Charter – Tissue Sample and Clinical Data Requisition

This charter aims to provide general guidelines for investigators interested in requesting tissue samples from the Neurosurgery Tissue Bank or obtaining clinical information from the Neurosurgery Database or the Neuro-oncology Database. Please be aware that certain requests may require CHR approval. Please consult with the CHR website listed below for detailed information on UCSF human research policy. This document should not take precedence over any CHR regulations. The content of this document is subject to change according to CHR policy.

http://www.research.ucsf.edu/chr/index.asp

(1) Requisition of Tissue Samples

As of September 2007, the CHR considers use of pre-existing, de-identified samples as Non-Human Research. The implication of this policy change is that investigators requesting de-identified tissue samples (SF# only) from the Neurosurgery Tissue Bank no longer need to apply for CHR certification. Instead, CHR suggests that investigators fill out a Self-Certifying Form (available on the CHR website) to declare that certain conditions are being met. Please submit the completed Self-Certifying form to the Tissue Bank manager, Cynthia Cowdrey, when requesting samples. The Tissue Bank will retain this record for future references.

For distributed de-identified samples, the Tissue Bank will provide only the following information:

- Histology
- Grade
- Tumor location
- Recurrent vs. newly-diagnosed
- Age
- Sex

Please be advised that the Tissue Bank will no longer provide patient identifiers or clinical information to investigators (e.g. MRNs) – regardless of their CHR status. If you have obtained tissue samples from the Tissue Bank and are interested in pursuing further clinical information associated with these samples, the Tissue Bank may coordinate with the Neurosurgery Database to provide the SF#-MRN links. For more information, please contact:

Cynthia J. Cowdrey, HT (ASCP)
Neurosurgery Tissue Bank, Manager
University of California, San Francisco
513 Parnassus, HSW 771
San Francisco, CA 94143-0520
415-476-9760
415-502-0613 (fax)
Tissue Bank Website: http://gnome.ucsf.edu/tbank/

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(2) Requisition of Clinical Information from the Neurosurgery Database

The Neurosurgery database (NSDB) aims to facilitate clinical research by gathering and maintaining minimal records on patients treated in the Neurosurgery Department. The NSDB contains complete information from 1996 to present and partial from 1995 to 1991. The searchable database holds demographic information, diagnoses and procedure descriptions. It is a resource for faculty members and residents, and serves as a starting point for further studies. The database consists of clinical data in a number of disease areas, such as: Neuro-Oncology, Vascular, Epilepsy, Chiari/Syringomelia, Pediatric, Pain and Functionality, Peripheral Nerve, Shunt/Ommaya each of which is supervised by a Faculty Advisor in Neurosurgery (Dr. McDermott, Dr.Barbaro, Dr.Gupta, and Dr. Mummaneni).

The NSDB focuses on entering new surgeries for new or current patients (higher priority is placed on Neuro-Oncology surgeries or surgical or non-surgical Neuro-Oncology Specialist visits. Investigators who request clinical information with patient identifiers will be required to obtain approval from the UCSF CHR. Once you have obtained the appropriate CHR approval, please send your request via email to the NSDB Data Manager, Ms. Nataliya Volskaya. Your request package should include: 1) a copy of the study’s CHR Approval and study protocol, and 2) data request Form. Request package will be review by Data Manager supervisor Jennette Sison. However, if you only need a count of patients, the count can be given without CHR approval\(^1\).

If the requester is a UCSF faculty physician who needs the confidential data solely for UCSF medical education purposes the following will be done: The Data Manager will ask the requester to specify, in writing, the educational purposes for which the data will be used and where and how it will be presented. This information will be kept with other records of NSDB requests to document that the request was solely for educational purposes.

Please notify the appropriate sub-database Faculty Advisors of any data request. For more information, please contact:

Nataliya Volskaya 
Neurosurgery Database Manager 
Box 0112, 505 Parnassus Ave, Moffitt 780 
University of California, San Francisco 
San Francisco, CA. 94143 – 0112 
Tel: (415) 353-3650 
Fax: (415) 353-3907

Jennette Sison, MPH 
Academic Coordinator III 
Box 1215, 44 Page St., #503 
University of California, San Francisco 
San Francisco, CA. 94143 – 1215 
Tel: (415) 514-0277 
Fax: (415) 502-1787

(3) Requisition of Clinical Information from Neuro-oncology

The Neuro-oncology program has an E-Velos database that contains clinical information on patients treated for brain tumors on clinical trials and may also have information on other patients. Investigators who are interested in obtaining clinical information on

\(^1\) Request form will be attached
Neuro-Oncology patients should contact Dr. Michael Prados or Dr. Susan Chang to discuss the feasibility of their study concept. CHR approval is required for requests that involve patient identifiers. If approved, Dr. Mei-Yin Polley will review data needed to assess what would be available in the Neuro-oncology database and determine the best approach to acquire the data. If data from charts would be required, further discussion with Dr.’s Prados or Chang and agreement on the person to do the chart review will be required.