

## MEMORANDUM OF UNDERSTANDING

BP-HOME: Patient Blood Pressure Device Trial

### **Monterey County Health Department**

Elsa Jimenez, Director of Health

**Principal Investigator:** Mark Pletcher, MD, MPH  
University of California-San Francisco (UCSF)

**OCHIN Site Principal Investigator:** Jonathan Todd, PhD, MSPH

This Memorandum of Understanding (“MOU”) is made between OCHIN and [Monterey County Health Department] (“Provider”), each wishing to establish a cooperative research relationship. OCHIN and Provider are collectively referred to as the “Parties” or individually as a “Party.” This MOU shall be effective upon the signature of both parties’ authorized officials.

WHEREAS, OCHIN has been engaged by the Patient-Centered Outcomes Research Institute (PCORI) on behalf of UCSF (“Researcher”) to provide certain assistance with respect to BP-HOME: Patient Blood Pressure Device Trial (“Project”), as is further described below; and

WHEREAS, Provider is a member of the OCHIN community and wishes to contribute to and participate in the Project as specified in this MOU;

NOW THEREFORE, OCHIN and Provider, as Parties to this MOU, agree as follows:

### **1. Project Scope**

#### *1.1 Purpose.*

The PCORnet Home Blood Pressure Monitoring (BP-HOME) study is an individual-level randomized controlled trial that will compare the effectiveness of Smartphone-linked versus standard home blood pressure monitoring (HBPM) cuffs for helping patients with uncontrolled hypertension achieve a reduction in systolic blood pressure. Through the advancement of home blood pressure (BP) monitoring technology, Smartphone-connected BP monitors provide a number of features including automated tracking of results, education to patients, reminders to take measurements, and facilitated transmission of results to providers. This study will assess if the additional features of a Bluetooth-enabled HBPM device improves patient experience, frequency of use, shared decision-making with clinicians and/or BP control compared with standard unconnected BP cuffs.

*1.2 Project Activities and Goals.* Researcher and the Parties intend to collaboratively pursue the following research activities and goals:

The purpose of this study is to better understand which home blood pressure monitors are most effective for helping patients get their blood pressure into a healthy range.

To achieve this goal, eligible patients will be identified by the OCHIN research team and invited to participate in this study. The Provider may assist in identifying potential participants for recruitment. The OCHIN research team will manage all recruitment activities.

To facilitate recruitment, the Provider will identify a clinic staff member who will serve as a point person to provide the OCHIN research team with the health center logo, which will be incorporated into the recruitment materials.

In addition, the point person will coordinate other research activities, as needed, such as the review of study outreach materials and methods. The point person will also provide study and recruitment information and updates to clinic staff and organizational leadership, as appropriate.

Eligible patients who receive an invitation and wish to participate in the study may go online to confirm eligibility and provide consent, which will initiate participation. Further details on eligibility requirements and participant activities are described below.

Patient recruitment for this study will begin in December 2019 and may continue until December 2020. Data collection for the at-home BP monitoring will occur for 6-18 months after a participant receives their BP cuff.

1.3 *Leadership.* The Project will be directed by the University of California-San Francisco (UCSF) Principal Investigator, Mark Pletcher, MD, MPH and OCHIN Site Principal Investigator, Jonathan Todd, PhD, MSPH.

1.4 *Oversight.* The Project consists of human subject research. The UCSF Institutional Review Board (“IRB”) has approved the Project and will exercise oversight of it for the duration of the Project. The Parties agree to perform the activities and responsibilities described in this MOU consistent with written protocol or waiver approved by the IRB, which is attached and incorporated herein.

1.5 *Duration.* The Project will be conducted until 7/31/2021. However, the Provider’s active participation will conclude after patient recruitment at the Provider’s health center(s) has been completed, which will be marked by notification from the OCHIN research team. Patient participation activities will last up to 18 months, subject to continued availability of funds.

## 2. **Activities & Responsibilities**

2.1 *Point of Contact.* Each Party and the Researcher will designate an individual to serve as a primary point of contact with respect to Provider’s participation in the Project. An IRB contact is also identified below.

