# **Research Protocol Application Instructions**

**ZSFG Services**

If this research utilizes ZSFG services for research purposes (Pharmacy, Clin Lab, Radiology, or CTSI), the investigator must separately engage with the service (see below). Some studies might engage with these services without completing this form (e.g., a study not using DPH data or recruiting DPH patients that was sending a lab to Clin Lab can do so by engaging directly with Clin Lab as described below, without completing this form), however in most cases research will also involve contact with SFDPH patients or SFDPH data, and thus this form will also need to be completed.

1. **PHARMACY**. If the study involves the administration of **any medications** in ZSFG or ambulatory care settings, approval for ZSFG [Pharmacy Investigational Drug Service (IDS)](https://zsfg.ucsf.edu/research-protocol-applications-zsfg#:~:text=Including%20Data%20Retrieval)-,Pharmacy,-Services) Service Request Form and Agreement must be obtained. For more information on Pharmacy IDS Services Fees, contact Pharmacy (628-206-8460) or email DPH-ZSFG-Pharmacy-IDS@sfdph.org
2. **RADIOLOGY**. If you plan to use any ZSFG radiology services in research, you must complete the [Imaging Research Application](https://radiology.ucsf.edu/research/core-services/img-srvs-piple/zsfg-imaging-app) (UCSF / ZSFG Radiology Research Proposal Request). For additional information, contact email Lorel.Hiramoto@ucsf.edu
3. **LABORATORY MEDICINE**. If you are accessing laboratory medicine services for research, you must complete the [Request to Set Up Research Study](https://www.testmenu.com/zsfglab). For additional information, contact Clinical Laboratory (628-206-6786) or Andy.Yeh@ucsf.edu
4. **CTSI**. If you plan to work with the ZSFG Clinical Translational Science Institute (CTSI) Clinical Research Services (CRS), you need to generate a budget and establish a plan/protocol. For additional information, contact the CRS budget team at crsbudgetrequest@ucsf.edu, then contact crsprotocolservices@ucsf.edu to schedule a start-up meeting.

**More information on Attachments**

There are multiple attachments you may need to include at the end of the application. These should all be attached into one PDF file.

1. Please attach the IRB approval letter, a printout of your entire IRB application, and any consent forms. Researchers requesting de-identified data generally do not require IRB review but still require DPH approval (approval is **not** required if using the UCSF-maintained de-identified database). If the UCSF IRB is relying on another institution, the relying IRB application may be required, depending on issues that arise in the review process.
2. Please attach any emails that will serve as “approvals” for any dataset access (Table in Section B) or clinical care setting involvement (Table in Section C).
3. If you are manually pulling data from Epic, please include a list of variables that will be taken; SFDPH has no other way of knowing what data are collected manually from Epic for research purposes.
4. If you are manually printing out data (e.g., lab records) for review by monitors in a clinical trial, include a similar list of the variables you anticipate printing out and a statement that additional data may be needed based on monitor needs. When printing data from Epic for research purposes, please select “External Research” or a similar option from the print dialogue box (see Figure).
5. If you are a UCSF investigator and this is NOT a clinical trial, you must include a **signed** [UCSF | SFDPH Research Statement of Work (Appendix A)](https://zsfg.ucsf.edu/protocol-applications-and-approvals). This is not required for clinical trials because Appendix A may conflict with clinical trials requirements.
6. If you are an outside researcher (non-DPH and non-UCSF) requesting DPH data, or you are a DPH researcher sending DPH data to an outside institution (non-DPH and non-UCSF), then you must 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$)

