

San Francisco General Hospital
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 _____

Mailing Address _____ Mailing Address _____

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

Use of SFGH/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 SFGH Clinical Translational Science Institute (CTSI) Clinical Research Center (CRC)? Yes No

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

If "No", please complete all of the following. Note any SFGH 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 SFGH 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 SFGH Special Research Account has been established? Yes NA

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

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

RADIOLOGY UTILIZATION (206-5196 or 206-6130)

A SFGH Special Research Account has been established? Yes NA

Signature/Date:
SFGH Radiology Administration
Or attach email approval from SFGH 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 SFGH Pharmacy Investigational Drug Service (IDS) form has been completed? Yes NA

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

ADMINISTRATIVE APPROVAL

A. Sue Carlisle, Ph.D., M.D. (Date)
Associate Dean, SFGH

Susan A. Currin (Date)
Executive Administrator