01_<SITE>.zip**

- Upload the zip file to the new CHR Secure File Transfer Site and select Brenda Ackerson and Weiming Hu (or if neither are available on your list, select Reesa Laws) as the Recipients:

    - https://sft.kpchr.org

- Please let the DCC know that your region has completed this workplan by emailing all: Brenda.B.Ackerson@kpchr.org, Weiming.R.Hu@kpchr.org and Reesa.Laws@kpchr.org.

APPENDIX I: PORTAL Data Sharing Matrix (what data can we share and with whom) (ver. date: 2015 02 25)

Institution Type / Data Type	1. External researchers/other CDRNs	2. PORTAL to PCORnet (query tool requests)	3. Within PORTAL network (site to site)
A. Datasets, Patient Level (includes non-LDS PHI)	Data sharing agreement needed	Data sharing agreement needed	Data sharing agreement needed
B. Datasets, LDS	DUA needed	DUA needed	DUA or other data sharing agreement (KP to KP and between PORTAL sites and DCC) needed
C. Datasets, De-identified (meet HIPAA definition of de-identified" see below)	Agreements may be needed – varies by institution	Sites confirm de-identification meets HIPAA requirements before data uploaded	Sites confirm de-identification meets HIPAA requirements before data are shared
D. Aggregate Summary Data Tables (meet HIPAA definition of de-identified, see below)	Agreements may be needed – varies by institution	• Individual sites review queries and opt out or run queries and return to PORTAL DCC • PORTAL DCC reviews and approves site-level results and uploads to PCORnet	• Pre-approved by PORTAL SC* • Sites informed of request and purpose of shared data is recorded
E. TBD - Aggregate Summary Data Tables (meet HIPAA definition of de-identified, see below)	Would be pre-approved by PORTAL SC (not individual site approval)**	Would be pre-approved by PORTAL SC (not individual site approval)**	Would be pre-approved by PORTAL SC (not individual site approval)**

LDS = Limited Data Set
PHI = Protected Health Information
DUA = Data Use Agreement—required by HIPAA
DUSA = Data Use Sharing Agreement (data transfers between KP regions)
SC = Steering Committee
*Request pre-approval by PORTAL SC as needed for ETL (Extraction, Transformation, Load) and cohort requests
**Tables TBD - PORTAL SC would discuss and approve the contents of these tables; once developed, these tables would not require individual site approval when shared

Data Sharing Agreement (DSA): A data sharing agreement is a general term for a contract that sets forth the circumstances under which data is transferred between institutions, i.e. Data Provider (the originating institution) to a Data Recipient (another institution) for various purposes including research. When not specifically required by HIPAA regulations, institutions vary on the types of DSAs needed for research or non-research activities. Even though not required by HIPAA regulations, some institutions may require a DSA to share de-identified data sets (contain no PHI), while other institutions do not have this requirement. Further, when a BAA or DUA is not required by HIPAA regulations, covered entities may include data transfer arrangements as part of financial contracts.

Data Use Agreement (DUA): HIPAA Privacy Rule required documentation for disclosure (or sharing) of a Limited Data Sets (LDS). HIPAA regulations define a limited data set as "a combination of information from medical records that constitute protected health information (PHI)."

Data Use and Sharing Agreement (DUSA): All KP regions negotiated a Memorandum of Agreement regarding data sharing between regions. The DUSA is an attachment to that MOA. It provides standard language that all regions have agreed upon. When the data being shared is a limited data set (LDS), the DUSA meets the HIPAA requirement for a DUA. A DUSA is only for KP region to KP region data sharing.

***Protected Health Information (PHI)**: PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

Limited Data Set: According to the HIPAA Privacy Rule, a data set that may be used for research when the data set recipient enters into a Data Use Agreement (DUA) with the site (data owner) providing the data set. A LDS can include dates, limited geographic information, and a link field (e.g., an encrypted identifier), such as:

- Dates (e.g., admission, discharge, and service dates; dates of birth and death) and ages of research participants;
- Certain general geographic information, including five or nine-digit zip codes and state, county, city, and precinct; and
- Links which may be used to identify individuals when the researcher maintains and holds confidential the key required for re-identification.

A LDS must ***exclude*** all other PHI identifiers, such as:

- Names and street or postal addresses;
- Telephone and fax numbers;
- E-mail and Internet Protocol (IP) addresses and web Universal Resource Locators (URL);
- Social Security, medical record, health plan beneficiary, and other account numbers;
- Certificate and license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Biometric identifiers, including finger and voice prints; and
- Full-face photos and any other comparable images.

