Study Application (Version 1.14)

1.0 General Information

***Enter the full title of your study:**

Teledermatology mobile apps: Implementation and impact on Veterans' access to dermatology

***Enter the study number or study alias**

Telederm Mobile Apps
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List the departments associated with this study. The Principal Investigator's department should be Primary.:

Primary Dept?	Department Name
◆	**UCSF** - *131020* - M_Dermatology

3.0 List the key study personnel: (Note: external and affiliated collaborators who are not in the UCSF directory can be identified later in the Qualifications of Key Study Personnel section at the end of the form)

3.1 *Please add a Principal Investigator for the study:

Oh, Dennis H

Select if applicable

☐ Department Chair ☐ Resident

☐ Fellow

If the Principal Investigator is a Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

Lachica, Olevie T
Research Assistant
Peracca, Sara
Study Coordinator

3.3 *Please add a Study Contact:

Oh, Dennis H
Peracca, Sara

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

3.4 If applicable, please add a Faculty Advisor/Mentor:

3.5 If applicable, please select the Designated Department Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

4.0 Initial Screening Questions

Updated January 2019 - Revised Common Rule (January 2018) Compliant - v92

4.1 * PROJECT SUMMARY: (REQUIRED) Give a brief overview of this project (250 words or less). Tell us what this study is about, who is being studied, and what it aims to achieve. If you have an NIH Abstract, paste it here (Click on the orange question mark to the right for more detailed instructions):

VA's Office of Connected Care has developed two mobile apps for teledermatology – VA Telederm and My Telederm. The proposed research will test the hypothesis that successful implementation of each app enhances access of Veterans to dermatologic care. Each mobile app will be rolled out in a stepped wedge cluster randomized trial design to sites most likely to benefit. Outcomes will be compared for sites that have received an app to those that have not yet received it. **Aim 1 (not the focus of this IRB application)** will test the hypothesis by measuring access to skin care as well as total instances of care. The data resides in VA's Corporate Data Warehouse, and will be obtained by VA's Center for Access Policy, Evaluation and Research under its own IRB application, and shared with the PI and other investigators. **Aim 2 (which is the focus of this IRB application)** will examine factors that affect successful implementation and impact of each app. Investigators at San Francisco, Providence, and Durham VA Medical Centers will conduct formative evaluations at 3 pilot sites for each app to determine characteristics that correlate with implementation of the apps. In addition, using nationally and remotely available enterprise-wide data, we will measure implementation and adoption of apps at all participating sites. At the end of the study, the research will have documented mobile teledermatology's effectiveness in enhancing access to dermatology, and enhance understanding of the factors leading to successful mobile telehealth implementation.

4.2 * HUD DEVICE: (REQUIRED) Does this application involve a Humanitarian Use Device (HUD):

- (●) No
- ( ) Yes, and it includes a research component
- ( ) Yes, and it involves clinical care ONLY

4.3 * TYPE OF RESEARCH: (REQUIRED) Select the option that best fits your project (Click the orange question mark to the right for definitions and guidance):

- ( ) Biomedical research (including medical records review, biospecimen collection and/or use, other healthcare or health outcomes related activities, research database, biospecimen bank, or recruitment registry)

- (●) Social, behavioral, educational, and/or public policy research
- ( ) Hybrid - includes aspects of BOTH types of research (check this option if your research is mainly social /behavioral but also involves specimen collection or blood draws to look at biological measures)

4.4 * SUBJECT CONTACT: (REQUIRED) Does this study involve ANY contact or interactions with participants:

- (●) Yes (including phone, email or web contact)
- ( ) No (limited to medical records review, biological specimen analysis, and/or data analysis)

4.5 * RISK LEVEL: (REQUIRED) What is your estimation of the risk level, including all screening procedures and study activities:

- (●) Minimal risk
- ( ) Greater than minimal risk

4.6 * REVIEW LEVEL: (REQUIRED) Requested review level (Click on the orange question mark to the right for definitions and guidance):

- ( ) Full Committee
- (●) Expedited
- ( ) Exempt

4.7 * EXPEDITED REVIEW CATEGORIES: (REQUIRED) If you think this study qualifies for expedited review, select the regulatory categories that the research falls under: (check all that apply)

- [ ] Category 1: A very limited number of studies of approved drugs and devices
- [ ] Category 2: Blood sampling
- [ ] Category 3: Noninvasive specimen collection (e.g. buccal swabs, urine, hair and nail clippings, etc.)
- [ ] Category 4: Noninvasive clinical procedures (e.g. physical sensors such as pulse oximeters, MRI, EKG, EEG, ultrasound, moderate exercise testing, etc.)
- [ ] Category 5: Research involving materials (data, documents, records, or specimens) that were previously collected for either nonresearch or research purposes
- [x] Category 6: Use of recordings (voice, video, digital or image)
- [x] Category 7: Low risk behavioral research or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

4.9 * DATA/SPECIMEN ANALYSIS ONLY: (REQUIRED) Does this study ONLY involve records review and /or biospecimen analysis (do not check 'Yes' if this is a registry, research or recruitment database, or biospecimen repository):

( ) Yes (●) No

4.10 * CLINICAL TRIAL: (REQUIRED)
Is this a clinical trial:

According to The World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE) a clinical trial is:

- Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

ICMJE requires registration of a clinical trial in a public database (such as ClinicalTrials.gov) prior to enrollment, for eventual publication of results in member biomedical journals.
Guidance: Public Law 110-85 requires that all investigators who perform an *applicable clinical trial* must ensure that the trial is registered on a government web site called **ClinicalTrials.gov**.

The FDA requires registration for 'applicable clinical trials,' defined as follows:

- For any trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation.
- For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

For additional information on the **ClinicalTrials.gov** registration process at UCSF and the definition of a clinical trial for purposes of registration, visit the **ClinicalTrials.gov section of the UCSF Clinical Research Resource HUB**.

(•) Yes ( ) No

Clinical Trial Registration - 'NCT' number for this trial:

SDR 16-192

4.11 * CLINICAL TRIAL PHASE: (REQUIRED) Check the applicable phase(s):

- [ ] Phase 0
- [x] Phase 1
- [ ] Phase 1/2
- [ ] Phase 2
- [ ] Phase 2/3
- [ ] Phase 3
- [ ] Phase 4
- [ ] Not Applicable

4.12 * INVESTIGATOR-INITIATED: (REQUIRED) Is this an investigator-initiated study:

(•) Yes ( ) No

The UCSF IRB recommends use of the Virtual Regulatory Binder to manage your study.

4.13 * CANCER: (REQUIRED) Does this study involve cancer (e.g., the study involves patients with cancer or at risk for cancer, including behavioral research, epidemiological research, public policy research, specimen analysis, and chart reviews):

( ) Yes (•) No

4.14 * RADIATION EXPOSURE: (REQUIRED) Does your protocol involve any radiation exposure to patients /subjects EITHER from standard care OR for research purposes (e.g., x-rays, CT-scans, DEXA, CT-

guided biopsy, radiation therapy, or nuclear medicine including PET, MUGA or bone scans):

○ Yes ◉ No

4.15 SCIENTIFIC REVIEW: If this study has undergone scientific or scholarly review, please indicate which entity performed the review (check all that apply):

☐ Cancer Center Protocol Review Committee (PRC) (Full approval is required prior to final IRB approval for cancer-related protocols.)
☐ CTSI Clinical Research Services (CRS) Advisory Committee
☑ CTSI Consultation Services
☐ Departmental scientific review
☑ Other:

* Specify **Other: (REQUIRED)**

VA Health Services Research scientific review panel on 3/8/17. Impact Score = 173

4.16 * STEM CELLS: (REQUIRED) Does this study involve human stem cells (including iPS cells and adult stem cells), gametes or embryos:

◉ No
○ Yes, and requires IRB and GESCR review
○ Yes, and requires GESCR review, but NOT IRB review

4.17 * FINANCIAL INTERESTS: (REQUIRED) Do you or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests related to this study:

○ Yes ◉ No

5.0 Funding

5.1 * FEDERAL FUNDING: (REQUIRED) Is this study currently supported in whole or in part by Federal funding, *even by a subcontract*, OR has it received ANY Federal funding in the past:

◉ Yes ○ No

5.2 * DoD INVOLVEMENT: Is this project linked in any way to the Department of Defense (DoD): (REQUIRED)

○ Yes ◉ No

5.3 SPONSORS: Identify all sponsors and provide the funding details. If funding comes from a Subcontract, please list only the Prime Sponsor:

External Sponsors:

View Details	Sponsor Name	Sponsor Type	Awardee Institution	Contract Type:	UCSF RAS "P number" or eProposal number	UCSF RAS System Award Number ("A" + 6 digits)

⊟	US Dept of Veterans Affairs	01	SF VAMC Research Office	Grant	not applicable	not applicable

Sponsor Name:	US Dept of Veterans Affairs
Sponsor Type:	01
Sponsor Role:	Funding Data Coordination Monitoring
CFDA Number:	
Grant/Contract Number:	SDR 16-192
Awardee Institution:	SF VAMC Research Office
Is Institution the Primary Grant Holder:	Yes
Contract Type:	Grant
UCSF RAS "P number" or eProposal number:	not applicable
UCSF RAS System Award Number ("A" + 6 digits):	not applicable
Grant Number for Studies Not Funded thru UCSF:	
Grant Title:	Teledermatology mobile apps: Implementation and impact on Veterans' access to dermatology
PI Name: (If PI is not the same as identified on the study.)	
Significant Discrepancy:	

Other Funding Sources and Unfunded Research - Gift, Program, Departmental or other Internal Funding (check all that apply):

- ☐ Funded by gift (specify source below)
- ☐ Funded by UCSF or UC-wide program (specify source below)
- ☐ Specific departmental funding (specify source below)
- ☐ Unfunded (miscellaneous departmental funding)
- ☐ Unfunded student project

6.0 Sites, Programs, Resources, and External IRB Review

6.1 UCSF AND AFFILIATED SITES (check all that apply):

- ☐ UCSF Benioff Children's Hospital Oakland (BCHO)
- ☐ UCSF China Basin clinics and facilities
- ☐ UCSF Helen Diller Family Comprehensive Cancer Center
- ☐ UCSF Langley Porter Psychiatric Institute (LPPI)
- ☐ UCSF Medical Center at Mission Bay (Benioff Children's Hospital, the Betty Irene Moore Women's Hospital, Bakar Cancer Hospital, or outpatient clinics)
- ☐ UCSF Mount Zion
- ☐ UCSF Parnassus (Moffitt-Long hospital, dental clinics or other outpatient clinics)
- ☐ UCSF Other Sites (including Laurel Heights and all the other sites outside the main hospitals)
- ☐ Zuckerberg San Francisco General (ZSFG)
- ☑ SF VA Medical Center (SF VAMC)
- ☐ Fresno - UCSF Fresno OR Community Medical Center (CMC)
- ☐ Gladstone
- ☐ Institute on Aging (IOA)

