

2012 ISCTR/ACCF TRANSLATIONAL RESEARCH SCHOLARSHIP

CURRICULUM

1) General approach to cardiovascular translational research

1. To be familiar with the overall concept of product development.
2. To learn about toxicology studies.
3. To learn how to write an Investigational New Drug (IND) Application.
4. To learn how to write an Investigational Device Exemption (IDE) Application.

2) Small and large animal models for cardiovascular evaluation – to include monitoring hemodynamics and various animal models (coronary occlusion model, occlusion/reperfusion model, disease states to be studied).

1. To learn about small animal model used for stem cell transplantation.
2. To learn how to produce an ischemic & myocardial infarction model in small and large animals.

3) Invasive, non-invasive and imaging methods to evaluate cardiovascular structure and function in animals and humans.

1. Measurement of pressures, flow, resistance
2. Performance of cardiac and vascular radiographic angiography
3. Performance and analysis of cardiac imaging by ultrasound, isotopes, and magnetic resonance.
4. Use of electrocardiographic monitoring and biomarkers

4) Anesthesia and care of the small and large animal for survival

1. To understand the regulatory aspects of laboratory animal care and use.
2. To perform pre-anesthesia physical evaluations of the most common laboratory animals.
3. To understand the proper use and effect of a variety of chemical agents for pre-anesthesia, anesthesia induction and maintenance, and post operative analgesia and care for common laboratory animals in cardiovascular research protocols.
4. To understand the proper use of anesthesia equipment, monitoring equipment, and critical care support equipment and protocols.

5. To be familiar with special considerations and protocols for laboratory animals with cardiovascular compromise and undergoing cardiothoracic surgery.

5) Regulatory pathway to IND

1. To understand the regulatory pathway for biological product development.
2. To understand the regulatory pathway for small and large animal toxicology.
3. To understand the regulatory requirements for a phase 1 clinical trial.
4. To understand the regulatory pathway for a combination product (biologic plus device).

6) Regulatory pathway to IDE

1. To understand the regulatory pathway for 510K approval.
2. To understand the steps of product development.
3. To gain expertise and knowledge about device testing and evaluation.
4. To understand the animal model for device evaluation.

7) Principles of biostatistics for phase 1, 2, and 3 clinical trials

1. To develop the ability to characterize various study designs for clinical trials in terms of their strengths and weaknesses and considerations for design selection.
2. To review statistical approaches to the analysis of clinical trial data, identify their appropriateness for specific trial designs, and elaborate issues that are likely to develop during the analytic process.
3. To learn to estimate sample size for various trial designs.
4. To characterize the flaws and successes in sample clinical trials.

8) Principles of tissue engineering

1. To understand guiding principles for the use of a cellular scaffold for treating MI and heart failure.
2. To understand guiding principles for the use of biomaterial scaffolds for enhancing cell retention and survival.
3. To understand guiding principles for biomaterial implant tissue

response.

9) Cellular therapy with regard to regulatory pathway and product release

1. To learn the overall process of stem cell isolation and expansion.
2. To learn and understand Quality Control.
3. To learn and understand Quality Assurance.
4. To learn final product release criteria.
5. To learn overall standards of GMP facilities.

10) Interacting with the private sector and fundraising (Venture capitalists, NIH, Foundation, Industry)

1. To learn the structure and objective of a business plan.
2. To learn how to communicate with venture capitalists.
3. To learn the infrastructure of NIH and grant application process.
4. To learn about nonprofit organizations and their participation in issuing grants.
5. To learn industry's point of view and industry's relationship with investigators, including conflict of interest.

11) Human subjects in research- Institutional Review Boards

12) (Elective Module) Regeneration of cardiac tissue via stem cells

1. To learn about the variety of stem cells that may play an important role in cardiac regeneration.
2. To learn about labeling, staining, and evaluation of engraftment of stem cells.
3. To learn about evaluation of cellular electrical activity (cellular electrophysiology).

13) Stem Cell Therapy Product Development