De-identified Data Set: According to the HIPAA, covered entities may use or disclose health information that is de-identified without restriction under the Privacy Rule. Covered entities seeking to release this health information must determine that the information has been de-identified using either statistical verification of de-identification or by removing certain pieces of information from each record as specified in the Rule. The Privacy Rule allows a covered entity to de-identify data by removing all 18 elements (see below) that could be used to identify the individual or the individual's relatives, employers, or household members. The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, the identifiers that must be removed are the following:

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
    a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
    b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

Appendix J: Data Incident Response Plan

Role descriptions:

PORTAL Data Coordinating Center (DCC) – reviews and approves PCORnet query results before posting to PCORnet PopMedNet™.

Lincoln Peak (LPP) – LPP is the secure data host for PCORnet queries. Once query result data is uploaded to the PCORnet site, the PORTAL data resides on the Lincoln Peak secure servers. For more information about this process see: https://popmednet.atlassian.net/wiki/display/DOC/PopMedNet+System+Administrator%27s+Guide.

KPNC – IRB of record for the PORTAL Common Data Model (CDM) and Congenital Heart Disease (CHD) cohort. The PORTAL DCC is following KPNC policies and procedures for reporting and mitigation.

KPCO – IRB of record for PORTAL Colorectal Cancer (CRC) cohort.

KPSC– IRB of record for PORTAL Obesity cohort.

This section identifies the PORTAL Data Incident Response Plan.

A **data incident** is a situation in which PORTAL study data are released, shared, and/or accessed in a way that is inconsistent with processes approved by the corresponding Institutional Review Board (IRB) of record: KPNC for the CDM and CHD, KPCO for CRC, and KPSC for Obesity) and the PORTAL Reciprocal Data Use Agreement that has been executed by all participating sites.

Should a data incident occur, this Response Plan will be followed along with appropriate mitigative actions to address the incident. All PORTAL Site PIs will be notified, within one business day, by the PORTAL Lead PI, Co-PI, or Lead Project Manager if a data incident occurs, and affected sites will be clearly identified so they can follow their local sites' policies and procedures for reporting and mitigation, if required.

A data incident may occur at a participating PORTAL site, at the PORTAL Data Coordinating Center (DCC) located at Kaiser Permanente Northwest (KPNW), at a cohort lead site performing cohort analyses (KPNC for CHD; KPCO for CRC; or KPSC for Obesity) or at the Lincoln Peak Partner (LPP) Hub. LPP is the secure data host for PCORnet queries. Once query result data is uploaded to the PCORnet site, the PORTAL data resides on the LPP secure servers. See the PopMedNet website for more information about this process: https://popmednet.atlassian.net/wiki/display/DOC/PopMedNet+System+Administrator%27s+Guide.

1. **For data incidents occurring at a participating PORTAL site**:

   a. A PORTAL site programmer (programmer) based at PORTAL participating site is responsible for executing all query requests sent to the DCC within the scope of a PORTAL activity. Queries will be sent through PopMedNet™ (PMN) or through a method external to the query infrastructure. PORTAL programmers have accountability for the dissemination of any data shared by their site within the PORTAL study. Programmers are required to review all SAS programs, as well as resulting log files, from any SAS queries. If a data incident occurs at a participating site, the Site PI will follow all applicable local policies and procedures for reporting and mitigation of the data incident (i.e., notifying their institution's Privacy Officer, local IRB, and other institutional officials as appropriate).

   b. **If the incident concerns the CDM**, after notifying their local IRB, privacy officer or others as required, the Site PI will, within one business day, notify the PORTAL PI and Co-PI of the data incident issue and any mitigative actions taken at their institution including the final resolution of the data incident. The PORTAL PI and Co-PI will be responsible for reporting, according to the time line required by that KPNC IRB the data incident with all relevant information, and within one business day, to PIs. The report will include an evaluation of the nature of the data incident (i.e. isolated issue or a system issue). A Corrective and Preventative Action (CAPA) plan may be required by the IRB.

   c. **If the incident concerns cohort work**[1], after notifying their local IRB, privacy officer or others as required, the Site PI will, within one business day, notify the Cohort Lead PI of the data incident issue and any mitigative actions taken at their institution including the final resolution of the data incident. The Cohort Lead PI will be responsible for reporting the data incident with all relevant information to the IRB of record (KPNC for CHD, KPCO for CRC, and KPSC for Obesity) according to the time line required by that IRB and to PORTAL Site PIs within one business day. The report will include an evaluation of the nature of the data incident (i.e. isolated issue or a system issue). A CAPA plan may be required by the IRB.

   d. The PORTAL PI, Co-PI, Cohort Lead PI, or Lead Project Manager will then inform all Site PIs, as soon as it is available, the final resolution of the issue.

   e. Depending on the severity of the data incident (as determined by the PORTAL PI and Co-PI in consultation with the KPNC Privacy Officer or others as required), procedures implemented can range from communication/education in the case of a low risk incident; up to contacting LPP to shut down the PORTAL instance of PopMedNet™ in the case of a request that was submitted through PopMedNet™ and resulted in a very high-risk incident (i.e., fully-identified datasets).

