

Research Subaward Agreement
14784sc
between
The Regents of the University of California
and
County of Ventura

This Research Subaward Agreement ("Subaward") is executed by and between The Regents of the University of California, on behalf of its San Francisco campus, a corporation of the State of California (hereinafter "UCSF") and County of Ventura (hereinafter "Subrecipient").

WHEREAS, UCSF is the recipient of a contract **HM-2022C2-28339** ("Award") from Patient-Centered Outcomes Research Institute ("Sponsor"), for the conduct of a program entitled "**Comparing Hypertension Remote Monitoring Evaluation Redesign (CHARMED)**" ("Project") as detailed in the application previously submitted to the Sponsor; and

WHEREAS it is considered in the best interests of the Sponsor and UCSF for Subrecipient to participate in this Project;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, UCSF and Subrecipient agree to a Subaward under this Award.

Article I – Scope of Work

Subrecipient shall perform those tasks described in the Subrecipient's Scope of Work (Attachment A), which is incorporated herein and made a part of this Subaward.

Article II – Project Management

Urmimala Sarkar is designated as UCSF's Principal Investigator, who is responsible for the overall conduct of the Project and is responsible for overall technical monitoring and guidance. Any significant changes in the performance of this Subaward as outlined in Subrecipient's proposal and Scope of Work require authorization by UCSF's Principal Investigator.

Rachel Stern is designated as Subrecipient's Principal Investigator, who shall be responsible for the technical and administrative conduct of the Project in accordance with Attachment A. In the event that a change in Subrecipient's Principal Investigator is necessary, UCSF must be notified in writing immediately and UCSF has the right to approve any Subrecipient Principal Investigator.

Article III – Period of Performance

The authorized period of performance is from **August 01, 2023** through **July 31, 2024**. The period of performance may be extended only by UCSF. Should UCSF extend the performance date, UCSF will then issue a written amendment, along with the budgetary document. UCSF may issue no cost extensions to the period of performance unilaterally, except that Subrecipient shall retain the right to decline such an extension by notifying UCSF's Authorized Official within 30 days from receipt of the amendment. Unilateral acceptance of the amendment does not bypass internal approval processes of the Subrecipient.

The total estimated period of performance is August 01, 2023 through November 01, 2029.

Article IV – Compensation

UCSF will reimburse Subrecipient on a cost-reimbursable basis for actual allowable costs in the performance of the work under this Subaward in the amount not to exceed **\$437,146** which is based on the budget incorporated herein and made

part of this Subaward as Attachment B. Expenditures shall be in accordance with Attachment B, Sponsor's policies, and the terms and conditions of this Subaward. This amount shall not be exceeded without written authorization of UCSF's Principal Investigator and subsequent formal amendment to this Subaward.

The anticipated amount for Year 2 is \$542,598.

The anticipated amount for Year 3 is \$542,598.

The anticipated amount for Year 4 is \$542,598.

The anticipated amount for Year 5 is \$424,363.

Subrecipient shall obtain written prior approval from UCSF's Principal Investigator if reallocation of approved funds exceeds the lesser of \$25,000 or 50% of the cumulative total for all budget years of any of the approved budget line items impacted by a proposed reallocation within the approved budget included as Attachment B.

Carry forward is not allowable and requests shall be sent to the UCSF Principal Investigator for approval.

Article V – Method of Payment

Subrecipient shall submit quarterly invoices for the allowable costs incurred in the performance of the work hereunder to UCSF. All invoices must provide a current and cumulative breakdown of costs by major cost category in accordance with Attachment B. All invoices shall be dated, numbered, and must include this Subaward number, **14784sc**. Invoices submitted without this information may delay payment. Invoices shall include certification that expenditures claimed represent actual allowable costs for committed effort and work performed under this Subaward. Subrecipient invoices shall be sent to the attention of:

University of California, San Francisco Campus (UCSF)

Supply Chain Management - Accounts Payable

Attn: Subcontracts Desk

Box 0812

1855 Folsom Street, Suite 304

San Francisco, CA 94143-0812

Email: subcontract@ucsf.edu

Include the UCSF Principal Investigator (urmimala.sarkar@ucsf.edu) and UCSF Financial Contact (amy.ossolaphillips@ucsf.edu) on the invoice emails.

For questions about invoicing, submit a ticket at https://ucsf.service-now.com/ucsfit?id=ucsf_public_scm_to_inc. UCSF will make provisional payment on all invoices submitted in accordance with the terms of this Subaward. The final invoice marked "FINAL" must be submitted within forty-five (45) days after the final end date of this Subaward.

Unexpended funds, if any, shall be returned to UCSF with the final financial report. The closeout of this Subaward does not affect the right of UCSF or Sponsor to disallow costs and recover funds on the basis of a later audit or other review.

Article VI – Progress and Financial Reporting Requirements

Subrecipient shall furnish to UCSF any financial, technical, or performance reports and assistance reasonably requested by UCSF's Principal Investigator as required to meet UCSF's obligations under the Award. Technical reports should include a summary statement of progress toward the achievement of the originally stated aims, a list of the positive and negative results which are considered to be significant by Subrecipient's Principal Investigator, and a list of any publications resulting from the Project, including planned publication. All such reports shall be submitted to UCSF's Principal Investigator.

Article VII – Audit and Records

a) Subrecipient shall maintain accurate records of all costs incurred in the performance of this work and agrees to allow representatives of UCSF and/or Sponsor reasonable access to its records to verify the validity of expenses reimbursed under this Subaward. Subrecipient shall maintain financial records, supporting documents, and other records pertaining to this Subaward for a period of six (6) years from either the termination date of this Subaward, the date of final payment of expenditures, or the receipt of the final financial report of this Subaward, whichever occurs later. Notwithstanding the foregoing sentence, any records pertaining to audit, appeals, litigation, or settlement of claims arising out of performance of this Subaward shall be retained until such audits, appeals, litigation, or claims have been disposed of.

b) All research records, including but not limited to original data and primary data-yielding materials, secondarily derived tables and figures, and statistical tabulations and other summaries pertinent to this Subaward, shall be made available to UCSF upon its request and shall be retained by Subrecipient for a period of six (6) years from the termination date of this Subaward, except that records pertaining to any allegation of scientific misconduct or investigation, appeal, administrative proceeding, or litigation relating to any charge arising out of the scientific performance of this Subaward, shall be retained until four (4) years after either the conclusion of the allegation, investigation, appeal, administrative proceeding, or litigation, or the acceptance by UCSF of a final report pertaining thereto, whichever occurs later.

c) If any audit report reflects major shortcomings in Subrecipient's internal control systems, UCSF may impose more stringent prior approval requirements for certain types of expenditures and/or rebudgeting, and may require detailed supporting documentation for all claims for reimbursement until UCSF is satisfied that necessary corrective action has been, or will be taken.

d) UCSF, the Sponsor, and any of their duly authorized representatives, shall have access at any reasonable time after prior written notification to pertinent books, documents, papers, and records of Subrecipient in order to make audits, examinations, excerpts, and transcripts. In the event that any payment made to the Subrecipient is determined on the basis of such audits to be unallowable, Subrecipient shall promptly refund the unallowable amount to UCSF upon demand.

Article VIII – Publicity and Publication

Neither party will use the name of the other party or its employees in any advertisement, press release, or other publicity without the prior written approval of the other party. Subrecipient understands that California Education Code Section 92000 provides that the name "University of California" is the property of the State of California and that no person shall use that name without the permission of The Regents of the University of California. Such permission may be granted by the Chancellor or his designee. UCSF has the right to acknowledge Subrecipient's participation in and support of the work performed under this Subaward in scientific publications and other scientific communications.

Subrecipient shall be able to disclose the identity of the parties, the existence of the agreement, and the nature and scope of the research in accordance with its institutional policies, but will not use Sponsor's name or logo without UCSF obtaining written permission of Sponsor's Director of Communications or equivalent position. The previous sentence notwithstanding, publication of Project results shall acknowledge the Award made to UCSF from Sponsor.

Article IX – Intellectual Property

Copyright:

Subrecipient may assert copyright ownership on materials that it produces in the performance of the work of this Subaward. Subrecipient shall grant to UCSF a non-transferable, irrevocable, royalty-free, non-exclusive license to use, reproduce, prepare derivative works, perform, display, publish, or otherwise disseminate such copyrighted materials first developed and delivered under this Subaward for non-commercial research, academic, and educational purposes, and as required to meet any obligations under the Award.

Patents and Inventions:

Subrecipient is subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR 401, "Rights to Inventions made by Non-profit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements." Acceptance of Award funds obligates Subrecipient to comply with the standard patent rights clauses at 37 CFR 401.14.

Article X – Independent Contractor

Subrecipient and its employees, consultants, agents, or independent contractors will perform all services under this Subaward as independent contractors. Nothing in this Subaward will be deemed to create an employer-employee or principal-agent relationship between UCSF and Subrecipient's employees, consultants, agents, or independent contractors. Subrecipient and its employees, consultants, agents, and lower tier Subrecipients will not, by virtue of any services provided under this Subaward, be entitled to participate, as an employee or otherwise, in or under any employee benefit plan of UCSF or any other employment right or benefit available to or enjoyed by employees of UCSF.

Article XI – Liability

Subrecipient shall defend, indemnify, and hold UCSF, its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damages arising out of the performance of this subaward but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of Subrecipient, its officers, employees, or agents.

UCSF shall defend, indemnify, and hold Subrecipient, its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damages arising out of the performance of this Subaward but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of UCSF, its officers, employees, or agents.

Article XII – Insurance

Subrecipient shall maintain at its expense, during the period of this Subaward, insurance or an equivalent form of self-insurance acceptable to UCSF in terms as follows:

a) Commercial Form General Liability (contractual liability included) with limits as follows:

Each Occurrence	\$1,000,000
Products, Completed Operations Aggregate	\$2,000,000
Personal and Advertising Injury	\$1,000,000
General Aggregate	\$2,000,000

b) If the above insurance is written on a claims-made form, it shall continue for three (3) years following termination of this Subaward. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Subaward.

c) Business Automobile Liability (Minimum Limits) for owned, scheduled, non-owned, or hired automobiles with combined single limit of not less than \$1,000,000 per occurrence

d) Workers' Compensation Coverage per statutory limits

e) The coverages referred to shall include The Regents of the University of California as an additional insured. Such a provision shall apply only in proportion to and to the extent of the negligent acts or omissions of the Subrecipient, its officers, employees, and agents. Subrecipient, upon request, shall furnish UCSF with certificates of insurance evidencing

compliance with all requirements. Certificates shall further provide for thirty (30) days (10 days for non-payment of premium) advance written notice to UCSF of any material modification, change, or cancellation of the above insurance coverages.

Article XIII – Suspension/Termination

In the event Sponsor suspends or terminates its award to UCSF, UCSF shall suspend or terminate this Subaward. Notification of suspension or termination by UCSF shall be provided to Subrecipient in writing as soon as practicable and shall state the effective date of such action.

Either party may terminate this Subaward upon thirty (30) days advance written notice to the other party. In the event of such termination, Subrecipient shall take all reasonable steps to minimize further costs, and shall be entitled to reimbursement for allowable costs and non-cancellable obligations incurred prior to the effective date of termination, except that in no event shall such reimbursement exceed the amount set forth in Article IV (Compensation). Unless otherwise agreed to by the parties, within thirty (30) days after the final end date, Subrecipient shall submit a final invoice to UCSF. The balance owed to Subrecipient will be paid contingent upon receipt of all final reports. The preceding sentence notwithstanding, UCSF will be unable to reimburse any expenses under suspension or termination unless and until Sponsor reimburses UCSF for such costs.

In the event of early termination, Subrecipient agrees to deliver such information and items which are either completed prior to the effective date of termination, or which Subrecipient can reasonably be expected to prepare and furnish to UCSF per the approved Scope of Work and the terms of this Subaward.

Article XIV – Protection of Human Subjects

Subrecipient agrees that any non-exempt human subjects research conducted under this Subaward shall be reviewed and approved by its Institutional Review Board (IRB) as applicable. Subrecipient agrees to maintain current and duly approved research protocols for all periods of the Subaward involving human subjects research. Subrecipient certifies that its IRB are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB approvals represent a valid, approved protocol that is entirely consistent with the Project. In no event shall Subrecipient invoice or be reimbursed for any human subjects-related expenses incurred in a period where any applicable IRB approval is not properly in place.

UCSF requires verification of IRB approval to be sent to UCSF's Principal Investigator prior to Subrecipient initiating human subjects research, and annually thereafter as applicable.

Article XV – Notices

Notices required or permitted under this Subaward shall be directed to the Administrative Contact listed in Attachment D.

Article XVI – Prime Award Provisions

The appropriate provisions of the Award set forth in Attachment C, which is incorporated herein and made a part of this Subaward, are applicable to Subrecipient, and Subrecipient hereby agrees to comply with such provisions. In all such provisions, context of the provision requires otherwise, the term "Recipient" or "you" shall mean "Subrecipient", and the terms "PCORI", "we" or "us" and equivalent phrases shall mean "UCSF". It is intended that the appropriate provisions shall apply to Subrecipient in such manner as is necessary to reflect the position of Subrecipient as a subgrantee to UCSF, to ensure Subrecipient's obligations to UCSF and to the Sponsor, and to enable UCSF to meet its obligations under its Award.

In all cases prior approval requests shall be submitted to UCSF's representative named in Article XIV.

In the event of a conflict between the Prime Award and this Subaward, the terms and conditions of this Subaward shall govern.

Article XVII – Governing Law

This Subaward is governed by the laws of the State of California.

Article XVIII – Entire Subaward

This Subaward, including its attachments, states the entire agreement between the parties with respect to the subject matter of this Subaward and supersedes any previous or contemporaneous written or oral representations, statements, negotiations, or Subawards. Subrecipient acknowledges that it has not been induced to enter into this Subaward by any oral or written statements or representations not expressly provided in this Subaward.

Attachment A – Subrecipient Scope of Work

Attachment B – Subrecipient Budget

Attachment C – Award

Attachment D – Contacts

IN WITNESS WHEREOF, the parties hereto have executed this Subaward on the month, day and year specified below.

FOR: The Regents of the University of California

FOR: County of Ventura

Date:

Date:

ATTACHMENT A

CHARMED | SCOPE OF WORK | VENTURA COUNTY HEALTH CARE AGENCY

Ventura County Health Care Agency will work in close partnership with UCSF on this study proposal to achieve the research aims throughout the project period. The healthcare system (HCS) leads, Drs. Rachel Stern and Theresa Cho, will ensure that Ventura County Health Care Agency accomplishes the activities described below.

The HCS leads will oversee, supervise, and hire staff for their sites who will support activities related to the codesigning, implementation, and evaluation of clinic- and patient-level intervention, provide administrative support with the local and UCSF CHARMED team, as well as facilitate data requests, collection, and cleaning for transmission to the UCSF study team. The HCS leads will provide scientific and intellectual contribution to study design and protocol, recruitment plan, instrument design, report writing, and manuscript drafts. They will participate in regular check-in calls with UCSF and the study team and contribute to data presentation and dissemination as well as continuously monitor overall study progress and milestones. The site's study team will be responsible for providing project management and administration support for their respective sites. These activities include supporting UCSF with site contracts, DUA, and IRB reliance and approvals. The HCS leads and their project managers will be responsible for hiring and supervision of their site's project team, e.g., Research Assistant, Clinical Research Coordinator, Data coordinator. The site's study team will coordinate with UCSF for progress report updates and drafts. HCS leads will disseminate key findings and results across a wide range of audiences. HCS leads will participate in regular meetings with the entire study team for all aim activities as well as ensure that project milestones are on time and on budget.

Aim 1 Codesign

HCS leads will participate in monthly CHARMED conference calls to engage in the prioritization, conceptualization, development, and testing of key patient safety measures related to test results management and monitoring of blood pressure. HCS leads will also engage in team discussion regarding how the intervention can be incorporated into clinic workflows and patient safety monitoring practices. Furthermore, they will also participate in characterizing the root causes for safety gaps and disparities within the system level context. They will facilitate the UCSF study team engaging stakeholders (approximately 35 patients, health care workers, and community members) in planning activities such as interviews and convenings to design the implementation strategies. They will also collaborate with UCSF on testing implementation strategies for their site. The site's team will also support UCSF in designing data collection instrument and analysis, coordinate and conduct focus groups and research convenings, send qualitative data for transcription, and coordinate with UCSF for participant incentives. HCS leads will advise on patient engagement strategies.

Aim 2 Implementation

The HCS leads will oversee recruitment of 10-12 clinics and an average of 100 patients per clinic for their HCS. They will also support in implementing remote BP monitoring workflows in their

clinics and provide coaching to support primary care clinics in integrating remote BP readings into standard care. The site team will collaborate with the UCSF study team to conduct patient- and clinic-level intervention activities. HCS leads will work with local stakeholders to implement patient safety monitoring measures as well as clinic-level workflow practices developed from Aim 1 with fidelity. HCS leads will also provide oversight for all local implementation and data request activities, including facilitation of EHR data requests, patient recruitment, enrollment, and data collection. The project manager will also oversee the contacts and orders for blood pressure cuffs as well as coordinate with UCSF for Eureka platform set-up. The intervention activities for this site will include randomization, screening, recruitment, and follow-ups as defined in the study protocol. The team at this site will also coordinate clinic and patient incentives with UCSF as needed.

Aim 3: Evaluation


The project team at this site will support UCSF with program evaluation design. They will also develop the programming for extracting site-specific clinical data from the electronic health record (EHR) of their HCS based on mutually agreed upon data standards to examine the effect of the intervention on clinical outcomes. The HCS leads will support UCSF in instrument design for interviews and focus groups. The HCS study team will coordinate focus groups for their sites, send interview data for transcription, coordinate participant incentives, and support data analysis as needed. The site team will collaborate with the UCSF study team to collect, analyze, and interpret qualitative data through activities such as qualitative interviews from intervention participants (approximately 35 patients and health care workers) to assess the impact of the program across several implementation domains (e.g., acceptability and adoption). The team will also perform initial programming and extraction of EHR data and quality assessment, and validation based on mutually agreed upon standards. Data from the electronic health record will be extracted at mutually agreed upon frequencies. Datasets will be de-identified and transferred to the UCSF for subsequent analysis. The site will also help with development and validation of data methods and tools as well as quality control testing. They will be responsible for data management and quality control at the site.


Engagement

HCS leads will oversee site involvement in the overall study and will assist UCSF with stakeholder engagement activities. HCS leads will work with UCSF Engagement team to elevate patient voices in the project. They will assist the UCSF Engagement team in engaging patient consultants and other key stakeholders in the engagement plan throughout the study period. The site will support recruitment by providing nominations of patient consultants, patient steering committee members and healthcare committee members. They will assist the UCSF Engagement team with making and maintaining contact with stakeholder partners. The UCSF team will manage steering committees, which includes scheduling and coordinating meetings and dispensing incentives for them. UCSF will be responsible for disseminating training materials to the stakeholders involved in the project. Site will be responsible for contributing to

data safety and monitoring for the trial, including weekly review of hospitalizations via EHR data and other safety reporting events.