☐ Jewish Home
☐ SF Dept of Public Health (DPH)
☐ Vitalant (formerly Blood Centers of the Pacific and Blood Systems Research Institute)

Research involving the SF VAMC: Please thoroughly review the Working with the SF VAMC webpage and/or consult the VA Research Office (V21SFCHRPP@va.gov or (415) 221-4810 x6425) prior to submitting your application to the IRB and:

- **If this study involves both UCSF and the VA, identify who is serving as the VA PI under 'Descriptions of Study Responsibilities' in the 'Qualifications of Investigators' section at the end of this form**
- **Include the additional required VA forms in the Study Documents section of the Initial Review Submission Packet form**

6.2 LOCATIONS: At what locations will study visits and activities occur:

San Francisco VA Health Care System
4150 Clement Street, San Francisco, CA 94121

6.3 OFF-SITE PROCEDURES: Will any study procedures or tests be conducted off-site by non-UCSF personnel:

○ Yes ◉ No

6.4 RESEARCH PROGRAMS: Check any UCSF research programs this study is associated with:

☐ Cancer Center
☐ Center for AIDS Prevention Sciences (CAPS)
☐ Global Health Sciences
☐ Immune Tolerance Network (ITN)
☐ Neurosciences Clinical Research Unit (NCRU)
☐ Osher Center
☐ Positive Health Program

6.5 * CTSI CRS SERVICES: (REQUIRED) Will this study be carried out at one of the UCSF Clinical Research Services (CRS) units or utilize CRS services:

○ Yes ◉ No

6.6 * MULTI-CENTER TRIAL: (REQUIRED) Is this a multi-center or multi-site research trial:

By **'multi-center trial'** we mean a study where the protocol is developed by an lead investigator, an industry sponsor, consortium, a disease-group, etc.,and multiple sites across the nation or in different countries participate in the trial. The local sites do not have any control over the design of the protocol.

◉ Yes ○ No

6.7 * COORDINATION: (REQUIRED) Is UCSF the coordinating center:

○ Yes ◉ No

6.8 OTHER SITE TYPES: Check all the other types of sites not affiliated with UCSF with which you are cooperating or collaborating on this project:

Do NOT check any boxes below if this is a multi-center clinical trial, UCSF is just one of the sites, and neither UCSF nor one of its faculty-linked affiliates (SF VAMC, Gladstone, ZSFG) are the coordinating center.

☐ Other UC Campus

☑ Other institution

☐ Other community-based site

☐ Foreign Country

☐ Sovereign Native American nation (e.g. Navajo Nation, Oglala Sioux Tribe, Havasupai, etc.)

6.11 * OUTSIDE RELIANCES: (REQUIRED) Are any of the collaborating sites requesting to rely on UCSF's IRB:

○ Yes ◉ No

6.12 * NIH sIRB APPLICABILITY: (REQUIRED) Is this research subject to the NIH's sIRB Policy:

○ Yes ◉ No

You indicated this study is a 'multi-site trial' and has federal funding. If this is a multi-center study with federal funding, domestic sites are most likely subject to the NIH sIRB review requirements. Talk to your RMS analyst about the terms of your grant if you are not sure.

6.14 * RELYING ON AN EXTERNAL IRB: (REQUIRED) Does this application include a request to rely on an external IRB (a central IRB (other than the NCI CIRB) or an external IRB (other UC campus, commercial, or institutional):

○ Yes ◉ No

7.0 Outside Site Information

7.1 Outside Site Information

If you have more than 10 sites to add, list the outside sites in the Outside Sites List document and upload it in the Other Study Documents section of the Initial Review Submission Packet form. Any sites requesting to rely on UCSF's IRB must be listed below.

Click "Add a new row" to enter information for a site. Click it again to add a second site again to add a third site, a fourth site, etc.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Providence VA Medical Center

Contact name:

Martin Weinstock, MD, PhD

Email:

martin.weinstock@va.gov

Phone:

415-935-5362

For Federally-funded studies only, corresponding FWA#:

FWA00001273

*** The research at this site will be reviewed by:**

- (•) The non-affiliated site's IRB or a private IRB
- ( ) The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ( ) The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Duram VA Health Care System

Contact name:

John D. Whited, MD, MHS

Email:

john.whited@va.gov

Phone:

919-286-0411

For Federally-funded studies only, corresponding FWA#:

FWA00001600

*** The research at this site will be reviewed by:**

- (•) The non-affiliated site's IRB or a private IRB
- ( ) The non-affiliated site is requesting UCSF to be the IRB of record for this study
- ( ) The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

Outside Site Information

Non-UCSF affiliated site information:

Site name:

Ann Arbor VA Health Care System

Contact name:

Aliya HInes, MD PhD

Email:

Aliya.Hines@va.gov

Phone:

(443) 414-7148

For Federally-funded studies only, corresponding FWA#:

FWA00001681

*** The research at this site will be reviewed by:**

- ( ) The non-affiliated site's IRB or a private IRB
- ( ) The non-affiliated site is requesting UCSF to be the IRB of record for this study
- (•) The non-affiliated site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

Or, if the other site is **not engaged** in human subjects research, attach the letter of support to your application.

8.0 Research Plan and Procedures

8.1 HYPOTHESIS: Describe the hypothesis or what the study hopes to prove:

Access to healthcare is currently a key priority for Department of Veterans Affairs (VA). Store-and Forward (SFT) Teledermatology has emerged as an important strategy to enhance the access of patients to high quality skin care within VA. The current practice of teledermatology in VA is effective but has not been uniformly implemented, and inefficiencies in the current workstation-based process may discourage teledermatology adoption by primary care clinics. VA Office of Connected Care's (OCC's) mobile app, *VA Telederm*, has been developed as a more facile and efficient option that may enhance teledermatology adoption among providers.

Once patients establish care in a dermatology clinic, they often need follow-up visits to evaluate responses to treatment and to adjust management, neither of which necessarily requires a face-to-face visit. To address these issues, OCC has additionally developed the *My Telederm* app to allow established dermatology clinic patients to follow-up remotely using their own mobile devices. By reducing the need for some patients to follow-up in person, the app may improve clinic access to in-person dermatology clinics.

The overall hypothesis of this proposal is that sites implementing VA's teledermatology mobile apps will significantly augment the use of teledermatology and improve Veterans' access to skin care relative to control sites. Specifically, we hypothesize that *VA Telederm* will facilitate the implementation and adoption of teledermatology among primary care clinic staff, increasing use by existing programs and potentially expanding teledermatology to new sites while reducing patient travel to dermatology clinics. Additionally, we hypothesize that *My Telederm* will improve established patients' ability to follow-up with dermatology care remotely, while opening up dermatology clinic space for other patients.

8.2 AIMS: List the specific aims:

Aim 1. Measure impact of apps on access to dermatology care. ***San Francisco VA Health Care System's involvement is limited in Aim 1. All data related to this aim is collected by the VA's Center for Access Policy, Evaluation Research (CAPER) located at the Boston VA Health Care System. All data collected from the Corporate Data Warehouse, or any other databases as approved by the Boston VA Health Care System IRB will be anonymously recorded, aggregated, and shared with investigators and study staff at the San Francisco VA Health Care System and other sites. No analysis of the primary data will occur at San Francisco VA.***

Both apps will be made available over a 2 year period in a randomized, stepped-wedge design to Veterans Health Administration (VHA) facilities, after each app becomes available. The *VA Telederm* app will be distributed to 36 eligible VHA facilities that currently have low teledermatology activity and thus have had relatively poor adoption of basic consultative teledermatology. The *My Telederm* app will be distributed to 24 facilities with dermatology clinics that currently have relatively high teledermatology activity and thus already have relatively mature teledermatology programs ready for advanced operations.

By using health factors and stop codes unique to each app, we will use the VA Corporate Data Warehouse (CDW) to measure the impact of both apps on the following outcomes reflecting dermatology access: 1) Consult and appointment completion times for both teledermatology and in-person consults, stratified by new and established patients (primary outcome); 2) Instances of

dermatologic care (associated with either teledermatology or in-person dermatology encounters); and 3) Travel costs for VA, as well as non-VA care consult rates and associated costs. In addition, the following outcomes will be measured specifically for the *My Telederm* app: 1) Proportions of new patient encounters in-person dermatology clinics; and 2) "No-show" rates and timeliness of follow-up. Results of each of these access measures will be stratified to examine the effect on rural/highly rural Veterans, as well as to determine whether a differential effect occurs for facilities with some pre-existing teledermatology relative to those that had none.

Aim 2. Determine the factors that affect personal and organizational adoption of mobile apps. Using the Replicating Effective Programs framework, we will work with OCC to implement and measure the deployment, adoption and utilization of both teledermatology apps throughout all eligible VA sites. In one sub-aim, which is the principal focus of the current IRB application, we will conduct a formative evaluation of the implementation process at 3 early adopter sites to develop implementation strategies to guide subsequent nationwide deployment and research. Surveys and semi-structured interviews will assess Organizational Readiness for Change (ORC) at these sites regarding the apps, and link ORC to stages of implementation, barriers and facilitators to implementation, and implementation effectiveness as measured by uptake of the apps and actual use of teledermatology.

In the second sub-aim, we will also monitor deployment, adoption and utilization of both teledermatology apps nationally by analyzing remotely accessible data from the CDW and OCC. The primary data will be collected by CAPER under its own IRB approval, and aggregate data will be shared with the PIs and co-investigators. We will then correlate the degree of adoption with reach of the program (i.e., number of Veterans served) and stratify analyses of primary outcomes from Aim 1 based on degree of adoption.

At the conclusion of the project, we expect to document important indicators of mobile teledermatology's effects on patient access in the nation's largest healthcare system and to comprehensively understand the implementation of mobile teledermatology. These novel achievements will guide future mobile telemedicine endeavors in VA, and will inform other large healthcare organizations interested in telehealth.