[1] For data incidents occurring at any of the lead cohort sites (KPNC for CHD; KPCO for CRC; or KPSC for Obesity) that involve multi-site data, see Section 3 below.

2. **For data incidents occurring at the PORTAL KPNW DCC**:

   a. The staff from the KPNW DCC will, within one business day, inform the PORTAL PI and Co-PI of the issue and provide all relevant information. All applicable KPNC regional policies and procedures will be followed for the reporting and mitigation of the issue (i.e. notifying the Privacy Officer, the KPNC IRB, and other institutional officials as required). This report should include an evaluation by the PORTAL PI and Co-PI on the nature of the data incident (i.e., isolated issue or a systemic issue). A CAPA plan may be required by the IRB.

   b. The PORTAL PI, Co-PI, or Lead Project Manager will, within one business day, inform all Site PIs about the incident and plans for mitigative actions. The site or sites whose data was involved should follow their institutional policies and procedures for reporting data incidents.

   c. The PORTAL PI, Co-PI, or Lead Project Manager will then inform all Site PIs, as soon as it is available, the final resolution of the issue.

   d. Depending on the severity of the data incident (as determined by the PORTAL PI and Co-PI in consultation with the KPNC Privacy Officer or others as required), procedures implemented can range from communication/education in the case of a low-risk incident; up to contacting LPP to shut down the PORTAL instance of PopMedNet™ in the case of a request that was submitted through PopMedNet™ and resulted in a very high-risk incident (i.e., fully-identified datasets).

3. **For data incidents occurring at any of the lead cohort sites (KPNC for CHD; KPCO for CRC; or KPSC for Obesity) that involve multi-site data**:

   a. Cohort Lead PIs from KPNC, KPCO, or KPSC will, within one business day, inform the PORTAL PI and Co-PI of the issue and provide all relevant information. All applicable local site policies and procedures will be followed for the reporting and mitigation of the issue (i.e. notifying the site's IRB, Privacy Officer and/or other institutional officials as required) to the IRB of record (KPNC for CHD, KPCO for CRC, and KPSC for Obesity). This report should include an evaluation by the Cohort Lead PI on the nature of the data incident (i.e. isolated issue or a systemic issue). A CAPA plan may be required by the IRB.

   b. The PORTAL PI, Co-PI, or Lead Project Manager will, within one business day, inform all affected Site PIs about the incident and plans for mitigative actions. The site or sites whose data was involved should follow their institutional policies and procedures for reporting data issues.

   c. The PORTAL PI, Co-PI, or Lead Project Manager, will then inform all Site PIs, as soon as it is available, the final resolution of the issue.

d. Depending on the severity of the data incident (as determined by the PORTAL PI and Co-PI in consultation with the KPNC Privacy Officer or others as required), procedures implemented can range from communication/education in the case of a low-risk incident; up to contacting LPP to shut down the PORTAL instance of PopMedNet in the case of a request that was submitted through PopMedNet and resulted in a very high-risk incident (i.e., fully-identified datasets).

4. **For data incidents occurring at the LPP Hub**:

   a. LPP will **IMMEDIATELY** shut down the LPP site for the PORTAL instance of PopMedNet™.

   b. The staff from the LPP will, within one business day, inform the PORTAL PI, Co-PI(s), site PIs, and KPNW DCC of the issue and provide all relevant information. The participating sites should follow their institutional policies and procedures for reporting data issues.

   c. LPP will provide to the PORTAL leadership and KPNW DCC a full investigative analysis in writing.

   d. All applicable KPNC regional policies and procedures will be followed for the reporting and mitigation of the issue (i.e. notifying the Privacy Officer, the KPNC IRB, and other institutional officials). This report should include an evaluation by the PORTAL PI and Co-PI on the nature of the data incident (i.e. isolated issue or a systemic issue).

