University of California
San Francisco

Schools of Pharmacy and Medicine
Bioengineering and Therapeutic Sciences

HEALTH POLICY POSTDOCTORAL FELLOWSHIP POSITION

UCSF Pediatric Device Consortium (PDC)
UCSF-Stanford Center of Excellence in Regulatory Sciences and Innovation (CERSI)
Department of Bioengineering and Therapeutic Sciences

Supervisor: Dr. Shuvo Roy, Director, Biodesign Laboratory (https://pharm.ucsf.edu/roy)

Description

The UCSF Pediatric Device Consortium (PDC) and the Biodesign Laboratory at UCSF, led by Dr. Shuvo Roy, is seeking a highly motivated Health Policy Postdoctoral Fellow to work with the PDC and the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI). **The Fellow will develop methodology to incorporate patient perspectives, including patient preferences and patient-reported outcomes (PRO), into the pediatric device development process.**

Patient preferences is an emerging field of regulatory science focused on identifying and developing methods for assessing patient valuations of benefit and risk related to what type of therapy or device attributes a patient might prefer that can be used to inform product review decisions. **Since the FDA launched its Patient Preference Initiative in 2013, increasing attention has been placed on incorporating patient voices into the regulatory decision-making process, but the methods to obtain and interpret such information – particularly in the pediatric population – must still be developed and validated.** Similarly, patient reported outcomes, defined as any report of a patient's health status that comes directly from the patient without interpretation by a clinician, are now considered one of the key aspects of assessing high value healthcare delivery, yet a framework for defining and collecting PROs in the pediatric population remains to be developed.

The UCSF PDC is partnered closely with the FDA and intends to proactively position its devices for regulatory clearance, a process that will increasingly involve incorporation of patient perspectives. **The Fellow will play a key role in this effort by helping to define methods for collecting and incorporating patient perspectives into the medical device product development process, with a focus on the pediatric population.** This work will be done in the context of various device innovation efforts underway in the PDC and Biodesign Laboratory. Such projects include the creation of a surgically implantable bioartificial kidney for end-stage renal disease patients, minimally invasive surgical and bracing treatments for

children with skeletal deformities, wireless patient monitoring systems, and more. The fellow will work in collaboration with biomedical engineers, surgeons, pediatric specialists, clinical researchers, regulatory scientists, and industry professionals in a creative and dynamic environment to pioneer this new paradigm of regulatory decision-making for pediatric devices.

Qualifications

The successful candidate should have a PhD degree in Health Policy, Public Health, Engineering, or other field related to the biomedical sciences or health policy, or an MD degree with advanced training (master's or certificate) in clinical research.

Expertise and proficiency with the methods and conduct of clinical research, including advanced biostatistical and epidemiologic methods, and proper conduct of medical research surveys is required. Strong written and oral communication skills are essential.

How to Apply

Please send a CV/resume, brief statement describing research interests and experience, career goals, and email contact information for three (3) references to shuvo.roy@ucsf.edu.