8.3 DESIGN: Briefly describe the study design (e.g., observational, interventional, randomized, placebo-controlled, blinded, cross-over, cross-sectional, longitudinal, pharmacokinetic, etc.):

VA Telederm is anticipated to be ready for national release in January 2017 and My Telederm in the spring of 2018, as part of VA's Office of Connected Care operations. Beforehand, technical field testing will occur at San Francisco, Providence and Denver VHA facilities. For national rollout, each app will be targeted to sites that are clinically appropriate and best positioned to benefit from the app. Within these sites, the apps will be released in three month intervals according to allow a cross-sectional stepped-wedge cluster randomized trial for each app. We anticipate the affected population will represent VA's as a whole.

The impact of teledermatology apps depends not only on their intrinsic effectiveness, but also on successful implementation and adoption by as many target sites and end-users as possible who then maintain the practice. Outcomes may be organized within the RE-AIM Framework, which encompasses multiple domains necessary for translating innovation into real-world practice. The Reach and Effectiveness domains are addressed in Aim 1; The Adoption, Implementation and Maintenance domains are the focus of Aim 2.

Aim 1 will assess each app's effect on Veterans' access to dermatology in a stepped-wedge cluster randomized trial. Corporate Data Warehouse (CDW) data pertaining to access will be collected remotely by the Center for Access Policy, Evaluation and REsearch (CAPER) under its own IRB approval. Multiple measures reflecting different aspects of access will be evaluated to achieve a comprehensive and accurate evaluation of each app's impact. Aim 2 will focus on measuring the degree to which each app was implemented. Using semi-quantitative interviews and surveys of key VA staff members at the three early adopter sites (San Francisco, Denver and Providence VA Medical Centers) involved in technical testing as well as data in CDW and OCC databases, we will monitor implementation and identify organizational, individual, and app-specific factors that affect each app's overall impact.

8.4 BACKGROUND AND SIGNIFICANCE: Briefly provide the background and significance of this study (e.g. why is this study needed) (space limit: one half page):

Telehealth and mobile health are rapidly growing segments of healthcare in VA and other government agencies such as the Department of Defense, as well as in the private sector. Teledermatology has been adopted by both large non-profit health care organizations as well as by for-profit companies and individual practices. The use of mobile apps in teledermatology is in a relatively early phase and it is important to validate their effectiveness in promoting teledermatology in diverse populations, and understand how best to integrate them into clinical operations. The proposed research is expected to have the following impacts:

Assess the ability of mobile teledermatology to bring expert dermatologic care to new populations. Tele dermatology has been well-studied with respect to its diagnostic and management reliability, and clinical outcomes. Its ability to enhance access to skin care has also been documented. However, little is known about the ability of teledermatology to expand the number of patients served, especially to those in underserved areas. Less is known about the effect of teledermatology on the performance of a healthcare system. The integrated nature and size of VA's teledermatology program offers an unparalleled opportunity to study the effect of the teledermatology intervention on patient access in the largest healthcare system in the United States, as well as to study implementation of apps on a large scale. The proposed project will document the ability of *VA Telederm* to expand consultative teledermatology within existing programs and to new VA CBOCs. This information will be particularly important to health care organizations responsible for large, geographically diverse populations in rural or otherwise remote areas.

Validate a new model for enhancing access to patients. Historically, teledermatology has been principally practiced as a consultative tool where a PCP requests guidance from a dermatologist. The preponderance of published research has similarly focused on consultative teledermatology. However, with the widespread availability of digital cameras and internet access, the ability to accept teledermatology consultations directly from patients has increasingly emerged in commercial ventures but with little scientific validation of their actual impact on healthcare. Within VA, there has also recently been an evolution toward delivering healthcare centered in patients' homes, and OCC has begun live-interactive telehealth encounters with patients in their homes. The effect of this type of telehealth is unknown. The *My Telederm* app will be VA's first attempt to bring store-and-forward telehealth into patients homes and may have significant impacts on not only the patients that it directly serves, but also indirect effects on new patients who need to be seen in person in clinics and who may benefit from the additional capacity created by allowing established patients to follow-up remotely. The proposed research seeks to measure the magnitude of this effect.

Understand factors affecting successful implementation of mobile apps. Implementation and adoption of telehealth, including teledermatology, in the VHA has proven to be a slow and heterogeneous effort, having taken over 8 years since the program was nationally disseminated by VA, with no systematic effort to collect data that would inform VA as to the reasons why teledermatology has been actively adopted and thriving at some sites, while being neglected or failing at others. It is thus significant that the proposed research will be the first large-scale attempt to understand the implementation science associated with a teledermatology program, and it will be the first to study VA apps that are intended to interface directly with existing clinical care pathways. The research will have strategic importance for VA and OCC as additional mobile apps serving other clinical needs, particularly those that directly interact with clinical care of patients, are rolled out in the future. Additionally, we believe that studying the process within the paradigm of OTIE and the REP framework will allow the findings to be broadly applicable to other healthcare organizations.

8.5 PRELIMINARY STUDIES: Briefly summarize any preliminary studies relevant to your proposed research (space limit: one half page):

The proposed research is to assess the implementation and impact of mobile apps that are in the final stages of development, validation and checks for compliance with VA's privacy and safety requirements. In anticipation of the stepped-wedge cluster randomized trial, all VA facilities were examined for teledermatology activity relative to total dermatology activity.

The inclusion criterion for the first trial (*VA Telederm*) was that a site had a minimum of 0.1% and < 8.8% of its total FY2016 dermatology encounters under secondary stop codes 695/696 (teledermatology readings). VA

medical centers with no 695/696 activity in FY2016 or with zero full-time equivalent dermatologists were excluded since these sites likely lack the expertise, support and infrastructure to feasibly adopt teledermatology during the study period. In total, we identified 36 sites eligible for *VA Telederm*, teledermatology constituting between 0.1% and 8.8% of all dermatology encounters.

Conversely, the inclusion criterion for the second trial with *My Telederm* was that a site had ≥8.8% of all FY2016 dermatology encounters under secondary stop codes 695/696. This indicated considerable pre-existing experience with consultative teledermatology and the likely presence of dermatology reader and support personnel needed to implement *My Telederm*. We identified 24 sites where teledermatology constituted 8.8% to 100% of total encounters.

In Aim 1, apps will be disseminated according to the stepped-wedge cluster randomization scheme determined by this research project, but otherwise is under the control of VA's Office of Connected Care as part of its operational plan to disseminate the apps to the clinical field. The main outcomes are measures that serve as proxies for access to dermatology services, and these are stored in VA's Corporate Data Warehouse (CDW) which is remotely accessbie.

8.6 * TREATMENT PROTOCOL: Is this a treatment study, i.e. does this study intend to provide treatment to individuals with a medical or psychological condition: (REQUIRED)

○ Yes ◉ No

8.7 * BILLABLE PROCEDURES: Does this study involve any procedures, lab tests or imaging studies that have a CPT code and could be billable to patients, their insurance, Medi-Cal, Medicare, or any other entity (answer 'Yes' even if the study is going to pay for all the procedures): (REQUIRED)

○ Yes ◉ No

If you are not sure if your study involves billable procedures, send an email to the UCSF Office of Clinical Research (OCR) for help answering this question.

8.8 * COMMON RESEARCH ACTIVITIES: Types of research activities that will be carried out. Check all that apply and describe in more detail in the 'Procedures / Methods' section: (REQUIRED)

- ☑ Interviews, questionnaires, surveys
- ☐ Educational or cognitive tests
- ☐ Focus groups
- ☐ Social media-based research activities
- ☐ Observation
- ☐ Fitness tests or other exertion activities
- ☐ Use of mobile health apps or other apps
- ☐ Collection of data from wearable tech such as Fitbit, Apple Watch, Garmin, motion actigraphs, etc.)
- ☐ Non-invasive imaging or testing (MRI, EEG, pulse oximetry, etc.)
- ☐ Imaging procedures or treatment procedures that involve radiation (x-rays, CT scans, CT-guided biopsies, DEXA scans, MUGA or PET scan)
- ☐ Administration of contrast agent
- ☐ Randomization to one intervention versus another
- ☐ Use of placebo
- ☐ Biopsy conducted solely for research purposes
- ☐ Sham surgical procedure
- ☐ None of the above

8.9 * PROCEDURES / METHODS: (REQUIRED)

Describe the research methods and study activities taking place at each site (e.g. what will participants be asked to do and what will members of the study team do?). If there will be multiple participant groups or study sites, explain what will happen with each group or study sites.

If some of the activities would occur even if the person were not in the study, as in the case of treatment or tests performed for diagnostic purposes, **clearly differentiate between those activities that will be done solely for research purposes and those that are happening as part of routine care.**

Please call our office at 415-476-1814 and ask to speak to someone on the Expedited Review team if you need help differentiating between what parts are research and what parts aren't.

In **Aim 1**, no patient contact is required for the research activity of this aim. Primary data for this Aim will be obtained by VA's CAPER under its own IRB authorization and will be stored at the CAPER's Boston VA facility. Aggregate data will be shared by CAPER with the PIs and co-investigators.

In **Aim 2**, technical field-testing prior to the start of the proposed study is a planned necessary step for VA's Office of Connected Care's clinical operations. Both *VA Telederm* and *My Telederm* will be field-tested by OCC at San Francisco, Denver and Providence VHA facilities and thus these sites cannot participate in the randomized study of Aim 1. However, as early adopters, these sites will be designated for formative evaluation in Sub-Aim 2.1. While these intensive studies cannot be conducted at all sites, we will monitor enterprise-wide implementation, adoption and maintenance using remotely accessible measures in Sub-Aim 2.2.

Sub-Aim 2.1: Formative Evaluation
This Sub-Aim's activities are the principal focus of the current IRB application. We will conduct an in-depth, theory-based formative evaluation of the three early adopter sites (same as technical field-testing sites), with the goals of understanding: 1) Factors that may impact ORC and implementation of the teledermatology apps; 2) Changes in these factors over the course of one year; and 3) Association between ORC to both successful implementation and sustainability over time. We will utilize a mixed methods approach to measure ORC and change in related components over time. The ultimate goal is to inform the process of implementing both teledermatology apps during the randomized implementation and among sites not part of the randomization process. Further, we will inform the implementation of future mobile clinical applications.

Survey data will be collected centrally using REDCap, hosted by the VA Information Resource Center (VIReC) and housed on a VA Informatics and Computing Infrastructure (VINCI) server at VA's Austin Infomration Techology Center. Interview data will be collected by recording phone conversations directly onto secure VA networked servers or encrypted computers, using MS Teams and Phillips recorder.

Site Selection for Formative Evaluation. In addition to their initial roles in field-testing, the three early adopter sites—San Francisco, Denver and Providence VA Medical Centers—are appropriate for evaluation since their primary care and dermatology leadership as well as CBOCs are willing to participate. These sites may have specific qualities that impact implementation. However, since they vary in terms of both organization and location, lessons learned will likely translate to the mix of other VA facilities with dermatology programs.

