# **Instructions**

Complete this form if your research plan includes use of any SFDPH data (including medical record data and public health datasets, even for recruitment only; do not fill out if using UCSF-maintained de-identified database) or recruitment of SFDPH patients or staff in the context of SFDPH services.

**Protocol Application Process, please read and follow the instructions carefully:**

Step 1: Review [RPA Instructions](https://zsfg.ucsf.edu/research-protocol-applications-zsfg) for DPH policies and for details on how to complete this application.

Step 2: Complete this form

* Complete section **A**
* Complete sections **B** and/or **C** as needed
* Obtain relevant signatures or approval emails for tables in **B** and/or **C**

Step 3: Create a submission package:

* + Remove this page and covert application to a PDF
	+ Attach to the PDF:
		- IRB application and approval letter (if this request is for de-identified data only, IRB may not be required)
			* If you are collecting sensitive data, such as mental health or substance use data, attaching a consent form may expedite approval.
		- Other relevant forms as needed:
		- Any email approvals for datasets or activities in clinical care settings (from **B** and **C**)
		- If collecting data manually from Epic charts, attach list of variables that will be collected
		- If printing out data for research monitoring (in some trials, a monitor may require printed out medical record data), attach a list of variables that you will print out; you may include a row noting that “potential additional data may be printed if requested by the monitor.”
* UCSF Investigators: if this is NOT a clinical trial, include **signed** [UCSF | SFDPH Research Statement of Work (Appendix A)](https://zsfg.ucsf.edu/protocol-applications-and-approvals)
* DPH investigators sharing DPH data with outside institutions, or outside investigators requesting DPH data: attach a completed [Data Use Agreement](https://urldefense.com/v3/__https%3A/www.sf.gov/sites/default/files/2023-05/FormHealthInformationDataUseAgreementForm_revised041411.pdf__;!!LQC6Cpwp!rvM0SYlD-4lUaaHzPh20y1DWXJXiH84IyfaznwWS2qE7QbCqto6kQNP7bLeB065Lmrh8nltXWkqJcLxfLSlDDefRd-OOjjZ3NA$)
* Name file as: IRB# (space) PI’s First Initial (underscore) Last Name (e.g., “55-5555 J\_Doe”)
* Submit single PDF to the UCSF Dean’s Office (ZSFGResearch@ucsf.edu)

Step 5: UCSF Dean’s Office at ZSFG will route all documents to the remaining required signature approvers, including Medical Records, Privacy, the UCSF Office of Sponsored Research and the DPH Office of Contract Management and Compliance. The Dean’s Office will notify you once this final approval is complete.

Step 6: Subsequent approval needs. The following type of changes to the study would require additional review and approval:

* Your study requires additional identifiable data elements
* You have approval for section B or C, but now need approval for the other section

**Research Protocol Application**

**A. All Studies**

1. This research is being conducted by:

[ ]  UCSF PI

[ ]  DPH PI

[ ]  Other institution PI

1. This research will involve from SFDPH:

[ ]  Data (e.g., Epic, other datasets, including if for recruitment only) – complete sections B

[ ]  Research activities with patients or staff (e.g., recruiting ZSFG or DPH patients or staff) – complete section C

1. Provide a paragraph summary (Include aims, design, sample size, etc. If study is a blend of research and clinical care, clearly distinguish which elements are research):

(Enter text here)

1. Complete the table below; when in doubt, include more details

|  |  |
| --- | --- |
| **Study Title:**  ​ Enter text here​  | **Beginning & end dates of study:** Enter text here​  |
| **Principal Investigator:** Enter text here​ **Phone:** Enter text here​  ​**Email:**  Enter text here​  ​ | **Primary Contact (if any):** ​ Enter text here​ **Phone:** ​ ​ Enter text here​ **Email:** ​ ​ Enter text here​  |
| **IRB** of record ​​[ ]  UCSF​​​[ ]  Other (Enter name here​) [ ]  UCSF reliance | ​​**IRB approval #** (attach application and approval letter)**:**  ​ Enter text here​  |
| **General type of study:**[ ] ​ Clinical trial[ ]  Observational[ ]  Secondary data[ ]  Other (Describe) | **Source of funding**​[ ]  None           [ ]  Industry[ ]  NIH/CDC[ ]  Other governmental, University, or NGO[ ]  Other (Describe) |
| **Target enrollment** (Total) Enter text here​  | **Estimated enrollment # of DPH patients or staff** (Total) Enter text here​  |
| **Waiver of consent** [ ]  Yes (Describe) [ ]  No |
| **Any additional key personnel relevant to approval** (e.g., DPH staff who may be able to explain DPH role, staff from non-DPH/UCSF institutions who will have access to DPH resources; do not list all staff) |
|  *Name/Role* | *Institution* |
| Enter text here​  | Enter text here​  |
| Enter text here​  | Enter text here​  |
| Enter text here​  | Enter text here​  |