2.1.1 **County of Monterey** Primary Contact: Dr. Caroline Kennedy

2.1.2 OCHIN’s Primary Contact:  
April Lee [leean@ochin.org](mailto:leean@ochin.org)

2.1.3 Researcher Primary Contact:  
Madelaine Faulkner [Madelaine.Faulkner@ucsf.edu](mailto:Madelaine.Faulkner@ucsf.edu) and Mark  
Pletcher [Mark.Pletcher@ucsf.edu](mailto:Mark.Pletcher@ucsf.edu)

2.1.4 IRB Contact:  
Madelaine Faulkner [Madelaine.Faulkner@ucsf.edu](mailto:Madelaine.Faulkner@ucsf.edu)

## 2.2 *Subject Engagement.*

2.2.1 The Provider allows OCHIN to identify eligible patients via viewing protected health information (“PHI”) within the OCHIN Epic Electronic Health Record (EHR). The study team will contact patients who are: at least 18 years old, have had at least one ambulatory visit during the past year, and who had a systolic blood pressure (SBP) > 145 mmHg at their most recent clinic visit.

2.2.2 Patients appearing to meet criteria for enrollment according to their EHR data will be sent a study recruitment letter, and in most cases, a follow-up mailing by the OCHIN study team with an invitation to further assess eligibility online and, if eligible, participate in BP-Home. The letter will include the most recent blood pressure reading from their last clinical visit, which will be used to verify patient participant eligibility. The letter will also include a Golden Ticket Number, which the patient can use to sign on to the study through the online patient portal. Instructions for this process will be documented within the recruitment mailings. Patients will be able to contact the UCSF study team by email with questions and/or requests for study-related information.

2.2.3 OCHIN will be using a third-party mailing house vendor, with whom we have executed a Business Associate Agreement, to distribute IRB approved patient recruitment mailings. The mailing house vendor will adhere to strict healthcare privacy and security requirements while handling PHI on behalf of OCHIN.

In order to participate, patients will need to confirm that they own a Smartphone, have a self-reported SBP goal that is at least 10 mmHg lower than their last SBP measurement and intention to document and work towards that goal at their next visit at your health center. Potential participants will also need to confirm that they can read/write English well enough to use English-based Smartphone apps and fill out online surveys in English, do not currently own a working HBPM device, and are not otherwise monitoring BP at home.

2.2.4 Once eligibility is confirmed and the participant consents to taking part in the study, they will be asked to complete a brief survey about their health. All of these activities will be completed through the online portal. Upon completion of the survey, participants will be randomized to receive either a standard or Bluetooth-enabled HBPM device.

After randomization, UCSF-based study staff will confirm contact information and ship the assigned device to participants free of cost, and follow up with the participant using the provided contact information (e.g. via electronic survey, text message and/or phone calls) to make sure the device is received.

Upon receipt of their device, participants in the Smartphone-linked arm of the study will also be taken through a “device consent” in which they will be instructed to download the Smartphone app associated with the device and link their device account to their study account. The device-linked account will enable the study to receive patient BP measurement data.

Participants in both arms of the study will be provided guidelines for HBPM (using publicly-available materials developed by the American Medical Association and American Heart Association for their Target: BP Program), and told to continue interacting with their treating physician as usual for BP medication management, etc.

Online survey data will be elicited at pre-specified time points – 4 to 6 times over 6 to 18 months, dependent upon patient study enrollment date. Participants will receive a variety of reminders to complete surveys, possibly including but not limited to email, text, and personal phone calls.

This study is supported by the Eureka Research Platform, which is a computer system that will be used to complete questionnaires about experience with the device, and blood pressure goals. Eureka is a digital research platform, sponsored by the NIH, designed to facilitate mobile and internet-based medical or health-related research.

Epic Research Functionality will be used, where available, to flag patient participants in the EHR system allowing providers to identify which patients are participants in this study.

### **3. Data Sharing**

3.1 The Parties agree that protected health information, as defined at 45 CFR 160.103 (“PHI”), of Provider’s patients will be shared in connection with the Project, as follows:

3.1.1 Provider hereby authorizes OCHIN to identify potential patient participants by accessing PHI within the OCHIN Epic Electronic Medical Record to assess eligibility. Such use shall consist only of (a) activities preparatory to research, consistent with the Health Insurance Portability and Accountability Act of 1996, its implementing regulations, and guidance issued by the Department of Health and Human Services; or (b) activities approved via a waiver issued by the IRB.