Formative evaluation process
Brief summary
The formative evaluation will begin by identifying baseline characteristics of the organization and team that may impact implementation (Site Process Guide is attached to this application). This will be followed by:

1. Assessment of readiness to implement teledermatology (to be determined by survey and by interviews; the email consent script and ORC survey, and telephone consent script and initial interview guide are attached to this application).
2. Bi-monthly (every other month) monitoring of the implementation process and progress (Bi-monthly Site Report is attached to this application).
3. Qualitative interviews addressing implementation factors suggested by the OTIE 6-8 months following initial implementation of teledermatology (The follow-up interview guide will be developed based on the initial evaluations in (1) and (2) and will be submitted as a modification to this protocol).

4. Qualitative and quantitative evaluation of program sustainability for each app 1 year after the first use of each of the teledermatology applications. (Program Sustainability Index survey attached to this application, the sustainability interview guide will be developed based on (1), (2), and (3) and will be submitted as a modification to this protocol.)

Each section of the formative evaluation is independent of the other, except when specifically noted. We are examining the perceptions of specific groups of individuals based on their roles within VA medical centers, as opposed to being based on the individual person. Furthermore since the apps are being released at different times, aside from the site information report the steps will be done separately for each app. The staff using the two teledermatology mobile apps are different. Steps of the formative evaluation process are summarized below.

Collection of Baseline Characteristics that may impact implementation. The three VA sites at San Francisco, Denver and Providence will be asked by research staff at San Francisco, Providence, and Durham VA sites using the Site Information Report to identify individuals (research subjects) directly involved in planning and execution of app implementation. These individuals make up the **core implementation team** which may vary among the sites, and has not yet been exactly defined at each site, including San Francisco VA, but may include those that function in the following roles:

1. Facility Telemedicine Coordinators
2. Primary Care Clinical Champions
3. Dermatology Clinical Champions
4. Imaging Master Preceptors
5. Clinical Applications Coordinators (CACs)
6. Teledermatology Readers

Additionally, the three sites will identify **other staff** whose work or clinical decision-making may change as a result of app implementation. These individuals are:

1. Primary Care Clinicians
2. Telehealth Clinical Technicians/Telehelath Imagers
3. Dermatology Clinicians
4. Other staff at the three early adopter sites whose work may be affected by teledermatology.

Detailed description of formative evaluation
The Principal Investigators will be asked to complete and provide San Francisco VA HCS research staff with a baseline site information document for each of the early adopter sites. This document will be used to identify core implementation team members and other staff involved in teledermatology and their relationships among each other, as well as teledermatology processes, size and composition of each medical centers, and impacted clinical services. We may supplement this information be examining organizational-level information (e.g., number of patients, number of providers) that is normally available to all VA employees through the VHA Reports and Measures Portal (RAMP) and/or VHA Report Services Center (VSSC).

Upon completion of the baseline site information document, the following specific steps will be overseen by the San Francisco VA Health Care system research staff.

1. **Measurement of ORC.** At each site, core implementation team members and other staff from impacted services will receive the validated Organization Readiness for Implementing Change measure, a 12-item computer-based ORC survey which examines perceptions of organizational-level change efficacy and commitment to newly implemented interventions. The ORC survey is submitted in its entirety as an attachment to application, along with the email consent script that will introduce the research subject to it and the consent process. In brief, survey questions ask participants to indicate their perceptions on the level of confidence that organizational members have in effecting changes in teledermatology operations using each of the mobile apps. Survey responses will objectively examine ORC as a two-dimensional construct encompassing change commitment and change efficacy. This instrument was developed specifically to measure aspects of the Weiner Theory of ORC. In addition, San Francisco research staff will conduct semi-structured qualitative telephone individual interviews of the core implementation team, 3 PCPs, 3 dermatologists, 2 dermatology staff members, as well as leadership positions overseeing and supporting teledermatology operations at the site (e.g., Network telehealth lead, Chief of Dermatology, Associate Chief of Staff for Ambulatory Care, informatics leads, IT specialists) at each site to assess ORC and factors that are hypothesized to predict ORC (i.e. change valance /value place on the apps and assessment of what it will take to implement the apps). These semi-structured interviews following the initial guide will allow us to study implementation processes, which tend to be fluid, non-linear, and context sensitive and will permit us to compare patterns

across cases. The telephone consent script and initial interview guide are attached to this application.

2. **Bi-monthly Monitoring of Implementation – Process of Implementation**. At the start of each app implementation, the research team will interview the core implementation team as a group during a conference call after obtaining verbal consent (the telephone consent script and Site Process Guide are attached to this application). Baseline information on the site's process of implementing each app and related clinical workflow will be collected through a series of questions based on expected workflow, such as identifying essential tasks in IT and informatics as well as staff training that need to occur. Additionally, we will collect baseline information on the organization of dermatology services, the referral process from PCPs, number of providers, and perceived volume of patients. Components of the workflow process will be stored in an Excel spreadsheet to be sent to the sites for updates every two months.
3. **Bi-monthly Monitoring of Implementation – Implementation Progress**. We will also measure the implementation process by bi-monthly site reports from the three sites. Implementation progress will be assessed utilizing the Stages of Implementation Completion (SIC). SIC enumerates key pre-implementation, implementation and sustainability milestones. Dates by which specific implementation milestones were reached will be identified. Bi-monthly (every other month) reports will also include assessment of barriers and facilitators identified through the ORC measurement process. Bi-monthly information will be fed back to project and OCC leadership so that program adjustments can be made. The Bi-Monthly Site Report survey is attached to this application.
4. **Evaluation of the Implementation Process – Qualitative Interviews.** At 6-8 months following the start of the implementation process of each app at the 3 early adopter sites, we will conduct follow-up semi-structured qualitative telephone individual interviews among the core implementation team, 3 PCPs, 3 dermatologists, 2 dermatology staff members, as well as leadership positions overseeing and supporting teledermatology operations at each site to assess OTIE factors suggestive of implementation success. The goal will be to interview the same individuals interviewed at baseline. The follow-up guide to be used for these interviews has not yet been developed as it will necessarily need to reflect the information obtained in the initial baseline studies above, but will in general allow participants to expand on the same areas covered by the bi-monthly site report survey that is attached, and described in (3) above. The follow-up interview will be introduced by the telephone consent script attached to this application.
5. **Assessment of Sustainability.** At one year, we will assess the sustainability of use of each of the mobile apps.
    1. The Mancini & Marek Model of Community-based Program Sustainability will be used to conceptually guide the evaluation of sustainability. Mancini & Marek propose that six elements are important to achieve long-term sustainability: Leadership competence, effective collaboration, demonstrating program results, strategic funding, staff involvement and integration, and program responsivity. The validated Program Sustainability Index (PSI) measures each of the 6 sustainability elements, and is attached to this application. Each core implementation team member and director of primary care and dermatology will be surveyed for each app.
    2. Using the semi-structured interview methods above, each core implementation team member, director of primary care, Chief of Dermatology, FTC, imager, and other staff members participating in processing or supporting teledermatology at each site will be interviewed. The sustainability interview will explore in more depth the areas surveyed in the PSI (Leadership, Collaboration, Demonstrating Program Results, Funding, and Program Responsivity. We have previously used the combination of PSI and qualitative interviews to evaluate the sustainability of a multi-facility program for the Office of Patient Centered Care and Cultural Transformation. This program sustainability interview guide will be introduced by the telephone consent script attached to this application.

Sub-Aim 2.2

Implementation of field sites will also be assessed at all participating sites by monitoring intermediate milestones and quantitative indicators of implementation that are available in CDW as well as from OCC's own telehealth database and Web and Mobile Solutions (WMS) device procurement program.

To understand how rapidly sites meet key milestones as a result of the OCC implementation process, and if the apps are more effective among sites that have reached more implementation milestones, randomized sites will be asked to complete a bi-monthly implementation site report monitoring key milestones, collected electronically via REDCAP on the VA intranet. This bi-monthly report is based on the bi-monthly site report utilized as part of the formative evaluation described above. Sites will be sent email reminders two weeks and one week prior to, and one week after the due date, with follow up via phone call, if necessary. Four of these randomized sites will be recruited to participate in semi-structured sustainability interviews using the same guides used in the formative evaluation and will be introduced by the telephone consent script attached to this application. These Interview data will be collected by

recording phone conversations directly onto secure VA networked servers or encrypted computers, using MS Teams and Phillips recorder.

8.11 INSTRUMENTS: List all questionnaires, surveys, interview, or focus group guides that will be used for this study:

If the instruments are not complete or not available because they will be developed as part of this study, describe the basic content or include an outline and submit the final versions to the IRB with a modification for approval prior to use.

1) Site Information Report (revision attached)
2) Site Process Guide (attached)
3) Organizational Readiness for Change (ORC) Survey (revision attached)
4) Initial Interview Guide (attached)
5) Bi-Monthly Site Report (survey revision attached)
6) Follow-up Interview Guide (Allows participants to expand on the same areas covered by the bi-monthly site report)
7) Program Sustainability Index (survey revisions attached) Now VA T Program Sustainabiltiy index (attached) and My T Program Sustainability index (attached)
8) Sustainability Interview Guide (attached-Allows participants to expand on the same areas covered by the PSI survey)
9) Bi-Monthly Site Report for National Sites (attached)

Telephone/Email Consent Scripts for Contacting Subjects:
1) Email consent script (introduction and consent to ORC, both Bi-monthly reports, and Program Sustainability Index surveys)
2) Telephone consent script (introduction and consent to Site Process Guide, Initial Guide, Follow-up Guide, and Sustainability Guide)

Attach any unpublished instruments in the 'Other Study Documents' section of the Initial Review Submission Packet form after completing the study application. Published instruments should NOT be attached.

8.12 * BIOSPECIMEN COLLECTION: Are you drawing any blood or collecting other biosamples (e.g. tissue, buccal swabs, urine, saliva, hair, etc.) for analysis under this protocol and/or storage for future research: (REQUIRED)

○ Yes ◉ No

8.13 STATISTICAL METHODS: Briefly summarize the methods and types of analyses that will be performed:

Aim 1-Due to a lack of participation by sites during the study which was in part conducted during the novel coronavirus (COVID-19) pandemic, we were not ale to follow the analysis plan for Aim 1 described below. Instead we focused on understanding factors associated with successful completion of consults with the mobile apps, examining differences between rural and urban Veteran users.

