In order to ascertain whether IRB Review is needed for a project, a Human Subject Research Determination (HSR) may be requested via email (IRBEducation@stanford.edu), phone (IRB Education line: 650-724-7141) or by completing this form and attaching it to the HSR application in eProtocol.
For additional guidance, please refer to: Does My Project Need IRB Review?

I. PROJECT INFORMATION - Please answer all questions.

Project Title: The Impact of Telehealth Expansion among Stanford Outpatient Clinics during COVID-19

Purpose of the project: This project aims to evaluate the impact of telehealth expansion on the ability of Stanford outpatient clinics to continue their activity during the COVID pandemic. Given the rapid increase in virtual care visits in response to COVID, we aim to better understand what determines the degree and persistence of telehealth adoption in different clinics. Moreover, we will assess whether telehealth expansion has affected the diversity of patients seen at Stanford. This QI project therefore lies at the interface of two Stanford Health Care strategic priorities: digitization of care and health equity.

Does this project use California State Death Records/Indices? If Yes, **STOP**, and submit an IRB application in eProtocol.	Yes ☐ STOP	No ☒
Does this project utilize Radiologic or other images?	Yes ☐	No ☒
Samples or data from deceased individuals (only)?	Yes ☐	No ☒
Is the activity primarily designed to **improve clinical care** at STANFORD/LPCH/SHC or VAPAHCS, or to **improve some other program**?	Yes ☒	No ☐

Indicate **where** the activities/project will take place (STANFORD/LPCH/SHC, VAPHCS or other site): SHC

Describe all project procedures. *If this project involves sites outside of STANFORD, please indicate that here, and specify exactly what Stanford's role is in the project.*
The data listed below will be collected in order to compare clinic operations and patient access to care before and during the pandemic.

As a first step, we will focus our analysis at the level of adult cardiovascular medicine clinics:
General Cardiology; Preventive Cardiology; Electrophysiology; Heart Failure/Transplant; Interventional Cardiology; Adult Congenital Heart Disease.

These clinics differ in their baseline reliance on remote patient monitoring and in-person physical exam, as well as in the acuity of their patient populations. We anticipate that these factors will influence their uptake of telehealth. Despite the underlying differences, we aim to identify transferrable factors and practices which enabled certain clinics to maximize the benefits of telehealth for their patients. The interpretation of these results will be performed in careful collaboration with local clinic stakeholders.

INFORMATION/DATA AND SPECIMENS:

a) List **all variables or data elements** that you will access or obtain for this project. Alternatively, please upload your data collection tool(s). HIPAA & PHI
Quantitative data

*: Denotes added data elements

Visit level data for January 1 2019 to March 1 2021:
Visit date
Clinic
Provider
Patient identifier
Visit modality: in-person, virtual, or telephone; new or follow-up
Visit status: complete, cancelled, no-show

*Start/End/Chart closure timestamps
*Video visit connectvity metrics
*Telemedicine platform used
*Visit scheduled and end-time
*Interpreter need and connection
*Tests and procedures
*Hospital admissions
*Video visit to telephone conversion
*Patient and provider telemedicine survey response
*Encounter ICD-10 and CPT codes

Patient characteristics: age, sex, race/ethnicity, insurance status, primary language (interpreter use), ZIP code, prior telehealth use

Qualitative data:

The qualitative portion of the analysis will yield a situation map describing clinic workflow, information exchange, resource allocation and a summary of adoptive practices across clinics.
Semi-structured interviews with key informants will be performed to understand adoptive practices towards telemedicine, aimed at:

1. Identifying how the adoption has influenced clinic workflow;
2. Obtaining staff/provider perspective on whether workflow has improved or become worse;
3. Gaining perspective on how adoption of telemedicine has affected patient care;
4. Understanding if any obvious barriers towards adoption have been identified;
5. Assessing the perceived usefulness and usability of this technology.

In order to preserve responder anonymity, qualitative data obtained from clinical stakeholders will be analyzed thematically and aggregated to include the most frequent elements mentioned across clinics.

b) Identify the source(s) of the information or specimens (i.e., from whom/where): The above mentioned variables will be obtained in partnership with the Stanford Health Care Digital Health Care Integration team.

If receiving data or specimens from outside of STANFORD, you may need a Data Use Agreement (DUA) or Material Transfer Agreement (MTA). See the Privacy office FAQs on DUAs or the Industrial Contracts Office - MTA page.

c) Were/are the data or specimens collected/obtained from participants specifically for this project(Y/N)? If for a different project, which one? If for clinical purposes, please explain: All quantitative data (clinic and patient-level) were collected routinely in the context of clinic operations and patient care.

Qualitative data will be collected through semi-structured interviews with a convenience sample of key informants, consisting of clinic coordinators and providers.

d) Are the data or specimens de-identified, or will they be? Yes ☐ No ☒

➔*If "yes", who did, or will, de-identify the data or specimens?*

e) Are the data or specimens coded, or will they be? Yes ☐ No ☒

➔*If "yes", Will you have access to the key to the code?* Yes ☐ No ☐

DRUGS OR DEVICES

a) Does the project meet the FDA definition of a clinical investigation? 21 CFR 50.3(c)* Yes ☐ No ☒

b) Does the project studying the safety or efficacy of a drug (either investigational or commercially approved)? Yes ☐ No ☒

c) Does the project include testing of a medical device including *In Vitro* Diagnostic (IVD) Device or software? ? Yes ☐ No ☒

d) Will any data resulting from this activity be submitted to the FDA? Yes ☐ No ☒

RESULTS

a) How will the results of this project be used? The impact of telehealth expansion in response to COVID-19 among Stanford outpatient clinics, including cardiovascular medicine clinics, is not well understood. The results of this project will provide cardiovascular medicine leadership with timely evidence on the impact of telehealth expansion on clinic operations and access to care. Through our analysis and comparisons between clinics, we aim to identify beneficial practices regarding the use and expansion of telehealth-related workflows, which can be taken from one Stanford outpatient clinic and applied in others.

b) Will the results be added to another ongoing research study? Yes ☐ No ☒

c) Results are **intended** to be widely applicable to populations beyond your specific project population at STANFORD/LPCH/SHC or VAPAHCS:

☐ **True** ☒ **False**

d) Extrapolation or generalization of the project results to other settings (e.g. outside of STANFORD/LPCH/SHC or VAPAHCS) is possible, but **not** the main intent of the project.

☒ **True** ☐ **False**

II. PROJECT DOCUMENTS

Please upload to the Attachments section any of the following that pertain to your project:

- ✓ Surveys/questionnaires/instruments
- ✓ Interview or focus group questions
- ✓ Data collection tools
- ✓ Data Use Agreements (DUA) or Material Transfer Agreements (MTA)

III. QUALITY ASSESSMENT AND/OR QUALITY IMPROVEMENT: An activity conducted to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements. **Note – projects can be published as QA/QI.**

	Yes	No
Do you consider this project to meet the definition of **QA/QI** as noted above?	☒	☐

IV. RESEARCH: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *MORE INFO*	Yes	No
Do you consider this project to meet the definition of ***research***?	☐	☒

V. STEM CELLS OR FETAL TISSUE	Yes	No
Does your project involve the use of fetal tissue? If yes, name the source in the procedures box and state whether you plan to create iPSCs. **If creating iPSCs, contact the SCRO Panel.**	☐	☒
Does your project involve human embryonic stem cells (hESC), adult human stem cells, pluripotent cells or somatic nuclear transplantation? **If yes, contact the SCRO Panel.**	☐	☒
Is your project being conducted all or in part at the VA, or with VA resources or personnel?	☐	☒

**Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.