**UCSF Research at Zuckerberg San Francisco General**

**Research Protocol Application**

Due to compliance regulations, data tracking, and reporting, all UCSF research activity conducted at ZSFG requires additional approval through completion of the [**UCSF Research at ZSFG Research Protocol Application**](https://zsfg.ucsf.edu/protocol-applications-and-approvals)**.** Research activity includes any interaction with DPH / ZSFG patients, their data or use of DPH / ZSFG personnel, resources, facilities, and space, including your own office.

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

Step 1. Complete all sections relevant to your study on the ZSFG Research Protocol Application. Find the most current version of the form and protocol resources at: <https://zsfg.ucsf.edu/protocol-applications-and-approvals>)

* + [IRB Information](https://irb.ucsf.edu/). Study must have an approved IRB number.
	+ Subject Category
	+ Brief Description of Protocol
	+ Utilization (Patient Volume and Frequency) (If not applicable, also indicate)
	+ Human Resource Information
	+ CTSI Section
	+ Space Utilization Approvals (If applicable, **you collect the signature before submitting the protocol** to the Dean’s Office for remaining approvals)

Step 2. Complete the DPH / ZSFG Resource Approval checklist (page 4) to identify any resources pertinent to your study requiring approval.

* + Medical Records / Patient Data (If Yes, PI must initial and date before submission)
	+ IT Build Needs and Data Access (**Automatically** required *if* Medical Records are needed)
	+ Privacy and Compliance (**Automatically** required *if* Medical Records are needed)
	+ Clinical Laboratory Services
	+ Radiology Services
	+ Pharmacy Services

Step 3. Attach your study’s IRB Outcome Letter Notification **at the end** of the Research Protocol Application.

Step 4: Attach your full UCSF IRB Application, as well.

Step 5. Remove the instructions page and convert your application to a **PDF** file. Name your file using the following naming convention: **IRB#\_PI’s First Initial (space) Last Name**. Email to the following:

**UCSF SOM Vice Dean’s Office at ZSFG**

ZSFGResearch@ucsf.edu

ZSFG, Building 5, Room 2A21

Box 0809, San Francisco, CA 94143

(628) 206-8505

**After submitting the form**

The Dean’s office will review your application and collect the necessary remaining approval signatures on your behalf based on your DPH / ZSFG Resource Approval checklist selections on page 5. If the application is incomplete, the form will be returned to you for revision. The Dean's office will email a PDF of the signed Protocol application to the PI and any additional contact(s) once the application is approved. Please allow for a typical turnaround time of 10-15 working days.

**Zuckerberg San Francisco General**

**PROTOCOL APPLICATION**

* I have visited <https://coronavirus.ucsf.edu/research> and reviewed the Guidance and Policies for Researchers set forth by UCSF Office of Research **and** believe I should still receive approval to conduct my research.

**IRB INFORMATION:** (All studies must have an IRB Number unless indicated otherwise by the IRB. Please attach your IRB outcome letter to the end of this form)

**Protocol Title:**­­­­­\_

**Grant Title (if different)**

**Grant No. if available:**

**Prin. Investigator:**

Phone:

Email:

**Beg. Date of Grant End Date of Grant:**

**Additional Contact (if any):**

 Phone:

 Email:

[ ]  Approved IRB #­: Expiration. Date: [ ]  NA

Indicate Study Status (e.g. Active, Active-Expedited, Exempt, Closed, etc.):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **RESEARCH:** [ ]  New [ ]  Continuing

**SUBJECT CATEGORY** Please select the appropriate classification(s) below:

**1** Subjects seen for research purposes only

Source of funding (e.g., NIH, industry, other)

**2** Subjects seen for research and for established medical care

Source of funding (e.g., NIH, industry, other)

Please answer the following questions: (REQUIRED)

* Who are the anticipated study participants?
* How will you obtain their information?
* How will your study recruit the participants?

**Brief Description of the Research (**Both Items are **required**)

[ ]  I have provided a brief description of the nature, goals and process of the study; incl. any hypotheses and study goals

[ ]  I have attached the complete UCSF IRB Application for the research study.