3.1.2 OCHIN shall obtain written authorization for use and disclosure of PHI in connection with the Project from each patient participant in a form approved by the IRB prior to sharing participant EHR data on research-related measures with the appropriate research partners.

### **4. Compensation & Benefits**

4.1 By participating, the Provider is offering its patients an opportunity to contribute to developing scientific evidence about how to choose the right technology for home BP monitoring for those trying to control BP rates.

4.2 In recognition of Provider's contribution to the Project, OCHIN will pay Provider a \$1,750 impact fee upon execution of study MOU and receipt of provider logo to be used for patient recruitment purposes.

4.3 When possible, OCHIN will inform Provider of Project results and any publications of such results

## 5. Timeline

The Parties anticipate the following activities to take place as described below:

5.1 After signing the MOU, OCHIN will request and/or confirm the Provider logo for recruitment purposes, and complete any additional administrative activities including the process for distributing clinic impact fees.

5.2 OCHIN's research team will work to identify and recruit patients that, according to EHR data, meet criteria to participate in the BP-Home study by sending personalized invitations by mail.

5.3 Once the interested participant confirms eligibility, electronically signs the study consent form and completes the initial survey, the UCSF research team will send the randomly selected device (Standard HBPM or Bluetooth-enabled HBPM) and instructions for completing online surveys.

5.4 Participants will use their device and complete online surveys for 6-18 months, dependent upon participant study enrollment date. The research team will follow EHR outcome data for 18 months to assess any changes to their clinical BP.

## 6. General Terms

6.1 *Term.* This MOU shall remain in effect until 7/31/2021. Either Party may terminate this MOU by providing at least thirty (30) days' prior written notice to the other Party.

6.2 *Amendments.* This MOU may be amended only in writing, signed by each Party's authorized signatory.

6.3 *Confidentiality.* In the course of the activities contemplated by this MOU, a Party may disclose Confidential Information to the other Party. Unless otherwise agreed in writing, "Confidential Information" includes any and all information, correspondence, financial statements, records, data, or information that is or would reasonably be understood to be competitively sensitive and generally not known to the public, including formulations, analysis, inventions, improvements, patient records, and activities of the disclosing Party and other documents that are marked as confidential or proprietary and are transmitted or communicated by the disclosing Party to the receiving Party. Except for PHI, which is always deemed Confidential Information, Confidential Information does not include information that (a) is publicly known at the time of the disclosure, (b) is lawfully received by the receiving Party from a third party which does not have confidentiality obligations to the disclosing Party, or (c) the receiving Party can demonstrate was in its possession or known prior to receipt from the

disclosing Party. Confidential Information shall be received and treated in confidence, and shall not be used except as necessary to perform the activities contemplated in this MOU and shall not be further disclosed except as permitted by Article 3 or Section 6.8 herein without prior written consent of the disclosing Party; provided that, if a receiving Party is required by law to disclose Confidential Information, the receiving Party shall notify the disclosing Party and reasonably cooperate with the disclosing Party's efforts to prevent disclosure.

6.4 *Compliance.* The Parties will each abide by applicable laws, including, without limitation, the disclosing and handling of intellectual property, developed technologies, and Confidential Information, including PHI.

6.5 *Indemnification.* Each Party agrees to hold harmless and indemnify the other Party and its officers, agents and employees from and against any and all liability, loss, expense, attorneys' fees, or claims for injury or damages arising out of the activities under this MOU, but only 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 the indemnifying Party.

6.6 *Notice.* All notices permitted or required by this MOU shall be in writing; given by registered or certified mail, postage prepaid, or delivered by nationally recognized courier service; addressed to the addresses set forth below the signature lines, or such other address for which a Party may provide notice in accordance with this Section from time to time; and deemed effective upon receipt by the receiving Party.

6.7 *Relationship.* The relationship of the Parties is that of independent contractors. Neither Party is the partner, joint venturer, or agent of the other, and neither Party has authority to make any statement, representation, commitment, or action which would bind the other without prior written authorization. Each Party shall be solely responsible for any wages, employment taxes, fringe benefits and work schedules of its own employees or agents.