   e. The PORTAL PI, Co-PI, or Lead Project Manager will then inform all Site PIs, as soon as it is available, the final resolution of the issue. The PORTAL leadership will share any investigative findings/reports provided by LPP so that local security resources can evaluate and make their own determination about the nature of the incident.

   f. Depending on the severity of the data incident (as determined by the PORTAL PI and Co-PI in consultation with the KPNC Privacy Officer or others as required), procedures implemented can range from communication/education in the case of a low-risk incident; up to contacting LPP to shut down the PORTAL instance of PopMedNet™ in the case of a request that was submitted through PopMedNet™ and resulted in a very high-risk incident (i.e., fully-identified datasets).

   g. If LPP is required to shut down the PORTAL instance of PMN, the PORTAL site will not resume until the PORTAL PI or Co-PI sends explicit written approval.

Appendix K: PORTAL Publications and Presentations Policy

(v2 approved 7/14/15)

PORTAL Publications and Presentations Guidelines

These guidelines are adapted from the three research networks that include Patient Outcomes Research to Advance Learning (PORTAL) Network data partners and investigators: the Cancer Research Network, the Cardiovascular Research Network, and the Surveillance, Prevention, and Management of Diabetes Mellitus Network.

Purpose:
The goal of these guidelines is to foster a high volume of high quality scientific publications and presentations. Another goal is to notify the PORTAL Network about the intent to submit a manuscript or develop a presentation to coordinate efforts and avoid duplication. Lead authors should complete the "Publications and Presentations Submission Request" form (see Appendix B) as early in the process as possible. The Publications Committee (PC) commits to responding to requests within 10 business days.

Types of documents these guidelines address:
Manuscripts. Any papers developed from the PORTAL project, including cohort (Congenital Heart Disease, Colorectal Cancer, and Obesity) and council (Clinician Engagement, Operational Engagement, and Patient Engagement) efforts that are intended for publication.

Presentations. Presentations of PORTAL work at professional meetings should be undertaken with the long-term goal of publishing the content presented. Presentations should be developed by writing groups using the guidelines described here.

Responsibilities:
These guidelines outline the roles and responsibilities for the PORTAL Team including the Publications Committee (PC), PORTAL co PIs, Steering Committee (SC), lead authors and co-authors.

PORTAL Publications Committee (PC):

- The PORTAL SC determines the make-up of the PORTAL PC. Members of the PC include: one patient, the PORTAL Co-PIs, and three Site PIs.
- The PC proactively encourages the quantity and quality of publications, provides an overall approach to publications and presentations, and facilitates and resolves disputes, if necessary.
- The PC meets (via email or conference call) when requests are made. The PC commits to responding to the requestor within 10 business days.
- The PC will review final versions of manuscripts and presentations within 5 business days of receipt.

PORTAL Co-Principal Investigators:

- To the extent possible, identify opportunities for interested investigators to take the lead on manuscripts.
- Encourage the appropriate representation of investigators across PORTAL sites on scientific papers.
- Encourage junior-level investigators to participate on writing groups and lead wherever possible.
- Find experienced mentors to assist junior-level investigators leading writing groups.
- Regularly monitor and report status of all manuscripts being planned or in progress to the SC and PCORI (if required).

Lead Author

The lead author has overall responsibility for organizing the writing group and completing the manuscript in a reasonable amount of time. Lead authors agree to:

- Prepare and submit the publications/presentations template (Appendix B) for review by the PC on behalf of his/her writing group as early in the writing process as possible.
- Extend a co-authorship invitation to Site PIs from all data contributing sites. All participating sites may be represented by at least one co-author (the Site PI or their designee), assuming that this individual meets all criteria for authorship in the PORTAL authorship policy and International Committee of Medical Journal Editors (ICMJE) guidelines, and that inclusion of data from co-authors' sites are approved by them.
- Inform the PI and SC about the progress of the writing group.
- Manage communications for the writing group.
- Identify an appropriate mechanism for sharing drafts and using it consistently.
- Write a detailed outline of the paper or presentation.
- Coordinate the development of a written data request (if necessary).
- Coordinate the writing of each section of the manuscript.
- Combine all sections of the manuscript into a completed paper.
- Monitor and resolve controversies in the writing group, documenting subsequent decisions, and discussing these decisions with the other authors.
- Include site data only with explicit approval from the co-author or other representative from the site.
- If an individual or site chooses not to participate in a publication or presentation as an author, and they approve the use of their data in the publication or presentation, that site should be listed in the acknowledgements section of the manuscript.
- Signify "network" authorship (e.g., "on behalf of the Patient Outcomes Research to Advance Learning (PORTAL) Network") when required. If the number of co-authors exceeds the number allowed by some journals, it may be necessary to signify network authorship. The lead author agrees to use this option only when required and, when required, agrees to make every effort to list the members of the writing group who met co-authorship criteria.
- Ensure that co-authorship is warranted, contingent on fulfilling all the responsibilities for authorship defined by ICMJE guidelines.
- Coordinate the final editing and approval of the paper by all authors.
- Determine the order of authorship based on the relative contributions of each co-author.
- Submit the approved manuscript for review by a journal or professional group, and submissions to subsequent journals if necessary.
- Coordinate the response to reviewers.