**B. Studies Involving Data**

1. Data requested include (Publicly reporting de-identified data should suppress small cell sizes. Cell size suppression rules can be reviewed in the [Publishing DPH Data to the Public Guidelines](https://www.sf.gov/resource/2022/publishing-dph-data-public)):

[ ]  De-identified data only: None of the 18 identifiers

[ ]  Includes identifiers: List potential identifiers requested (e.g., birthdate, zipcode). (Enter text here)​

[ ]  EMR data (Epic, Avatar, or other patient dataset), accessed by:

[ ]  UCSF Academic Research Services (ARS)

[ ]  Manual review (not using ARS or other service, but manually going through patient records)

* Attach a complete list of all variables that will be collected from chart to this form (or a printout of the data collection form / RedCap dictionary, etc)
* All research data collected from the chart must be maintained in a database that does not include identifying data (i.e., if a dataset has names and MRNs, research data collected from the chart must be maintained in a separate database that is linked with a unique identifier)

[ ]  Printing out data for trial monitoring activities

[ ]  Other (Describe)

1. Data will be used for:

[ ]  Recruitment purposes (Optional description)

[ ]  Analysis (Optional description)

[ ]  Monitoring for clinical trial (e.g, printing out clinically-obtained labs to share with sponsors)

1. Data originating from SFDPH systems will be maintained at:

[ ]  UCSF IT-approved servers (e.g., Data Center, RedCap, drives)

[ ]  DPH servers

[ ]  Only on local devices/paper **owned by** DPH or UCSF

[ ]  Personal server or device (Explain reason)

[ ]  Outside vendor or institutional server or device (Describe here [e.g., outside institution RedCap], and if any identifiers noted in Question 5 may be shared)

1. Artificial intelligence (some questions may be redundant to above but should be answered if your research meets the SFDPH definition of [AI](https://www.sf.gov/sites/default/files/2024-09/DPH__AI_policy_-_Signed.cleaned%20%281%29.pdf))

[ ]  Use of AI (defined by [SFDPH AI policy](https://www.sf.gov/sites/default/files/2024-09/DPH__AI_policy_-_Signed.cleaned%20%281%29.pdf)) (Describe)

[ ]  AI use will involve shared with or stored by a software vendor or other non-SFDPH / non-UCSF organization? (Describe) ​

[ ]  Research involves an AI implementation component at SFDPH (e.g., the research involves deploying AI as part of clinical workflow or operations at SFDPH) (Describe)

1. Agreements (attach as needed)

[ ]  DPH researchers: If sharing DPH data with non-UCSF external parties for research purposes, sign a [Data Use Agreement](https://www.sf.gov/sites/default/files/2023-05/User-Agreement-for-Confidentiality-Data-Security-and-Electronic-Signature_Revised_1_25_2023.pdf)

[ ]  UCSF Researchers:

* + Complete [UCSF | SFDPH Research Statement of Work (Appendix A)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) form (not required if study is a clinical trial)
	+ If this project has undergone [UCSF IT Security Risk Assessment](https://it.ucsf.edu/service/it-security-risk-assessment), attach findings letter.