ATTACHMENT B

Subcontract Organization:		Ventura County Health Care Agency						
Institution Name:		University of California, San Francisco						
Principal Investigator (Last, First, Middle):		Sarkar, Urmimala and Lyles, Courtney Rees						
DETAILED BUDGET - YEAR ONE						FROM	THROUGH	
<i>For each project year, complete a Detailed Budget for each subcontractor organization proposed in your application. All personnel information must be entered in the Personnel tab corresponding to that year in this template. Add additional rows for personnel as needed. Refer to the PCORI Submission Instructions, available on the PCORI Funding Opportunities page, for more guidance. Upload this template as a PDF file to PCORI Online in the designated field.</i>						8/1/2023	7/31/2024	
PERSONNEL: Enter dollar amounts requested (omit cents) for salary requested and fringe benefits.								
SENIOR/KEY PERSON. & OTHER PERSONNEL						DOLLAR AMOUNT REQUESTED		
NAME	ROLE	KEY PERSONNEL	TYPE APPT. (MONTHS)	INST. BASE SALARY	PERCENT EFFORT	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Rachel Stern	Co-I	<input checked="" type="checkbox"/>	12	200,000	20%	40,000	6,480	46,480
Theresa Cho	Co-I	<input checked="" type="checkbox"/>	12	200000	20%	40,000	6,480	46,480
TBN	Project Manager	<input type="checkbox"/>	12	99498	100%	99,498	16,120	115,618
TBN	Research Assistant	<input type="checkbox"/>	12	80000	100%	80,000	12,961	92,961
TBN	Data and Quality Coord	<input type="checkbox"/>	12	85000	50%	42,500	6,885	49,385
TBN	Clinical Research Coord	<input type="checkbox"/>	12	80000	50%	40,000	6,480	46,480
		<input type="checkbox"/>	0	0	0%	0	0	0
A. SUBTOTAL PERSONNEL COSTS						\$341,998	\$55,407	\$397,405

Subcontract Organization:	Ventura County Health Care Agency							
Institution Name:	University of California, San Francisco							
Principal Investigator (Last, First, Middle):	Sarkar, Urmimala and Lyles, Courtney Rees							
DETAILED BUDGET - YEAR ONE (CONTINUED)								
OTHER DIRECT COSTS								
							SUBTOTALS	TOTALS
CONSULTANT COSTS								
								0
EQUIPMENT								
SUPPLIES (Itemize by Category)								
								0
TRAVEL								
								0
OTHER EXPENSES (Itemize by Category)								
								0
SUBCONTRACTOR COSTS				Direct Costs				0
B. TOTAL OTHER DIRECT COSTS FOR BUDGET PERIOD								0
C. SUBTOTAL DIRECT COSTS FOR BUDGET PERIOD (A+B)								397,405
D. SUBCONTRACTOR COSTS				Facilities and Administrative Costs				\$0
E. TOTAL DIRECT COSTS FOR BUDGET PERIOD (C+D)								\$397,405
F. TOTAL INDIRECT COSTS FOR BUDGET PERIOD (10% MTDC)								\$39,741
TOTAL COSTS FOR BUDGET PERIOD (E+F)								\$437,146

UCSF CHARMED

Institution Name (Subcontracted Organization): Ventura County Healthcare Agency (VCHCA)

Personnel Costs:

Key Personnel

Rachel Stern MD, Co-Investigator and Site Leader (20% effort for base salary of \$200,000 for Years 1-4, 15% in Year 5, fringe benefits requested) will serve as the Site Lead and Co-Investigator for Ventura County Health Care Agency (VCHCA). Dr. Stern is the Chief Medical Quality Officer of Ambulatory Care for VCHCA and will collaborate with UCSF test implementation strategies for remote blood pressure monitoring for hypertension at VCHCA. Dr. Stern will be responsible for VCHCA's involvement in the study including stakeholder engagement, trial involvement, and electronic health record data collection. In addition, Dr. Stern will participate in quarterly calls with the investigative team and contribute to data presentation and dissemination. Dr. Stern has a track record of collaborating with Dr. Sarkar through a prior research study assessing patient engagement in safety (PMCID: PMC7060147). Dr. Stern will collaborate with Dr. Theresa Cho, VCHCA Co-Investigator, and she will supervise the Research Assistant and Data and Quality Coordinator.

Theresa Cho, MD Co-Investigator (20% effort for base salary of \$200,000 for Years 1-5, fringe benefits requested) will serve as a Co-Investigator and work closely with Dr. Stern on VCHCA's contributions to this project. Dr. Cho is the Chief Executive Officer and Medical Director for Ambulatory Care at VCHCA. She has extensive experience working with health systems, particularly the safety-net, and will provide operational leadership. For this project, Dr. Cho will lead the clinic-level components of the trial, supporting with the implementation of workflows at VCHCA. In collaboration with Dr. Stern, Dr. Cho will also be responsible for managing and facilitating the collection of clinical outcomes data.

Other Personnel

TBN, Project Manager / Staff Site Lead (100% effort for a base salary of \$99,498 for Years 1-5, salary and fringe benefits requested) will be responsible for project management at VCHCA. The TBN project manager will oversee the Research Assistant, Data Quality Coordinator, and Clinical Research Coordinator to ensure the timely completion of grant activities. The TBN project manager will have extensive experience in conducting quantitative and qualitative research in the proposed site, including facilitating collaborative meetings and conducting qualitative interviews with diverse patients and health care workers.

TBN, Research Assistant (100% effort for a base salary of \$80,000 for Years 1-5, salary and fringe benefits requested) will assist Dr. Stern and Dr. Cho by coordinating activities across all aims. The TBN research assistant will manage VCHCA's involvement in the project, coordinating study activities in partnership with the UCSF study team, supporting in-clinic activities during the trial, and facilitating stakeholder engagement. This individual will be experienced in VCHCA's clinical and research enterprise.

TBN, Data and Quality Coordinator (50% effort for a base salary of \$85,000 for Years 1 and Year 5, 100% effort for Year 2-4, salary and fringe benefits requested) will assist Dr. Stern and Dr. Cho in ensuring thorough collection of quality data for this study. This individual will be skilled in the collection of data from the electronic health record at VCHCA, including the development and validation of data methods

and tools as well as quality control testing. The Data and Quality Coordinator will be responsible for data management and quality control at VCHCA. They will be supervised by Dr. Stern and collaborate closely with the Data and Quality Coordinator at UCSF.

TBN, Clinical Research Coordinator (50% effort for a base salary of \$80,000 for Years 1 and Year 5, 100% effort for Year 2-4, salary and fringe benefits requested): This individual will be focused on supporting all trial-related activities. They will help set up the trial (including protocols), iterate trial protocols and materials based on DSMB feedback, pilot test and iterate data collection tools including the Eureka platform, collect electronic health record-based measures and other clinical outcomes data, and clean data in preparation for analysis.

Consultant Costs: None

Supply Costs: None

Travel Costs: None

Other Expenses: None

Equipment Costs: None

Subcontractor Costs:

Other Sources of Funding: *None*

SOURCE	TIME PERIOD	TOTAL AMOUNT

Peer-Review Budget

We request funds for Prime and Subcontract Personnel, to ensure appropriate peer review of study results in accordance with the PCORI Process for Peer Review of Primary Research and Public Release of Findings. Costs will include time for PIs and staff to register the project and report results via ClinicalTrials.gov, develop the Draft Final Research Report (DFRR), submit the DFRR for PCORI peer review, and revise the final report based on peer review feedback.

Rachel Stern MD, Co-Investigator and Site Leader (5% effort for a base salary of \$200,000 for Peer Review, fringe benefits requested). Dr. Stern will contribute to developing the Draft Final Research Report (DFRR) and revising the final report based on peer review feedback.

ATTACHMENT C



Patient-Centered Outcomes Research Institute

Contract for Funded Research Project Standard CR10

The Regents of the University of California, San Francisco
Comparing Hypertension Remote Monitoring Evaluation
Redesign (CHARMED)
HM-2022C2-28339



Contract for Funded Research Project

Table of Contents

Recitals 1

I. Definitions 1

II. Agreement 3

III. Research Compliance 3

 A. Human Subjects 3

 B. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Federal Food, Drug and Cosmetic Act (FD&C Act) 4

 C. Compliance with All Applicable Laws 4

IV. Payments 4

 A. Payment Method 4

 B. Payment Terms and Invoicing 4

 1. Payment Structure 4

 2. Invoicing 4

 3. Final Invoice 5

 C. Expenditures Incurred Prior to Contract Execution 5

V. Administrative, Audit, and Review Requirements 5

 A. Record Retention 5

 B. Standards of Financial Management 5

 C. Audits and Reviews 6

 1. Independent Audit under 2 CFR 200 Subpart F 6

 2. Other Audits and Reviews 6

VI. Dissemination, Peer Review, and Other Requirements 7

 A. Registration of Research Project and Submission of Results 7

 1. Registration 7

 2. Submission of Results 7

 B. PCORI Methodology Standards 7



C. Expert Advisory Panels.....	7
D. Peer Review of Primary Research	7
E. Research Project Findings.....	8
F. Public Dissemination.....	8
1. Making Research Findings Publicly Available	8
2. In-Person Presentation(s) and Other PCORI-Initiated Events	8
3. Other Dissemination.....	9
4. Ensuring Public Access to Journal Articles Reporting Research Findings	9
G. Data Management and Data Sharing Plan and Deposit of Data Package in Repository.....	9
VII. Responsibilities, Changes, Notifications, and Reporting	9
A. Recipient Responsibilities.....	9
B. Changes.....	10
1. Required Prior Approvals	10
2. Required Notifications	11
C. Reporting	11
1. Interim Progress Reports	11
2. Draft Final Research Report	12
3. Final Report.....	13
4. Progress Reports on Recruitment, Subcontracting, and IRB and DSMB Oversight.....	14
5. Special Progress, Recruitment, Expenditure, and Other Reporting.....	14
6. Notifications of Presentations and Publications and Dissemination	14
VIII. Intellectual Property and Use of Names.....	15
A. Intellectual Property.....	15
B. Use of Names and Logos, Acknowledgement of Funding, and Public Announcements.....	15
1. Use of Names and Logos	16
2. Acknowledgements	16
3. Public Announcements.....	16
4. Disclosure of Certain Factual Information Regarding the Research Project	16
IX. Enforcement Actions and Termination.....	16
A. Payment Hold	17



B. Recovery of Funds.....	17
C. Term, Suspension and Termination	17
1. Term	17
2. Suspension or Termination by PCORI.....	17
3. Termination by Recipient.....	18
4. Obligations Related to Termination.....	18
X. General Terms and Conditions.....	18
A. Confidentiality	18
B. Conflicts of Interest.....	18
C. Research and Financial Misconduct	20
D. Indemnification and Insurance	20
1. Indemnification	20
2. Insurance	21
E. Dispute Resolution	21
F. Miscellaneous.....	21
1. Waiver	21
2. No Assignment	21
3. Subcontractors	21
4. Relationship with PCORI	21
5. Survival	22
6. Governing Law.....	22
7. Captions.....	22
8. Severability	22
9. Amendment; Entire Agreement.	22
10. Authority.....	23
11. Counterparts	23
12. Notices.....	23
Attachment A: PCORI-Approved Project Plan.....	26
Attachment B: Final Budget	43
Attachment C: Milestone Schedule	44



Attachment D: Conflicts of Interest Disclosure Form Research Project Award	50
Attachment E: Sample Invoice	53



THIS RESEARCH CONTRACT **HM-2022C2-28339** (together with all attachments hereto, this "Contract"), is made effective as of **August 1, 2023** (the "Effective Date") through the period of performance ending on **November 1, 2029** (the "Contract Term Date"), by and between the Patient-Centered Outcomes Research Institute, a District of Columbia non-profit corporation whose principal office is at 1333 New Hampshire Ave, NW, Suite 1200, Washington, DC 20036 ("PCORI") and The Regents of the University of California, San Francisco, whose principal office is at 3333 California Street, Suite 315, San Francisco, CA 94143-6215 ("Recipient"). PCORI and Recipient shall be referred to individually, as, a "Party" and collectively, as the "Parties."

Recitals

- A. PCORI is an independent non-profit research organization and pursuant to its Authorizing Law is not a Federal agency, and as such, is subject to different statutory requirements than Federal agencies;
- B. PCORI was created to help people make informed health care decisions and improve health care delivery. PCORI funds research that is guided by patients, caregivers, and the broader health care community;
- C. PCORI desires to fund Recipient's research project in connection with "Comparing Hypertension Remote Monitoring Evaluation Redesign (CHARMED)" (the "Research Project"); and
- D. This Contract contains the general terms, conditions, and policy requirements for the Research Project. It is the responsibility of the Recipient to ensure that all documentation submitted to PCORI conforms to all terms, conditions, policies, and procedures set forth in this Contract.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, PCORI and Recipient agree as follows:

I. Definitions

"Administrative Official" means the individual designated and authorized by the Recipient as the person responsible for the proper administration of this Contract.

"Application Submission Guidelines" means the document(s) (including the applicable PCORI Funding Announcement and the Application Submission Instructions) that defines PCORI's guiding principles for applicants to the PCORI Funding Announcement to which Recipient submitted an application.

"Authorizing Law" shall mean of Title VI, Subtitle D, Sections 6301 and 10602 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by



Pub.L.No.116-94, 133 Stat. 2534 (2019) (codified at 42 U.S.C. §§ 1320e – 1320e-2 and 299b-37; 26 U.S.C. §§ 501, 4375 – 4376, and 9511).

“Budget” means the PCORI-Approved financial plan for the Research Project.

“Budget category” means any of the PCORI budget categories, including personnel, consultant costs, supplies, travel, other costs, research-related patient costs, equipment, consortium and contractual costs, and indirect costs.

“Contract” means the general terms, conditions, and policy requirements set forth in this document, including all referenced documents and Attachments and all amendments (including modifications) to this Contract agreed to by the Parties consistent with this Contract.

“Dispute” means any controversy, claim or dispute arising out of or relating to this Contract.

“Human Subjects Research Laws” shall mean federal state and local laws, rules, regulations and related guidelines of any applicable jurisdiction relating to the conduct of research involving human subjects, including but not limited to the U.S. Department of Health and Human Services regulations at 45 C.F.R. Part 46 (including the Common Rule), National Institutes of Health guidance, and the U.S Food and Drug Administration regulations at 21 C.F.R Parts 50 and 56.

“Key Personnel” means an individual designated by the Recipient as an individual, subcontractor, or consultant who contributes to the scientific development or execution of the Research Project in a substantive, measurable way, whether or not he or she receives salaries or compensation under this Contract.

“PCORI Methodology Standards” means standards for research as defined by the PCORI Methodology Committee and adopted by the PCORI Board of Governors.

“PCORI Peer Review and Findings Release Process” means the Process for Peer Review of Primary Research and Public Release of Research Findings adopted by the PCORI Board of Governors and related procedures.

“Principal Investigator” (“PI”) means the individual designated by the Recipient as the primary programmatic contact for this Contract.

“Recipient” means the agency, organization, entity, or institution funded by PCORI based on the terms and conditions outlined in this Contract, as set forth above.

“Research Project” means the PCORI-Approved Project Plan, including the PCORI-approved scope, timeline, budget, milestones, deliverables, and activities (including peer review activities), that is the subject of this Contract.

“Work Products” means tangible products, such as reports, papers, data sets, books, or other materials resulting from the Research Project.



II. Agreement

Recipient shall conduct the Research Project in compliance with this Contract, including as described in detail in the PCORI-Approved Project Plan, which is incorporated by reference as Attachment A, and made a part of this Contract.

This Contract also includes any or all of the following attachments, which are incorporated by reference and made a part of this Contract:

- a. The Budget, attached hereto as Attachment B, the Milestone Schedule, attached hereto as Attachment C, the Conflict of Interest Disclosure Form, attached hereto as Attachment D, and the sample Invoice Form, attached hereto as Attachment E.
- b. Any relevant special terms and conditions set forth in any attachments or addendums to this Contract, as applicable.

III. Research Compliance

A. Human Subjects

Recipient shall fulfill the requirements of Human Subjects Research Laws in conducting the Research Project. If the Research Project involves human subjects as defined by federal regulations at 45 C.F.R. 46.102, Recipient shall ensure that an Institutional Review Board (IRB), or for international recipients, an internationally recognized equivalent provides initial and continuing review and approval of the Research Project. Recipient shall comply with all local laws and regulations of any applicable jurisdiction regarding the participation of human subjects.

A Research Project with human subjects must have and maintain up-to-date IRB approval records, or for international recipients, records of an internationally recognized equivalent, at all times and must provide PCORI with copies of the approval documentation. Recipient shall have and maintain a Data and Safety Monitoring Plan ("DSMP") as specified in the PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research available at <https://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>, or available as otherwise directed by PCORI. It is the responsibility of the Recipient to ensure that PCORI receives required, up-to-date documentation of actions of the IRB (or internationally recognized equivalent) and, if applicable, the Data Safety Monitoring Board ("DSMB"), throughout the duration of the Research Project.



B. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Federal Food, Drug and Cosmetic Act (FD&C Act)

Recipient's conduct of the Research Project shall comply with applicable requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended ("HIPAA"), and all other applicable federal, state, and local laws and regulations of any applicable jurisdiction governing the privacy and security of health information.

Recipient's conduct of the Research Project shall comply with applicable requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq, and its implementing regulations, as amended ("FD&C Act").

C. Compliance with All Applicable Laws

Recipient shall comply with all applicable federal, state, and local laws, regulations, and requirements of any applicable jurisdiction.

IV. Payments

A. Payment Method

All payments are made by PCORI via Direct Deposit (ACH Fund Transfer) unless otherwise specified. However, should a check be issued, checks will be made payable to the Recipient.

B. Payment Terms and Invoicing

1. Payment Structure.

This is a cost-reimbursement contract. The total approved budget for the Research Project, including for peer review activities, is not to exceed **\$17,845,883.00**.

2. Invoicing.

Recipient shall submit invoices for all allowable costs electronically to PCORI no more frequently than monthly but no less frequently than quarterly, not to exceed ninety (90) days in between invoices. Except as otherwise provided below, invoices shall be paid by PCORI within thirty (30) days of receipt of an approved invoice. During the Contract Term, invoices not received by PCORI within the maximum specified ninety (90) days will be paid by PCORI within a maximum of forty-five (45) days after receipt and approval by PCORI. Notwithstanding the foregoing, in light of the PCORI Fiscal Year End of September 30, Recipient shall ensure that an invoice is



submitted to PCORI by October 31 of each calendar year for all available unbilled allowable costs incurred by September 30 of such calendar year.

Invoices submitted to PCORI must be consistent with the approved Final Budget set forth in Attachment B, must comply with PCORI cost principles, including relating to allowable and unallowable costs, and must contain all of the information requested in Attachment E: Sample Invoice. Invoices missing requested information will not be approved for payment by PCORI. Upon request, PCORI may require additional supporting documentation relating to this Contract, such as receipts, a system-generated general ledger, or a system-generated labor detail report.

3. Final Invoice.

Recipient shall submit a final invoice to PCORI for all allowable costs under this Contract to PCORI on or before ninety (90) days after the Contract Term Date. Recipient shall clearly mark the final invoice as 'FINAL'.

C. Expenditures Incurred Prior to Contract Execution

Recipient may incur Research Project expenditures up to three (3) months prior to the Effective Date, but in no event earlier than March 14, 2023, as long as all expenditures and activities are directly related to the Research Project and subject to the terms and conditions of this Contract.

All such expenditures must be allowable and approved costs as reflected in the Budget set forth in Attachment B. Recipient is responsible for the initial financing of these expenditures and will be paid once this Contract is fully executed. If this Contract is not executed, PCORI will not be responsible for any expenditure. PCORI reserves the right to deny any expenditure incurred prior to the execution of this Contract that is inconsistent with the approved Budget.

V. Administrative, Audit, and Review Requirements

A. Record Retention

Financial records, supporting documents, statistical records, and other records relevant to this Contract and performance under it must be retained by Recipient for a period of three (3) years from the (i) Contract Term Date, (ii) date of the final payment under this Contract, or (iii) conclusion of any audit or litigation related to this Contract, whichever is later. Notwithstanding the foregoing Research Project data shall be retained by Recipient for such longer period of time and in such form as required by PCORI's Policy for Data Management and Data Sharing, as set forth in Section VI.G.

B. Standards of Financial Management



Recipient must maintain separate records and accounts that identify adequately the source and application of funds for the PCORI-funded Research Project. These records must contain information pertaining to obligations, unobligated balances, assets, outlays, income, and interest. Recipient must exercise effective control over and accountability for all funds, property, and other assets. Recipient must safeguard all such assets and assure they are used solely for authorized purposes.