- Provide reasonable deadlines for each review/revision and promote an understanding among collaborators that these deadlines will be met unless scheduling issues are discussed with lead author prior to a review deadline.
- Submit final version to the PC for review.
- Lead authors who are not part of the PORTAL Network are expected to follow these guidelines.

Site PIs

Site PIs agree to take one of the following actions:

- Accept the invitation to be a co-author and agree to satisfy all requirements of the PORTAL authorship policy;
- Inform the lead author that the invitation will be delegated to another investigator at the site (for example, one who might be better suited due to specific expertise);
- Decline the invitation with a request that their site is mentioned in the acknowledgments; or
- Decline the invitation and decline request to include this site's data in the manuscript.

Co-authors

Co-authors will actively participate in all aspects of the writing process and agree to:

- Participate actively in all writing group meetings.
- Reasonably consider appropriate writing assignments and deadlines.
- Promptly complete all writing assignments.
- Promptly respond to requests for review and editing of manuscript drafts.
- Work cooperatively with the other authors in resolving disagreements.
- Take responsibility for the accuracy and content of the final manuscript in its entirety, consistent with International Committee of Medical Journal Editors guidelines.
- Promptly respond to recommended revisions from peer review.
- Co-authors who are not part of the PORTAL Network are expected to follow these guidelines.

The writing process

The SC encourages early deliberation about papers that are likely to result from a research project, with designation of a leader or first author for each paper. The SC further encourages open discussion among co-authors of each paper about the order of authorship early in the research process, with final decisions made by the first author. Final authorship order may change during the writing and editing of the paper – it is the responsibility of the lead author to communicate such changes to the writing group. In the event of disagreements regarding authorship on a given manuscript, the PI or PC will arbitrate the dispute.

The lead author should schedule regular meetings of the writing group, either in person or by conference call. Lead authors are responsible for scheduling and conducting these meetings. Each member of the writing group agrees to participate in the conference calls and to promptly complete writing and editing assignments.

Most of the work of the writing groups occurs off-line, with individuals and small working groups taking responsibility for preparing a data request, literature reviews, writing sections of the manuscript, etc. Writing, editing, and discussion of the paper continues until the lead author feels that the paper is ready for submission. At times, there may be methodologies or analytic disagreements that are difficult to resolve through the editing process. The PI and/or the PC will serve as mediators for any issues where necessary; making decisions based on respect, equity,

and justice. If an author cannot agree with the final consensus then he or she may withdraw from authorship, recognizing that the paper will still go forward as a PORTAL paper.

Abstract Submissions and Presentations:
Investigators who present on behalf of the PORTAL Network will lead the abstract submission. If the abstract is accepted for presentation (or poster), this investigator is responsible for drafting the slide presentation or poster and circulating it to other PORTAL investigators and staff as appropriate for edits and feedback including submitting the final draft to the PC for review. All PORTAL sites and co-authors that participated in this effort will be acknowledged in the presentation or poster.

Studies that use the PORTAL infrastructure
Studies that use the PORTAL infrastructure are defined as separately funded studies that include a PORTAL component, cohort, or other element. The long-term viability of PORTAL depends on its ability to demonstrate impact, including studies that may not be funded under the core award. PIs of separately funded grants that include a PORTAL component accept and acknowledge their responsibility to inform the PORTAL PI and Core or Cohort Lead of their publications. All such publications must adhere to recommendations PCORI requirements regarding the description and acknowledgement of the PORTAL Network.

Authorship guidelines
The PORTAL PI and PC will adjudicate disputes regarding authorship for multi-cohort or within-cohort manuscripts. The latter occurs when participating investigators and the cohort lead or core lead cannot come to agreement regarding authorship of a particular manuscript. In such cases, PC members with an apparent conflict of interest will not participate in the deliberations.

The following standard of the International Committee of Medical Journal Editors should in dealing with authorship issues in PORTAL. A complete version of that document may be found at http://www.icmje.org (also see Appendix A).