[ ]  Non-UCSF/SFDPH researchers who use DPH data must sign a [Data Use Agreement](https://www.sf.gov/sites/default/files/2023-05/User-Agreement-for-Confidentiality-Data-Security-and-Electronic-Signature_Revised_1_25_2023.pdf)

1. **Dataset Representative Pre-Submission Approvals**

Check the relevant boxes for where data will come from. Except for Epic/LCR/ECW, you must obtain approval from the owner of the dataset. If data are from Epic, but focused on a specific population (e.g., data from specific BHS mental health clinics), obtaining a signature from that stakeholder will expedite approval. If the dataset is not listed, add the dataset description and dataset representative name and signature. If you find names to be out of date, please email ZSFGResearch@ucsf.edu to request a revision. You may obtain approval through email; attach the email with approval and write “email attached” in the signature box.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Data access needed** | ***Category*** | **SFDPH Electronic Health Record or Data Source** | **Dataset representative** | **Signature**(or attach email) |
| **Patient Data Datasets** |
| ​​ [x]  | *ZSFG* | Epic for any care at ZSFG campus | *Approved during Dean’s Office process.* |
| ​​ [ ]  | LCR or ECW (pre-Epic EHRs, data prior to Epic launch in August 2019) for any care at ZSFG campus |
| [x]  | *Ambulatory* | Epic for any outpatient care (on or off ZSFG campus) |
| [ ]  | LCR or ECW for any outpatient care (on or off ZSFG campus) |
| ​​ [ ]  | *BHS* | Avatar or Epic Behavioral Health Services data | Petra Jerman PhD or Chet Valentino |  |
| ​​ [ ]  | *Ambulatory* | CCMS/WPIC Data  | Spencer Williams JD  |  |
| ​​ [ ]  | *Ambulatory* | JIM (Jail Health) Ambulatory  | Lisa Pratt MD  |  |
| ​​ [ ]  | *Ambulatory* | Maternal, Child, & Adol Health Amb. | Aline Armstrong MSN RN  |  |
| ​​ [ ]  | *ZSFG* | Pharmacy - QSI  | David E Smith PharmD |  |
| **Non-Patient Data Datasets – *Some datasets cannot be released to non-DPH investigators*** |
| ​​ [ ]  | *PHD* | DPH COVID Task Force Database  | Eric Morris MPH orMelissa Sanchez PhD  |  |
| ​​ [ ]  | *PHD* | OSHPD / HCAI citywide ER and Hospitalizations | Phil Lowenthal (de-identified; cannot share outside DPH) |  |
| ​​ [ ]  | *PHD* | HIV Surveillance, PHD  | Arpi Terzian PhD |  |
| ​​ [ ]  | *PHD* | MAVEN (viral hepatology & general ELR, non-TB) PHD  | Melissa Sanchez PhD orMelissa Ongin PhD |  |
| ​​ [ ]  | *PHD* | Vital statistics (VRBIS birth, death data)  | Cathleen Xing or Jason Melo (see [RPA Instructions](https://zsfg.ucsf.edu/research-protocol-applications-zsfg); must obtain CDPH approval) |  |
| ​​ [ ]  | **Check >= one**:[ ]  ZSFG[ ]  Any Ambulatory care (except BHS / PHD)[ ]  LHH[ ]  BHS[ ]  PHD | Other: | Other: ​​ |  |

**C. Studies Involving Patient Contact or Staff as Research Participants**

1. How will your study recruit SFDPH patients? You may provide additional details under “Other” to help speed up approval.

[ ] Passive (e.g., flyers posted at clinical sites)

[ ] Waiting room / onsite recruitment approved by clinic leadership

[ ] Member of patient’s care team gives approval to approach patient

[ ] Leader at clinical site approves list of patients to be contacted and script to be used (e.g., mailings, phone calls)

[ ] Other (Describe)