C. Audits and Reviews

1. Independent Audit under 2 CFR 200 Subpart F.

Recipient that conducts an independent annual single audit that meets the requirements contained in 2 CFR 200 Subpart F must provide a full copy of the audit to PCORI upon request. Recipient shall contact designated PCORI personnel for additional guidance if needed.

2. Other Audits and Reviews.

PCORI is subject to oversight by the U.S. Government Accountability Office (GAO). GAO may audit Recipient at any time.

PCORI may, on a random basis or because of a concern, with reasonable advance written notice to Recipient, commission a third-party audit of the Research Project. If so, the Recipient must provide access to all contract and financial records, documents, files, and other materials related to the Research Project, make project staff and subcontract staff available for interviews or discussions, and allow the facilities and PCORI-funded equipment, if any, to be inspected within a reasonable time and no later than thirty (30) days following a written request by PCORI.

PCORI reserves the right, with reasonable advance written notice to Recipient, to visit a Research Project site, send its authorized representatives, or commission a PCORI or third-party review of the Research Project under this Contract. If such a visit, or review is requested by PCORI, Recipient must provide reasonable access to all contract and financial records, documents, files, and other materials related to the PCORI-funded Research Project, make project staff and subcontract staff available for interviews or discussions, and allow the facilities and PCORI-funded equipment, if any, to be inspected.

Third parties commissioned by PCORI for an audit or review will be bound by PCORI to confidentiality obligations, consistent with the nature of the audit or review.



VI. Dissemination, Peer Review, and Other Requirements

A. Registration of Research Project and Submission of Results

1. Registration.

Recipient shall ensure that the Research Project is registered at ClinicalTrials.gov (<https://clinicaltrials.gov>), to the extent the Research Project meets the eligibility requirements for registration, and/or other site(s) specified in the Milestone Schedule set forth in Attachment C. Any such registration shall be completed prior to enrollment of the first patient or as otherwise specified in the Milestone Schedule set forth in Attachment C and shall include in the naming convention a reference to PCORI's funding application number (e.g., "PCORI-PCORI application number" PCORI-XXXX-XXXX).

2. Submission of Results.

Recipient shall ensure that the results of the Research Project are submitted to ClinicalTrials.gov and/or other site(s) specified in the Milestone Schedule set forth in Attachment C, consistent with applicable legal requirements and no later than thirty (30) days prior to the due date for submission of the Draft Final Research Report to PCORI, as specified in the Milestone Schedule set forth in Attachment C.

B. PCORI Methodology Standards

Recipient shall comply with, and certify adherence to, the applicable PCORI Methodology Standards with respect to the Research Project, as adopted by the PCORI Board of Governors.

C. Expert Advisory Panels

If applicable, Recipient shall consult with the expert advisory panel(s) for clinical trials and rare disease established by PCORI pursuant to its Authorizing Law.

D. Peer Review of Primary Research

PCORI is required to ensure that there is a process for peer review of PCORI-funded primary research that fulfills requirements of the Authorizing Law, including "to assess scientific integrity and adherence to methodological standards adopted [by the PCORI Board of Governors]." Consistent with the Authorizing Law, PCORI's Board of Governors has adopted the PCORI Peer Review and Findings Release Process. Recipient shall cooperate with PCORI to ensure that the Research Project is peer reviewed consistent with the PCORI Peer Review and Findings Release Process. Recipient shall abide by applicable timelines of the



PCORI Peer Review and Findings Release Process and shall consider and address comments and recommendations emanating from the PCORI Peer Review and Findings Release Process. The PCORI Peer Review and Findings Release Process required to meet its Authorizing Law may be in addition to peer-review processes for other purposes, such as for purposes of journal publication, as long as such other peer-review processes are consistent with the obligations of Recipient under this Contract, including as set forth in Sections VI.F [“Public Dissemination”], VII.C.6.a [“Notification of Presentation and Publication Acceptance”] and VIII.A [“Intellectual Property”].

E. Research Project Findings

In accordance with PCORI’s Authorizing Law, Recipient’s research findings from the Research Project shall “not include practice guidelines, coverage recommendations, payment, or policy recommendations” and shall “not include any data which would violate the privacy of research participants or any confidentiality agreements made with respect to the use of data.”

F. Public Dissemination

1. Making Research Findings Publicly Available.

Recipient shall cooperate with PCORI in order for PCORI to make the PCORI-funded research findings “available to clinicians, patients, and the general public” “not later than ninety (90) days after the conduct or receipt of the research findings,” in accordance with its Authorizing Law. Consistent with the PCORI Peer Review and Findings Release Process, Recipient shall cooperate with PCORI, including meeting applicable timelines and requirements for submission of reports and in the development of a summary of the findings of the Research Project for patients, consumers, and the general public, to ensure that the research findings are conveyed to the public in a manner that is “comprehensible and useful to patients and providers in making health care decisions.”

2. In-Person Presentation(s) and Other PCORI-Initiated Events.

Recipient may be required by PCORI to attend a PCORI meeting(s) or other events to present findings of or other matters relating to the Research Project. Recipient will be notified by PCORI of any specific requirements prior to any such meeting or events. Other than travel specifically required (a) by the PCORI Funding Announcement under which this Contract is funded or (b) in connection with the Research Project and made a part of the Budget set forth in Attachment B, PCORI will reimburse Recipient for reasonable travel expenses incurred in connection with PCORI-requested travel to a meeting or event. All expenses must comply with PCORI’s travel and other policies and be specifically approved in advance and in writing by PCORI.



3. Other Dissemination.

Recipient is encouraged to pursue dissemination of PCORI-funded research findings through multiple channels, as appropriate, including journal publications, existing and emerging internet distribution models, open access journals, non-researcher communications, and similar mechanisms that result in broad access for the interested field and public. Any research findings released shall not violate any research participants' privacy or any confidentiality agreements relating to the use of the data.

4. Ensuring Public Access to Journal Articles Reporting Research Findings.

To the extent that Recipient reports research findings arising from the Research Project in a peer reviewed journal article, Recipient shall ensure that an electronic copy of the final peer-reviewed manuscript is submitted to the National Library of Medicine's PubMed Central, to be made available publicly, consistent with the PCORI Policy on Public Access to Journal Articles Presenting Finding from PCORI-Funded Research, available at <http://www.pcori.org/awardee-resources>, or available as otherwise directed by PCORI.

G. Data Management and Data Sharing Plan and Deposit of Data Package in Repository

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. Recipient shall develop, maintain, and implement a plan that addresses the management, retention, and sharing of Research Project data in a manner that is appropriate for the nature of the Research Project and the types of Research Project data, and that is consistent with applicable privacy, confidentiality, and other legal requirements. Recipient's Data Management and Data Sharing Plan shall be consistent with the PCORI's Policy for Data Management and Data Sharing ("PCORI Data Policy") available at <https://www.pcori.org/about-us/governance/policy-data-management-and-data-sharing>, or available as otherwise directed by PCORI. Recipient shall comply with the PCORI Data Policy including depositing and maintaining Research Project data in such manner and for such period of time as specified in the PCORI Data Policy and abiding with applicable timelines.

VII. Responsibilities, Changes, Notifications, and Reporting

A. Recipient Responsibilities

To the extent permitted under applicable law, Recipient has full responsibility and liability for the conduct of the Research Project and for the results reported. PCORI is not the "sponsor" or "responsible party" of the Research Project under the FD&C Act, Human



Subjects Research Laws, and other applicable laws and regulations. In its role as a funder, PCORI has the right to monitor the progress of the Research Project and receive reports regarding the Research Project as provided in this Contract. Recipient must perform the Research Project and ensure adherence to deliverables, milestones, and other requirements described in this Contract.

Recipient shall at all times comply with all PCORI awardee policies and procedures and the Application Submission Guidelines.

B. Changes

1. Required Prior Approvals

A request for PCORI prior approval of a change in the Research Project must be submitted by Recipient at least thirty (30) days in advance of the proposed change. All such requests must be made in writing to designated PCORI Contract personnel and must include a complete description of the situation, the requested changes, and a full justification and explanation. The Administrative Official of the Recipient must sign the request. PCORI reserves the right to approve or deny any requested changes in its sole and reasonable discretion. Recipient must request prior approval for:

- a. Significant changes in the scope of the Research Project or its specific aims.
- b. Significant changes in approach, methodology, or number of participants.
- c. Transfer of Principal Investigator.
- d. Significant new contracting or otherwise transferring the Research Project effort.
- e. Naming of new or replacement Principal Investigator or Key Personnel.
- f. A decrease in the percentage effort of a Principal Investigator that exceeds 25% of the approved effort.
- g. Budget adjustments for the Salaries of Personnel or for Travel that exceed 25% of the total amount approved for that Budget Category as set forth in the Budget incorporated as Attachment B. No budget adjustment shall cause an increase in the Total Contract Value, as specified in the Budget incorporated as Attachment B.



- h. Deviation from the adopted PCORI Methodology Standards.

2. Required Notifications

Recipient must provide written notice to PCORI within thirty (30) days of becoming aware of or making decisions related to certain actions or events as described below. Notifications must be made in writing, by the Administrative Official of the Recipient, to the designated PCORI Contract personnel. Recipient must provide notification of any of the following:

- a. Absence of a Principal Investigator for a time period exceeding three (3) continuous months but that does not otherwise exceed a variance of 25% of the approved effort;
- b. Absence of Key Personnel for a time period exceeding three (3) continuous months or a change in the overall time to be spent on the Research Project by 25% or more of the approved effort; or
- c. Conflicts of interest that Recipient becomes aware of during the term of and related to this Contract.

C. Reporting

Recipient shall submit all reports to the designated PCORI Contract personnel via email, or through PCORI Online when available, or available as otherwise designated by PCORI. The Administrative Official must sign and certify all reports.

1. Interim Progress Reports

Recipient shall submit Interim Progress Reports to PCORI. Interim Progress Reports shall document Research Project accomplishments, challenges, the status of Milestones set forth in Attachment C to this Contract, and such other information requested by PCORI.

General requirements for Interim Progress Reports include:

- a. Interim Progress Reports shall be submitted by Recipient on the Milestone Schedule set forth in Attachment C to this Contract.
- b. Interim Progress Report instructions can be found at <http://www.pcori.org/awardee-resources/>, or available as otherwise directed by PCORI.



2. Draft Final Research Report

Recipient shall submit the Draft Final Research Report to PCORI. The Draft Final Research Report shall document Research Project findings and other information, including for purposes of peer review by PCORI, consistent with the PCORI Peer Review and Findings Release Process.

General requirements for the Draft Final Research Report include:

- a. The Draft Final Research Report shall be submitted by Recipient on the Milestone Schedule set forth in Attachment C to this Contract.
- b. The Draft Final Research Report Instructions for Awardee Institutions can be found at <http://www.pcori.org/awardee-resources>, or available as otherwise directed by PCORI.
- c. The Draft Final Research Report shall include sections and information as provided in the PCORI Peer Review and Findings Release Process, including:
 - (i) A description of the main study results from the Research Project;
 - (ii) An abstract for medical professionals;
 - (iii) Results tables posted on ClinicalTrials.gov, and/or as specified in the Milestone Schedule set forth in Attachment C to this Contract; and
 - (iv) Ancillary information, including conflict of interest disclosures.
- d. Consistent with PCORI's Authorizing Law, the Draft Final Research Report shall not include:
 - (i) Practice guidelines, coverage recommendations, payment, or policy recommendations; or
 - (ii) Any data which would violate the privacy of research participants or any confidentiality agreements relating to the use of data.

Recipient shall cooperate with PCORI in PCORI's peer review of the Draft Final Research Report, consistent with the PCORI Peer Review and Findings Release Process.



3. Final Report

Recipient shall submit the Final Report to PCORI. The Final Report will include both a Final Research Report and a Final Progress Report.

- a. **Final Research Report.** The Final Research Report shall document Research Project findings and other information reflecting revisions and responses from PCORI's peer-review process, consistent with the PCORI Peer Review and Findings Release Process. General requirements for the Final Research Report include:
 - (i) The Final Research Report is due on the Milestone Schedule set forth in Attachment C to this Contract, or as otherwise specified by PCORI in connection with the PCORI Peer Review and Findings Release Process.
 - (ii) The Final Research Report instructions can be found at <http://www.pcori.org/awardee-resources>, or available as otherwise directed by PCORI.
 - (iii) The Final Research Report shall be the Draft Final Research Report, as revised, to reflect PCORI's peer-review process.
 - (iv) Following PCORI's acceptance of the Final Research Report, Recipient shall cooperate with PCORI in developing a summary of the research findings of the Research Project for patients, consumers, and the general public, consistent with the PCORI Peer Review and Findings Release Process.
 - (v) PCORI shall make the Final Research Report available to the public, consistent with the PCORI Peer Review and Findings Release Process.
- b. **Final Progress Report.** The Final Progress Report shall document the accomplishments, challenges, and status of Milestones set forth in Attachment C to this Contract. General requirements for the Final Progress Report include:
 - (i) The Final Progress Report is due on the Milestone Schedule set forth in Attachment C to this Contract, or as otherwise specified by PCORI.



- (ii) The Final Progress Report instructions can be found at <http://www.pcori.org/awardee-resources/>, or available as otherwise directed by PCORI.

4. Progress Reports on Recruitment, Subcontracting, and IRB and DSMB Oversight

Recipient shall submit reports on the status of recruitment, subcontracting, and IRB and DSMB oversight to PCORI as specified on the Milestone Schedule set forth in Attachment C to this Contract, or as otherwise specified by PCORI.

5. Special Progress, Recruitment, Expenditure, and Other Reporting

PCORI may require additional progress or other types of specialized reports, including recruitment, subcontracting, and IRB or DSMB reports, expenditure reports, or other reports or deliverables relating to the Research Project on a timeline other than as set forth in the Milestone Schedule set forth in Attachment C.

6. Notifications of Presentations and Publications and Dissemination

Recipient shall provide written notice to PCORI of accepted presentations and publications and other dissemination relating to the Research Project as specified below.

- a. **Notification of Presentation and Publication Acceptance.** Recipient is required to submit to PCORI all accepted presentations and full-length peer reviewed publications related to the Research Project prior to the presentation or publication date in such manner as specified by PCORI and within thirty (30) days of acceptance, during the Term of this Contract and, in good faith, for five (5) years post-Contract Term Date. A notification to PCORI as required by this subsection shall be provided as described in the instructions available at <https://www.pcori.org/funding-opportunities/awardee-resources/reporting>, or available as otherwise directed by PCORI. Recipient is responsible for ensuring that any presentation, publishing or copyright agreements concerning submitted presentations and articles reserve adequate right to enable PCORI to fully comply with the requirements of its Authorizing Law and the PCORI Peer Review and Findings Release Process to make research findings available as set forth in this Contract, including consistent with Sections VI.E [“Research Project Findings”] and VIII.A [“Intellectual Property”] of this Contract.



- b. **Notification of Other Dissemination.** Recipient is required to submit reports on its dissemination of research findings relating to the Research Project that has been pursued through additional channels, including non-researcher communications. Plans for such communication should be reported in the Interim Progress Reports, Draft Final Research Report, and Final Report, and, in good faith, annually for five (5) years post-Contract Term Date. Recipient shall provide any such reports to its PCORI in such manner as specified by PCORI.

VIII. Intellectual Property and Use of Names

A. Intellectual Property

The Research Project will generally result in tangible products, such as reports, papers, data sets, books, patient tools, or other materials ("Work Products"). PCORI addresses the ownership, use, copyright to, and distribution of the Work Products by balancing PCORI's interests with those of the Recipient, the public, and other interested parties, consistent with PCORI's Authorizing Law.

PCORI's policy is to ensure that the Work Products further PCORI's mission and benefit the public. As a result, PCORI seeks prompt and broad dissemination of Work Products. Recipient shall own the rights to Work Products created under this Contract. Recipient grants to PCORI a royalty-free, paid up, worldwide, perpetual, irrevocable, non-exclusive, non-transferable license to reproduce, publish, distribute, and disseminate, adapt, modify, create derivatives of, or otherwise use the Work Products created under this Contract for public purposes consistent with PCORI's mission and Authorizing Law.

As reflected in this Contract, including in Sections VI.F.3 ["Other Dissemination"] and VII.C.6 ["Notifications of Presentations and Public Acceptance"] and as addressed in the PCORI Peer Review and Findings Release Process specified in Section VI.D ["Peer Review of Primary Research"], PCORI strongly encourages dissemination of PCORI-funded research findings, including through journal publication. For clarity and the avoidance of doubt, PCORI recognizes and confirms its understanding that manuscripts prepared by Recipient for submission for journal publication and resulting published articles are subject to the intellectual property framework of the applicable journal and PCORI shall not construe such manuscripts or published articles to be Work Products, as long as such manuscripts and published articles do not constitute Recipient's Draft Final Research Report or Final Research Report, as set forth in the PCORI Peer Review and Findings Release Process.

B. Use of Names and Logos, Acknowledgement of Funding, and Public Announcements



1. Use of Names and Logos

Except as provided below, neither Party shall use the names or logos of the other Party without the prior written consent of the Party whose name and/or logo is requested to be used. The Guidelines for Use of PCORI Names and Logos ("PCORI Guidelines") serve as written consent for use that is consistent with the PCORI Guidelines. The PCORI Guidelines are available at <https://www.pcori.org/sites/default/files/PCORI-Guidelines-For-Use-Of-PCORI-Names-Logos.pdf> (or available as otherwise directed by PCORI).

2. Acknowledgements

Recipient shall ensure that the PCORI-funded Research Project is properly acknowledged in any presentation, journal article, public announcement, press release, research report, or other material produced by, or on behalf of, the Recipient that relates to the Research Project. Recipient shall acknowledge PCORI's funding of the Research Project funded under this Contract and shall only use the PCORI names and logos consistent with the PCORI Guidelines for Use of PCORI Names and Logos. In any such statement, the relationship of the Parties shall be accurately and appropriately described.

3. Public Announcements

Recipient shall not issue any public announcement (e.g., press release, website posting, social media posting, and public email announcement) or public release relating to PCORI's award of the Research Project, the Research Project, or of any research findings relating to the Research Project without the advance written consent of PCORI, including relating to content, branding, and timing. Such requests shall be submitted with draft announcements and intended distribution dates and shall be coordinated with PCORI via email to fundedpfa@pcori.org (or available as otherwise directed by PCORI) to enable proper coordination.

4. Disclosure of Certain Factual Information Regarding the Research Project

Notwithstanding the foregoing, each Party may publicly make available the fact of PCORI's funding of the Research Project and the Research Project title and period and may respond to inquiries with factual information regarding the Research Project without seeking and obtaining the other Party's written consent, so long as any such statement is accurate and so long as each Party makes no more than fair use of the other Party's name and does not use the other Party's logo.

IX. Enforcement Actions and Termination



A. Payment Hold

PCORI reserves the right to withhold payments on a Contract at any time, in cases where the Recipient is non-compliant or in breach of this Contract. Such cases include, but are not limited to failure to submit proper documentation or reports by the appropriate due date, submission of unsatisfactory reports, failure to meet approved milestones, or failure to submit appropriate and updated IRB approvals, as determined at PCORI's reasonable discretion. Payments may be reinstated when all outstanding documentation and/or reports have been approved by PCORI and/or all required corrective measures have been taken and documented to PCORI's satisfaction.

B. Recovery of Funds

Should a Recipient be paid any amount of funds for which Recipient is eventually determined to be ineligible under the terms of this Contract (e.g., due to any audit findings that payments were made in error, overpayments, misspent funds, or unallowable costs under the Budget), Recipient shall return such ineligible funds to PCORI within thirty (30) days of the determination, and to the extent permitted under applicable law, Recipient shall also reimburse PCORI for all reasonable attorneys' fees incurred by PCORI in connection with the recovery of such ineligible funds.