- All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content.
- The ICMJE recommends that authorship be based on the following 4 criteria:
    1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
    2. Drafting the work or revising it critically for important intellectual content; AND
    3. Final approval of the version to be published; AND
    4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All persons designated as authors on PORTAL publications should fulfill these four criteria of authorship. These criteria provide an inclusive rather than exclusive approach to authorship, but rightfully exclude “guest” authors. Furthermore, PORTAL publications should not have “ghost” authors, persons who made substantial contributions to a research project or wrote substantial portions of a manuscript without attribution. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author. Editors may ask authors to describe what each contributed; this information may be published.

Increasingly, multicenter trials are attributed to a corporate author. All members of the group who are named as authors, either in the authorship position below the title or in a footnote, should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the acknowledgments or in an appendix.

Because the order of authorship is assigned in different ways, its meaning cannot be inferred accurately unless it is stated by the authors. Authors may wish to explain the order of authorship in a footnote. In deciding on the order, authors should be aware that many journals limit the number of authors listed in the table of contents and that the US National Library of Medicine (NLM) lists in MEDLINE the first 24 plus the last author, when there are more than 25 authors."

When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms.

When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

All manuscripts should acknowledge

- Contributions that need acknowledging but do not justify authorship
- Technical help
- Financial and material support, which should specify the nature of the support, and
- Relationships that may pose a conflict of interest.

<u>Acknowledgment of funding support</u>
All presentations and manuscripts should include the following statement:
"This study used the infrastructure developed by the PORTAL (Patient Outcomes Research to Advance Learning) Network, a consortium of 4 integrated delivery systems (Kaiser Permanente, Group Health Cooperative, HealthPartners, and Denver Health) and their affiliated research centers, with funding support from a contract awarded by the Patient-Centered Outcomes Research Institute (PCORI)."

<u>Adhering to PCORI's "Peer Review of Primary Research and Public Release of Research Findings"</u>
(A link to the policy will be inserted when finalized.)

The PORTAL Network requires that the following criteria are met in each publication or presentation:

- Each health plan name and research center name appear according to the site PIs' preference.
- Clear affiliation with PORTAL is acknowledged and adequately described (refer to acknowledgment language above).
- No conflicts with other PORTAL papers or writing groups.
- No serious or major scientific flaws in study design or data interpretation.

Appendix C assists authors in meeting these criteria.

The PC may provide content feedback and suggestions for the authors, but these comments generally will not influence the PC's decision to approve or disapprove the manuscript. However, if the PC believes that the manuscript contains flaws in methodology or interpretation of data that are sufficiently serious that they reflect negatively on the scientific integrity of the PORTAL Network, then the manuscript will not be approved. If the author disagrees with this disapproval, the issue and decision may be discussed with members of the PC and SC for resolution. If the manuscript raises reputational concerns for any of the participating organizations, a strategy to address those concerns will be developed.

Time for review

The PC commits to review final drafts of papers and presentations within five business days of receipt.

Tracking progress

The PI and PM will track the progress of manuscripts and presentations updating the SC on a regular basis. Lead authors will be asked for updates.

Communicating with PCORI

- The PORTAL PI will notify PCORI of manuscripts submitted to journals for publication and of publication dates when manuscripts are accepted for publication.
- The lead author of all PORTAL manuscripts will adhere to PCORI policies for peer review and public dissemination
- PCORI will add a link to the manuscript on their website.

Publicity regarding PORTAL publications and activities

- The lead author of a publication or presentation is responsible for notifying co-authors, the PI, and the SC regarding publication plans (acceptance, expected publication dates, etc).
- At each site, the participating co-author (or the PORTAL site PI) is responsible for notifying appropriate communications or public relations staff at the research center or health plan.
- In general, press releases about study findings will be prepared by the lead author of the paper or their designee in conjunction with the Media Relations department of the institution and reviewed by the SC.
- Press releases should be given to the media when interviews are requested to help ensure uniformity and accuracy in the information disseminated through the media.
- Press releases based on papers pending publication must contain accurate information about the time when the embargo will be lifted as stipulated by the journal publishing the paper.
- The lead author is responsible for notifying the PI and SC that an interview took place and with whom. When possible, a copy of any printed article should be sent to the PORTAL lead project manager for posting and archiving.

Appendix A: Authorship Guidelines

These authorship guidelines are from the International Committee of Medical Journal Editors (ICMJ Authorship Guidelines).

