

## Stem Cell Clinical Trials Course at UCSD Extension

This course focuses on practical application of the principles of translating stem cell-based therapies, especially those in early development and in phase 1 studies. Students will acquire skills to translate these interventions from the bench to the bedside by designing a trial. Differences between drug development and stem cell-based therapies will be highlighted.

Featuring expert guest speakers primarily affiliated with the Sanford Consortium and UCSD CIRM Alpha Stem Cell Clinic

- Michael Choi, MD, Moores Cancer Center
- UCSD Division of Regenerative Medicine and representation from the GMP Facility
- Joseph Ciacci, MD, Department of Surgery (Neurosurgical stem cell studies)
- UCSD Regulatory Expert
- Eric Ahrens, PhD, Imaging Expert
- Michael Caligiuri, PhD, Former Chairman of UCSD IRB & Professor Emeritus of Psychiatry
- Others experts on pertinent matter from our own CIRM Alpha Stem Cell Clinic

## Highlights of the Stem Cell Translation course

- 20 hours of face-to-face interaction (2 units; course CLRE-237)
- Once weekly on Mondays: April 2 June 11, 2018
- 4:00 6:00 pm
- Location: UCSD Extension, UCC, 6256 Greenwich Drive, Suite 150: Room 111
- Final project: individually design a rational, ethical clinical trial featuring a cell-based therapy
- Grade based on participation, homework and a final exam/individual project
- Build the cost into your upcoming grants! The cost is \$1,500.00 for non-MAS or non-CREST seekers. For MAS or CREST members, the cost is about \$575.00. This cost may be able to be built into grants to be submitted.

## Course Objectives:

- Understanding to bench to bedside concept
- Understanding the process of development of new stem cell-based therapies
- Determining the preclinical work needed to support first-in-human studies
- Articulate the rationale and objectives for a stem cell study
- Identify and describe the appropriate study design and methods
- Select a study population and methods for their recruitment and selection of study subjects for a stem cell study
- Select outcome measures for safety and efficacy
- Design a monitoring plan to protect both participants and the scientific and ethical integrity of the study
- Determine methods of data collection, sample size and analysis plan

Please visit https://actri.ucsd.edu/education/crest-program/Pages/default.aspx to apply and for contact information for the CTRI CREST Program administrators. The Alpha Clinic is unable to answer enrollment related questions.

## DEADLINE TO ENROLL IS APRIL 30th, 2018

**Contact the CTRI CREST Course team with Questions** 

**UC San Diego CIRM Alpha Stem Cell Clinic** 

http://stemcells.ucsd.edu/sanford-center/ | 9500 Gilman Dr MC 0695, La Jolla CA 92093-0695