Data analysis. Primary data will be collected and analyzed by CAPER and shared in aggregate with the PIs and other investigators. Stepped wedge - cluster randomized trials (SW-CRTs) need to employ data analysis strategies that account for the causal structure implied by this design and mitigate its potential shortcomings. Two related issues which may confound the treatment effect are the within-cluster correlation and potentially significant secular trends in the outcomes of interest given the long duration of the trials (2.5 years). In fact, the exposure of each cluster to both the control and intervention allows the researcher to partially exploit the within cluster variance towards estimation, which renders this type of trial less sensitive to the intra-cluster correlation coefficient. To further ensure that these confounding factors are properly handled, we will analyze the data using mixed models that allow for time fixed effects and cluster random effects.

Second, we are interested in the average effect of the treatment among compliers (patients who only receive the treatment as a direct result of their exposure to the intervention), referred to as the Local Average Treatment Effect (LATE). This effect better reflects the efficacy of teledermatology compared to regular practice. In order to estimate LATE, we will follow an instrumental variable (IV)-based two-stage residual inclusion (2SRI) procedure.

Finally, we will also conduct an intent-to-treat analysis, yielding an estimate of the average effect of being randomized to receive one of the telederm apps (average treatment effect). From a policy perspective, this effect can be interpreted as the efficacy of deploying an app in real-world outpatient clinics, where overall uptake to clinical practice is likely less than 100%.

Aim 2

Sub-Aim 2.1: Formative Data Analysis. Core to the concept of formative evaluation is continual analysis of results and feedback to stakeholders. That will be done in this formative evaluation. Key data sources are qualitative interviews, surveys to assess ORC, and collection of detail about organizational characteristics and implementation process and progress. All qualitative interviews will be transcribed in full. Rapid analysis approaches will generate preliminary findings to share among the research team. This effort will involve an initial review of factors identified as directly impacting the process of supporting app implementation and impact of the apps on clinical workflow. Rapid analysis will be followed by in-depth content analysis. Content analysis to examine the telephone interviews will involve three phases: data coding, within-case analysis, and between-case analysis. In the data coding phase, we will use qualitative data analysis software (ATLAS.ti 5.0) to code the study data. The OTIE will provide a starting list of codes, which we will supplement with emergent codes as analysis proceeds. Using a common codebook, two investigators will conduct a preliminary test of codes by independently coding five transcripts. Based on the preliminary test, the investigators will sharpen the coding manual's definitions, decision rules, and examples. Research assistants will code the remaining documents.

In the second phase, we will conduct a within-case analysis of each VA using ATLAS.ti to generate reports of all text segments for each code. We will assess the degree to which the construct emerges in the data (its "strength"), the degree to which the construct positively or negatively affects implementation (its "valence"), and the degree to which relationships among constructs are consistent with the hypothesized model. We will assess support for the hypothesized relationships by using three criteria proposed by Trochim and Miles and Huberman. First, we will look for the overall covariance of the constructs (e.g., whether VA clinics exhibiting strong implementation climate have supportive administration). Second, we will look for explicit attributions or the identification of plausible mechanisms to link the two constructs (e.g., participants attribute a strong implementation climate to the deployment of appropriate implementation policies and practices).

In the third phase, we will apply the same criteria across the cases to determine if cross-case variation in implementation is consistent with the hypothesized relationships in the model. Consistent with the organization-level focus of the model, we will aggregate and analyze quantitative data on implementation policies and practices (e.g. staffing levels) and other study constructs using simple statistics. In addition, we will create within-case and between-case data displays that cross-tabulate the quantitative and qualitative data in order to facilitate the use of pattern-matching logic.

Sub-Aim 2.2: Collection of this data will be descriptively summarized to understand how rapidly sites meet key milestones as a result of the OCC implementation process, correlate the milestones to the number of patients serviced via the apps (i.e., reach), and allow for stratified analyses of main quantitative study results by degree of implementation based on reaching milestones to determine if the apps are more effective among sites that have reached more implementation milestones. We will analyze the qualitative data from the interviews in the same manner as described above for the formative evaluations using direct content analysis to examine themes within each case and to determine cross-case variation.

8.14 REFERENCES: List only the 5-10 most relevant references (a separate bibliography can be attached for reference purposes if this study involves novel approaches, agents, or an emerging technology that the IRB may not be familiar with):

1. Landow, S.M., D.H. Oh, and M.A. Weinstock, *Teledermatology within the Veterans Health Administration, 2002-2014.* Telemed E Health, 2015. **21**(10): p. 769-773.
2. Kilbourne, A.M., M.S. Neumannn, H.A. Pincus, et al., *Implementing evidence-based interventions in health care: application of the replicating effective programs framework.* Implement. Sci., 2007. **2**: p. 42.

3. Neumann, M.S. and E.D. Sogolow, *Replicating effective programs: HIV/AIDS prevention technology transfer.* AIDS Educ. Prev., 2000. **12**(5 Suppl.): p. 35-48.

4. Moullin, J.C., D. Sabater-Hernandez, F. Fernandez-Llimos, et al., *A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation.* Health Res. Policy Syst., 2015. **13**: p. 16.

5. Klein, K. and J. Sorra, *The challenge of innovation implementation.* Academy of. Management Review, 1996. **4**: p. 1055-1080.

6. Weiner, B.J., M.A. Lewis, and L.A. Linnan, *Using organization theory to understand the determinants of effective implementation of worksite health promotion programs.* Health Educ Res, 2009. **24**(2): p. 292-305.

7. Copas, A.J., J.J. Lewis, J.A. Thompson, et al., *Designing a stepped wedge trial: three main designs, carr-over effects and randomisation approaches.* Trials, 2015. **16**(1).

8. Pizer, S.D., M.L. Davies, and J.C. Prentice, *Consult timeliness strongly predicts patient satisfaction.* Am. J. Accountable Care, 2016. **in press.**

9. Prentice, J.C., M.L. Davies, and S.D. Pizer, *Which outpatient wait-time measures are related to patient satisfaction?* Am. J. Med. Qual., 2014. **29**(3): p. 227-235.

10. Shaw, R.J., M.A. Kaufman, H.B. Bosworth, et al., *Organizational factors associated with readiness to implement and translate a primary care based telemedicine behavioral program to improve blood pressure.* Implement. Sci., 2013. **8**(1): p. 106.

9.0 Drugs and Devices

9.1 * DRUGS AND/OR BIOLOGICS: Are you STUDYING any drugs and/or biologics that are either approved or unapproved: (REQUIRED)

○ Yes ◉ No

9.3 * MEDICAL DEVICES: Are you STUDYING any medical devices, in vitro diagnostics, or assays that are either approved or unapproved:(REQUIRED)

○ Yes ◉ No

10.0 Sample Size and Eligibility Criteria

10.1 ENROLLMENT TARGET: How many people will you enroll:

50

If there are multiple participant groups, indicate how many people will be in each group:

Aim 1 will collect aggregate data relating to access exclusively by Veteran patients to VHA dermatology. While some characteristics such as Veteran patient rurality and location will be monitored for individual encounters, the research has no direct or indirect patient contact or involvement. Our randomized study of a total of 60 nationally distributed VA facilities will include encounter data from Veteran patients who are expected to generally reflect the diversity of VA's patient population with respect to age, gender, race and ethnicity. Children will be excluded since VHA does not serve pediatric populations and since children are not a target population for the apps.

Aim 2, as part of formative evaluation, will involve structured interviews and surveys of VHA staff at three early adopter sites, including VISN and facility organizational leadership (VISN Telehealth Leads, Dermatology Chiefs, Facility Telehealth Coordinators), support staff (Information Security Officers, Clinical Application Coordinators, Information Technology specialists), and clinical end-users (primary care providers, Telehealth Clinical Technicians, dermatologists) and clinical support staff (Medical Support Assistants). Thus we anticipate 16-17 subjects will participate at each site. Since there are 3 sites that will participate in the formative evaluation, we estimate that 50 subjects will participate via surveys and interviews overall. For the formative evaluation, some but not all subjects may be Veterans, and will

reflect the composition and diversity of VHA's workforce. For sub aim 2.2, 28 site leads will receive the bi-monthly report and 4 of these 28 sites will be asked to participate in a semi-structured interview. Two will have high usage of the app and two with low to no usage of the app.

10.2 TOTAL PARTICIPANTS: For multicenter studies, how many people will be enrolled in total:

50

10.3 SAMPLE SIZE JUSTIFICATION: Explain how and why the number of people was chosen. For multi-site studies, this is referring to the number that will be enrolled across all sites:

In **Aim 1**, the number of participating medical center facilities (clusters) was determined as follows: The inclusion criterion for the first trial (*VA Telederm*) was that a site had a minimum of 0.1% and < 8.8% of its total FY 2016 dermatology encounters were attributable to teledermatology (stop codes 695/696). We also used clinical FTE data from FY 2016 and FY 2017 to make sure that they had at least some dermatologists on staff available. VA medical centers with no teledermatology activity in FY 2016 or with zero full-time equivalent dermatologists were excluded. In total, we identified 36 sites eligible for *VA Telederm*. Conversely, the inclusion criterion for the second trial with *My Telederm* was that a site had ≥8. 8% of all FY 2016 dermatology encounters as teledermatology. This indicated considerable pre-existing experience with consultative teledermatology and the likely presence of dermatology reader and support personnel needed to implement *My Telederm*. We determined, based on average treatment effects in the literature, that under most scenarios we are well-powered to detect conservative differences of 10% from baseline.

In **Aim 2**, as described in 10.1 above, we anticipate that 16-17 subjects will be enrolled for formative evaluation at each of the three sites (San Francisco, Denver and Providence). Each job title has been selected since it will either play be end-users of the mobile app program (e.g., primary care provider or imager or dermatologist), or be important support staff or mediators (e.g., Clinical Application Coordinator, program support assistants), or will be important leadership whose buy-in is necessary for successful implementation (clinical leadership). Sub aim 2.2 an additional 4 sites, two that have used the apps extensively in the last year and two that have not will provide additional insight into the facilitators and barriers at these sites.