C. Term, Suspension and Termination

1. Term

The Term of this Contract shall begin on the Effective Date set forth above and shall extend until the Contract Term Date set forth above (the "Contract Term"), unless earlier terminated as set forth in this Contract or extended by written agreement of the Parties.

2. Suspension or Termination by PCORI

- a. PCORI may suspend or terminate this Contract, in whole or in part, if:
 - (i) The Recipient has materially failed to comply with the terms and conditions of this Contract; or
 - (ii) PCORI has other reasonable cause.

PCORI will not suspend or terminate this Contract unless it has provided Recipient with thirty (30) days prior written notice of the proposed action or informed Recipient of any material breach. Recipient must correct the breach on or before thirty (30) days



from the date of written notice of breach. In the absence of a correction reasonably satisfactory to PCORI within the specified timeframe, or in the event that the breach is reasonably incapable of correction, then PCORI may terminate this Contract by providing written notice of termination to Recipient.

- b. PCORI may suspend or terminate this Contract with thirty (30) days advance written notice if funds to continue this Contract become unavailable, or are interrupted, suspended, terminated, or modified.
- c. Notwithstanding the above, In the case of research misconduct or if public health or human welfare requires urgent action, PCORI may suspend or terminate this Contract immediately by providing written notice of termination to Recipient.

3. Termination by Recipient

Recipient may terminate this Contract upon sixty (60) days prior written notice to PCORI that includes a full explanation of the reason for the termination.

4. Obligations Related to Termination

Within ninety (90) days of the termination date, Recipient will furnish the required reports (as described in Section VII.C), including a Final Report, and a final invoice. Upon termination, any final payment shall be based upon allowable costs incurred up through the termination date including any non-cancelable obligations made in good faith in accordance with the approved Budget set forth in Attachment B.

X. General Terms and Conditions

A. Confidentiality

Materials and information submitted to PCORI, including but not limited to Interim Progress Reports, Draft Final Research Reports and Final Reports, are for use and disclosure by PCORI consistent with its mission and Authorizing Law. If Recipient has any concerns or questions regarding inclusion of materials or information in a particular report or submission, Recipient should contact the designated PCORI Contract personnel.

B. Conflicts of Interest

In the interest of maintaining objectivity in research, Recipient is expected to have established policies about, and safeguards against, conflicts of interest. Recipient shall have protections in place that prevents Recipient and its employees, consultants, subcontractors



from using their positions for personal gain (for themselves, or for other individuals—friends, business associates, family members, or others), financially or via gifts, favors, or other similar actions. Recipient is also responsible to ensure that all aspects of PCORI-funded research are not influenced by conflicts of interest, financial or otherwise. Recipient agrees to implement and enforce written policies and guidelines to prevent such conflicts of interest that meet the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service available at <http://grants.nih.gov/grants/policy/coi/>.

Additionally, PCORI is required by its Authorizing Law to make available to the public and disclose through its website the identity of each research entity and the investigators conducting such research and any conflicts of interest of such parties, including any direct or indirect links to industry concurrent with the release of research findings.

Recipient certifies that, as of the Effective Date:

- a. Recipient has established policies about, and safeguards against, conflicts of interest that meet the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service available at <http://grants.nih.gov/grants/policy/coi/>;
- b. Recipient has reported the existence of any conflicting financial interests, using the Conflicts of Interest Disclosure Form provided by PCORI in Attachment D and has provided a mitigation plan to address identified conflicts (acceptable mitigation strategies, include, but are not limited to, a letter on institutional letterhead certifying that the financial interest does not constitute a conflict); and
- c. Recipient has fully disclosed any direct or indirect links to industry that have the potential to bias PCORI research, using the Conflicts of Interest Disclosure Form provided by PCORI in Attachment D.

Recipient shall complete and submit to PCORI a Conflicts of Interest Disclosure Form on an annual basis. The Conflicts of Interest Disclosure Form and any attachments must be completed and returned to PCORI even if the Recipient and/or Key Personnel have no conflicts or industry links to disclose.

Additionally, Recipient must notify PCORI promptly if any conflicts arise during the term of this Contract.

Recipient acknowledges and agrees that any conflicts of interest and/or any direct or indirect links to industry submitted to PCORI may be disclosed to the public via the PCORI website, in its Annual Report, or in some other format that may be released to the public. Recipient acknowledges and agrees to cooperate should PCORI investigate further any identified conflicts of interest.



C. Research and Financial Misconduct

The responsible and ethical conduct of research is critical for excellence, as well as for the public trust. Recipient is responsible for ensuring that the research team for the Research Project, including undergraduate students, graduate students, postdoctoral researchers supported by funds under the Research Project budget to conduct the Research Project, have received training in the responsible and ethical conduct of research.

Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Financial misconduct refers to any act to acquire financial gain for oneself or for those of relatives, friends, or associates from or through activities and transactions related to the conduct of any PCORI-funded research.

Recipient shall have its own policies and procedures for the avoidance and reporting of research and financial misconduct, including with respect to data privacy, and is expected to enforce those guidelines (when applicable) to any PCORI-funded research. Recipient acknowledges it has such established policies and procedures and agrees to abide by them while conducting research or other activities relating to this Contract.

Recipient is required to report any findings of research or financial misconduct to PCORI within thirty (30) days of the conclusion of an investigation into research or financial misconduct related to any PCORI-funded research. Should research or financial misconduct occur with respect to any PCORI-funded research, the Recipient must notify PCORI, in writing, of the nature of the violation, the corrective actions that will be taken to correct the violation, and a timeline within which those corrective actions will be executed. Pursuant to Section IX ["Enforcement Actions and Termination"] of this Contract, PCORI reserves the right to take any corrective action or to terminate this Contract.

D. Indemnification and Insurance

1. Indemnification.

To the extent permitted under applicable law, Recipient agrees to indemnify, defend, and hold PCORI and its directors, officers, employees, agents, and volunteers harmless with respect to any and all third-party claims, losses, damages, liabilities, judgments, or settlements, including reasonable attorney's fees, costs, and other expenses incurred by PCORI on account of any willful or negligent act or omission of the Recipient (or any of its directors, officers, employees, investigators, agents, contractors, or affiliates), any breach of this Agreement by Recipient, or any infringement or violation of a person's copyright or property rights by the Recipient. Recipient's obligation to indemnify, defend and hold harmless shall be limited to the extent that Recipient is afforded sovereign immunity under



applicable federal, state, or local laws. In such cases where Recipient's obligation to indemnify may be limited due to the requirements of federal, state, or local laws, Recipient shall be responsible for the ordinary negligent acts and omissions of Recipient's agents and employees causing harm to persons not a Party to this Contract.

2. Insurance.

To the extent permitted under applicable law, Recipient will, at its own cost and expense, have and maintain in full force and effect for so long as any obligations remain in connection with this Contract, insurance coverage for general liability and professional liability for an amount sufficient to cover all of its obligations under this Contract, and at PCORI's written request, shall provide proof of insurance coverage acceptable to PCORI.

E. Dispute Resolution.

PCORI and Recipient recognize that a bona fide Dispute may arise under this Contract that may relate to either Party's rights and/or obligations hereunder. PCORI and Recipient agree that they will act in good faith and use all reasonable efforts to resolve, in an amicable manner, any Dispute that may arise. If the Parties cannot resolve their Dispute after good faith negotiations, either Party may seek resolution by a court of competent jurisdiction.

F. Miscellaneous

1. Waiver.

Either Party's waiver of, or failure to exercise, any right provided for in this Contract shall not be deemed a waiver of any further or future right under this Contract.

2. No Assignment.

This Contract may not be assigned by Recipient without the prior written consent of PCORI.

3. Subcontractors.

Recipient is responsible for ensuring that any subcontractor(s) complies with the terms and conditions of this Contract. Recipient remains fully responsible for the actions, omissions, and performance of any subcontractors in activities related to this Contract.

4. Relationship with PCORI.



Recipient agrees that this Contract is not intended to create an agency, partnership, or employment relationship of any kind; and both agree not to contract any obligations in the name of the other or to use each other's credit in conducting any activities under this Contract. Recipient is and will be acting as an independent contractor in the performance of this Research Project, and it shall be solely responsible for the payment of any and all claims for loss, personal injury, death, property damage, or otherwise, arising out of any act or omission of its employees or agents in connection with the performance of this Contract. PCORI does not assume responsibility for activities supported by its research funding, for Research Project findings or outcomes, or for their interpretation.

5. Survival.

The terms of this Contract that by their sense and context are intended to survive termination of this Contract, including relating to intellectual property, data management and data sharing, indemnification, audit, and reporting, shall survive the termination of this Contract.

6. Governing Law.

This Contract shall be governed in all respects by the laws of the District of Columbia (without giving effect to principles of conflicts of law thereunder). All suits or other proceedings arising out of this Contract shall exclusively be brought in the courts of the District of Columbia, and Recipient consents to the jurisdiction of such courts for purposes hereof. Notwithstanding the foregoing, this governing law and venue provision shall not apply to a Recipient that is a state or public institution and afforded sovereign immunity under applicable state law.

7. Captions.

The captions of each paragraph of this Contract are inserted solely for the reader's convenience, and are not to be construed as part of this Contract.

8. Severability.

If any term or provision of this Contract shall be invalid or unenforceable in any respect, such term or provision shall be ineffective to the extent of such invalidity or unenforceability only, without in any way affecting the remaining terms of such provision or the remaining provisions of this Contract.

9. Amendment; Entire Agreement.

This Contract, including all referenced documents and Attachments, constitutes the entire agreement between the Parties with respect to the subject matter hereof,



and supersedes all prior writings or oral agreements with respect to the subject matter hereof. This Contract shall be amended only in writing and signed by all parties thereto, excluding the following exceptions. For modifications resulting from prior approvals or notifications as set forth in Sections VII. B. 1 [“Required Prior Approvals”], VII.B.2 [“Required Notifications”], or VII. C.6 [“Notifications of Presentations and Publications and Dissemination”], PCORI reserves the right to request signature by all Parties or may choose to use the Recipient originated written request to indicate approval of the Recipient-requested modifications. All amendments, including all modifications, agreed to as set forth herein shall be part of this Contract.

10. Authority.

The Parties executing this Contract represent that they have the authority to enter into and bind the Recipient and PCORI, respectively.

11. Counterparts.

To facilitate execution, this Contract may be executed in as many counterparts as may be required. All counterparts shall collectively constitute a single Contract. This Contract may be executed through delivery of duly executed signature pages by facsimile or electronic transmission.

12. Notices.

All deliverables, notices, and other communications required by this Contract shall be in writing and shall be delivered either by mail delivery or by email. If delivered by mail, notices shall be sent by overnight mail delivery; or by certified or registered mail, return receipt requested; with all postage and charges prepaid. All notices and other written communications under this Contract shall be addressed as indicated below, or as specified by subsequent written notice delivered by the Party whose address has changed.

Recipient will be assigned both a designated PCORI Contract personnel and a Program Officer who will be responsible for receipt of reports, answering inquiries, and remaining informed about the progress of the Research Project. Recipient is encouraged to work closely with these staff to seek guidance; request needed approvals, and provide updates, when needed or required.



Contract for Funded Research Project

HM-2022C2-28339

If to **PCORI**:

1333 New Hampshire Ave,
NW, Suite 1200
Washington, DC 20036

Invoices Sent to:

<https://pcori.force.com/engagement>

Contractual Matters:

fundedpfa@pcori.org

If to **The Regents of the University of California, San Francisco**

490 Illinois Street, 4th Floor San Francisco, CA 94143-6215 333 California Street

cgawardteam@ucsf.edu

Suite 315

Marico Moredo

San Francisco, CA 94143-6215

Administrative Official

Urmimala.sarkar@ucsf.edu

Urmimala Sarkar

Principal Investigator

[SIGNATURES APPEAR ON FOLLOWING PAGE]

Urmimala Sarkar, The Regents of the University of California, San Francisco
10/7/20)

Standard CR10 (Rev.



Contract for Funded Research Project

HM-2022C2-28339

IN WITNESS WHEREOF, the Parties have executed this Contract as of the day first set forth above.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

DocuSigned by:
Carolyn JM Best
By: _____
3BDDEZA191FE43E...
Name: Carolyn JM Best, PhD
Title: Program Operations Chief
Date: 9/21/2023

The Regents of the University of California, San Francisco

DocuSigned by:
Marico Moredo
By: _____
D0C6E8168FAC4A3...
Name: Marico Moredo
Title: Award Contract Officer
Date: 9/5/2023



Attachment A: PCORI-Approved Project Plan

(this page left blank intentionally)



Health System Strategies to Address Disparities in Hypertension Management & Control PFA: RESEARCH PLAN

RESEARCH STRATEGY

A. Research Question/Background

A.1 Impact of the condition on the health of individuals and populations (Criterion 1). **A.1a. Hypertension (HTN) is a significant health problem and improving HTN control is a public health priority.** Over 115 million Americans have HTN, the leading risk factor for cardiovascular disease and the most common cause of avoidable death and disability in the U.S.¹ HTN represents \$131 billion in health care costs annually, yet the majority of patients with HTN are out of range.^{1,2}

A.1b. Black and Hispanic/Latine populations, those with limited English proficiency (LEP), and those with low-income face HTN disparities. It is well known that certain groups (such as Black and Hispanic/Latine populations, those with LEP, and those from lower socioeconomic backgrounds) are significantly more likely to be diagnosed with HTN, more likely to have uncontrolled HTN,^{3,4} and more likely to experience disparities in HTN treatment. (We use the term Latine in this grant because it is gender inclusive and linguistically appropriate.)⁵ For some of the highest risk patients served in safety-net health care systems (HCS), there are high rates of multiple co-morbidities and a high burden of social needs that make self-management more challenging.⁶⁻¹⁰ (Methodology Standard RQ-3)

A.2 Effective interventions for HTN management exist but have not been widely or equitably implemented across population groups and health care settings. Effective, evidence-based interventions for HTN management, including self-monitoring of blood pressure (BP) at home linked to clinical care (termed “remote BP monitoring” here) exist.¹¹ These interventions allow for greater patient engagement in HTN self-management in everyday life,¹¹ as well as expanded opportunities for remote treatment adjustments beyond short, infrequent doctor visits.¹²⁻¹⁴ However, these interventions have not been scaled appropriately – especially within under-resourced HCS.^{15,16} To date, remote BP monitoring is less utilized among non-white patients, those with LEP, and those with low-income, as well as in safety-net HCS,¹⁷⁻²² despite high interest in the convenience of remote care²³ and an urgent need to address disparities among these populations.²⁴⁻²⁷ Thus, significant adaptation work is required so interventions with proven efficacy in well-resourced settings, but unproven effectiveness in the safety-net, have the optimal chance at being effective in safety-net settings. Additionally, recent systematic reviews underscore the need for coordinated implementation engaging patients and providers,^{10,13,28,29} and no study to date has directly compared patient- and provider-facing strategies within safety-net settings to advance our understanding of how to roll out evidence-based practices into routine care.

A.3. Research question that the proposed study will address (Criterion 1). What health system implementation strategies are effective in improving HTN control among populations and health care settings experiencing disparities?

Our proposal has the potential to fill gaps in understanding of how to feasibly and sustainably implement effective strategies to improve HTN control for patients experiencing disparities because it is in multiple safety-net settings serving racially, ethnically, and socioeconomically diverse patients that speak English and Spanish, as specified in the PCORI PFA³⁰. Existing evidence-based practices are not often specifically adapted and spread within public HCS, which disproportionately serves minoritized and low-income populations in the U.S. A recent systematic review and meta-analyses highlight the need to include populations experiencing disparities, such as older, minoritized, limited educational attainment populations.^{31,32} (RQ-1)

The 2017 ACC/AHA Guidelines recommend out-of-office BP monitoring to confirm and manage HTN.³³ A systematic review found that both ambulatory and remote BP monitoring are each associated with improved clinical outcomes, however, the authors concluded that there was no strong data to support the superiority of either BP monitoring technique.³⁴ Our proposal aims to fill this research gap by providing more information on out-of-office BP testing, specifically remote BP monitoring, and its impact on the initiation and intensification of treatment, patient engagement and experience, and clinical outcomes. (RQ-1)

This research is focused on questions that affect outcomes of interest for patients and their caregivers (e.g., BP control, communication with health care team, satisfaction with care, quality of life, and empowerment)^{6,35,36} as well as health care workers (e.g., how to improve HTN control leveraging team-based models of care, how to maximize one-on-one visit communication to support understaffed clinical settings,^{37,38} and how to adopt current evidence-based practices



that have not been tailored to safety-net HCS).³⁹ We will also dedicate Aim 1 of the project to co-develop and co-design standard implementation components with patients and caregivers to ensure the research is focused on their outcomes of interest.⁴⁰⁻⁴² (RQ-6)

A.4. Patient-centeredness (Criterion 5).

A.4.a. Patients are interested in using technology to manage their health. Differences in digital health use are not due to a lack of patient interest.^{23,43} Drs. Sarkar and Lyles have conducted multiple interview- and survey-based studies in the proposed setting and other public health systems in which marginalized communities (individuals with low-income, limited educational attainment opportunities, barriers to health literacy and/or English proficiency, and racial/ ethnic minority populations) expressed their strong desire to use technology to self-manage chronic conditions and communicate with providers.⁴⁴⁻⁴⁶ Dr. Lyles and Khoong recently demonstrated that the majority of patients in their public health network are interested in video visits;⁴⁷ with higher interest among Spanish-speaking patients compared to English-speaking patients. BP monitoring is an essential strategy for HCS to facilitate asynchronous communication and data sharing, which is even more critical in resource-limited settings in which patients face many competing barriers and there is a pressing need for novel delivery care models.^{37,38} (RQ-3)

A.4.b. Patients from marginalized and minoritized groups face barriers to using technology to manage their health.

Research led by Drs. Sarkar, Lyles, Sharma, and Khoong demonstrate disparities in the current use of technology by device access, health literacy, and race/ ethnicity, suggesting that existing technologies and related policies are not reaching diverse populations.^{48,49} A systematic review and meta-analysis of technology for HTN management, conducted by Drs. Khoong, Lyles, and Sarkar as well as Ms. Olazo, revealed that while mobile health tools are promising for chronic disease management, few studies include minoritized populations, older adults, and those with limited educational attainment. Direct observation of patients using digital health tools suggests that the tools are not optimized for patient's needs,^{50,51} such as processes for electronic communication⁵² and overall patient portal use,^{48,50} to bridge equity gaps. This research has underscored the need for tailored interventions to address widespread concerns that existing technology approaches may widen health disparities. (RQ-3)

A.4.c. Similarly, safety-net HCS face challenges implementing and sustaining technology-enabled interventions. Public HCS are central to providing health care to marginalized communities in the US, such as individuals with low income and those who are uninsured or Medicaid-insured. Public HCS provide essential public health care services throughout the US, in parallel but separate from networks of community health centers--caring for 34% of publicly insured and 8% of uninsured people in the US.^{53(p2019)} In order to address HTN at scale, interventions must include safety-net settings. These settings simultaneously face steep resource and staffing challenges, which are often unique to their public status (e.g., hiring and contracting through county or city governments), which can additionally impede efforts to participate in research and innovation collaboratives, including participation in PCORNet. To develop interventions effective in safety-net settings, studies must take into account their unique implementation contexts.^{39,54}

For example, well-resourced, integrated delivery systems like Kaiser have demonstrated success with comprehensive BP control programs like a system-wide HTN registry and an easy-to-use pharmacologic treatment algorithm, achieving BP control rates of >80%.⁵⁵ Yet, although health system approaches have been shown to be efficacious in multiple previous studies,⁵⁶⁻⁵⁸ they have not been implemented at scale within safety-net HCS. These HCS need a viable way to support patients in disease self-management and teams in provision of chronic disease care within the context of busy, relatively understaffed clinical operations, with seamless ways to receive and remotely communicate with patients about home monitoring to ensure timely changes to treatment plans.⁵⁹

A.4.d. This study incorporates patient-centeredness by partnering with patients in the creation of the final intervention components, ensuring marginalized communities served in safety-net settings are at the core of the study. It is clear that the evidence for remote BP monitoring is solid,⁶⁰ and, like other patient-generated health data, is now becoming central to chronic disease management programs.⁶¹ But providing patients with BP monitors alone is not sufficient for achieving success,^{15,61} and recent Cochrane systematic reviews underscore the need for coordinated implementation approaches/studies engaging both patients and providers.⁶² Therefore, we need *informatics-based implementation research* to test rigorous but real-world digital communication strategies between providers and patients surrounding remote BP monitoring.⁶³ Proactive remote/digital communication strategies must be robust with lifestyle support in addition to medication adjustments to improve outcomes.^{11,64,65} Finally, these digitally-enabled communication strategies to support remote BP monitoring must be integrated into real-world clinical workflows for maximum success,⁶⁶ especially to connect to ongoing care relationships.⁶⁷ We cannot continue to develop the newest



technology interventions without ensuring that implementation is considered and evaluated simultaneously with effectiveness.⁶⁸ Current dissemination approaches disadvantage resource-limited settings that might require thoughtful adaptation; instead, implementation can be reframed in health technology research with disparities reduction and patient-centeredness as a central tenet.²⁹

A.4.e. Examining implementation in a range of safety-nets will identify HTN management approaches that lead to sustained patient engagement, which is a key aspect of sustainability. We aim to measure patient engagement across our diverse clinic and participant characteristics. These findings will inform the extent of sustainability of the proposed intervention, filling a gap in the evidence. Based on our prior studies, we expect high levels of patient engagement, as described below.

