**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: (Note: Find the most current version of the form and protocol resources here: <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 / Space Utilization (If applicable, you collect the signature)
  + CTSI Section (If applicable, you collect the signature)

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

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

[ZSFGResearch@ucsf.edu](mailto: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 approval signatures on your behalf based on your DPH / ZSFG Resource Approval checklist selections on page 4. If a box is not selected or incorrectly chosen, the form will be returned to you for completion.
* 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**

Please provide a brief description of the nature, goals and process of the study:

**UTILIZATION (Patient Volume and Frequency)**

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 RESOURCE / SPACE UTILIZATION**

**Human Resources:** Please indicate the number of UCSF staff involved in this study (e.g., 1 CRC and 2 ACRCs).

**Number Job classification**

**Total Staff**

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

**Job classification Task**

**Space Utilization:** Where will this study be conducted?

€ Clinical Space @ ZSFG € Office or Lab Space @ ZSFG € Other, please specify:

\*\* Signature Always Required \*\*

Please obtain approval from the Unit where research will occur (if applicable).

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

I have approved the above: Yes € No € NA €

***Signature/Date: Unit Head Nurse / Manager***

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

***Printed Name of Unit Head Nurse/ Manager:***

**PARTICIPANT RECRUITMENT** (if applicable)

Will participant recruitment take place in the ED or In-Patient unit? Yes  No  NA 

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

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

Will this study be conducted entirely 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](mailto:crsbudgetrequest@ucsf.edu) to set up the budget for the study.
2. Once the budget portion is set up, contact [crsprotocolservices@ucsf.edu](mailto:crsprotocolservices@ucsf.edu) to schedule a start-up meeting.

**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:

|  |  |
| --- | --- |
| **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](mailto: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](mailto: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](mailto:Catherine.Argumedo@sfdph.org) | Yes € No € NA €  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *PI initial and date* |
| **CLINICAL LABORATORY SERVICES**  If yes, please complete the [Request to Set Up Research Study](http://labmed.ucsf.edu/sfghlab/test/research_testing.html) form to establish a ZSFG Special Research Account **before** submitting the Research Protocol Application form.  Clinical Laboratory (628-206-6786) or [Andy.Yeh@ucsf.edu](mailto:Andy.Yeh@ucsf.edu) | Yes € No € NA € |
| **RADIOLOGY SERVICES**  If yes, please complete the [Imaging Research Application](https://radiology.ucsf.edu/research/core-services/img-srvs-piple/zsfg-imaging-app) (UCSF / ZSFG Radiology Research Proposal Request) to establish a ZSFG Special Research Account **before** submitting the Research Protocol Application form.  Radiology email [Lorel.Hiramoto@ucsf.edu](mailto:Lorel.Hiramoto@ucsf.edu) | Yes € No € NA € |
| **PHARMACY SERVICES**  If the study involves the administration of **any medications**, please complete the ZSFG [Pharmacy Investigational Drug Service (IDS)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) Service Request Form and Agreement **before** submitting the Research Protocol Application form. 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](mailto:DPH-ZSFG-Pharmacy-IDS@sfdph.org) | Yes € No € NA € |

**Signature Collection Section (**Signatures collected by the Dean’s Office)

**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***

**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***

**CLINICAL LABORATORY SERVICES**

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

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

**RADIOLOGY SERVICES**

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

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

**PHARMACY SERVICES**

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

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

**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 \*\*\***

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*Submission process finalized.*

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