10.4 * PARTICIPANT AGE RANGE: Eligible age ranges: (REQUIRED)

- [ ] 0-6 years
- [ ] 7-12 years
- [ ] 13-17 years
- [x] 18-64 years
- [x] 65+

10.5 * STUDY POPULATIONS: Data will be collected from or about the following types of people (check all that apply): (REQUIRED)

- [ ] Inpatients
- [ ] Outpatients
- [ ] Family members or caregivers
- [x] Providers
- [ ] People who have a condition but who are not being seen as patients
- [ ] Healthy volunteers
- [ ] Students
- [x] Staff of UCSF or affiliated institutions
- [ ] None of the above

10.6 * SPECIAL SUBJECT GROUPS: Check the populations that may be enrolled: (REQUIRED)

- [ ] Children / Minors
- [ ] Adult subjects unable to consent for themselves

- [ ] Adult subjects unable to consent for themselves (emergency setting)
- [ ] Subjects with diminished capacity to consent
- [ ] Subjects unable to read, speak or understand English
- [ ] Pregnant women
- [ ] Fetuses
- [ ] Neonates
- [ ] Prisoners
- [ ] Economically or educationally disadvantaged persons
- [x] None of the above

10.7 INCLUSION CRITERIA: Briefly describe the population(s) that will be involved in this study. Include anyone that data will be collected from or about (e.g. patients, healthy controls, caregivers, providers, administrators, students, parents, family members, etc.):

For **Aim 1**, the number of participating medical center facilities (clusters) was determined as follows: The inclusion criterion for the first trial (*VA Telederm*) was that a site had a minimum of 0.1% and < 8.8% of its total FY 2016 dermatology encounters were attributable to teledermatology.
Conversely, the inclusion criterion for the second trial with *My Telederm* was that a site had ≥8.8% of all FY 2016 dermatology encounters as teledermatology. This indicated considerable pre-existing experience with consultative teledermatology and the likely presence of a dermatology reader and support personnel needed to implement *My Telederm*. We determined, based on average treatment effects in the literature, that under most scenarios we are well-powered to detect conservative differences of 10% from baseline.

For **Aim 2,** inclusion criteria are:

- Job title or functional role is one of the following: Network telehealth lead, Facility Telehealth Coordinator, primary care leader or designee, dermatology chief or designee, master preceptor, Clinical Application Coordinator, teledermatology reader, primary care provider, dermatology staff physician, program support assistant.
- VA appointment is at least 25% time

10.8 EXCLUSION CRITERIA: List any exclusion criteria (e.g. reasons why someone would not be included in the study):

For **Aim 1**, VA medical centers with no teledermatology activity in FY 2016 or with zero full-time equivalent dermatologists were excluded.

For **Aim 2**, exclusion criteria are:

- Subject has no role in implementation of apps (unless subject is primary care or dermatology chief or designee)
- Subject is a staff member who is also a Veteran patient whose care is affected by the apps

10.9 * RESEARCH CONDUCTED ON PATIENT CARE WARDS: Do any study activities take place on any patient care units including inpatient wards, peri- or post-operative care units, operating rooms, or in the Emergency Department at UCSF Health medical facilities: (REQUIRED)

○ Yes ◉ No

10.11 * EMERGENCY DEPARTMENT: Does your protocol or study involve any of the following patient related activities in the emergency department (e.g. subject identification, recruitment, consent, blood draws, specimen retrieval, involvement of ED staff (nursing, tech, and/or physician), or any other ED based procedures): (REQUIRED)

○ Yes ◉ No

11.0 Recruitment and Consent

11.1 * COMPETITIVE ENROLLMENT: Is this a competitive enrollment clinical trial? By competitive enrollment, we mean that sites who do not enroll participants early may not get to participate at all: (REQUIRED)

- ○ Yes
- ◉ No

11.2 * SUBJECT IDENTIFICATION METHODS: What kinds of methods will be used to identify potential participants for recruitment (check all that apply): (REQUIRED)

- ☐ Review of patients' conditions, history, test results, etc. (includes patients seen in clinic, scheduled for surgery, a procedure, imaging, or tests, or seen in the Emergency Department as well as searching through medical record data for possible cohort identification)
- ☐ Already approved recruitment registry
- ☐ Re-contact of participants from the investigators' previous studies
- ☐ Referrals from colleagues (attach the 'Dear Colleague' letter or other recruitment materials you will provide to colleagues)
- ☐ Referrals from the community / word of mouth
- ☐ Advertisements (flyers, brochures, radio or t.v. ads, posting on clinical research sites or social media, presentation of the study at community events/media, etc.)
- ☐ Online recruiting tool (describe below)
- ☐ CTSI Recruitment Services unit
- ☐ Posting on UCSF Clinical Trials, ClinicalTrials.gov or other publicly available clinical trial website
- ☑ Other method (describe below)

* Provide details about the subject identification methods: **(REQUIRED)**

For **Aim 1**, there is no subject recruitment.

For **Aim 2**, subjects will be identified from their job titles or roles in telehealth/teledermatology, as described in Section 10. Subjects will initially be contacted through scripted emails or telephone calls (see attached) that describe the study goals and nature of the participation, and invite the subjects to participate.

11.4 DETERMINATION OF ELIGIBILITY: How, when, and by whom will eligibility for recruitment be determined:

For **Aim 1**, there is no recruitment of subjects.

For **Aim 2**, eligibility of VA staff members for recruitment is determined initially by the job title or functional role that a staff member plays in managing dermatology consults or in the telehealth process. At time of initial email or phone contact, subjects will be asked to confirm their eligibility.

11.5 * INITIATION OF CONTACT: Who initiates contact (check all that apply): (REQUIRED)

- ☑ Investigators/study team
- ☐ UCSF recruitment unit (e.g. CTSI Consultation Services)
- ☐ Potential participant
- ☐ Other (explain below)

11.6 * HOW IS CONTACT INITIATED: (check all that apply): (REQUIRED)

- ☐ In person
- ☐ Phone
- ☑ Letter / email
- ☐ Website or app
- ☐ Other (explain below)

Attach the recruitment letter or email template in the Other Study Documents section of the Initial Review Submission Packet Form.

11.7 RECRUITMENT PLAN: Based on the checkboxes you chose above, please provide a narrative describing your recruitment plan. We want to know:

- **Who is conducting the search for potential participants, and how?**
- **How are potential subjects being approached for recruitment? By whom, and when?**

If there will be more than one participant group (e.g. patients, healthy controls, caregivers, family members, providers, etc.), provide details about the recruitment plans for each group. (Recommended length - 100-250 words)

For **Aim 1**, there is no recruitment of subjects.

For **Aim 2**, research staff will communicate with Office of Connected Care and/or the Chief of Dermatology at each site to identify potential candidate subjects.

Once candidates have been identified, research staff will individually email each candidate using VA's internal Outlook email system (see email recruitment template). After a week, if there is no response, research staff will attempt to initiate contact by phone.

11.8 * CONSENT METHODS: How will permission to participate (i.e., informed consent) be obtained from each potential participant. If there will be multiple groups and different plans for consenting each, check all that apply. See the orange Help bubble to the right for more detailed guidance. Participants will (check all that apply): (REQUIRED)

- [ ] Sign a consent form at the end of the consent discussion (signed consent)
- [ ] Provide online 'eConsent' using an E-Signature system
- [x] Click through a link in a survey or email after reading about the study and then complete the study online (electronic consent)
- [x] Be told about the study and be given a handout/information sheet and be asked if they agree to participate (verbal consent)
- [x] Complete the study activities and turn in materials, as in the case of a completed survey that is placed in a drop box or mailed to the study team (implied consent)
- [ ] Not be able to provide consent and will have a family member consent for them, as in the case of a critically ill or unconscious patient (surrogate consent)
- [ ] Not be able to provide consent (emergency waiver of consent - allowed for minimal risk research or greater than minimal risk research with an approved community consultation plan)
- [ ] Not know about the study, as in the case of chart reviews or observations of public behavior (waiver of consent)
- [ ] Other method (describe below)

Attach your consent form, information sheet, or electronic consent text in the Informed Consent Documents section of the Initial Review Submission Packet Form.

11.9 * CONSENT PROCESS: Describe the process for obtaining informed consent, including details such as who will have the consent discussion and when participants will be asked to sign the consent form in relation to finding out about the study: (REQUIRED) We encourage researchers to review our guidance on obtaining and documenting informed consent.

- **If there are multiple groups being consented differently, provide details about the consent process for each group.**
- **If you are relying on verbal or implied consent, provide details about how that will happen.**
- **For studies using online recruitment and consent or consent via mail, provide details here.**

For **Aim 1**, where there is no subject contact and no retention of individually identifiable data, there is no consent process.

For **Aim 2**, we request a waiver of documentation of signed informed consent. Following reply to the initial contact, if the subject agrees, arrangements will be made by the study coordinator to meet over the phone to review the study and discuss the informed consent process, as described in the Telephone Consent Script attached to this application

* It is important that the people obtaining consent are qualified to do so. Briefly describe the training and experience these individuals have in obtaining informed consent: **(REQUIRED)**

For **Aim 2**, consent will be obtained by research staff who have met all the online training required by VA for employment and for human subjects research, including TMS training and CITI training. In addition, research staff will be trained by the PIs and co-investigators in the key aspects of the research project, including obtaining consent, and role-playing prior to actual encounters with candidate subjects.

11.10 * CONSENT COMPREHENSION: Indicate how the study team will assess and enhance the subjects' understanding of study procedures, risks, and benefits prior to signing the consent form (check all that apply): (REQUIRED) Tip: Review the Consent Comprehension - Learning Notes in the Help bubble at the right for specific questions that can be asked to assess comprehension, consider using the UCSF Decision-Making Capacity Assesment Tool, and review our guidance on obtaining written or verbal informed consent for more detail on how to conduct the assessment.

- [x] The study team will engage the potential participant in a dialogue, using open-ended questions about the nature of the study or the experimental treatment, the risks and benefits of participating, and the voluntary nature of participation
- [ ] Potential participants will be asked or shown a series of questions to assess their understanding of the study purpose, procedures, risks and benefits, as well as the voluntary nature of participation (especially appropriate when the consent process happens online or through a mobile health app)
- [ ] Other method (describe below):

Provide details of the other approaches that will be used, if using another method to assess comprehension:

11.11 * DECEPTION: Does this study rely on some deception or misinformation about what the researchers are observing to get valid data? (REQUIRED)

- ○ Yes
- ◉ No

11.13 * WAIVER OF DOCUMENTATION OF SIGNED CONSENT: Select the regulatory category under which the IRB may waive the requirement to obtain *signed* consent for this study:

- ○ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether they want documentation linking them with the research. 46.117(c) (1)
- ◉ 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. 46.117(c) (2)

11.14 TIME: What is the estimated time commitment for participants (per visit and in total):

For **Aim 1**, there is no time commitment.