**UTILIZATION (Patient Volume and Frequency):** State ‘0’ if not applicable

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Indicate number of subjects per year: Year | 1:  | 2:  | 3: | 4: | 5: |

Yes [ ]  Total number of outpatient visits per subject No [ ]  NA [ ]

Yes [ ]  Total number of inpatient visits per subject No [ ]  NA [ ]

**HUMAN RESOURCES** (State ‘0’ or “None’ if not applicable)

Please indicate the number of UCSF staff involved in this study (e.g., 1 CRC, 2 ACRCs, UCSF graduate student).

**Total # of Staff: \_\_\_\_**

|  |  |
| --- | --- |
| **Names of Staff** | **Job Titles** |
|  |  |
|  |  |
|  |  |

Please indicate the classification(s) of DPH/ZSFG staff who may be involved in this study.

|  |  |
| --- | --- |
| **Job Classification**  | **Task** |
|  |  |
|  |  |
|  |  |

**Total # of Staff: \_\_\_\_**

**CTSI / CRS SECTION** (if applicable)

Will part or all of the study be conducted in the ZSFG Clinical Translational Science Institute (CTSI) Clinical Research Services (CRS)? Yes [ ]  No [ ]  NA [ ]

**If yes, please complete the following:**

1. Contact the CRS budget team at crsbudgetrequest@ucsf.edu to set up the budget for the study.
2. Once the budget portion is set up, contact crsprotocolservices@ucsf.edu to schedule a start-up meeting.

**SPACE UTILIZATION** Where will this study be conducted? (Select **all** that apply)

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  Clinical Space at ZSFG | [ ]  Lab Space at ZSFG | [ ]  Office Space at ZSFG | [ ]  Other, please specify: |

 **Service/Department**: **Building**/**Room**:

Please obtain approval from the Unit where research will occur (if applicable) **before submitting the Protocol Application for remaining approval routing**. Signature is always required. Please see authorized approvers for clinical space on page 4.

**CLINICAL RESEARCH OR PATIENT RECRUITMENT PRE-APPROVAL** (if applicable)

The operational stakeholders listed below must approve protocols if study procedures or patient recruitment will occur in any of the following inpatient or outpatient clinical service areas. Please add information for other clinical areas.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study procedures in area | Recruiting patients receiving care from this area | ZSFG Clinical Area\* | Nursing Director (Medical Director) | Nursing DirectorSignature**Must be obtained before submitting Research Protocol** |
| [ ]  | [ ]  | Emergency Services  | Beverlyn Navarro (Chris Colwell) |  |
| [ ]  | [ ]  | Intensive Care  | Christina Bloom (Antonio Gomez) |  |
| [ ]  | [ ]  | Maternal & Child Inpatient | Gillian Otway (Biftu Mengesha) |  |
| [ ]  | [ ]  | Medical-Surgical Inpatient  | Leslie Holpit(Gabriel Ortiz) |  |
| [ ]  | [ ]  | Occupational Health  | Angelica Boillard (Jessica Chuang) |  |
| [ ]  | [ ]  | Perioperative Care | Patty Coggan (Laura Lang) |  |
| [ ]  | [ ]  | Primary care, including ZSFG sites | Anna Robert(Catherine James) |  |
| [ ]  | [ ]  | Psychiatry | Kathy Ballou (Mark Leary) |  |
| [ ]  | [ ]  | Specialty Ambulatory Care | Rosaly Ferrer (Delphine Tuot) |  |
| [ ]  | [ ]  | Tuberculosis Clinic | Rocio Agraz-Lara (Susannah Graves) |  |
| [ ]  | [ ]  |  |  |  |
| [ ]  | [ ]  |  |  |  |

\* Medical and nursing leadership may require advance discussion and approval from local clinic/unit leader for an area ***before*** signing the form.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DPH / ZSFG Resource Approval Checklist**