**A. All Studies**

1. **Site PI:** Required reviews may differ based on the site of the PI. DPH and UCSF have a special relationship, which reduces some of the burden of review.
2. **What is being requested from SFDPH:**
	1. “Data” includes any datasets (e.g., mortality data, substance use disorder treatment data, etc.) or medical record (e.g., EPIC) data. This includes data manually abstracted in a chart review or provided through a service (e.g., UCSF’s ARS). This does NOT include data from the UCSF-managed de-identified database; use of those data involve a different process. If you are gathering data for recruitment purposes only, this also requires checking this box. If you are NOT accessing any DPH data, but are merely recruiting from DPH (e.g., posting flyers or approaching patients at random in a waiting room), and no DPH data will be used in the study, do NOT check this box and you will skip the data section of this form.
	2. “Interactions with patients or DPH staff” should be checked if the research involves research-related interactions with DPH patients or DPH staff (e.g., surveys of clinic staff). This includes things like posting recruitment flyers, recruiting from a waiting room, sending letters, surveying providers, etc. If you are conducting research only outside of DPH settings, such as venue-based recruitment, and might encounter DPH patients or staff by chance, there is no need to check this box.
	3. “Radiology”. Check this box if you are sending study participants to ZSFG Radiology for research procedures. This is not necessary if the procedures are part of routine care or if you are accessing data for research but not conducting procedures.
3. **Please provide a prose summary of your research:** This is an opportunity to address potential issues that could otherwise delay approval at DPH, such as clarifying how you are protecting privacy and autonomy of DPH patients. Simply “pasting” a summary from your IRB application is unlikely to be helpful.
4. Details on how to complete the table are provided below.

|  |  |
| --- | --- |
| **Study Title:**  Full title of study​ | **Beginning and end dates of study:  ​**Provide anticipated dates of study activity**​**  |
| **Principal Investigator:** Name and contact details for PI | **Additional Contact (if any):** ​Name and contact details of primary contact person for the study if not PI |
| **IRB** of record: SFDPH relies on UCSF as their primary IRB. If using UCSF as the IRB, RPA may be approved more rapidly. Other IRBs may not understand issues related to DPH or San Francisco, and thus RPA review may take longer. | **IRB approval #** (attach application and approval letter)**:**  Attach approval letter and a PDF of the full IRB application |
| **General type of study:** please check the type of study that represents the most complicated part of your study (e.g., if you are doing a trial and some qualitative interviews, check “clinical trial”): “Clinical trial” = intervention study; “Observational” = data-gathering study that does not involve an intervention; “Secondary data” = only using pre-existing data for analyses | **Source of funding**: DPH will more closely review studies funded by industry (e.g., pharmaceutical companies). If a study is unfunded, it may expedite review if investigators can explain how the study has been scientifically evaluated. |
| **Target local enrollment** (total expected local enrollment of the study team) | **Estimated enrollment # among DPH patients or staff** (helps DPH understand burden on staff & patients; e.g., for a very large study, DPH may want to ensure benefit to patients) |
| **Waiver of consent**: DPH prefers to obtain consent from participants, but we understand that some studies cannot be conducted without a waiver of consent. Please provide the details regarding why a waiver is needed and what will be done to minimize the invasiveness of data gathered without consent. |
| **Key personnel**: please list the name, role, and institution of staff members relevant to DPH approval. Do NOT include all staff on the study. Do include internal DPH staff relevant to the study or approval process, staff members from outside institutions who will have access to DPH data, or others who you feel are important for the approval process. |

**B. Studies Involving Data**

*If you checked “Data” in question 2, you should proceed to this section. Otherwise, you should be able to skip this section entirely.*

1. **Select what data you will need.** You may select as many that apply to you.
	1. **De-identified data only:** De-identified data has none of the 18 identifiers. When reporting de-identified data, there are also limitations on the counts you can report. For example, you cannot report on two deaths due to opioid overdose that occurred among Native American people in a specific zip code, because that could potentially be reidentified. Please include the cut-off for public reporting you will use. This is generally 10, but may be higher or lower in specific circumstances. Please see the [Publishing DPH Data to the Public guidelines](https://www.sf.gov/resource/2022/publishing-dph-data-public) on determining minimum cell size for reporting.
		1. The 18 identifiers are:
			1. Names
			2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