For **Aim 2**, we anticipate the following time commitments:
30-45 minutes per interview for the three semi-structured interviews: the intial, follow-up, and sustainability interviews;
15-20 minutes for the ORC Survey and the Sustainability Index, 5 minutes for the Bi-Monthly Site Report every 2 months for 2 years;
1-2 hours for completion of the conference call with the Site Process Guide.

IMPORTANT TIP: Ensure this information is consistent with the information provided in the consent form.

11.17 OTHER ALTERNATIVES: Describe other alternatives to study participation, if any, that are available to prospective subjects:

None

12.0 Risks and Benefits

12.1 RESEARCH-RELATED RISKS: Check if your study involves any of these specific research-related risks to participants that may need to be disclosed in the consent form:

- [ ] Physical discomforts or pain
- [x] Risks to employment, or social or legal standing
- [ ] Risk that the study team may observe possible evidence of child abuse, elder abuse, or a threat to self or others that they are required to report

* For any boxes checked above, describe how you will minimize these risks and discomforts, e.g., adding or increasing the frequency of monitoring, additional screening to identify and exclude people with diminished kidney or liver function, or modification of procedures such as changing imaging studies to avoid giving contrast agent to people who are more likely to suffer side effects from it, etc.: **(REQUIRED)**

For **Aim 1**, the risk is minimal as there is no subject contact and data is collected in aggregate without individually-identifiable information by VA's CAPER under its own IRB approval.

For **Aim 2**,

- There is a small risk of losing anonymity through the use of demographic or job title information.
- Some individuals may feel self-conscious or embarrassed if asked questions about something with which they are unfamiliar, and they may be concerned that their responses will become known to colleagues and supervisors.

12.2 * RISKS: Describe any anticipated risks and discomforts not listed above: (REQUIRED)

None

12.3 MINIMIZING RISKS: Describe the steps you have taken to minimize the risks/discomforts to subjects. Examples include:

- **designing the study to make use of procedures involving less risk when appropriate**
- **minimizing study procedures by taking advantage of clinical procedures conducted on the study participants**
- **mitigating risks by planning special monitoring or conducting supportive interventions for the study**
- **having a plan for evaluation and possible referral of subjects who report suicidal ideation**

For **Aim 1**, there is no subject contact and data is collected in aggregate without individually-identifiable information.

For **Aim 2**,

- The risk of loss of anonymity will be minimized by not reporting demographic information for individual VA facilities participating in the study when aggregate results are provided to any VA administrators, colleagues, affiliated university colleagues, or affiliated university administrators. No individual respondents will be identified in any presentations or reports from this study.

- To minimize the risk that subject responses will become known to colleagues or supervisors, research staff will not interview or survey subjects at their own facility. For example, San Francisco researchers will interview Providence staff, and *vice versa*. In all cases, research staff is trained to maintain the strict confidentiality and anonymity of subject responses in their daily interactions during and outside of work hours. Subject interviews are stored on secure VA servers accessible only to authorized research staff approved for this specific study. Additionally, supervisors will not have access to any data.

12.5 * BENEFITS: (REQUIRED) Note: These are the benefits that the IRB will consider during their review. They are not necessarily appropriate to include in the consent form.

Possible immediate and/or direct benefits to participants and society at large (check all that apply):

- [ ] Positive health outcome (e.g. improvement of condition, relief of pain, increased mobility, etc.)
- [ ] Closer follow-up than standard care may lead to improved outcomes or patient engagement
- [ ] Health and lifestyle changes may occur as a result of participation
- [ ] Knowledge may be gained about their health and health conditions
- [x] Feeling of contribution to knowledge in the health or social sciences field
- [ ] The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
- [x] Other benefit (describe below)
- [ ] None

Briefly discuss the other possible benefits:

Participation may lead to knowledge that will help the subject and others in their jobs in the future. Specifically, knowledge may be gained about organizational factors involved in the implementation of telehealth programs and technology that may facilitate future programs in which the subject may be involved.

12.6 RISK TO BENEFIT RATIO: Explain why the risks to subjects are reasonable in relation to anticipated benefits, if any, to the participant or society:

The formative evaluation will allow monitoring of the apps in detail at the pilot sites, and if safety issues are identified, will allow corrections to be made before most other sites have been exposed the apps. The benefits of understanding organizational and individual factors that affect implementation of new processes in VA are considerable given that VA will likely undertake similar implementations of other interventions in the future. The principal risk of inadvertently revealing employees attitudes and knowledge of the process to peers and supervisors is minimal in absolute terms and in relation to the potential benefit to VA.

12.7 * DATA AND SAFETY MONITORING: Do you have a Data and Safety Monitoring Plan (DSMP) for this study (A DSMP is required for Greater than Minimal Risk research): (Click the Help link for guidance on risk determination) (REQUIRED)

(•) Yes ( ) No

This is not required for minimal risk research but the UCSF IRB strongly recommends one to ensure the data collected are adequate to meet the research aims:

13.0 Data and Safety Monitoring Plan

13.1 * DATA AND SAFETY MONITORING PLAN (DSMP): (REQUIRED) Provide a summary of the DSMP:

All greater than minimal risk studies are required to provide a plan. Lack of an adequate plan is one of the most common reasons why IRB approval is delayed.

Instructions:

Describe the plan for monitoring data quality and participant safety. Key areas that should be included in the plan are:

- An explanation of the plan to monitor data collection, study progress, and safety
- A description of who will perform the monitoring and at what frequency (e.g., the PI only, a contract research organization, a Data and Safety Monitoring Board or Data Monitoring Committee, etc.)
- The type of data and events that will be reviewed (e.g., adverse events, breaches of confidentiality, unanticipated problems involving risk to participants or others, unblinded efficacy data, etc.)
- Procedures and timeline for communicating monitoring results to the UCSF IRB, the study sponsor, and other appropriate entities

As appropriate:

- A plan for conducting and reporting interim analysis
- Clearly defined stopping rules
- Clearly defined rules for withdrawing participants from study interventions

The monitoring plan consists of both local and national oversight:

For **Aim 1**, data monitoring is done by CAPER under its own IRB approval. Aggregate data will also be reviewed by the PIs at routine conference calls every other week and during the annual investigators' meeting with Office of Connected Care in Washington, DC. However, this will be performed in consultation with VA's Office of Connected Care which is responsible for the overall implementation of the mobile apps throughout VA, and has its own independent Quality Improvement team to monitor implementation and safety.

For **Aim 2**, local monitoring includes the following:

- The consenting process informs research subjects of their ability and right to contact the local PI and research office should they have questions or concerns regarding their well-being, and provides them with contact information. Since research subjects will be interviewed and surveyed remotely by research staff not associated with their facility, it will be the responsibility of the local PI to notify the PI responsible for the remote research staff.

- The PIs and co-investigators at San Francisco, Providence and Durham, as well as CAPER investigators in Boston will hold phone conference calls every other week to discuss the project, including progress in subject recruitment, data collection, and safety.

- The PIs for each site will have first-line responsibility for ensuring that subject interactions are appropriate and safe, and that the data collected by their research staff is of sufficient quality and properly stored in REDCap. Interview data will be collected by recording phone conversations directly onto secure VA networked servers or encrypted computers. Data from these interviews will be stored on the Research (R:) drive of the San Francsico VA Health Care System server.

- Survey data will be collected centrally using REDCap, hosted by the VA Information Resource Center (VIReC) and housed on a VA Informatics and Computing Infrastructure (VINCI) server at VA's Austin Infomration Techology Center. Data is backed up nightly and every 6 hours. REDCap provides data de-identification features, and captures audit trails and logging with individualized user rights management. One is able to restrict access to PHI at the user level if needed, and limit access between different sites' data within multi-site studies if needed.

- Events triggering PI notification will include the following: Complaints generated by research subjects, change in employment status of research subjects identified by research staff (e.g.,

inability to administer follow-up interviews with research subjects due to transfer to new jobs or lack of response), and real or suspected loss of data or breach of subject confidentiality.

- If PIs identify issues with patient safety or confidentiality, the PIs will notify the local VA Research Office, UCSF's IRB as well as VA Office of Research and Development will be notified per VA protocol. Minor issues in data quality and project progress will be addressed directly with the site (s) involved, as well as during biweekly conference calls among all the investigators and/or during the annual investigators' meeting in Washington, DC.

13.2 * DATA AND SAFETY MONITORING BOARD (DSMB): (REQUIRED) Will a Data and Safety Monitoring Board (DSMB) be established:

- ○ Yes
- ◉ No

Guidelines

A Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) is a formal, independent committee that is specifically established to conduct interim monitoring, oversight and analysis of study information and data to assure the continuing safety, efficacy, appropriateness, relevance, and integrity of the study.

The UCSF IRB reserves the right to request a DSMB/DMC for any study. However, the following are factors that the IRB will consider when making this determination:

- There is a significant likelihood of a serious adverse event to subjects
- The study is conducted at multiple sites and the level of risk is greater than minimal
- The study generates data that are blinded or randomized
- The study involves a large number of patients randomized to one of two or more interventions
- A study for which the performance of an interim analysis is crucial for the protection of the subjects
- First use in humans
- First use in children
- The study involves gene therapy, stem cell therapy, or other novel interventions for which long-term outcome data are not known or available

14.0 Confidentiality, Privacy, and Data Security

14.1 PROTECTING PRIVACY: Indicate how subject privacy will be protected:

- ☑ Conduct conversations about the research in a private room
- ☑ Ask the subject how they wish to be communicated with – what phone numbers can be called, can messages be left, can they receive mail about the study at home, etc.
- ☑ Take special measures to ensure that data collected about sensitive issues do not get added to their medical records or shared with others without the subject's permission
- ☐ Other methods (describe below)

14.2 SENSITIVE DATA: Do any of the instruments ask about illegal or stigmatized behavior:

○ Yes ◉ No

14.3 SIGNIFICANT CONSEQUENCES OF A LOSS OF PRIVACY OR CONFIDENTIALITY: Could a breach of privacy or confidentiality result in any significant consequences to participants, such as criminal or civil liability, loss of state or federal benefits, or be damaging to the participant's financial standing, employability, or reputation:

(•) Yes ( ) No

Check all that apply:

- [x] Embarrassment
- [ ] Criminal or civil liability
- [ ] Loss of state or federal benefits
- [x] Damaging to the participant's financial standing, employability, or reputation
- [ ] Potential risks to insurability (health, disability, or life insurance)

Describe the potential consequences:

For **Aim 2**, the research will record employees' attitudes or knowledge about telehealth, mobile apps, teledermatology or broader VA-related issues. It is possible that loss of privacy/confidentiality regarding this data could prove embarrassing or damaging to reputations for employees if released to peers or supervisors. In such cases, some employees may feel job insecurity.

