Guideline for the Distribution and Filing of Informed Consent Forms For Subjects in Clinical Trials at UCSF Medical Center at Parnassus and Mt. Zion, and San Francisco General Hospital Medical Center

Patients receiving experimental treatments in research studies are at risk of unforeseen events due to their experimental treatment for which they may seek treatment without the knowledge or oversight of the investigator. Subjects receiving experimental treatments may also seek medical care for illness or injury unrelated to their participation in a clinical trial without the knowledge or oversight of the investigator. In both these cases, knowledge on the part of the caregiver that the patient seeking treatment is on an experimental therapy and the specifics of that therapy could affect their care.

Therefore, it is recommended that copies of informed consent forms for subjects receiving experimental treatments and who are UCSF patients be filed in the subject's central medical record. In this way, in the event the patient is admitted to a UCSF affiliated facility without the investigator's knowledge, the caregiver will have access to details regarding the patient's participation in a treatment study. This also increases the chances of the investigator being notified of the subject's admission, thus facilitating research subject study management, data collection, and safety reporting.

To file the informed consent form for subjects at UCSF Medical Center at Parnassus or Mt. Zion, make a copy of the original signed consent form and write the study subject's UCSF medical record number on the informed consent form copy. Send or deliver the copy of the signed informed consent form to HIMS, Master File unit, Box 0308. To file the informed consent form for subjects at San Francisco General Hospital Medical Center (SFGH), make a copy of the original signed consent form and write "file as an advanced directive" at the top of the informed consent form copy. Send or deliver the copy of the signed informed consent form to: Chris Elliott, Director of Health Information Services, 1001 Potrero Avenue, Room #2B1, San Francisco, CA 94110.

The original signed informed consent form should be retained for audit for two years after completion or discontinuation of the investigation, or longer if specified by applicable regulations, by the unit conducting the research.

If a subject is participating in a clinical trial and is receiving their medical care from a primary care provider at another institution, it is recommended that a copy of the subject's informed consent form be sent by the study staff to the provider with the subject's permission. Permission for release of the signed informed consent form should be obtained from the subject by the study staff utilizing the appropriate UCSF or SFGH Authorization For Release of Medical Information Form and the form retained in the research record.