[ ] No patient recruitment; staff only

1. **Clinical Research and/or Patient Recruitment Pre-Submission Approval**

Operational stakeholders listed below must approve protocols if procedures or patient recruitment will occur in any DPH inpatient or outpatient clinical service areas. In general, this includes REMOTE recruitment activities (i.e., you are calling or mailing to the patients), and also includes if you are recruiting staff for research. Please add information for other clinical areas. Obtaining a signature here does not necessarily mean you can work with a given clinic – many have separate approval processes (see [RPA Instructions](https://zsfg.ucsf.edu/research-protocol-applications-zsfg) for those sites know of, which are marked here with an asterisk) and, regardless, you should reach out to any individual site you want to work with to ensure that the leadership is okay collaborating with you. If attaching an email with approval, write “email attached” in the signature box.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study procedures in area** | **Recruiting patients receiving care from this area** | ***Category****[for Dean’s office use]* | **Clinical Area** | **Approver (Nursing or Medical Director)** | **Signature** (or attach email) |
| **ZSFG & Ambulatory Care** |
| ​​[ ]  | ​​[ ]  | *ZSFG* | Emergency Services\* | David Staconis (Chris Colwell MD)  |  |
| ​​[ ]  | ​​[ ]  | *ZSFG* | Intensive Care   | Christina Bloom  (Antonio Gomez MD)  |  |
| ​​[ ]  | ​​[ ]  | *ZSFG* | Maternal & Child Inpatient\* | Jennifer Kerns MD |  |
| ​​[ ]  | ​​[ ]  | *ZSFG* | Medical-Surgical Inpatient   | Tanvi Bhakta (Lisa Winston MD)  |  |
| ​​[ ]  | ​​[ ]  | *ZSFG* | Perioperative Care  | Patty Coggan  (Nandini Palaniappa MD)  |  |
| ​​[ ]  | ​​[ ]  | *ZSFG, Ambulatory* | Occupational Health   | Zaw Maung or Allyson Villanueva  |  |
| ​​[ ]  | ​​[ ]  | *ZSFG* | ZSFG Psychiatry  | Mark Leary MD  |  |
| ​​[ ]  | ​​[ ]  | *ZSFG, Ambulatory* | Specialty Ambulatory Care  | Merjo Roca (Shreya Patel MD) |  |
| ​​[ ]  | ​​[x]  | *ZSFG, Ambulatory* | SFDPH Primary Care based at ZSFG (including FHC\*, RFPC\*, Pediatrics, Ward 86 Primary Care) [List of Clinics](https://www.sf.gov/resource/2022/sf-health-network-clinics) | Carol Taniguchi (Joseph Pace MD); (some sites also have their own process – see [instructions](https://zsfg.ucsf.edu/research-protocol-applications-zsfg))  |  |
| ​​[ ]  | ​​[ ]  | *Ambulatory* | SFDPH Primary Care NOT at ZSFG [List of Clinics](https://www.sf.gov/resource/2022/sf-health-network-clinics) | Carol Taniguchi (Joseph Pace MD)  |  |
| ​​[ ]  | ​​[ ]  | *Ambulatory* | SFDPH Maternal, Child, and Adolescent Health\*  | Aline Armstrong MSN RN or Jennifer Lopez   |  |
| ​​[ ]  | ​​[ ]  | *ZSFG, Ambulatory* | SFDPH Jail Health Services, Ambulatory  | Lisa Pratt MD MPH  |  |
| ​​[ ]  | ​​[ ]  | *Ambulatory* | SFDPH Whole Person Integrated Care (Ambulatory)  | Dara Papo MSW  |  |
| ***Laguna Honda*** |
| ​​[ ]  | ​​[ ]  | *LHH* | Laguna Honda Hospital  | Crystal Figlietti RN orLisa Pascual MD  |  |
| ***Behavioral Health Services*** |
| ​​[ ]  | ​​[ ]  | ​​ *BHS* | SFDPH Behavioral Health Services  | Petra Jerman PhD or Chet Valentino   |  |
| ***Population Health Clinics*** |
| ​​[ ]  | ​​[ ]  | *PHD* | TB Clinic, City Clinic,Adult Immun. & Travel Clinic | Seema Jain MD |  |
| ***Pharmacy Sites*** |
| ​​[ ]  | ​​[ ]  | *ZSFG, Ambulatory* | Pharmacy at ZSFG or Primary Care  | Swati Patel PharmD  |  |
| ​​[ ]  | ​​[ ]  | *LHH* | Pharmacy- Laguna Honda Hospital  | Jeanette Cavano PharmD orEugenio Ocampo PharmD   |  |
| ​​[ ]  | ​​[ ]  | *BHS* | Pharmacy-BHS  | Michelle Geier PharmD  |  |
| **Other Sites** |
| ​​[ ]  | ​​[ ]  | **Check at least one**:[ ] ZSFG[ ]  *Any* ambulatory care (except BHS or PHD clinics)[ ]  LHH[ ] BHS[ ] PHD | Other:  |   |  |

**Equity Review Checklist**: Research involving direct contact with people at ZSFG or SFDPH clinical sites must complete questions below. **If YES is checked on questions 14-18**, no further action is required; if **NO** is checked, email your IRB application and protocol form to equity@sfdph.org for review (contact Tracy Burris tracy.burris@sfdph.org with questions) and await response prior to submitting this application.