6.8 *Publication.* Subject to Section 6.3 above, OCHIN and/or Researcher may, at their respective discretion, release information or publish any data, writings, or material resulting from the Project, or use such information or publications in any way for their educational and research purposes.

6.9 *Independent Inquiry.* Nothing in this MOU is intended or shall be construed as limiting any Party's right to engage in similar research, whether independently or pursuant to grants, contracts, or other agreements with third parties.

6.10 *Governing Law.* This MOU is made in accordance with and shall be governed and construed under the laws of the State of Oregon, without regard to conflicts of laws principles.

6.11 *Other Agreements.* This MOU is not intended to conflict or supersede any term of the Master Service Agreement ("MSA") between OCHIN and Provider ("Agreement"). In the event of a conflict between this MOU and the Agreement with respect to matters specifically pertaining to the Project, this MOU shall control.

6.12 *Other Agreements.* OCHIN is permitted to share service area, clinic and/or department-level identified information with the Researcher and additional external partners involved in this initiative, provided they are bound by the same confidentiality provisions that OCHIN has with you and/or as stated in the IRB review and approval.

Additional BP-Home research partners include the American Medical Association (AMA), the American Heart Association (AHA), the Health eHeart Alliance, and Patient-Centered Outcomes Research Institute's (PCORI) Clinical Data Research Networks.

**Monterey County Health Department**

**OCHIN**

By:

By:

Title:

Title:

Address:

Address:

Attn:

Attn:

Date:

Date:

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Attachment A  
[attach IRB approval/waiver]

Reviewed as to Form 5/27/2020 by [unclear]

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University of California  
San Francisco

**Human Research Protection Program  
Institutional Review Board (IRB)**

**Expedited Review Approval**

Principal Investigator

Dr. Mark Pletcher, MD, MPH

Co-Principal Investigator

Dr. Vally Fontil MD, MAS, MD, MAS, MPH

**Type of Submission:** Continuing Review Submission Form  
**Study Title:** The PCORnet Blood Pressure Home Monitoring Study

**IRB #:** 18-25453  
**Reference #:** 269529  
**Committee of Record:** San Francisco General Hospital Panel  
**Study Risk Assignment:** Minimal

**Approval Date:** 01/16/2020 **Expiration Date:** 01/15/2021

**Regulatory Determinations Pertaining to this Approval:**

The IRB has determined that the devices used in this study are IDE Exempt (21 CFR 812) based on the information provided to the IRB.

The research meets all of the conditions of 45 CFR 46.204 for the involvement of pregnant women or fetuses.

Individual Research HIPAA Authorization is required of all subjects. Use the Permission to Use Personal Health Information for Research form.

A waiver of HIPAA Authorization and consent is acceptable for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose minimal risk to their privacy, based on, at least, the presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law; (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; (4) the research could not practicably be conducted without the waiver; and (5) the study recruitment could not practicably be conducted without access to and use of the requested information. Study participants will sign a consent form prior to participation in the study.

A waiver of the requirement to obtain a signed consent form is acceptable for the survey portion of this study because, as detailed in the application, the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The waiver applies to all subjects for filling out the surveys.

**All changes to a study must receive UCSF IRB approval before they are implemented.** Follow the [modification request](#) instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these [instructions](#).

**Expiration Notice:** The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time. In addition, you are required to submit a [study closeout report](#) at the completion of the project.

#### Documents Reviewed and Approved with this Submission:

#### Consent Documents

Study Consent Form			
Title	Version #	Version Date	Outcome
Consent_UMC_v.1_2019.03.19	Version 1.1	06/06/2019	Approved
Consent_UF_V.2_2019.05.16	Version 1.1	05/23/2019	Approved
Consent_OCHIN_V.2_2019.05.16	Version 1.2	05/16/2019	Approved
Consent_DoCh_V.2_2019.05.16	Version 1.2	05/16/2019	Approved
Consent_Access_V.2_2019.05.16	Version 1.2	05/16/2019	Approved
Consent_UCSF_V.2_2019.05.16	Version 1.5	05/16/2019	Approved

For a list of [all currently approved documents](#), follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

**San Francisco Veterans Affairs Medical Center (SFVAMC):** If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The UCSF IRB [website](#) has more information.