pcornet The National Patient-Centered Clinical Research Network	**Form Title:** **Request for Network Collaborator**	
	Version: 2.0	**Effective Date: 6/1/2020**

Details

Requester Last Name	Nidey	First Name	Nidey	Date	3/13/2024
PI Last Name (if different)		First Name			
Institution	University of Iowa College of Public Health				
Funding Source	☒ PCORI ☐ NIH ☐ Industry ☐ Foundation ☐ Other, Describe funding source				
Is study awarded?	☐ Yes ☒ No				
Please include your estimated total and site budget.	Total 5-yr budget: $6,128,061 Individual Site Budget: up to $70,000				
Project Title	Evaluating implementation of obstetric patient safety bundles: A CER Study				
Type of Study	☐ Intervention Trial ☒ Retrospective Observational Study ☐ Prospective Observational Study ☐ Other study type, Describe:				

Area(s) being studied	☐ Pediatrics ☐ Cardiovascular ☒ Health Disparities ☐ Cancer ☐ Behavioral Health ☐ Gastroenterology ☐ Autoimmune ☐ Neurosciences ☐ Pulmonary ☒ Healthcare Delivery ☐ Obesity/Diabetes ☐ Renal ☐ Rare Diseases, Specify: ☒ Other, Specify: Severe maternal mortality and morbidity, Substance Use, Cardiovascular Conditions
Study Population	500 patients with substance use disorder and 500 patients with severe hypertension during the perinatal period from 10 PCORnet sites where the Alliance for Innovation on Maternal Health (AIM) bundles on Severe hypertension in Pregnancy or Care for Pregnant and Postpartum People with Substance Use Disorder have been implemented.
Primary Aims or research questions to be addressed	Measure the receipt of respectful, equitable, and supportive care among patients from 10 PCORnet sites with either a severe hypertension or substance use disorder diagnosis using a survey co-developed with patient stakeholders.
Secondary Aims or research questions to be addressed	
Interventions (if any)	NA
Describe how participants/patients are engaged or your intent to engage participants/patients in planning, conducting, and disseminating the research study (*See NCR*	PCORnet sites will recruit a total of 500 patients with a substance use diagnosis and 500 patients with a severe hypertension diagnosis during pregnancy from 10 PCORnet sites. Recruited patients/participants will complete an online survey through RedCap. The Redcap survey will be developed and managed by the University of Iowa team. We anticipate each site will enroll and complete ~ 100 participants. EMPOWER project stakeholders, which included persons with lived/living expertise of substance use during pregnancy, healthcare providers, community partners and researchers will co-create the survey document for this aim. Further the study team will provide PCORnet sites training on recruiting and engaging patients with substance use disorder and

Engagement Guidance Document)	severe hypertension for CER studies. The training will be co-led by patient stakeholders from EMPOWER. Findings from this study will be dissemination with key stakeholders, including healthcare providers and patients.
Areas you are seeking collaboration.	☐ Feasibility, Provide Detail: ☐ CDM data request, Provide Detail: ☒ Participant/Patient recruitment/enrollment, Provide Detail: ☐ Participant/Patient engagement, Provide Detail: ☐ Investigator expertise Provide Detail: ☐ Participant/Patient expertise, Provide Detail: ☐ Other, Specify:
Will you be requesting data from the collaborating Network?	☐ Yes ☒ No
If yes, what type of data?	☐ De-identified (aggregate) ☐ Limited data set ☐ PHI with consent ☐ Not identified
What stage is this project? (e.g., protocol development, implementation, recruiting)	Protocol development.
Please describe your proposed timeline.	10 PCORnet sites identified by 4/10/2024. Invited PCORI proposal due to PCORI 5/7/2024 If project funded, start date will be April 2025

Please explain your need from each collaborating site (recruitment/enrollment, budget, etc). Also, please explain if you are using PCORnet sites ONLY or if you plan to work with sites outside of PCORnet.	Each collaborating site will be asked to enroll ~100 participants. The site will then share a link for the participants to complete a survey through RedCap. We have budgeted a total of 70,000 (indirects+directs) for each site to support recruitment. We are only working with PCORnet sites for this aim of the project.
Please specify your short and long term expectations from the collaborating investigator/sites.	Short term – Training with our team to recruit participants Long term – Recruitment of 100 participants who complete survey
Please explain the benefits for participating sites.	Sites will learn how to recruit particpants with a history of SUD and severe hypertension from a team comprise of persons with lived and living expertise of these conditions.