14.4 EXTRA CONFIDENTIALITY MEASURES: Explain any extra steps that will be taken to assure confidentiality and protect identifiable information from improper use and disclosure, if any:

For **Aim 2**, subjects at one site will be interviewed by research staff at another site. For example, Providence staff will be identified, consented, and interviewed as research subjects by San Francisco research staff. Interview records and contact information will be kept on encrypted local computers temporarily and saved on the San Francisco VA Medical Center's R: drive server. Survey data will also reside on the San Francisco VA Medical Center's R: drive server. Study results will be reported in aggregate. Data and results collected from individual VA employees will not be reported outside of individuals included on the study staff list. As a result, individual-level data/results collected from individual VA employees will not be shared with colleagues, supervisors, or other VA stakeholders. Research records will be retained in accordance with the VHA Records Control Schedule.

14.5 * REPORTABILITY: Do you anticipate that this study may collect information that State or Federal law requires to be reported to other officials, such as elder abuse, child abuse, or threat to self or others: (REQUIRED)

( ) Yes (•) No

14.6 CERTIFICATE OF CONFIDENTIALITY: Will this study obain a Certificate of Confidentiality:

( ) Yes (•) No

14.7 SHARING OF RESEARCH RESULTS: Will there be any sharing of EXPERIMENTAL research test results with subjects or their care providers:

( ) Yes (•) No

14.9 * HIPAA APPLICABILITY: Study data will be: (REQUIRED)

- [ ] Derived from a medical record (e.g. APeX, OnCore, etc. Identify source below)
- [ ] Added to the hospital or clinical medical record
- [ ] Created or collected as part of health care
- [ ] Used to make health care decisions
- [x] Obtained from the subject, including interviews, questionnaires
- [ ] Obtained ONLY from a foreign country or countries
- [ ] Obtained ONLY from records open to the public
- [ ] Obtained from existing research records
- [ ] None of the above
- [ ] Derived from the Integrated Data Repository (IDR) or The Health Record Data Service (THREDS) at SFGH

14.10 * IDENTIFIERS: Check all identifiers that will be collected and included in the research records, even temporarily: (REQUIRED)

- [x] Names
- [x] Dates
- [ ] Postal addresses
- [x] Phone numbers
- [ ] Fax numbers
- [x] Email addresses
- [ ] Social Security Numbers*
- [ ] Medical record numbers
- [ ] Health plan numbers
- [ ] Account numbers
- [ ] License or certificate numbers
- [ ] Vehicle ID numbers
- [ ] Device identifiers or serial numbers
- [ ] Web URLs
- [ ] IP address numbers
- [ ] Biometric identifiers
- [ ] Facial photos or other identifiable images
- [x] Any other unique identifier
- [ ] None

*** Required for studies conducted at the VAMC**

* Could study records include *ANY* photos or images (even 'unidentifiable' ones): **(REQUIRED)**

- ( ) Yes
- (•) No

14.11 * PATIENT RECORDS: Will health information or other clinical data be accessed from UCSF Health, Benioff Children's Hospital Oakland, or Zuckerberg San Francisco General (ZSFG): (REQUIRED)

- ( ) Yes
- (•) No

14.18 * DATA COLLECTION AND STORAGE: (check all that apply): (REQUIRED)

Collection methods:

- [x] Electronic case report form systems (eCRFs), such as OnCore or sponsor-provided clinical trial management portal
- [ ] UCSF ITS approved Web-based online survey tools: Qualtrics or RedCap
- [x] Other web-based online surveys or computer-assisted interview tool

- [ ] Mobile applications (mobile or tablet-based)
- [ ] Text Messaging
- [ ] Wearable devices
- [x] Audio/video recordings
- [ ] Photographs
- [ ] Paper-based (surveys, logs, diaries, etc.)
- [ ] Other:

* What online survey or computer assisted interview tool will you use: **(REQUIRED)**

- [ ] Qualtrics (Recommended)
- [x] RedCAP (Recommended)
- [ ] Survey Monkey (NOT recommended and may require UCSF ITS Security review)
- [ ] Other

* Data will be collected/stored in systems owned by (check all that apply): **(REQUIRED)**

- [ ] Study sponsor
- [ ] UCSF data center (including OnCore, RedCap, Qualtrics, and MyResearch)
- [ ] UCSF encrypted server, workstation, or laptop residing outside of UCSF data center
- [ ] Personal devices, such as laptops or tablets that are not owned or managed by UCSF
- [x] SF VAMC
- [ ] Zuckerberg San Francisco General Hospital
- [ ] Benioff Children's Hospital Oakland
- [ ] Langley Porter Psychiatric Institution
- [ ] Other UCSF affiliate clinic or location (specify below)
- [ ] Cloud vendor such as Amazon Web Services (AWS), Salesforce, etc. (specify below)
- [ ] Other academic institution
- [ ] 3rd party vendor (business entity)
- [ ] Other (explain below)

Please consult with the VA's Clinical Research Office at 415-221-4810 x 2-6425 about the VA's requirements for data storage and security.

14.20 * DATA SHARING: During the lifecycle of data collection, transmission, and storage, will identifiable information be shared with or be accessible to anyone outside of UCSF: (REQUIRED)

- ○ Yes
- ◉ No

15.0 Financial Considerations

15.1 * PAYMENT: Will subjects be paid for participation, reimbursed for time or expenses, or receive any other kind of compensation: (REQUIRED)

- ○ Yes
- ◉ No

15.4 COSTS TO SUBJECTS: Will subjects or their insurance be charged for any study activities:

- ○ Yes
- ◉ No

16.0 Other Approvals and Registrations

16.4 OTHER APPROVALS: Indicate if this study involves other regulated materials and requires approval

and/or authorization from the following regulatory committees:

☐ Institutional Biological Safety Committee (IBC)

Specify BUA #:

☐ Institutional Animal Care and Use Committee (IACUC)

Specify IACUC #:

☐ Controlled Substances

17.0 Qualifications of Key Study Personnel and Affiliated Personnel

NEW: January 2019 - Affiliated personnel who do not need access to iRIS no longer need to get a UCSF ID. Instead, add them below in the Affiliated Personnel table below.

17.1 Qualifications of Key Study Personnel:

Instructions:

For UCSF Key Study Personnel (KSP)* listed in **Section 3.0,** select the KSP from the drop down list and add a description of their study responsibilities, qualifications and training. In study responsibilities, identify every individual who will be involved in the consent process. Under qualifications, please include:

- Academic Title
- Institutional Affiliation (UCSF, SFGH, VAMC, etc.)
- Department
- Certifications

NOTE: This information is required and your application will be considered incomplete without it. If this study involves invasive or risky procedures, or procedures requiring special training or certification, please identify who will be conducting these procedures and provide details about their qualifications and training. Click the orange question mark for more information and examples.

Training Requirements:
The IRB requires that all Key Study Personnel complete Human Subjects Protection Training through **CITI** prior to approval of a new study, or a modification in which KSP are being added. More information on the CITI training requirement can be found on our **website.**

* **Definition of Key Study Personnel and CITI Training Requirements (Nov, 2015):** UCSF Key Study Personnel include the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the course of

the research. Key Personnel also include faculty mentors/advisors who provide direct oversight to Postdoctoral Fellows, Residents and Clinical Fellows serving as PI on the IRB application.

KSP Name	Description of Study Responsibilities - Briefly describe what will each person be doing on the study. If there are procedures requiring special expertise or certification, identify who will be carrying these out. Also identify who will be obtaining informed consent.	Qualifications, Licensure, and Training
Oh, Dennis H	Principal Investigator	Dr. Oh is Assistant Chief of Dermatology at SFVAMC, co-lead for teledermatology in VA's Office of Connected Care, and has been principal investigator for NIH and VA studies for over 20 years. He has completed the Human Subjects Training through CITI.
Peracca, Sara	Study Coordinator	Dr. Peracca is a sociologist with a specialization in demography. She is a research health science specialist in the research department of the SFVAMC. She also has an MPH and an MS. She has over 20 years experience conducting research using quantitative and qualitative methods for studies of varying size for public and private entities throughout the world. She has completed the Human Subjects Training through CITI.
Lachica, Olevie T	Research Assistant	Ms. Lachica is a program support assistant in the dermatology department of the SFVAMC. She has a BA in Health Education and is currently obtaining her masters in health informatics administration. She completed the Human Subjects Training through CITI.

17.2 Affiliated Personnel:

Instructions:

This section is for personnel who are not listed in **Section 3.0: Grant Key Personnel Access to the Study** because their names were not found in the User Directory when both the iRIS Database and MyAccess directories were searched. Add any study personnel who fit ALL of the following criteria in the table below:

- They meet the definition of Key Study Personnel (see above), **and**

- They are associated with a UCSF-affiliated institution (e.g., VAMC, Gladstone, Institute on Aging, Vitalant, NCIRE, SFDPH, or ZSFG), **and**
- They do not have a UCSF ID, **and**
- They do not need access to the study application and other study materials in iRIS.

Note: Attach a **CITI Certificate** for all persons listed below in the **Other Study Documents** section of the **Initial Review Submission Packet Form** after completing the **Study Application**.

Click the orange question mark icon to the right for more information on who to include and who not to include in this section.

Do not list personnel from outside sites/non-UCSF-affiliated institutions. Contacts for those sites (i.e. other institution, community-based site, foreign country, or Sovereign Native American nation) should be listed in the **Outside Sites** section of the application.

If there are no personnel on your study that meet the above criteria, leave this section blank.

Name	Institution	Telephone	E-mail	Role
No External Personnel has been added to this IRB Study				

Please describe the study responsibilities and qualifications of each affiliated person listed above:

18.0 End of Study Application

End of Study Application Form

To continue working on the Study Application:
Click on the section you need to edit in the left-hand menu. Remember to save through the entire Study Application after making changes.

If you are done working on the Study Application:
Important: Before proceeding, please go back to Section 4.0 Initial Screening Questions and **Save and Continue** through the form to make sure all the relevant sections and questions have been included. If you've changed any answers since you started, the branching may have changed. Your application will be incomplete and it will have to be returned for corrections.

Once you are sure the form is complete, click **Save and Continue**. If this is a new study, you will automatically enter the **Initial Review Submission Packet Form**, where you can attach **consent forms** or other **study documents**. Review the **Initial Review Submission Checklist** for a list of required attachments.

Answer all questions and attach all required documents to speed up your approval.

The UCSF IRB welcomes feedback about the IRB Study Application Form. Please click the link to answer a **survey** about the application form.