

Zuckerberg San Francisco General Research Protocol Applications Procedure

If you are planning to enroll patients at ZSFG, are using ZSFG personnel, resources, facilities, space (even if it is your own office) or ZSFG patient data (even if you are only collecting names and numbers), you must complete an ZSFG Research Protocol Application (see below). We use the data collected in these forms to explain all ZSFG research activity on our campus.

Protocol Application Process:

1. Complete ZSFG Research Protocol Application (scroll down)
2. Gather all signatures except for Administrative approvals at the end of the application (see contacts)
3. Please sign the HIPAA acknowledgement
4. Send completed application to the ZSFG Vice Dean's Office (see contacts)
5. We will process your application and collect the Administrative approvals. Please allow for a typical turnaround time is 7-10 days.
6. The Dean's office will send the signed original to the PI and a copy to the additional contact when the application has been approved.
7. If you need to contact us about your application status please provide the CHR number.

Contacts for ZSFG Protocol Approvals:

Medical Records

Diane Premeau
diane.lovko-premeau@sfdph.org
(415) 206-6210
ZSFG, Building 5, Room 2B1

Pharmacy Services

Jeanette Cavano
jeanette.cavano@sfdph.org
(415) 206-2504
ZSFG, Building 5, Room 1C28

Clinical Labs

Chav Doherty
chav.doherty@ucsf.edu
(415) 206-6786
ZSFG, Building 5, Room 2M

UCSF ZSFG Vice Dean's Office

jeanine.craven@ucsf.edu
(415) 206-8505
(415) 285-2037 (fax)
ZSFG, Building 5, Room 2A21
Box 0809

**Zuckerberg San Francisco General
PROTOCOL APPLICATION**

Protocol Title: _____

Grant Title (if different) _____

Grant No. if available _____ **Beg. Date of Grant** _____ **End Date of Grant** _____

Prin. Investigator _____ **Additional Contact** _____

Phone _____ Phone _____

Email: _____ Email _____

IRB STATUS

Approved CHR No. _____ Exp. Date _____

SUBJECT CATEGORY Please circle appropriate classification

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) _____

BRIEF DESCRIPTION OF PROTOCOL Please provide a brief description of the nature and goals of the study

UTILIZATION

Indicate number of subjects per year Year 1 _____ 2 _____ 3 _____ 4 _____ 5 _____

Total number of outpatient visits per subject _____

Total number of inpatient visits per subject _____

CHART REVIEW/PATIENT DATA (MUST BE SIGNED IF YOU ARE USING ANY ZSFG/DPH PATIENT DATA)

Use of ZSFG/DPH patient information is approved: Yes NA

*Signature/Date: Director, Medical Records
DPH Privacy Officer
Or attach email approval from Director, Medical Records*

Per HIPAA regulations, all patient health information (PHI) will be encrypted/password protected if stored on computers and/or portable electronic devices. PI please initial/date here _____

****If this is a chart review only, STOP here.****

Will this study be conducted entirely in the ZSFG Clinical Translational Science Institute (CTSI) Clinical Research Center (CRC)? Yes No

If "Yes", proceed to "Pharmacy Utilization" section and contact ZSFG GCRC 206-8239 for required forms.

If "No", please complete all of the following. Note any ZSFG equipment, services, or personnel needed, and department(s) involved. Sign all sections where you indicate "NA".

HUMAN RESOURCE / SPACE UTILIZATION (approval from the Unit where research will occur)

Where will this study be conducted? Building _____ Room _____

Please describe any and all tasks which ZSFG staff may be asked to perform which they would not perform but for this protocol: _____

I have approved the above: Yes No

Signature/Date: Unit Head Nurse / Manager
Or attach email approval from Unit Head Nurse / Manager

CLINICAL LABORATORY UTILIZATION (206-8588)

A ZSFG Special Research Account has been established? Yes NA

Signature/Date: ZSFG Clinical Lab Administration
Or attach email approval from ZSFG Clinical Lab Admin.

If applicable, refer to Procedure for Establishing and Using a Research and Special Study Account.

RADIOLOGY UTILIZATION (206-68420 or 206-6130)

A ZSFG Special Research Account has been established? Yes NA

Signature/Date:
ZSFG Radiology Administration
Or attach email approval from ZSFG Radiology Admin.

If applicable, refer to Procedure for Establishing and Using a Research and Special Study Account.

PHARMACY UTILIZATION (206-8460)

Does this study involve the administration of **any** medications? Yes No A

ZSFG Pharmacy Investigational Drug Service (IDS) form has been completed? Yes NA

Signature/Date: ZSFG Pharmacy Administration
Or attach email approval from ZSFG Pharmacy Admin.

ADMINISTRATIVE APPROVAL

A. Sue Carlisle, Ph.D., M.D. (Date)
Vice Dean, ZSFG

Susan P. Erhlich, M.D.,M.P.P. (Date)
Chief Executive Officer