B. Specific Aims (Criterion 3). We propose to conduct a multi-site, cluster randomized trial in safety-net HCS to evaluate the effectiveness of two levels of implementation strategies, patient-focused vs. clinic -focused, to improve HTN outcomes. Our proposed study is entitled Comparing Hypertension Remote Monitoring Evaluation Redesign (CHARMED). (RC-1)

B.1. Aim 1. Use stakeholder-engaged methods, including in-depth interviews and convenings, to adapt and tailor the components of the evidence-based, (a) patient-focused, and (b) clinic-focused interventions that work best for patients, clinicians/staff, and systems in the local context, using the theoretical model Framework for Reporting Adaptation and Modification – Expanded (FRAME).⁶⁹ This model is a roadmap for the process of adapting complex interventions for local implementation, and will be applied to give the intervention the optimal chance of being effective in real-world, safety-net HCS. Evidence-based practices focused on patients include: (1) Digital accessibility for patients without extensive skills (e.g., cellular-enabled BP monitors, SMS [Short Message Service] text reminders, upfront training, ongoing technical support), (2) Regular feedback and monitoring on home BP readings that connect to actionable patient behavior change, and (3) Language accessibility for English and Spanish speakers at a minimum, and additional languages as prioritized across HCS. Clinic-focused practices include (1) Anti-hypertensive medication intensification algorithms, (2) Standardized workflows for in-person and home-based BP readings, and (3) Use of a non-physician workforce at the top of their licenses with team-based responsibilities.

Goals. To generate the final suite of core intervention elements that will be implemented and evaluated across HCS.

Participant population(s). Patients, clinicians/staff, and health system leaders across all three HCS.

Comparators. N/A

Expected outcomes. Aim 1 activities will yield tailored, finalized interventions adapted from existing evidence-based practices according to FRAME and co-designed with patients, clinicians/staff, health systems, and the research team. The process of intervention development will also be rigorously documented for dissemination of the adaptation process to other settings embarking on complex multi-site and multi-level program rollout.

B.2. Aim 2. Conduct a 2x2 factorial cluster randomized trial of two different patient-focused interventions (high-intensity vs. standard remote BP monitoring) and clinic-focused interventions (training vs. facilitation for team-based HTN management) across 25 clinics spanning three large safety-net health systems.

Goals. To compare the effectiveness of evidence-based, adapted, and tailored, patient-focused and clinic-focused strategies to improve BP control among patients with HTN.

Participant population(s). English- and Spanish-speaking patients with HTN (covered on public insurance (primarily Medicaid or uninsured) and primary care clinics.

Comparators. The patient-focused “high-intensity” intervention (randomized at the patient-level within clinics) will provide patients with a cellular-enabled digital BP monitor and mobile tracking application (app) that can facilitate tailored, feedback messaging to support patients, adapted with patient and stakeholder input in Aim 1, compared with remote BP monitor and “standard” automated reminder SMS text messaging reminders. The clinical team-focused “facilitation” intervention (randomized at the clinic level) will provide standard workflows and coaching to support clinics in integrating home BP readings into routine care (e.g., implementing the recommendations for medication intensification by specific care team members), tailored to the local context through stakeholder engagement in Aim 1, compared with “training,” consisting of one-time clinical training without ongoing support from the intervention team.

Expected outcomes. The primary outcome will be changes in clinic-based systolic BP over the 6-month intervention, and secondary outcomes will include sustained changes in systolic BP up to 1 year post-intervention, patient-reported assessment of chronic disease care, and patient-reported medication adherence, as well as subgroup analyses of disparities in BP control by race/ethnicity and language. We expect to see a measurable and clinically significant



decrease in systolic BP, with variability by HCS. We expect to see some differences by race/ethnicity and language, though the direction and magnitude of such differences are not clear.

B.3. Aim 3. Within the cluster randomized trial (RCT), simultaneously evaluate key implementation outcomes of patient engagement with messaging and home monitoring and clinic team adoption of evidence-based practices.

Goals. Using a mixed methods approach, we will determine the effect of implementation strategies on patient-level and clinic-level adoption, overall and by key subgroups and HCS.

Participant population(s) and Comparators. Same as Aim 2.

Expected outcomes. We expect patient engagement to vary by HCS, race/ethnicity, and language, and we expect overall strong patient engagement with the intervention, as measured by cellular monitor and app usage. Adoption of the clinic-focused intervention, as measured by views of remote BP monitoring data, is likely to vary based on size, location, and organizational structure of each HCS, as well as vary by individual clinician. We expect that greater engagement and adoption will be associated with greater effectiveness as assessed in Aim 2.

C. Outcomes. (IR-2, IR-4, CI-3, SCI-5, RC-1) The primary outcome is patient-level systolic BP measured at clinic visits, utilizing all clinic-based BP readings collected in the electronic health record (EHR) for outpatient visits. We also include a range of secondary process and implementation outcomes, prioritizing outcomes of interest to patients and other key stakeholders elucidated during Aim 1, such as satisfaction and health-related quality of life, which have also been previously identified by adults with high BP as outcomes of interest.^{6,35,36}

Table 1. Primary and Secondary Outcomes				
Primary or secondary	Name of outcome	Specific measure to be used	Timepoints	Estimated power (if applicable)
Primary	Systolic BP (clinic)	clinic-based BP readings	Baseline, 6-mo (primary timepoint), 12-mo, 18-mo	Patient-facing intervention: 80% power to detect a systolic BP change at the patient level of 2.29mmHg. Clinic-focused intervention: 80% power to detect a systolic BP change of 5.83 mmHg
Secondary	Systolic BP (home)	Home-based BP readings ⁷⁰	Baseline, 6-mo (primary), 12-mo, 18-mo	Same as systolic BP (clinic)
Secondary	Patient activation and satisfaction	Patient Assessment of Chronic Illness Care (PACIC) ⁷¹	Baseline, 6-mo	80% powered to detect a smaller 0.5 difference for a 1-5 scale with 91 participants per arm ⁷²
Secondary	BP control	<140/90mmHg, at the patient level	Baseline, 6-mo, 12-mo, 18-mo	80% power to be able to detect a 6% difference in the proportion patients with BP control, assuming ICC of 0.05 and approximately 60% of patients in control at baseline. The corresponding clinic-level effect size would be 5.95, or a difference of 14 percentage points in BP control.
Secondary	Medication intensification when BP is uncontrolled	Number of classes of anti-hypertensive medications prescribed per patient	Baseline, 6-mo, 12-mo, 18-mo	We would be able to detect with 80% power a 0.34 mean difference in number of anti-hypertensive medications at the patient-level, assuming an average of 3 medication classes at baseline (s.d.=3) and an ICC of 0.05. The corresponding clinic-level mean detectable difference of 0.87 classes of anti-hypertensive medications.
Secondary	Patient-reported medication adherence	Krousel-Wood medication adherence scale ⁷³	Baseline, 6-mo	
Secondary	Patient Implementation outcome: Reach	Proportion of eligible patients enrolled / eligible	Over entire study period	We would have 80% power to detect a 5% enrollment difference at the patient-level, assuming ICC of 0.05 and that approximately 20% of patients would complete enrollment in the standard arm. The corresponding clinic-level detectable



				difference would be 13% difference in proportion enrolled.
Secondary	Patient Implementation outcome: Adoption	Proportion of patients enrolled who send remote BP monitoring data	Over entire study period	We would have 80% power to detect a 4% difference in those sending any vs. no BP readings at the patient-level (assuming at least 80% of patients send any BP readings in the standard arm), and 10% difference at the clinic level.
Secondary	Patient implementation outcome: Adoption	Mean number of home BP readings	Over entire study period	We would have 80% power to detect a mean difference of 5.7 BP readings sent at the patient level, assuming mean of 40 BP readings sent over entire intervention period in standard arm (s.d.=50) and ICC=0.05. The corresponding clinic-level detectable difference in mean number of BP readings would be 14.6.
Secondary	Clinic implementation outcomes: Adoption	Clinic views of remote BP results	Over entire study period	We would have 80% power to detect a mean difference of 0.34 clinician views of home BP readings at the patient-level, assuming the average of 1 view of home BP readings by clinicians in standard arm (s.d.=3) and ICC=0.05. The corresponding clinic-level detectable difference in mean clinician views of home BP reading would be 0.87.
Secondary	Patient/Clinic Implementation outcomes: Engagement	Patient interviews and clinic team interviews measuring satisfaction and perceived benefit	Baseline (Aim 1) and post-intervention (Aim 3)	NA- qualitative
Secondary	Clinic implementation outcomes: Implementation	Direct observation of how and to what extent clinics adopt the intervention	6-mo, 12-mo	NA- qualitative
Secondary	Clinic Implementation outcomes: Maintenance	Direct observation of how and to what extent clinics sustain the intervention	18-mo	NA- qualitative

Systolic BP. Systolic BP will be measured and assessed via the EHR in all HCS at every primary care visit throughout the baseline and follow-up time periods. We chose this outcome because this measure is routinely documented among all primary care patients receiving ongoing care, regardless of intervention status. This will allow us to model BP improvements longitudinally. There is ample evidence that improvement in systolic BP is of primary importance in HTN management, predicting the risk of cardiovascular disease better than diastolic BP.⁷⁴ Because out-of-office BP is consistently associated with HTN-related morbidity and mortality,⁷⁰ we will also examine remote BPs in a secondary analysis, among the subset for whom remote BP readings are available. (IR-4)

Patient Assessment of Chronic Illness Care (PACIC). Among the patients with complete survey data when enrolling into the patient-facing intervention, we will also be able to examine secondary patient-reported outcomes of PACIC, which is a key measure that will signal patient engagement and satisfaction with care.⁷¹ We are using PACIC given its importance both among our patient and stakeholder leadership team, the alignment of the measure with the conceptual model underlying the intervention, as well as in the published literature as a measure of perceived quality of patient-centered, collaborative chronic disease care.^{75,76} (PC-3, IR-4, SC-5)

BP control. A dichotomous measure of BP control (defined as <140/90 mmHg by performance metrics used by participating HCS) will be taken for each patient, averaging the last four available outpatient BP readings at baseline (i.e., 3 months prior to intervention), during the intervention (i.e., 6 months), and follow-up (i.e., 6 and 12 months post intervention) periods. This dichotomous measure of BP control is often used for treatment decisions and reimbursement/payment for care,⁷⁷ and can be aggregated at the clinic and HCS levels. If HTN performance metrics change towards a goal of <130/80, we will update the threshold accordingly. (IR-4)

Medication intensification and adherence. We will measure the number of classes of anti-hypertensive medications prescribed per patient (also assessed at the baseline and follow-up time periods), to indicate medication intensification over time.⁷⁸ Measuring the number of classes of medication prescribed is representative of physician responses that are intended to make treatment more effective in reducing HTN-related cardiovascular morbidity and mortality. (IR-4) We



will also measure on the baseline and 6-month intervention surveys patient-reported medication adherence, using the validated Krousel-Wood scale.

Implementation outcomes. We will use a mixed methods approach and the RE-AIM framework to assess quantitative and qualitative implementation outcomes. The RE-AIM Framework will guide our evaluation plan, identifying potential factors that might influence intervention impact.^{79,80} This will include RE-AIM components of Reach (the percent and representativeness of individuals willing to participate to an initiative);⁸¹ Engagement (the extent to which patients/team members participate in their respective intervention components), Adoption (the numbers of clinics implementing the remote BP workflows and reasons why or why not); Implementation (the degree to which the intervention was delivered as intended); Effectiveness (the outcomes achieved and consistency across groups); and Maintenance (the long-term implementation success and effectiveness). Quantitative and qualitative approaches are required to evaluate implementation. RE-AIM is one of the most frequently used frameworks to evaluate implementation outcomes across diverse populations, settings, and health conditions.⁸² (IR-4)

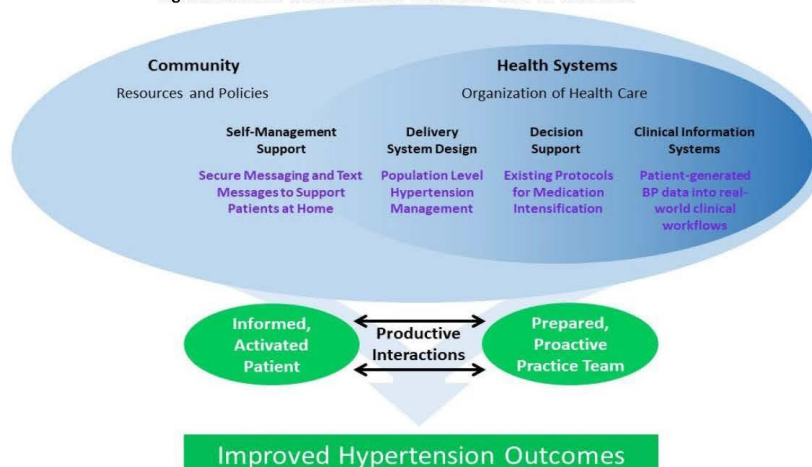
D. Study Design and Methods (Criterion 3). This will be a multi-site, cluster RCT, with individual-level randomization of (a) patients within the clinics to receive high-intensity self-management support and remote BP monitoring with cellular-enabled devices versus standard automated SMS text message reminders for remote BP monitoring and (b) clinic-level randomization of clinics to facilitation versus training for clinical workflows (Table 2). We will also conduct a mixed methods evaluation to understand critical implementation outcomes and support widespread dissemination. This work will be based in public HCS in California, which are not often included in clinical or implementation research studies.⁸³⁻⁸⁵ (RQ-2, SCI-1)

Table 2. Study groups in the 2x2 Factorial Trial		
Patient Intervention	Clinic Intervention	
	Training	Facilitation
Standard	Clinic: one-time training Patient: automated "reminder" SMS messages and remote BP monitors	Clinic: facilitation with ongoing training and online coaching Patient: automated "reminder" SMS messages and remote BP monitors
High-intensity	Clinic: one-time training Patient: interactive, digitally facilitated self-management with "feedback and reminder" SMS messages and remote BP monitoring	Clinic: facilitation with ongoing training and online coaching Patient: interactive, digitally facilitated self-management with "feedback and reminder" SMS messages and remote BP monitoring

D.1. Conceptual Framework/ Causal Model (Criterion 3). The CHARMED study will be informed by the Chronic Care Model (CCM, Figure 1). The CCM, developed at Kaiser Washington (formerly Group Health), has been implemented in multiple health settings and has led to improved health outcomes and improved patient experience of care.⁸⁶⁻⁸⁹ The CCM specifies that improved chronic disease care is achieved through productive interactions between an informed, activated patient and prepared, proactive, practice team⁹⁰ – the two primary levels of implementation within this proposal. The CCM also identifies levels of influence: the a) individual patient, b) interpersonal patient-clinician relationship, and c) community, at which we can work across multiple domains: 1) behavioral (support for self-management), 2) sociocultural (specific emphasis on patients with lower income and those with LEP, and 3) health care system (integrate into existing workflows and addressing limited health literacy). (CI-1, SCI-2)

The CCM conceptual framework informs the multi-level study design, key variables, and relationships between the patient- and clinic-level interventions being tested and implementation outcomes, and thus is the basis for how we

Figure 1. Chronic Care Model and Theoretical Basis for CHARMED





anticipate that improving productive interactions between the patient and care team can result in improved HTN outcomes. (CI-1, SCI-2)

The proposed intervention addresses both key drivers of successful remote BP monitoring to improve HTN management at scale. First, in order to be informed and activated, patients need to be engaged in self-management of their chronic condition in their daily lives, enhanced by digital reminders and support.⁹¹ Second, to be prepared and proactive, clinical teams need seamless ways to receive and remotely communicate with patients about remote BP monitoring to ensure timely changes to treatment plans.⁵⁹ Both of these approaches have been shown to be efficacious in multiple previous studies,^{56–58} yet neither has been implemented at scale within safety-net HCS.

D.2. Comparators. (SCI-1)

D.2.a Patient-focused interventions: Both arms in the patient-level intervention will receive evidence-based interventions for remote BP monitoring, but with differing levels of implementation intensity. The core evidence-based interventions are:

Remote BP monitoring: Robust evidence indicates that home BP monitoring is acceptable, feasible, has strong patient engagement, and can contribute to enhanced BP control.^{57,91–95} In terms of current use and acceptability, remote BP monitors are currently in use on ad-hoc basis at participating clinics. Their availability and connectivity vary, as do procedures for obtaining data from home monitors. The most common currently used strategy is patient self-monitoring of BP at home with patients writing down or bringing home BP readings to their clinic visits to discuss with their clinician. For this proposal, we will utilize technology from an existing cellular-enabled BP monitor for the intervention, a validated device manufactured by CareSimple.^{96,97} This device enables participants to take their home BP reading and automatically sends this data to the cloud via a cellular data transmission; no smartphone, WiFi, or Bluetooth connection are required, dramatically reducing the digital access and digital literacy barriers for many patients with low income.