1. Why Authorship Matters?

Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work. The following recommendations are intended to ensure that contributors who have made substantive intellectual contributions to a paper are given credit as authors, but also that contributors credited as authors understand their role in taking responsibility and being accountable for what is published.

Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy that identifies who is responsible for the integrity of the work as a whole. Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship. The ICMJE has thus developed criteria for authorship that can be used by all journals, including those that distinguish authors from other contributors.

2. Who is an Author?

Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy that identifies who is responsible for the integrity of the work as a whole. Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship. The ICMJE has thus developed criteria for authorship that can be used by all journals, including those that distinguish authors from other contributors.

The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged—see Section II.A.3 below. These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses. It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria; it is not the role of journal editors to determine who qualifies or does not qualify for authorship or to arbitrate authorship conflicts. If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed, not the journal editor, should be asked to investigate. If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.

The corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer review, and publication process, and typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and gathering conflict of interest forms and statements, are properly completed, although these duties may be delegated to one or more coauthors. The corresponding author should be available throughout the submission and peer review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication. Although the corresponding author has primary responsibility for correspondence with the journal, the ICMJE recommends that editors send copies of all correspondence to all listed authors.

When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms.

Some large multi-author groups designate authorship by a group name, with or without the names of individuals. When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article identifies who

is directly responsible for the manuscript, and MEDLINE lists as authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.

3. Non-Author Contributors

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").

Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.

Appendix B: Publications and Presentations Submission Request

Please complete the attached submission form as early in the manuscript or presentation preparation process as possible, and submit it to Stephanie Prausnitz (stephanie.r.prausnitz@kp.org). The PC commits to responding to requests within 10 business days.

Section A: General

1. **Lead Investigator (Submitting/Requesting)**

   (Print Name)_____(signature)_____

2. **Date form was submitted:**

3. **Proposed Title:**

4. Purpose **(place an "x" in the box or boxes below and provide the additional information requested)**:

   a. **Peer-reviewed manuscript submission** ☐

      Targeted journal:

      Proposed submission date:

   b. **Abstract submission* to professional meeting** ☐

      Meeting name and location:

      Meeting date:

      Abstract submission deadline:

      *Please let the PC know if the abstract is accepted and if it will be an oral presentation or a poster presentation.

   c. **Other communication**: Letter ☐; Press Release ☐; Interview ☐; Other ☐

      Journal/media outlet/interviewer/other name and location:

      Proposed submission/interview/press release/other date:

5. Writing Group Members.

Name (please add more lines as needed)	Organization	Role (e.g., Lead author, co-author, principal investigator; co-investigator)

6. Site Level Participation (check one)**:** Any external communication from the PORTAL team will be classified as a PUBLICATION, PRESENTATION, PRESS RELEASE, LETTER, or INTERVIEW.

☐ A = Study-wide: on behalf of the entire PORTAL Network (e.g., papers that are considered major priorities for the Network and describe key methods or involve analyses of the major aims)

☐ B = Non-study-wide: from work of a single Cohort or Council with multi- or single-site authors (e.g., initiated by a member or members of the cohort or council teams)

List of sites from which data will be accessed and used:_____

☐ C = Single-site: single- or multi-site author subgroup (e.g., primary data from single site-specific work)

☐ D = Others (Single of multi-site collaborations that focus on conceptual or methodological issues that are initiated by PORTAL investigators or team members)
Explain:_____

7. **Your manuscript or presentation will be based on the following subject area(s) of PORTAL** (choose all that apply)**:**

- ☐ Common Data Model
- ☐ Colorectal Cancer
- ☐ Congenital Heart Disease
- ☐ Obesity/Weight Cohort
- ☐ Clinical Engagement
- ☐ Operational Engagement
- ☐ Patient Engagement
- ☐ PORTAL Network (broadly)
- ☐ Other (please specify): _____

Section B: Details

Please provide the following information in 1 to 2 pages.

1. Brief Background and Rationale:

2. Study Aims or Question(s)/Research Hypotheses:

3. Research Design and Methods (e.g., study design [RCT, cohort, case-control, etc.], observation period, study population and subgroups, key dependent variable(s) and source(s), key independent variable(s) and source(s), planned data extraction and analyses [including who and where performed and proposed statistical analyses]:

4. Key Methodological Challenges Anticipated (if any)**:**

5. Results:

6. Discussion/Conclusions:

7. **Please identify potential overlap with previously approved manuscripts or presentations** (if any)**:**

8. Proposed Timeline:
Note: The lead investigator (PI) will be asked to provide progress reports based on this timeline.

9. Additional Comments (Optional)**:**

Appendix C: Standard language to use in PORTAL publications and presentations

Acknowledgment of funding support
All presentations and manuscripts should include the following statement:

"This study used the infrastructure developed by the PORTAL (Patient Outcomes Research to Advance Learning) Network, a consortium of 4 integrated delivery systems (Kaiser Permanente, Group Health Cooperative, HealthPartners, and Denver Health) and their affiliated research centers, with funding support from a contract awarded by the Patient-Centered Outcomes Research Institute (PCORI)."