The i​nitial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

* + - 1. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older,
			2. Telephone numbers
			3. Fax numbers
			4. Electronic mail addresses
			5. Social security numbers
			6. Medical record numbers
			7. Health plan beneficiary numbers
			8. Account numbers
			9. Certificate/license numbers
			10. Vehicle identifiers and serial numbers, including license plate numbers
			11. Device identifiers and serial numbers
			12. Web Universal Resource Locators (URLs)
			13. Internet Protocol (IP) address numbers
			14. Biometric identifiers, including finger and voice prints
			15. Full face photographic images and any comparable images; and
			16. Any other unique identifying number, characteristic, or code
	1. **Data with identifiers:** Please include all potential identifiers requested and the count at which fields will be suppressed in reporting (see “a” above for details). To be considered a Limited PHI Data Set, all of the identifiers listed under De-Identified Data Sets above must be removed, except as specified in the [DPH Privacy and the Conduct of Research Policy](https://www.sf.gov/sites/default/files/2023-05/HIPPA_ConductOfResearchPolicy121421.pdf), Sections III.3.
	2. **EMR data**: This includes Epic, Avatar, and limited other datasets within DPH. Please specify which dataset and how you will access. DPH prefers investigators access data through ARS, although other means of access can be acceptable as appropriate.
		1. Manual review is needed in some cases (e.g., data needed are not discrete fields but instead require interpretation; number of patients studied is too small to justify ARS use; etc.); if manual review is to be used, investigator must (a) include as an attachment a list of all variables to be abstracted from the medical record so that DPH has some record of what data were taken, and (b) maintain all research related data in a database SEPARATE from the database that has protected health information (i.e., the investigator may need a database with patient information in order to be able to identify patients whose charts will be reviewed – this must be a different database than the database that is used to collect data from the chart).
		2. In some trials, clinical data must be printed out for monitoring purposes. In these cases, patient data (usually labs) may be printed out by clinicians and retained for review by monitors to, for example, confirm eligibility. The clinician who prints out the materials should select “Research” or “Monitoring” as the purpose for printing out the materials if that option is available. These data must be maintained separately from research data as they include PHI and should be destroyed at the conclusion of the study. Include as an attachment a list of all data that will be printed for monitoring purposes.
1. **Describe what the data will be used for:** recruitment and/or analysis/research purposes. Data for recruitment are generally gathered with a waiver of consent, and so should be minimized to limit privacy concerns. Providing description here may expedite review.
2. **Describe where SFDPH data will be maintained:** This includes any data taken from or abstracted from SFDPH sources (e.g., manual taken from Epic, collected through ARS, etc); this does NOT include other data gathered directly from study participants during a trial. Data maintained at DPH are the easiest to approve, as DPH has control over those servers. Data maintained at UCSF, on IT-approved servers or devices, are the next easiest to maintain, as UCSF is responsible for its data use agreements with outside institutions, and UCSF security and privacy review can be done. In general, data should not be maintained on personal devices; further explanation would be required to approve this. If DPH data are being shared outside of these institutions, please provide the details of what institutions and what identifiers will be shared. This does NOT include sharing research-generated data (e.g., data generated during your clinical trial may be shared under separate agreements, but if you will also be sharing data collected from DPH Epic, that will require review and approval).
3. **Artificial intelligence:** There is a [new DPH policy](https://sfgov1.sharepoint.com/%3Ab%3A/r/sites/DPH-ITCommunication/ITPolicies/Artificial%20Intelligence%20Policy.pdf?csf=1&web=1&e=6lcNLF) on use of AI. Please review this policy and determine if your project falls under DPH-defined AI. Nonetheless, this is a new area for research and how policies apply are rapidly evolving. Please also determine if SFDPH data will be shared with OR stored by a vendor outside of DPH and outside of UCSF for AI purposes. This is similar to but slightly different from Question 7, as it applies specifically to AI. SFDPH wants to know what vendor will be used for AI. Finally, please determine if the AI involves just research (e.g., language processing to find themes) or will involve implementation into clinical workflow or operations (e.g., providing feedback to providers to guide their care decisions), as the latter has significant implications and will require additional review.
4. **Agreements**: There are different agreements based on the institution of the PI. If the PI is based at DPH, they may share data with UCSF based on existing agreements. If they are sharing DPH data with non-UCSF parties, they should complete and attach 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 must complete the [UCSF | SFDPH Research Statement of Work (Appendix A)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) form (this is not required for clinical trials). In addition, if the project has undergone  UCSF IT Security Risk Assessment (<https://it.ucsf.edu/service/it-security-risk-assessment>), investigators should attach the findings report. Finally, 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).
5. **Dataset Representative Pre-Submission Approvals:** Prior to submitting the RPA, investigators need to obtain approval from the “owners” of datasets to be used. For Epic, as well as older EMR data including LCR and ECW, approval will be obtained **after** submission of the RPA. If approval is obtained by email, please attach the email to this submission. Some names may be out of date on this form; please note if you obtain approval from a different person and we will try to update the form.