1. Describe target population and if study is addressing a health disparity for the group

|  |  |  |
| --- | --- | --- |
| **Demographic variables**  | **Groups to be included in this research project:**  | **Is this group disproportionately affected by the health problem to be studied?**  |
| Age    |  ​Enter text here​  | Enter text here |
| Sex & Gender Identity  |  ​Enter text here | Enter text here |
| Race-ethnicity   |  ​Enter text here |  ​Enter text here |
| Income   |  Enter text here |  ​Enter text here |
| Other key variables:    |  ​Enter text here |  ​Enter text here |

1. Does the research question and procedure integrate input on the topic from members of the target population?

​​[ ]  YES. Research process involved input from people with lived experience, relied on prior research or other sources to understand the input of people with lived experience, and/or study plan includes engagement with people with lived experience.

​​[ ]  **NO**, unsure, not possible (Explain)

1. Have the study materials been reviewed with members of the study population?

​​[ ]  YES. Materials were co-designed or reviewed by people with lived experience and/or the study uses materials from past studies that involved input from that population.

[ ]  Not applicable. The study does not utilize materials

​​[ ]  **NO**, unsure, not possible (Explain)

1. Materials for this project are written at an 8th grade literacy level and in the most common languages spoken at home by the study participants?

|  |  |
| --- | --- |
| ​​[ ] YES  | ​​[ ] **NO**, unsure, not possible (explain) |

1. Is there a plan to report findings to the community?

|  |  |
| --- | --- |
| ​​[ ] YES. Directly to study participants ​​[ ] YES. Through internal media (e.g., newsletters from DPH or UCSF)  [ ] YES. Through public media (e.g., press, online availability).  | ​​​​[ ] **NO**. The results are inappropriate for sharing (Explain)​​[ ] **NO**, unsure, not possible (Explain) |

1. Is any equity training (cultural humility, racial disparities, historical trauma, etc.) being offered to or been completed by research staff interacting with participants?

|  |  |
| --- | --- |
| ​​[ ] YES. Required internal training from DPH or UCSF ​​[ ] YES. Training specific to this study | ​​[ ] **NO**, unsure, not possible (Explain) |

**D. For Deans Office Use Only**

**Data, Privacy, and ZSFG Service Approval Signatures**

**DATA ACCESS, DATA SHARING, or IT BUILD** (Must be signed if “Data” checked in Question 2)

 Use of SFDPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: Professor of Medicine, OHI Director of Research***

**PRIVACY** (Must be signed if “Data” checked in Question 2)

 Use of SFDPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: SFDPH Compliance Officer***

***Additional Notes/Comments:***

**MEDICAL RECORDS / PATIENT DATA** (Must be signed if “Data” checked in Question 2)

 Use of SFDPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: Director, Medical Records***

***Additional Notes/Comments:***

**Executive Approval Signatures**

Jeffrey Critchfield, MD (Date)  Susan P. Ehrlich, MD, MPP (Date)

Interim UCSF SOM Vice Dean at ZSFG Chief Executive Officer, ZSFG

*(****ZSFG*** *data or patient care)*

*(****ZSFG*** *data or patient care)*

Albert Yu, MD (Date)  Diltar Sidhu, LNHA, MBA (Date)

Interim Director of Ambulatory Care, SFDPH Interim CEO, Laguna Honda Hospital

*(****Ambulatory*** *Care)*

*(****LHH*** *data or patient care)*

Hillary Kunins, MD, MPH, MS (Date)  Susan Phillip, MD, MPH (Date)

Director of Behavioral Health Services & MHSF Population Health Division Clinics

*(****BHS*** *data or patients)*

*(****PHD*** *data or patients)*

*Submission process finalized.*

*Copy of final document forwarded to the study’s Principal Investigator and additional contact(s)*