PORTAL Network description:
Patient Outcomes Research To Advance Learning (PORTAL) is a research network that brings together leading health-care delivery systems to study the effectiveness of different approaches to diagnosis, treatment and management, in order to assist patients, their caregivers, and doctors in making better-informed decisions.
The PORTAL network consists of Kaiser Permanente, Group Health Cooperative, HealthPartners, and Denver Health, and their 11 affiliated research centers; these health care systems collectively enroll nearly 12 million members (PORTAL network sites and site PIs). Stakeholder engagement is an integral component of PORTAL's work, with patients, doctors, and other health system leaders actively engaged with researchers in every stage of study planning and design. We are building robust online communities that enables us to more broadly engage patients in this work.
The research network that PORTAL is building will help address critical questions, including comparing treatment and ongoing management options for:

- Patients with a diagnosis of colorectal cancer
- Adolescents and adults with severe congenital heart disease
- Adults who are overweight or obese, including those who have pre-diabetes or diabetes

Through PORTAL, participating health care systems will expand their capacity to conduct studies for patients and doctors that provide better information about real world care delivery.

PORTAL Network authorship example statement:
If the number of co-authors exceeds the number allowed by a journal, it may be necessary to signify network authorship. Here is an example statement: "on behalf of the Patient Outcomes Research to Advance Learning (PORTAL) Network." The lead author will utilize this option only when required. When it is required, the lead author agrees to make every effort to list the members of the writing group who met co-authorship criteria.

Appendix L: Requesting a Letter of Support

Protocol for Requests for Letters of Support

1. The request is forwarded to Stephanie Prausnitz, PORTAL Project Manager.
2. Stephanie obtains required project information from the requestor using the associated form.
3. The completed form is forwarded to Elizabeth McGlynn and Tracy Lieu, Lead Co-Investigators.
4. Pending Beth and Tracy's favorable preliminary review, the form is forwarded to the PORTAL Steering Committee with request for replies (objections) within 3 working days.
5. Pending no objections from the Steering Committee, Stephanie
    a. Obtains a draft letter of support from the requestor,
    b. Puts the text onto PORTAL letterhead with Beth and Tracy's signatures, and
    c. Forwards to Beth and Tracy for review.
6. After revisions by Beth and Tracy, Stephanie
    a. Saves the letter in pdf format and
    b. Submits the letter of support to the requestor.

Request for Letter of Support

Thank you for your interest in the Kaiser Permanente & Strategic Partners Patient Outcomes Research to Advance Learning (PORTAL) Clinical Data Research Network (CDRN). Your brief description of the research concept or project will help us determine whether we can offer you a letter of support.

Please provide the following information and submit to Stephanie Prausnitz (Stephanie.R.Prausnitz@kp.org) so we can follow up on your inquiry.

ADMINISTRATIVE ITEMS

First and Last Name	
Job Title	
Institution and Department	
Email Address	
Phone number	

PORTAL AFFILIATION

Are you an investigator at a PORTAL organization?	☐ No ☐ Yes
Are you an investigator at a PCORnet organization other than PORTAL? (see http://www.pcornet.org/member-networks for a list of PCORnet organizations)	☐ No ☐ Yes
Are there researchers at other PORTAL sites involved in this research concept or project?	☐ No ☐ Not sure ☐ Yes – The following researchers are involved:
Describe how PORTAL investigators may be expected to support you	
What is the Letter of Support due date?	

RESEARCH OBJECTIVE

Please provide an abstract that describes your specific aims, study population, and methods.	☐ Abstract attached ☐ Described here:

(continued on next page)

PROJECT STATUS

Federal Support for your project (mark all that apply)	☐ Grant support has already been awarded by (list agency): ☐ A grant proposal is currently under review by (list agency): ☐ We plan to submit a grant proposal in the next 9 months ☐ Just exploring at this time
For-Profit Support for your project	Does this study involve the support or collaboration of a for-profit entity? ☐ No ☐ Yes, we have support and/or are collaborating with (list entity(ies)):