Self-management support: Self-management support for BP management is a longstanding, evidence-based strategy that has been delivered with varying intensity and effectiveness.^{98–103} One approach to self-management support is the use of general disease education and reminders. For example, reminder SMS text messages have been used to support medication monitoring and adherence across a range of chronic conditions, and a prior RCT of more intensive self-management support for HTN have demonstrated short-term effectiveness.^{104,105} A more intensive approach involves tailored information, such as feedback on remote BP readings in real time and tailored recommendations for behavior changes.¹⁰⁶ Outside of

clinical trials, neither of these approaches are widely implemented within primary care; instead, ad-hoc practices such as clinician-provided education or referral to team members for education are in use. Therefore, this study will utilize a ready-to-use cellular BP monitor and companion app (CareSimple,

available in multiple languages, including English and Spanish) to facilitate both home BP monitoring as well as seamless reminders and feedback communication (Figure 2). (RQ-5)

D.2.b Clinic-level interventions: There are three evidence-based, clinic-level elements in each arm of the clinic level intervention: (1) standard work and algorithm for medication intensification, (2) integration of remote BP results into clinical care, and (3) panel-based outreach for HTN management. In the training arm, these elements will be delivered in a one-time training to clinic teams. In the facilitation arm, ongoing practice coaching and peer support will undergird the use of these three elements. In terms of the evidence base, use of a standard HTN medication algorithm improves HTN-related cardiovascular morbidity and mortality⁵⁵ and has been successfully translated into safety-net settings.¹⁰⁷ RCTs of remote BP monitoring have integrated remote values into clinical care with positive results.^{32,99} Finally, panel management for HTN is an element of many effective complex interventions. The current use of these intervention

Figure 2: CareSimple Patient- and Provider-Facing Platforms





components varies across HCS. All HCS have existing protocols for BP intensification and team-based outreach. All HCS have an electronic registry of patients with HTN. The extent of implementation and fidelity to the existing protocols is unknown. We believe that both intervention arms have potential to improve HTN outcomes. (RQ-5)

In the clinic, all clinicians will also have access to a provider-facing dashboard within CareSimple to see the home BP readings of their patients enrolled into the study. When onboarding into the study and after receiving informed consent, the research team will connect primary care providers to their empaneled primary care patients within the system, which will provide online access to the remote BP readings as needed within the context of usual care and HTN treatment. The ability to integrate remote BP readings from CareSimple dashboard directly into the EHR at each HCS is also possible and will be explored, but it is not a requirement for HCS to be able to use this cellular BP monitoring system. Two of the HCS are on Epic EHR systems (SFHN and CCHS), and the third HCS is on Cerner EHR (VCHCA), and CareSimple has developed API integration for both of these EHRs. (RQ-5)

D.3. Study population and setting. This proposal will test implementation strategies for remote BP monitoring for HTN in three large, county- or state-run safety net HCS serving Medicaid and uninsured populations, with a high prevalence of Black and Hispanic/Latine patients who are chronically ill and have LEP, inclusive of urban, suburban, and rural areas. We anticipate the study will produce generalizable results due to the diversity of patients cared for in the state's public health systems (see A.4.c). The HCS are described below:

San Francisco Health Network (SFHN) - SFHN includes twelve primary care clinics at Zuckerberg San Francisco General Hospital (ZSFG) and community-based clinics located throughout the city. These clinics serve over 80,000 low-income adult patients, the vast majority of whom are on Medicaid or are uninsured, from the city and county of San Francisco. About 40% of patients speak a primary language other than English (15% monolingual Spanish speakers), and about 40% have limited health literacy. Investigators Drs. Sarkar, Sharma, and Khoong have clinical practices within SFHN, and along with Dr. Lyles are experienced at including marginalized populations in research and implementation projects.

Contra Costa Health Services (CCHS) - CCHS includes 10 federally qualified health centers (FQ), as well as school-based health clinics and mobile health services. CCHS offers a county-sponsored HMO, Contra Costa Health Plan (CCHP), the first federally qualified, state licensed, county-sponsored health maintenance organization (HMO) in the United States. CCHP now serves 200,000 people, including Medi-Cal and Medicare beneficiaries. Drs. Pramanik and Abtahi possess experience engaging racially, ethnically, and socioeconomically diverse participants in this setting.

Ventura County Health Care Agency (VCHCA) - VCHCA includes two hospitals, 22 primary care sites, and provides more than 500,000 patient visits annually. Nearly two-thirds of VCHCA's patient population identifies as Hispanic/Latine. One-third of the system's patients speak Spanish. Ventura is a rural county and VCHCA serves a large farmworker population. Drs. Stern and Cho will collaborate with VCHCA's patient engagement leads to ensure an inclusive approach at this HCS.

The three HCS received support from organizational leaders, all of whom affirmed that this project aligns with organizational priorities and that information technology resources are available. Additionally, all these leaders communicated that this project will directly impact health care delivery at their respective HCS and a commitment to sustaining the intervention (see **letters of support**).

D.4. Study design (Fig. 3) (Criterion 3).

Aim 1: We will use stakeholder-engaged methods to adapt remote BP monitoring, so it has the optimal chance at being effective in real-world, safety-net HCS.

Focus Group Procedures: We will convene focus groups with several stakeholder groups including (a) clinicians/system leaders (physicians, informaticists, nurses, medical assistants, advanced practice providers (such as nurse practitioners), and clinical pharmacists) and (b) patient and family advisory boards (PFABs) (in English and Spanish) as a means of guiding the adaptation of the intervention and the implementation process (SCI-3). Our discussion guides will be informed by the literature and input from representatives of stakeholder groups.¹⁰⁸ We will conduct focus groups with English- and Spanish-speaking patients affected by HTN (n=6, English and Spanish at each of the 3 HCS). For clinical and system staff, we will hold 5 focus groups (mixing participants across HCS) to understand work systems and processes impacting HTN management, including the team-based management of home vital signs into everyday workflows, the use of medication algorithms to support standard intensification of medication across clinics, and the use/non-use of differing care team members to support remote monitoring. Each focus group will consist of 6-8 individuals, conducted

by a trained facilitator accompanied by staff taking detailed notes. All focus groups will be recorded and transcribed. (QM-1, QM-2)

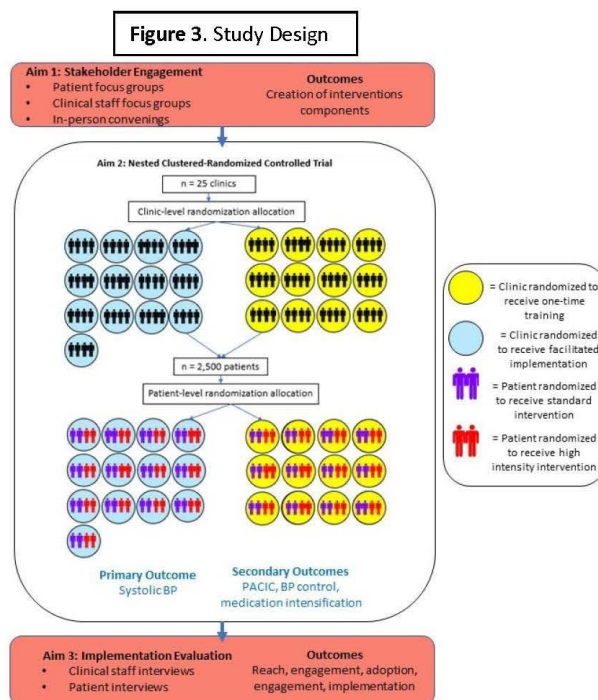
In-person Convening Procedures: Sampling from the same participants and stakeholders from the focus group processes, we will then convene an all-day event to bring together all HCS to 1) provide results from the focus groups, 2) elicit input on proposed implementation strategies and tailor as needed, and 3) build relationships between stakeholders by understanding unique values, structures, and processes of clinics and other stakeholders.¹⁰⁹ We will plan and facilitate this convening using stakeholder-engaged and human-centered design principles such as mutual respect and trust, shared decision making, capacity building, empowerment, co-ownership of data and research products, and processes for dissemination of findings to stakeholders.^{110 111,112}

During this event, we will present intervention components and draft implementation protocols to provide to each breakout group for direct feedback and editing. We will also facilitate conversations about a) barriers and logistical challenges to implementation, b) technical capacity and assistance, c) fostering relationships and trust, d) identifying and supporting implementation leaders, champions, and change agents, e) best practices for communication and coordination, and f) any additional themes that emerged. Discussions will focus on challenges, opportunities, and strategies, with key points recorded on flipcharts by a research team member in attendance within each breakout group. Each facilitated group session will be recorded and transcribed verbatim. Flipchart data and other written documents will be photographed and transcribed. We will use onsite translation and bilingual staff to accommodate Spanish speakers. (QM-1)

Aim 2: Cluster randomized trial. We will compare 2 levels of evidence-based bundled interventions for remote BP monitoring in a 2x2 factorial design: (1) patient-focused intervention: **“High-intensity” remote BP monitoring and self-management support** using cellular-enabled BP monitors and patient outreach conducted via interactive SMS text message reminders and messaging for feedback and monitoring, **versus “standard” remote BP monitoring and self-management support** in which patients will receive automated, generic, one-way SMS text message reminders to support remote BP monitoring and HTN self-management; and (2) clinical team-focused intervention, we will provide **ongoing clinic-level “facilitation”** for workflows, ongoing peer collaboration, and active, longitudinal coaching to support clinics in integrating remote BP readings into standard care, compared with a **one-time clinical team “training”** to optimize evidence-based HTN management.¹⁰⁷ It is designed as a superiority comparison for both sets of interventions. (RC-1)

Rationale: There is existing evidence to support both patient-facing interventions for remote BP monitoring as well as clinic-facing interventions to support team-based and population-level management of patients with HTN to improve the standardization of HTN care amid busy clinical workflows. In this cluster RCT, we will specifically randomize clinics and patients to receiving different levels of implementation support for both evidence-based interventions. This will enable us to examine the independent as well as joint effects of these interventions on BP improvements among patients treated in the three HCS in this study. (RC-2)

Clinic-based Intervention Procedures: Each clinic (n=25) will meet with the lead HCS (UCSF, spearheaded by Dr. Sarkar) to document baseline activities related to HTN management, using the activities outlined in Aim 1 as the starting place.





Then, we will randomize half of the clinics (stratified by HCS and median clinic size to ensure balance) to receive facilitated implementation for the first 12 months of the intervention. A staff member not involved in data collection and analysis will randomize clinics, stratifying by HCS to ensure balance within the three HCS. Clinics randomized to receive facilitated implementation will designate a clinical champion to partner with the lead HCS on adapting standardized remote BP monitoring intervention components from Aim 1 to their specific clinic needs. This includes medication algorithm steps (e.g., the need to adjust medication algorithm based on local formulary), identifying the staff role for tasks (e.g., medical assistant vs. nurse reviewing remote BP readings in routine fashion), and the use of the EHR for the program (e.g., how remote BP readings might feed into EHR directly, vs. staff checking separate dashboard for patient-generated data). After adaptations are completed, the clinical champions in the supported arm will continue to participate in monthly coaching meetings (facilitated by Dr. Sarkar) as well as site visits to clinics in the facilitated group at 6 months and 18 months (at least 4 and up to 8 per site for a total of 12-24 visits) to further refine and expand their processes as relevant, reporting out on clinic-level BP control rates and implementation activities in parallel.¹¹³ Clinics randomized to training implementation will receive a one-time coaching call to identify implementation plans for home BP reading at their HCS, but no detailed assistance with coaching as the implementation unfolds. (RC-1)

Patient-level Intervention Procedures: Each clinic will also send their HTN registry database to the lead HCS (UCSF, spearheaded by Dr. Lyles) to generate the total denominator of eligible patients with HTN for patient-focused intervention. Patients with the two BP values in the past year out of range ($\geq 140/90$ mmHg) will be contacted by phone, SMS text message, and/or patient portal message about the study to assess their interest. To promote wide use of the remote BP monitors, we will only exclude individuals with conditions that might complicate remote BP monitoring (such as pregnancy, end-stage liver or renal disease, those on dialysis, pacemaker use, heart failure with reduced ejection fraction, serious arrhythmia, dementia, hospice/palliative care, and behavioral health condition impeding participation (e.g., schizophrenia)), but we will include all other patients with HTN from all age groups who are English or Spanish speaking. Enrolled patients (n=2,500) will be remotely consented and randomized to high-intensity (receiving the easy-to-use cellular-enabled BP monitor from CareSimple and feedback and monitoring) vs. standard (remote BP monitoring and generic SMS text messaging reminders). Those in the active intervention arm will be mailed the cellular BP monitor to their home along with onboarding materials in either English and Spanish (including instructions for downloading and using the companion mobile app), with the contact information for technical support questions. Each participant will also receive digital communication via SMS text messaging in either language to 1) remember to check their BP at home at least 6 times per week (3x in a morning and 3x in an afternoon), and 2) rotating weekly SMS text messages with lifestyle advice and tips about HTN management, such as medication adherence and diet. (RC-1)

Masking procedures. It will not be possible to blind research staff in this intervention given that the patient-focused and clinical-focused intervention components will differ based on the assigned trial arm. However, analysis will be blinded to randomized arm assignment (IR-6). We will also publish a detailed RCT protocol for Aim 2, to be submitted to our IRB, ClinicalTrials.gov, and published in a peer-reviewed journal (RQ-2). We will report our trial procedures according to the CONSORT guidelines so that internal and external validity can be assessed (IR-5).

Data collection and management procedures. In addition to using CareSimple for BP data collection, we will utilize the Eureka research platform to facilitate the multi-site RCT, including the critical patient-reported outcomes that are not collected by CareSimple. Eureka is an NIH-funded (5U2CEB021881) direct-to-participant, rapid, efficient, and cost-effective electronic consent (eConsent), data collection, and study management system available in multiple languages including English and Spanish. The Platform was developed by Dr. Pletcher and colleagues¹¹⁴ and has been used for web-based recruitment of over 260,000 consented research participants (see **Project/Performance Sites and Resources**), including for a recent, successfully-recruited individually randomized trial of over 2000 patients with uncontrolled BP.¹¹⁵ Eureka can provide a site-specific onboarding experience for patients, establish a connection between the patient's Eureka account and the CareSimple data system (with patient's authorization, for the purpose of BP data collection from CareSimple and linkage), accomplish the stratified randomization by patient described below, deliver randomization assignments to patients and providers, provide research staff with study management reports, deliver surveys to patients (with reminders) to collection patient-reported outcomes, and provide ready-to-analyze study datasets including linked data from enrollment, randomization and CareSimple devices (e.g., BP measurements).

Aim 3: Implementation Evaluation. We will use a mixed methods approach to conduct the implementation evaluation. We will use in-depth interviews with all stakeholders (patient, clinical care team, leadership) to identify intervention and context factors necessary for implementation within and across health care settings. We will aim to interview a diverse



range of participants and stakeholders by both demographics and HCS. We expect approximately 105 qualitative interviews with key informants from SFHN, VCHCA, and CCHS. We aim to interview approximately 10-15 clinicians and 15-20 patients per HCS. In our experience conducting qualitative interviews, this is the approximate number of interviews required to reach thematic saturation, but we can conduct more interviews if necessary. (SCI-4, QM-1, QM-2) We will also quantitatively capture patient reach (proportion of patients enrolled in trial), patient adoption (proportion of patients enrolled submitting data), clinic adoption (proportion of clinic reviewing data). (MM-1) Rationale: A mixed methods approach will allow us to build a comprehensive understanding of HSC implementation strategies at the clinic and patient level. It will also provide opportunities for our stakeholders to share their experience throughout the research process. (MM-2)

Provider/Staff Interview Procedures: We will interview 45 clinicians across all primary care sites who participated in the RCT to understand clinic hierarchies, workflows, competing priorities, and implementation readiness.

Patient Interview Procedures: We will interview 60 patients (approximately 50% English and 50% Spanish speaking) who participated in the RCT to understand their experiences. This will include purposive sampling of those engaged (i.e., home BP readings more than 3 months), as well as those who dropped out or were not engaged. We will pay careful attention to the sampling of patient participants to ensure diversity by gender, race/ethnicity, age, and language preference, as well as their level of engagement with the intervention during the trial. Patient interviews will cover concepts of feasibility and care management processes, but also ease of use and usefulness.¹¹⁵

All interviews will be audio recorded and professionally transcribed. Spanish-language sessions will be translated. From the transcripts of the interviews, we will apply content analysis informed by existing RE-AIM domains as well as open coding that captures new categories as they emerge.^{116,117} Two investigators will read a portion of the transcripts and generate a list of “observer identified” themes related, which will be developed into a coding template by consensus. These codes will be applied to the remaining transcripts, also employing open-coding to identify novel themes as the analysis continues. As the analysis progresses, the research team will develop a more refined understanding of implementation successes and barriers. The major categorization of the findings around the RE-AIM framework will allow us to dive into specific domains and subdomains that emerge as critical. While we expect the qualitative analysis to impact our understanding/interpretation of all 5 of the RE-AIM domains, we specifically expect the *Implementation* and *Maintenance* domains of RE-AIM to be qualitatively fleshed out.

D.5. Randomization. We propose two levels of randomization. First, clinics will be randomized to receiving training vs facilitation for implementation of bundled, team-based, standardized BP management practices (n=12-13 clinics in each arm). Second, patients within the clinics will be randomized to receiving high-intensity remote BP monitoring with cellular-enabled BP monitors and tailored, interactive, digitally facilitated self-management support vs. standard dispensing of remote BP monitoring with automated SMS text messaging support for monitoring HTN at home (n=1,250 patients in each arm). The randomization of the clinics will be stratified by HCS (SFHN, CCHS, VCHCA), and the randomization of patients will be stratified by clinic, with blocking to ensure relative balance in randomization arm within clinic. (RC-5) Enrolled patients (n=2,500) will be remotely consented and receive the easy-to-use cellular-enabled BP monitor from CareSimple. They will be randomized to interactive messaging for feedback and monitoring vs. generic automated SMS text remote BP monitoring reminders. Eureka enables randomization within the platform, and the study team will program the randomization such that it is stratified by each clinic with blocking to ensure balance at both the clinic- and HCS-levels.

D.6. PCORnet® or Other Networks. Safety-net health care systems face challenges to participating in PCORnet due to limited research infrastructure, which makes research and implementation efforts in these settings so critical (see section A.4.c). Instead of PCORnet, we will use our own network of collaborators among safety net HCS in California serving large diverse populations of historically marginalized patients.

E. Analytic Plan (Criterion 3).

Aim 1: For Aim 1, we will use qualitative data analysis on recordings of the interviews, convenings, and other activities to document the final intervention elements that will be implemented in all clinical settings. (QM-3, QM-4)

Aim 2: For Aim 2, we will use mixed effects regression models to evaluate changes in repeated systolic BP readings, with both sets of interventions as primary predictors, a fixed effect for site and random effects for clinic and participant. We will also include an interaction term between the patient-level and clinic-level intervention terms to determine their independent and joint effects (RC-3, RC-4). If there is a significant interaction, we will describe the effect of the patient-focused intervention within levels of the clinic-focused interventions and vice versa. In the interaction analyses, the



minimum effect size, as usual, would be about twice the magnitude of the minimum detectable marginal effects (i.e., the main effects in the primary analysis) – and our power calculation below reflects this.

In a priori planned heterogeneity of treatment effect analyses, we will also use regression models to assess whether disparities in BP control differ by patient race/ethnicity and language in subgroup analyses, but these are not powered to detect the same clinical improvements (RQ-4, IR-1, HT-1, HT-2, HT-3). More specifically, SBP improvements *within* Black patients by intervention arms will require triple the primary analysis effect size (i.e., 6.9mmHg pre-post difference) if Black patients represent 33% of the final recruited sample. This same effect size also holds for all other within subgroup analyses, such as for Spanish speakers. Furthermore, the interaction analyses needed to examine changes *between* groups (e.g., Black-White SBP disparities over time) will require even larger effect sizes, dependent upon final enrollment numbers within each subgroup. However, despite limited power, we will complete these as a priori analyses. We believe we are ethically obligated to investigate heterogeneity of treatment effects, given the diversity of the sample and the necessity to report on difference-in-difference approaches within our randomized design.

The trial will run during Years 2-4, with analysis occurring in Year 5.

Aim 3: For Aim 3, we will use a mixed methods approach and the RE-AIM framework to assess quantitative and qualitative implementation outcomes within each reach, effectiveness, adoption, implementation, and maintenance domain.^{80,118} **Quantitative implementation outcomes:** We will report summary statistics for the Reach of our intervention among eligible participants.¹¹⁹ We will determine the proportion of enrollees who complete the intervention (Reach) and clinicians who participate in recruitment (Adoption). We will examine Reach overall and by patient age, language, income, and race/ethnicity comparing those who enrolled and those who did not, using EHR data. We will examine Adoption overall and by clinician characteristics of HCS, age, gender, and race/ethnicity. We will use chi-squared to determine the significance of observed differences. **Qualitative implementation outcomes:** The study team will apply a qualitative, mixed inductive-deductive analytic approach to the sample,¹²⁰ as we have done in prior work.^{39,121,122} For interview data, we will review a subsample of 5 interviews to develop a preliminary codebook, applying the RE-AIM domains as well as open coding of other concepts that emerge from the sample. We will identify content relating to each of the domains, from each stakeholder group. As an example, if a clinic leader describes the intervention as “really useful for our patients,” we could identify that as high acceptability within the Implementation domain. The group will meet to finalize the codebook content. Once the codebook is developed, this will be applied to the remaining samples of interviews. We will import interview transcripts into Dedoose, a qualitative data analysis software.¹²³ All coding notes and thematic findings will be reviewed with all stakeholder groups (described in our Engagement Approach) for their input on the interpretation of results. (QM-3, QM-4, MM-3)

E.1. Sample size and power (Criterion 3).