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

*If you checked “Interactions with DPH patients or staff” in question 2, you should proceed to this section. Otherwise, you should be able to skip this section entirely.*

1. **Please select all the ways in which your study will recruit SFDPH patients:** This includes any hospital or outpatient sites. SFDPH prefers methods of recruitment that are either passive or involve approval from patients’ providers (options a-d), to minimize the risk of patients feeling their privacy has been violated. In some cases, these strategies may not be possible, and we will attempt to work out a different approach with the research team. If your study requires contacting specific patients directly without provider-level approval, you may wish to reach out to DPH to discuss your approach prior to submitting this form.

Of note, certain approvals will be required prior to submitting this form. You are not required to obtain the approval of every site you want to recruit at on this form (e.g., if you want to recruit at all ambulatory care clinics, you will obtain only the approval of the Director of Ambulatory Care for this form); however, you must separately ensure the leadership of any individual site is okay with your research activity at that site prior to beginning activities. For example, after receiving approval to post flyers at ambulatory care clinics, **you should reach out to the leadership (e.g., medical director, nurse manager) of any given clinic to make sure it is okay to post flyers at that site**; you may need to describe the study, attach the approval letter and flyers, and ask if you may post the flyers at their site. You do not need to submit any such approvals but should retain documentation for your own records and in case of staff turnover or questions from staff.

1. **Clinical Research and/or Patient Recruitment Pre- Submission Approval:** Please obtain signatures for any recruitment or study procedures happening in these various patient areas. This includes remote contact (e.g., calling patients who attended a specific targeted clinical setting), as well as if you are recruiting staff from targeted clinical settings. In some cases, you can obtain the signature of a person in charge of a broad array of clinics; however, you may NOT conduct on-site activities at any clinic without the assent of the leadership of that specific clinic (e.g., if you get ambulatory care approval to post flyers at clinics, you still must ensure the leadership at any given clinic is okay with posting of flyers, a process that can be done as needed before or after the approval of this form). Of note, the names of approvers may have changed; please note any new names identified and we will attempt to update the form.
2. **Questions 13-18 are the Equity Review Checklist:** These questions should be completed for any study that will recruit from other otherwise enroll SFDPH patients through contact via SFDPH clinical care settings (e.g., not needed if you are recruiting from clubs). The purpose of this review is to ensure that you have attended to community concerns and needs in the development and implementation of your research endeavor. If you check YES or “not applicable” for questions 14 through 18, there will be no further review. If you check NO for any of those questions, you will email the application and any relevant details to equity@sfdph.org. If you have additional questions, contact Tracy Burris at tracy.burris@sfdph.org.

**D. For Deans Office Use Only**

The UCSF Dean’s office will obtain the necessary signatures for privacy (if you are accessing any DPH data), medical records and data access (if you are accessing any DPH patient data), and executive approvals.

Routing instructions:

1. **Review for completeness**
	1. Check for appropriate attachments
		1. If UCSF is conducting research and is not a clinical trial, the SOW is required
		2. If research is conducted by “Other institution” DUA and SOW may be required
	2. Ensure IRB dates correct
	3. Ensure correct signature approvals present
2. **Route application for initial reviews**
	1. If Epic/LCR/ECW checked in Question 10: Medical records - Mary Holloway
	2. If “Data” checked in Question 2:
		1. Liz Goldman (Lauren.Goldman@ucsf.edu), then
		2. Privacy (628-206-4104) or Kim.Oka@sfdph.org
	3. If “Radiology” is checked in Question 2, route to Loral Hiramoto
3. **Final reviews**
	1. If any row in questions 10 or 12 is checked that includes:
		1. **ZSFG**: Jeff Critchfield (interim vice dean) and Susan Ehrlich
		2. **Ambulatory**: Rowena Cape / Albert Yu
		3. **LHH**: Diltar Sidhu
		4. **BHS**: Hillary Kunins
		5. **PHD**: Susan Philips
	2. If any additional needed reviewers are identified in these steps, route to those reviewers
	3. If there is a **SOW**: UCSF Office of Sponsored Research
4. **Dissemination of final approval**
	1. Investigator team
	2. Signatories