Please indicate if your research will use **any** of the following DPH / ZSFG resources by selecting Yes, No, or NA for all. Unless indicated to contact before submitting the form, please do not request approvals directly

|  |  |
| --- | --- |
| **MEDICAL RECORDS / PATIENT DATA** This section must be marked Yes if your study will access (read or write) any DPH / ZSFG paper or electronic patient data or interacting with patients via phone/letter/in-person. Per HIPAA regulations, all patient health information (PHI) must be encrypted/password protected. If stored on computers and/or portable electronic devices, PI must initial/date here:Medical Records (628-206-6210) or Diane.Lovko.Premedue@sfdph.org**IT BUILD NEEDS AND DATA ACCESS** (also **required** if study will access any DPH/ ZSFG data) Liz Goldman (628-206-5452) or Lauren.Goldman@ucsf.edu  **PRIVACY AND COMPLIANCE** (also **required** if study will access any DPH/ ZSFG data) Privacy & Compliance (628-206-4104) or Catherine.Argumedo@sfdph.org  | Yes [ ]  No [ ]  NA [ ] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*PI initial and date* |
| **CLINICAL LABORATORY SERVICES** If yes, approval for the [Request to Set Up Research Study](http://labmed.ucsf.edu/sfghlab/test/research_testing.html) must be obtained **before** submitting the ZSFG Research Protocol Application Form. *Indicate Clinical Labs Request to Set Up Research Study Form* approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Clinical Laboratory (628-206-6786) or Andy.Yeh@ucsf.edu  | Yes [ ]  No [ ]  NA [ ]   |
| **RADIOLOGY SERVICES** If yes, approval for the [Imaging Research Application](https://radiology.ucsf.edu/research/core-services/img-srvs-piple/zsfg-imaging-app) (UCSF / ZSFG Radiology Research Proposal Request) must be obtained **before** submitting the ZSFG Research Protocol Application form. Indicate *Imaging Research Application* approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Radiology email Lorel.Hiramoto@ucsf.edu  | Yes [ ]  No [ ]  NA [ ]  |
| **PHARMACY SERVICES** If the study involves the administration of **any medications**, approval for ZSFG [Pharmacy Investigational Drug Service (IDS)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) Service Request Form and Agreement must be obtained **before** submitting the ZSFG Research Protocol Application form. Indicate *Pharmacy Investigational Drug Service (IDS) Service Request Form* approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ For more information on Pharmacy IDS Services Fees, send an email to the email address below.Pharmacy (628-206-8460) or email DPH-ZSFG-Pharmacy-IDS@sfdph.org | Yes [ ]  No [ ]  NA [ ]   |

**Signature Collection Section** (Signatures are collected by the Dean’s Office. Please do not request approvals directly from approvers below as this may slow down the process)

Dean's Office obtains approvals

**MEDICAL RECORDS / PATIENT DATA** (Must be signed **if** you are using any DPH / ZSFG patient data)

 Use of ZSFG/DPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

***Additional Notes/Comments:***

**IT BUILD NEEDS AND DATA ACCESS** (Must be signed **if** you are using any DPH / ZSFG patient data)

 Use of ZSFG/DPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**PRIVACY AND COMPLIANCE** (Must be signed **if** you are using any DPH/ ZSFG patient data)

 Use of ZSFG/ DPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: ZSFG Privacy and Compliance Officer***

***Additional Notes/Comments:***

**CLINICAL LABORATORY SERVICES**

 Use of Clinical Laboratory is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: ZSFG Clinical Lab Administration***

***Additional Notes/Comments:***

**RADIOLOGY SERVICES**

 Use of Radiology is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 ***Signature/Date: ZSFG Radiology Administration***

***Additional Notes/Comments:***

**PHARMACY SERVICES**

 Use of Pharmacy is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: ZSFG Pharmacy Administration***

 ***Additional Notes/Comments:***

**ADMINISTRATIVE APPROVAL**

A. Sue Carlisle, Ph.D., M.D. (Date)

Susan P. Ehrlich, M.D., M.P.P. (Date)

UCSF SOM Vice Dean at ZSFG Chief Executive Officer, ZSFG

***\*\*\* FOR DEAN’S OFFICE USE ONLY \*\*\****

*Submission process finalized.*

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