For the primary analysis of improvement in systolic BP in the Aim 2 cluster randomized trial, we anticipate the ability to randomize 100 patients each (n=2,500 in total) within 25 clinics with an average baseline systolic BP of 145 mmHg (s.d.=20mmHg). When stratifying the analysis by clinic intervention, we would have 80% power to be able to detect patient-level differences in systolic BP of 3.23 mmHg and clinic-level differences of 8.64 mmHg (assuming an intra-cluster correlation of 0.05). (CI-2, RC-3) We estimate enrollment of 70 patients per month over a 3-year period. We expect to have mostly complete data on clinical outcomes from the EHRs at SFHN, VCHCA, and CCHS given that BP is routinely collected as a part of clinical care. For this outcome, the missingness would arise from patients who fail to attend health care visits or leave the delivery system during the study. We expect this missingness to be <10% of our sample for our primary clinical outcome. (MD-1).¹²⁴ While we are powered on the primary outcome despite missingness, we will monitor non-random missingness and use multiple imputation methods as needed (MD-2, MD-4, SCI-4).

Another outcome will be PACIC.⁷² A RCT at the SFHN improved PACIC by 0.83 points (on a 1-5 scale range).⁷² Using the previously reported standard deviation of 1.2 on this measure, this proposed RCT would be able to detect a smaller 0.5 difference for this scale with 91 participants per arm and 80% power. This analysis assumes a type 1 error rate of 0.05 is an acceptable, meaningful change from prior work. Thus, our planned sample size should detect meaningful change.

F. Recruitment Plan and Participant Information (Criterion 3) for all aims. (PC-2)

F.1 Inclusion/Exclusion Summary. We will include patients 18 years or older, with HTN or high BP (BP >140/90 mmHg at least twice in the previous 12 months), and able to provide consent. We will exclude patients if they have severe self-management limitations due to disability or medical condition, active psychosis or mania, a health condition that precludes program participation, or cannot read and write in English or Spanish. We will include clinicians and staff



personnel if they currently work in a primary care clinic at one of the three HCS and participate or have experience in population health management of HTN. We will exclude clinicians and staff personnel if they have a mental health or physical condition that precludes program participation. Please see **Appendix Tables 1 and 2** for detailed inclusion/exclusion criteria.

F.2 Recruitment Summary. For **Aim 1** patients, potential participants will be identified through existing HTN chronic disease registries and referrals from existing PFABs at each HCS. For **Aim 1** clinical team members, each HCS PI will identify clinical champions to facilitate clinician and staff participation. All **Aim 1** participants will be compensated for their time in the amount of \$50 for approximately 1 hour (Target: 6-8 participants per focus group). For **Aim 2**, the clinic-level intervention will randomize 25 clinics (12 in one arm and 13 in another arm) to support the implementation of standard HTN workflows (Figure 4). We will begin enrolling clinics in each arm in Year 2 until the beginning of Year 3, with 18 months of follow-up. For the patient-level intervention, we will recruit an average of 70 patients each month over a 3-year period (Years 2-4) (Table 3). Potential participants will be identified through existing HTN registries and flyers at HCS. We will invite patients into the study via telephone after obtaining their PCP’s permission. We target 2,500 participants per HCS from an eligible population of >20,000 per HCS. Patient participants will be compensated in the amount of \$25 every month for a total of \$300 over 12 months. For **Aim 2** clinic team participants, HCS PIs will identify champions at all clinics to participate. Clinics that participate (target: 25 clinics across 3 HCS) will be provided with a \$250 honorarium.

For **Aim 3**, RCT enrolled patients and clinic team participants will be asked to participate in a semi-structured, remote debrief interview following the intervention (Target: 15-20 patient participants per HCS, 60 total participants; 10-15 staff participants per HCS, 45 total). **Aim 3** participants will be compensated for their time in the amount of \$75. HCS leadership have articulated their support for these interventions and recruitment approach (see **Letters of Support**).

F.3 Retention Plan. We will leverage the following strategies to address barriers to accrual and participation, based on evidence and prior experience. We will communicate the requirements and commitment to participants in advance; be flexible in scheduling options and mode of participation (e.g., phone/video); provide fair compensation for participation and build flexibility in to scheduling and the mode of participation; provide appropriate staffing effort to support patient-centered recruitment and retention; hire staff with lived experiences in the condition of interest, native language skills in the target language, and cultural knowledge of the target population; and for clinic staff, align project work with daily work activities. Additionally, we will engage with PFABs at each HCS, develop language-concordant study materials and resources, and conduct ongoing staff and investigator training in recruitment and retention of target participants. The Eureka platform can also enable retention by providing participants with reminders to update their contact information, issuing broad communications about the RCT timeline, and collecting secondary contact information in case of difficulty reaching participants. The study team has significant experience retaining patients and clinic participants in similar interventions in the proposed setting.

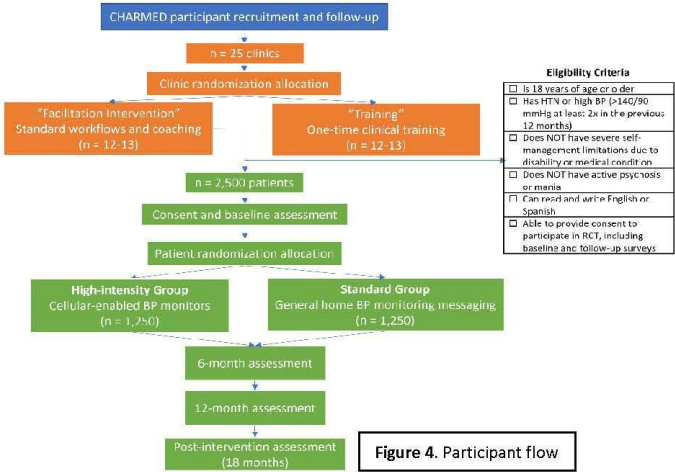


Figure 4. Participant flow

Table 3. Recruitment, Enrollment, and Retention Plans	Number
1. Estimated number of potentially eligible study participants with a description of how this number was determined (e.g., electronic health records, claims data, clinic logs, administrative data, other)	60,000 via clinic HTN registries
2. Total number of potentially eligible study participants expected to be screened	24,000
3. Total number of screened study participants expected to be found eligible	18,000
4. Target sample size (use same number stated in milestones)	2,500
5. Total number of practices or centers that will enroll participants, if applicable	3



6. Projected month first participant will be enrolled (month after project initiation)	February 1, 2024 (Aim 1) October 1, 2024 (Aim 2)
7. Projected month last participant is expected to be enrolled (month after project initiation)	September 1, 2026
8. Projected rate of enrollment (anticipated number enrolled per month of enrollment period)	70
9. Estimated percentage of participant dropout	20%

G. Engagement Approach (Criterion 6). (PC-1)

G.1. Overview The study team will espouse the PCORI Engagement Principles including but not limited to the ways described in Table 4.

G.2. Engagement Approach Goals. The goals for our engagement approach are to develop an intervention (including an implementation and evaluation strategy) that are acceptable, feasible, usable, and relevant for patients most likely to be affected by HTN, HTN disparities, and the individuals and settings that care for them.

G.3. Engagement Levels. Stakeholders will be engaged on a continuum using the PCORI Continuum of Engagement Practices. At the input level, we will interview patients and other stakeholders to collect rapid-turnaround feedback on iterated materials, such as recruitment flyers, and dissemination materials, that have been developed with consultants, collaborators, and shared leaders. This will include patients from each HCS' PFABs as well as health care workers involved in HTN care at each HCS. At the consultation level, we will engage patient consultants at all three HCS for a total of 6-7 English- and Spanish-speaking consultants to represent the population of interest (PC-1). The study team has discussed the expectations for patient consultants with these individuals (see LOS). At the collaboration level, we will convene Steering Committees at each HCS and across HCS that will meet annually. Each HCS will have an English and Spanish-speaking Patient Steering Committee recruited from existing English- and Spanish-speaking PFAB at each HCS (PC-1). The PIs (Drs. Sarkar and Lyles) will also convene three additional Steering Committees: a Community Steering Committee (e.g., consisting of local, regional, and national community-based organizations and community representatives involved in HTN care and health equity work), a Health Care Stakeholder Steering Committee (e.g., consisting of local, regional, and national health care leaders and participants involved in HTN care, health equity work, and safety-net health systems), and an External Stakeholder Steering Committee (e.g., consisting of technology designers and developers, payers, insurers, and advocacy groups). At the shared leadership level, we will conduct co-design and co-development activities (e.g., interviews, focus groups, and in-person/remote convenings) with patients, families, community-based organizations, clinicians, hospital/health system representatives, purchasers, and technology developers in Aim 1,^{40,41,125} and conducting a mixed methods evaluation utilizing activities such as interviews, surveys, direct observation with these stakeholders in Aim 3. Our approach will also build on patients' existing primary care medical home (rather than comparing stand-alone telehealth to clinic-based care),⁸⁵ and will utilize the existing work on population management at each HCS (integrating remote BP monitoring into feasible, standardized workflows).

Table 4. PCORI Engagement Principles used in CHARMED	
Principle	Potential application to CHARMED
Reciprocal relationships	- Collaboratively define and communicate roles and decision-making authority. Develop and agree upon principles of partnership with all stakeholders, communicating the principles regularly (e.g., prior to each meeting) and iterating as needed. Foster an environment in which all partners are welcomed in defining, developing, communicating, and iterating the principles of partnership.
Co-learning	- Dedicate time and effort to providing preparatory training for patients, other stakeholders, and personnel to be able to participate fully. Dr. Sharma and members of the Patient and Family Steering Committee will train the scientific personnel in engagement practices and patient-centeredness, and members of the scientific team and the UCSF library will provide patients with training in research methods.
Partnerships	- Honor the lived experiences of patients and other stakeholders who can provide unique perspectives. - Include representatives of populations that reflect the diversity of people affected by HTN and HTN disparities, including Black, Hispanic/Latine, Asian, and other racially and ethnically minoritized groups, people with limited English proficiency, people with low income, people with multiple chronic conditions, LGBTQIA+ populations, and people with intersecting identities. - Provide appropriate compensation for stakeholders using PCORI's Compensation Framework (see budget justification). - Plan ahead to lower barriers to participation (e.g., providing transportation vouchers in advance of in-person meetings so that patient and caregiver stakeholders do not have to pay out of pocket) and design inclusive engagement activities (e.g., selecting accessible, convenient, and welcoming meeting locations). - Be flexible in the mode of engagement (e.g., virtual – phone or video – and in person) to support inclusive participation. - Dedicate study personnel effort, including the Patient Engagement Lead and Engagement Coordinator, to support quality engagement activities, including orientation to the study and its processes. - Take time prior to initiating engagement to understand partners' resource needs to be able to fully participate in planned activities, and then invest in providing that support (e.g., interpreter services, technical support and training, phone minutes).
Transparency, honesty, and trust	- Make inclusive and transparent decisions. From the outset, ask partners how they would like to be included in study decisions and how they would like them to be communicated. Revisit this discussion regularly and adjust it based on feedback. - Communicate with partners in a manner (including frequency and mode of communication) that is collaboratively agreed upon.



	<ul style="list-style-type: none"> - Commit to open and honest communication with all partners. - Provide study personnel with training in best practices of engagement.
--	--

G.4. Engagement across study phases.

Planning the study. We will partner with patients and other stakeholders to ideate how to structure, develop, iterate, and implement participant-facing study activities, identify outcomes of interest, as well as develop and refine human subjects protection protocols (such as inclusion/exclusion criteria, recruitment protocols, and ongoing participant engagement protocols) with the goal of promoting inclusion, lowering barriers to participation, and human-centeredness in all interactions with priority populations. Conducting the study. Additionally, we will partner with patients and other stakeholders to revise study materials and protocols based on real-time feedback from participants and study personnel, participate in data collection, analysis, and interpretation of results, act on the data safety monitoring board (additional compensation will be allocated to patient and other stakeholders who serve as representatives on the DSMB), as well as help engage study participants and advising on patient engagement strategies. Disseminating the study results. Last, we will partner with patients and other stakeholders to identify key partners to help with dissemination (such as community-based organizations), develop, review, and iterate lay-friendly materials for dissemination, participate as co-authors on publications and presentations to scientific audiences, and provide feedback on potential gaps in dissemination efforts.



RESEARCH TEAM EXPERIENCE AND ENVIRONMENT

Research Team (Criterion 4)

Our team is highly experienced in the design, implementation, and evaluation of technologies relevant for diverse populations.^{31,46,126,127} Drs. Sarkar, Lyles, Khoong, Sharma, Pletcher, and Glidden all possess experience conducting large-scale clinical and implementation trials within multiple HCS, including the SFHN. They have each used EHRs for recruitment and outcomes assessment, and Dr. Pletcher has specific expertise leading the use of a technology platform, Eureka, designed for large-scale participant recruitment, consent, data collection, and reporting.

Complementing their experience addressing patient-level barriers to technology access and use, the investigators have led clinic-driven initiatives at San Francisco Health Network (SFHN) that improved technology enrollment and uptake through multiple research and operational initiatives.^{125,126,128–132} This has similarly involved stakeholder-engaged approaches, focus groups, semi-structured interviews, and direct observation, allowing key stakeholders to participate in intervention design and development. These methods have enabled the investigative team to delineate workflows for complex care pathways¹²⁵ and team-based care,¹³³ as well as identify opportunities to improve current processes, which in turn informed how complex interventions are finalized and implemented.

Drs. Lyles, Sarkar, Khoong, and Sharma have a long track record of research collaboration, engagement, and implementation with HCS serving diverse populations, including with the Contra Costa Health Services (CCHS) team included in this proposal.¹³⁴ In a prior study (AHRQ, R01HS024426), they collected and analyzed data from five health systems, including SFHN and CCHS, for follow-up of abnormal cancer screening and for test results management.¹³⁵ This illustrates the investigative team's experience collecting patient-level data from various EHRs and managing challenges associated with data extraction in safety-net health care settings.¹³⁶ Additionally, Drs. Lyles, Sarkar, Khoong, and Sharma previously collaborated with Dr. Rachel Stern at Ventura County Health Care Agency (VCHCA), demonstrating their abilities to partner on complex projects.^{137,138} Finally, Dr. Lyles will be taking over a leadership role in the UC Davis School of Medicine directing the Center for Healthcare Research and Policy beginning on July 1, 2023, and will complete the scientific leadership of this study via an administrative subcontract to UC Davis.

SFHN. Dr. Urmimala Sarkar, MD, MPH (Dual PI) is a primary care physician (PCP) and researcher with 14 years of experience in the proposed study setting, including 12 years of close collaboration with Dual PI Dr. Lyles.^{54,139–141} She will provide her implementation science, technology design and evaluation expertise to this project. **Dr. Courtney Lyles, PhD (Dual PI)** is a trained health services researcher and has been studying applied health technology projects within the primary care safety net in SFHN for 12 years,^{142–145} including the system-wide implementation of the online patient portal within our healthcare setting.¹⁰⁸ She is a national expert in implementation science and improving equitable approaches of health information technology. **Dr. Elaine Khoong, MD, MS (Co-I)** is a PCP in the SFHN and an expert in clinical informatics, health communication, and improving disparities in chronic disease management.^{146–148} **Dr. Anjana Sharma, MD, MAS (Co-I)** is a family physician at SFGH whose research focus is the study of patient and community engagement within primary care, and the impact of patient engagement on quality and safety outcomes.^{137,149–151} **Dr. Mark Pletcher, MD, MPH (Co-I)** is an epidemiologist and PCP with decades of research experience in cardiovascular disease.^{152–159} He will provide key input in study design and innovative data collection approaches. **Dr. Fan Xia, PhD (Co-I)** is an epidemiologist with extensive expertise in cluster randomized trials, particularly in resource-limited settings, who will lead the team's overall analytical plan, including data sharing and quality approach.^{160–163} **Yunina Graham, Patrick McKenna, and Gisela Venegas** will represent the patient voices of SFHN, all of whom receive HTN care within SFHN.

CCHS. Dr. Rajiv Pramanik, MD (Co-I), is Chief Medical Informatics Officer with experience studying and implementing systems-level interventions to improve chronic disease management.^{134,164,165} He will partner with **Dr. Nooshin Abtahi, MD (Co-I)** to lead CCHS's contributions to this project. **Edmund B. Balaoing** and **Jeremias Sanchez Lopez** will work with Drs. Pramanik and Abtahi as members of the Patient and Family Steering Committee to elevate the patient voice.

VCHCA. Dr. Rachel Stern, MD (Co-I) is Chief Medical Quality Officer and responsible for quality and system improvements, including those addressing HTN care.^{137,166–169} She will work with **Dr. Theresa Cho, MD (Co-I)**, Chief



Contract for Funded Research Project

HM-2022C2-28339

Attachment B: Final Budget

PCORI Final Budget								
Cost Category	Year 1	Year 2	Year 3	Year 4	Year 5	Research Period Total	Peer-Review Period Total	Contract Total
Direct Costs								
1. Personnel Costs								
Salaries	\$792,634.00	\$854,056.00	\$854,056.00	\$854,056.00	\$790,754.00	\$4,145,556.00	\$63,303.00	\$4,208,859.00
Fringe Benefits	\$324,335.00	\$324,335.00	\$324,335.00	\$324,335.00	\$300,631.00	\$1,597,971.00	\$5,927.00	\$1,603,898.00
Subtotal Personnel Costs	\$1,116,969.00	\$1,178,391.00	\$1,178,391.00	\$1,178,391.00	\$1,091,385.00	\$5,743,527.00	\$69,230.00	\$5,812,757.00
2. Consultant Costs	\$20,280.00	\$20,280.00	\$20,280.00	\$20,280.00	\$20,280.00	\$101,400.00	\$0.00	\$101,400.00
3. Supplies	\$13,652.00	\$11,245.00	\$11,245.00	\$11,245.00	\$11,245.00	\$58,632.00	\$0.00	\$58,632.00
4. Travel	\$3,519.00	\$7,904.00	\$7,904.00	\$7,904.00	\$7,904.00	\$35,135.00	\$0.00	\$35,135.00
5. Other Costs	\$177,906.00	\$762,293.00	\$731,242.00	\$734,411.00	\$135,232.00	\$2,541,084.00	\$0.00	\$2,541,084.00
6. Inpatient/Outpatient Costs	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
7. Equipment	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
8. Consortium/Contractual Costs								
Direct Costs	\$903,845.00	\$1,089,767.00	\$1,089,767.00	\$1,089,767.00	\$867,925.00	\$5,041,071.00	\$35,920.00	\$5,076,991.00
Facilities and Administrative	\$138,638.00	\$164,335.00	\$164,335.00	\$164,335.00	\$130,325.00	\$761,968.00	\$8,313.00	\$770,281.00
Subtotal Consortium/Contractual Costs	\$1,042,483.00	\$1,254,102.00	\$1,254,102.00	\$1,254,102.00	\$998,250.00	\$5,803,039.00	\$44,233.00	\$5,847,272.00
Total Direct Costs								
Total Direct Costs	\$2,374,809.00	\$3,234,215.00	\$3,203,164.00	\$3,206,333.00	\$2,264,296.00	\$14,282,817.00	\$113,463.00	\$14,396,280.00
Indirect Costs								
9. Indirect Costs	\$562,931.00	\$792,045.00	\$779,625.00	\$780,892.00	\$506,418.00	\$3,421,911.00	\$27,692.00	\$3,449,603.00
Grand Total								
Total Direct and Indirect Costs	\$2,937,740.00	\$4,026,260.00	\$3,982,789.00	\$3,987,225.00	\$2,770,714.00	\$17,704,728.00	\$141,155.00	\$17,845,883.00



Attachment C: Milestone Schedule

Milestone - Deliverable ID	Milestone - Deliverable Name	Description	Due Date
A	Effective Date	-	8/1/2023
B1	Develop, finalize, and submit copy of study protocol in PCORI Online.	Refer to the PCORI Methodology Standards for required elements of the study protocol.	11/1/2023
B2	Submit IRB approval in PCORI Online (Continuing approval submitted annually).		11/1/2023
B3	Select and register project at appropriate site for the study design (Clinicaltrials.gov, RoPR, or other as approved by PCORI before study start date).	Submit Study Identification Number and the Primary Completion Date to PCORI. List PCORI as a collaborator so that PCORI's role as the funder (not sponsor) can be identified and tracked.	11/1/2023
B4	Submit updated Data and Safety Monitoring Plan to PCORI.	Refer to the PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research.	12/1/2023
B5	Submit updated Engagement Plan in PCORI Online.	Access Engagement Plan Template here.	12/1/2023
B6	Submit updated Recruitment Plan in PCORI Online.	Elements in the recruitment plan should, at a minimum, include the following: a. Timeline b. Total target sample size for primary analysis c. Name and # study sites d. Historical patient volume and estimated eligible N across study sites e. Estimated yield/consent f. Estimated lost to follow up/attrition g. Estimated monthly enrollment	1/5/2024
B7	Begin recruitment for Aim 1	Site(s) activated and screening for study enrollment.	2/1/2024



Contract for Funded Research Project

HM-2022C2-28339

B	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	2/1/2024
C1	Enroll first patient for Aim 1.	From this point forward, submit monthly enrollment update to PCORI to include cumulative and interval recruitment, accrual, and retention for the overall study (e.g. number eligible/approached/consented/enrolled, retained). Discuss due dates for monthly reports with your Program Officer.	3/1/2024
C2	Recruit and Convene Data and Safety Monitoring Board	DSMB activated; DSMB conducts final review of study protocol and Data and Safety Monitoring Plan prior to Aim 2 recruitment	7/1/2024
C3	Recruit and convene Steering committee	Steering committee will convene to review and inform the study process. Members will receive training in research methods, engagement practices and patient-centeredness.	7/1/2024
C4	100% of focus group complete (N=11) for Aim 1	Conduct 100% of focus groups (N = 11 focus groups) for Aim 1	7/31/2024
C	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	8/1/2024
D1	100% of the IRB approvals across sites submitted to PCORI	Update IRB information in PCORI Online	10/1/2024
D2	Status report detailing executed subcontract agreements across sites	Submit in PCORI Online. Contact PO for details on format of update.	10/1/2024
D3	Begin recruitment patient for Aim 2	Site(s) activated and screening for study enrollment.	10/1/2024
D4	Data and Safety Monitoring Board Review	Convene DSMB. DSMB will review conduct, including recruitment, enrollment, intervention adherence, protocol deviations, and progress.	1/1/2025
D	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	2/1/2025
E1	100% clinic enrollment completed (N = 25)	Onboard and prepare clinics for RCT launch (N = 25 clinics) for Aim 2	3/31/2025



Contract for Funded Research Project

HM-2022C2-28339

E2	25% of patient enrollment complete for Aim 2 (N = 625)	Enroll 25% of patients to RCT (N = 625) 25% of participants (N = 625) screened, enrolled, and consented to the study for Aim 2	4/1/2025
E3	6-month follow-up for Aim 2 participants begin	Begin collecting primary outcome data for first enrolled patients.	4/1/2025
E4	Programmatic Evaluation Materials Due to PCORI	Submit document that demonstrates study progress and feasibility based on metrics provided by PCORI to awardee. PCORI initiates Programmatic Evaluation.	4/1/2025
E5	Submit Aim 1 manuscript	Submission of manuscripts to peer-reviewed scientific journals	5/1/2025
E6	Convene Steering committee	Steering committee will convene to review and inform the study process.	7/1/2025
E7	Data and Safety Monitoring Board Review	Convene DSMB. DSMB will review conduct, including recruitment, enrollment, intervention adherence, protocol deviations, and progress.	7/1/2025
E8	Begin patient recruitment for Aim 3	Site(s) activated and screening for study enrollment.	8/1/2025
E	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	8/1/2025
F1	50% of patient enrollment complete for Aim 2 (N = 1,250)	50% of participants (N = 1,250) screened, enrolled, and consented to the study for Aim 2	10/1/2025
F2	12-month follow-up for Aim 2 participants begin	Begin collecting 12-month follow-up data for first enrolled patients.	10/1/2025
F3	Data and Safety Monitoring Board Review	Convene DSMB. DSMB will review conduct, including recruitment, enrollment, intervention adherence, protocol deviations, and progress.	1/1/2026
F4	25% of focus group enrollment complete for Aim 3 (N = 26)	Conduct qualitative interviews with 25% participants (N = 26) 25% of participants (N = 26) screened, enrolled, and consented to the study for Aim 3 of qualitative interviews	1/30/2026
F	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	2/1/2026
G1	18-month follow-up for Aim 2 participants begin	Begin collecting 18-month follow-up data for first enrolled patients.	3/1/2026



Contract for Funded Research Project

HM-2022C2-28339

G2	75% of patient enrollment complete for Aim 2 (N = 1,875)	Enroll 75% of patients to RCT (N = 1875) 75% of participants (N = 1,875) screened, enrolled, and consented to the study for Aim 2	3/31/2026
G3	Convene Steering committee	Steering committee will convene to review and inform the study process.	7/1/2026
G4	Data and Safety Monitoring Board Review	Convene DSMB. DSMB will review conduct, including recruitment, enrollment, intervention adherence, protocol deviations, and progress.	7/1/2026
G5	50% of focus group enrollment complete for Aim 3 (N = 52)	Conduct qualitative interviews with 50% participants (N = 52) 50% of participants (N = 52) screened, enrolled, and consented to the study for Aim 3 of qualitative interviews	7/31/2026
G	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	8/1/2026
H1	100% of patient enrollment complete for Aim 2 (N = 2,500)	Enroll 100% of patients to RCT (N = 2500) 100% of participants (N = 2,500) screened, enrolled, and consented to the study for Aim 2	9/30/2026
H2	Data and Safety Monitoring	Convene DSMB. DSMB will review conduct, including recruitment, enrollment, intervention adherence, protocol deviations, and progress.	1/1/2027
H	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	2/1/2027
I1	75% of focus group enrollment complete for Aim 3 (N = 79)	Conduct qualitative interviews with 75% of participants (N = 79) 50% participants (N = 52) 75% of participants (N = 79) screened, enrolled, and consented to the study for Aim 3 of qualitative interviews	2/28/2027
I2	100% 6-month follow up for Aim 2 participants	Completed primary outcome data collection.	3/31/2027
I3	Convene Steering committee	Steering committee will convene to review primary outcomes.	7/1/2027
I4	Data and Safety Monitoring Board Review	Convene DSMB. DSMB will review conduct, including recruitment, enrollment, intervention adherence, protocol deviations, and progress.	7/1/2027
I5	Draft dissemination toolkit	Begin collecting materials for toolkit to disseminate learnings	7/1/2027
I	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	8/1/2027



J1	100% 12-month follow up for Aim 2 participants	Completed 12-month secondary outcome data collection.	10/1/2027
J2	100% of focus group enrollment complete for Aim 3 (N = 105)	Conduct qualitative interviews with 100% participants (N = 105) 50% participants (N = 52) 100% of participants (N = 105) screened, enrolled, and consented to the study for Aim 3 of qualitative interviews	11/30/2027
J3	Data and Safety Monitoring Board Review	Convene DSMB. DSMB will review conduct, including recruitment, enrollment, intervention adherence, protocol deviations, and progress.	1/1/2028
J	Report Submission	Submit Interim Progress Report to PCORI via PCORI Online.	2/1/2028
K1	100% 18-month follow up for Aim 2 participants	Completed primary and secondary outcome data collection	3/1/2028
K2	Completion of Data Collection for All Study Aims	Awardee must ensure that all data collection for all study aims as specified in the research plan is completed	4/1/2028
K3	Primary Completion Date	An estimated Primary Completion Date must be provided when registering the study in Clinicaltrials.gov. For studies that are not clinical trials or non-prospective observational studies registered on ClinicalTrials.gov, the Awardee and PCORI shall agree on a primary completion date as a milestone that precedes the agreed-upon date to submit a Draft Final Research Report.	4/1/2028
K4	Results submitted to ClinicalTrials.gov or other applicable database	Awardee ensures results are submitted to ClinicalTrials.gov or other appropriate database. Results must be submitted to ClinicalTrials.gov no later than one month before submission of the Draft Final Research Report.	6/1/2028
K5	Completion of Data Analysis for All Study Aims	Awardee must ensure that all analysis and evaluation for all study aims as specified in the Research Plan are completed.	7/1/2028
K6	Convene Steering committee	Steering committee will convene to review primary and secondary outcomes.	7/1/2028
K7	Submit Aims 2 and 3 manuscripts	Submission of manuscripts to peer-reviewed scientific journals	7/1/2028



Contract for Funded Research Project

HM-2022C2-28339

K	Final Progress Report	Submit Final Progress Report to PCORI via PCORI Online.	8/1/2028
L	Draft Final Research Report Submission	Submit Draft Final Research Report per these instructions.	10/1/2028
M	Data Sharing Kick-Off Call	Attend kick-off meeting (in-person or remotely)	10/16/2028
N	Obtain Signed Data Contributor Agreement	Submit copy of signed agreement in PCORI Online.	10/30/2028
O	Transfer Data Package to Data Repository	Submit proof of submission (such as email confirmation) in PCORI Online.	11/30/2028
P	Mutual Agreement Between Awardee and Data Repository That Curation of the Data Package is Complete.	Submit verification of completion (such as email confirmation) in PCORI Online	1/31/2029
Q	Submit Data Sharing Report to PCORI	Submit 3-page report to PCORI summarizing experience and lessons learned from data sharing activities in PCORI Online.	2/14/2029
R	Draft Final Research Report Revisions	Upon receipt of written summary, and as applicable, PI will make revisions and submit revised Draft Final Research Report and disposition of comments table for acceptance in accordance to PCORI policy and process.	7/1/2029
S	Approval/sign off of the Lay Abstract	No later than 90 days beyond the date PCORI accepts the final report	
T	Contract Term Date		11/1/2029
U	Notification of Publication Acceptance	See Contract for instructions	



Attachment D: Conflicts of Interest Disclosure Form Research Project Award

All fields are required.

1. Name of Recipient (Awardee Institution): The Regents of the University of California, San Francisco

2. Name of PCORI-funded Research Project:

Comparing Hypertension Remote Monitoring Evaluation Redesign (CHARMED)

3. Names and Institutions of Principal Investigator (PI) and Key Personnel:

Name:	Role:	Recipient (Awardee Institution):
Urmimala Sarkar	Principal Investigator	UC San Francisco (UCSF)

Key Personnel Name:	Institution:
Courtney Lyles	UC Davis
Mark Pletcher	UCSF
Elaine Khoong	UCSF
Anjana Sharma	UCSF
Fan Xia	UCSF
Rachel Stern	Ventura County Healthcare Agency
Theresa Cho	Ventura County Healthcare Agency
Rajiv Pramanik	Contra Costa Health Services
Nooshin Abtahi	Contra Costa Health Services

4. Does Recipient have a Conflicts of Interest Policy or Guidelines that meets the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service (<http://grants.nih.gov/grants/policy/coi/>) that it applies to PCORI-funded research?

☒ YES

☐ NO



5. If you checked “No,” Recipient must provide information describing how Recipient will ensure that the PCORI-funded Research Project is not influenced by conflicts of interest.

N/A

6. Report the existence of any financial or personal interests or associations of Recipient, Principal Investigator, and Key Personnel related to the PCORI-funded Research Project under this Contract that constitute a conflict of interest. Attach the management plan that addresses identified conflicts of interest.

Print “None” if Recipient, Principal Investigator, and Key Personnel have no financial or personal interests or associations that constitute a conflict of interest. (Attach additional documents, if needed).

None

7. Please list any direct or indirect links to industry (such as pharmaceutical, medical device, health insurance, and other healthcare-related companies) that Recipient has related to the PCORI-funded Research Project.

Print “None” if there are no direct or indirect links to industry as described above. There is no need to include disclosures here that are reported under Question 6 above. (Attach additional documents, if needed).

None

8. If Recipient has any additional material information relating to disclosures or management of conflicts of interest, or other protections against bias pertinent to the PCORI-funded Research Project, please describe it here. Print “None” if there is no additional material information as described above.

None

**Contract for Funded Research Project****HM-2022C2-28339**

The undersigned certify that the above information is complete and true to the best of their knowledge and understand that this completed form, with these disclosures, will be made publicly available by PCORI in conjunction with the research findings relating to the Research Project. Both the Administrative Official and Principal Investigator must complete and sign one form.

Administrative Official:

Signed:

DocuSigned by:
Marico Moredó
D0C8E8168FAC4A3...

Print Name: Marico MoredóTitle: Award Contract OfficerDate: 9/5/2023**Principal Investigator:**

Signed:

DocuSigned by:
Urmimala Sarkar
9AC62E3245D6404...

Print Name: Urmimala SarkarTitle: Principal InvestigatorDate: 9/6/2023

Attachment D Rev. 12/2019



Attachment E: Sample Invoice

Invoices should contain the following elements and additional supporting details as requested by PCORI, through <https://pcori.force.com/engagement>. This format is for presentation purposes. Final invoices must clearly be marked as Final.

PCORI Invoice Template - Cost Reimbursable	
A Date	E Contract Number
B Invoice Number	F Project Title
C Billing Period	G Period of Performance
D PI Name	H Organization Name

I J K L

Budget Category		Project Budget	Current Period Expenses	Cumulative Expensed to Date	Available Funds Remaining
1. Personnel Costs					
Salaries:					
Last Name, First Name 1		\$0.00	\$0.00	\$0.00	\$0.00
Last Name, First Name 2		\$0.00	\$0.00	\$0.00	\$0.00
Last Name, First Name 3		\$0.00	\$0.00	\$0.00	\$0.00
Salaries		\$0.00	\$0.00	\$0.00	\$0.00
	Fringe Benefits	\$0.00	\$0.00	\$0.00	\$0.00
Subtotal Personnel Costs		\$0.00	\$0.00	\$0.00	\$0.00
2. Consultant Costs		\$0.00	\$0.00	\$0.00	\$0.00
3. Supplies		\$0.00	\$0.00	\$0.00	\$0.00
4. Travel		\$0.00	\$0.00	\$0.00	\$0.00
5. Other Costs		\$0.00	\$0.00	\$0.00	\$0.00
6. Equipment		\$0.00	\$0.00	\$0.00	\$0.00
7. Consortium/Contractual Costs		\$0.00	\$0.00	\$0.00	\$0.00
Total Direct Costs		\$0.00	\$0.00	\$0.00	\$0.00
8. Indirect Costs		\$0.00	\$0.00	\$0.00	\$0.00
Grand Total		\$0.00	\$0.00	\$0.00	\$0.00

**Contract for Funded Research Project****HM-2022C2-28339**

CERTIFICATION: I certify that all payments requested are for appropriate purposes, are in accordance with the agreements set forth in the application and Contract documents, and will not be reimbursed by any other funding source or agency.

Signature of Financial Official _____

Financial Official Name:

Financial Official Telephone Number:

Financial Official Email Address:

A.	Date
B.	Invoice Number
C.	Billing Period is beginning and ending dates for work performed during the period being billed
D.	PI Name
E.	Enter the PCORI Contract Number
F.	Project Title
G.	Period of Performance is the entire term of the Agreement
H.	Organization Name
I.	Enter the Approved Budget - Enter in the details for each person based on the budgeted level of effort. Enter the Approved Budget amount for each budget category or budget sub-category (if applicable) for the appropriate period.
J.	Current Period on each invoice reflects expenditures from the Billing Period C. Note: Direct costs should not include any costs that should be included in the indirect cost rate.
K.	Cumulative Amount is the sum of all expenses billed to PCORI to date.
L.	Available Budget Amount is the Approved Budget (I) less the Cumulative Amount (L)

Attachment E Rev. 12/19

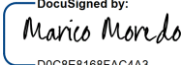
Certificate Of Completion

Envelope Id: 5575B3E4C1A84A8DB39CF5760D84C68D		Status: Completed
Subject: Complete with DocuSign: Sarkar_HM-2022C2-28339_Contract_9.5.23_final [CA-0228146]		
Source Envelope:		
Document Pages: 59	Signatures: 3	Envelope Originator:
Certificate Pages: 2	Initials: 0	Marico Moredo
AutoNav: Enabled		1855 Folsom St
Envelopeld Stamping: Disabled		Suite 601
Time Zone: (UTC-08:00) Pacific Time (US & Canada)		San Francisco, CA 94103
		marico.moredo@ucsf.edu
		IP Address: 128.218.42.219

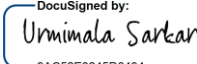
Record Tracking

Status: Original	Holder: Marico Moredo	Location: DocuSign
9/5/2023 6:44:14 PM	marico.moredo@ucsf.edu	

Signer Events	Signature	Timestamp
---------------	-----------	-----------

Marico Moredo	<div>DocuSigned by:  D0C8E8168FAC4A3...</div>	Sent: 9/5/2023 7:18:16 PM
marico.moredo@ucsf.edu		Viewed: 9/5/2023 7:18:26 PM
Contracts & Grants Officer		Signed: 9/5/2023 7:18:34 PM
University of California, San Francisco	Signature Adoption: Pre-selected Style	
Security Level: Email, Account Authentication (Optional)	Using IP Address: 128.218.42.219	

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

Urmimala Sarkar	<div>DocuSigned by:  9AC52E3245D6494...</div>	Sent: 9/5/2023 7:18:16 PM
urmimala.sarkar@ucsf.edu		Viewed: 9/6/2023 9:27:54 AM
Prof		Signed: 9/6/2023 9:28:42 AM
University of California, San Francisco	Signature Adoption: Pre-selected Style	
Security Level: Email, Account Authentication (Optional)	Using IP Address: 128.218.42.81	

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp
-------------------------	-----------	-----------

Editor Delivery Events	Status	Timestamp
------------------------	--------	-----------

Agent Delivery Events	Status	Timestamp
-----------------------	--------	-----------

Intermediary Delivery Events	Status	Timestamp
------------------------------	--------	-----------

Certified Delivery Events	Status	Timestamp
---------------------------	--------	-----------

Carbon Copy Events	Status	Timestamp
--------------------	--------	-----------

Witness Events	Signature	Timestamp
----------------	-----------	-----------

Notary Events	Signature	Timestamp
---------------	-----------	-----------

Envelope Summary Events	Status	Timestamps
-------------------------	--------	------------

Envelope Sent	Hashed/Encrypted	9/5/2023 7:18:16 PM
Certified Delivered	Security Checked	9/6/2023 9:27:54 AM

Envelope Summary Events	Status	Timestamps
Signing Complete	Security Checked	9/6/2023 9:28:42 AM
Completed	Security Checked	9/6/2023 9:28:42 AM
Payment Events	Status	Timestamps

Attachment D

Subaward Number:

UCSF Contacts

UCSF Information

Entity Name:

Legal Address:

Website:

UCSF Contacts

Central Email:

Principal Investigator Name:

Email:

Telephone Number:

Administrative Contact Name:

Email:

Telephone Number:

COI Contact email (if different to above):

Financial Contact Name:

Email:

Telephone Number:

Email invoices? Yes No Invoice email (if different):

Authorized Official Name:

Email:

Telephone Number:

PI Address:

Administrative Address:

Invoice Address: