

## University of Miami Calabresi Clinical Oncology Research Career Development Program (K12)

### Curriculum for Faculty Scholars 2022 cycle

#### A. Overview of the K12

The purpose of this K12, the *University of Miami Calabresi Clinical Oncology Research Career Development Program*, is to identify and help establish new faculty leaders in patient-oriented, clinical cancer research. The program will recruit a diverse group of talented clinical research Scholars for two-year terms and provide them with dedicated time for research, optimal mentorship, formal education, and practical experience in developing hypothesis-driven clinical trials that translate to improved cancer care delivery and patient outcomes. Short-term outcomes will be evaluated and Scholars' professional trajectories tracked to ensure the program's continuous growth and improvement.

The K12 program stipulates that Scholars devote 75% of their time to clinical research. Therefore, K12 Scholars will spend 1-1.5 days per week in outpatient clinics and/or surgery in the care of cancer patients. The K12 curriculum offers coursework, seminars, and workshops that will enhance Scholars' ability to design, obtain grant funding for, and carry out clinical research projects and clinical trials.

#### Outcomes

Over the course of the two-year program, Scholars will develop and initiate a clinical protocol and submit at least one grant application for an externally peer-reviewed NIH K award, R21, R01, or equivalent federally funded or foundation award. Scholars are expected to present their research at the leading cancer professional society conferences and to publish their work with recognition of the contributions of the K12 funding mechanism.

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## B. Required Program Components

### B.1. Mentorship

All Scholars, regardless of their career trajectory, will have both a [clinical mentor](#) and a [translational research mentor](#) in molecular or population science research. At least one mentor from the dyad must have external, peer-reviewed funding as defined by the National Cancer Institute.

If the translational scientist is lab-based, Scholars will attend lab meetings and become familiar with the goals and approaches used in the mentor's lab. For most Scholars, this long-term affiliation with a host lab will allow them, as clinical investigators, to work with laboratory-based scientists to develop molecular correlative tests for use in trial(s). Scholars will learn how to perform these tests and interpret data. Scholars may choose to perform pre-clinical translational studies to develop new drug combinations for testing in the clinic, or pursue additional training to develop an in-depth laboratory research program, devising, conducting, and analyzing hypothesis-driven experiments.

Scholars pursuing population-based cancer research will choose a mentor to help them develop a career focus that engages community and academic partners from diverse disciplines to ensure that research and associated findings translate from the bench to the community and back. These Scholars will develop programs that aim to demonstrate an impact on SCCC's catchment area through innovative interventional studies addressing the local cancer burden as well as disparities across the cancer continuum from prevention to survivorship.

Depending on the individual's career development and educational needs, they may wish to add a third mentor.

Scholars will meet individually with each mentor at least monthly, preferably more often, throughout the two-year program, and together with both mentors at least quarterly.

### Research Mentoring Training Program

In the first year of their K12 term, Scholars will participate in the annual Research Mentoring Training Program with one of their mentors. The training is designed for early-stage faculty and their mentors to strengthen mentoring skills and build successful relationships. Interactive workshops using evidence-based strategies take place over three non-consecutive days (one each in December, January, March), with individual and joint sessions for mentors and mentees.

### B.2. Individual Development Plan (IDP)

Each Scholar will customize their own course of study, to include Calabresi Program requirements and optional activities, as detailed in this document. At the beginning of the program, each Scholar will define general goals and complete a questionnaire assessing his or her current knowledge of clinical and translational research. This information will be used in the drafting of a formal IDP, to be signed by the Scholar, mentors, and K12 director. Preparation of an R01, K award, or equivalent application(s) is required of all Scholars. The Master of Science in Clinical and Translational Investigation (see C.1. below) is strongly recommended for Scholars who have not earned such a degree. Scholars may pursue a "tracked" course of study in population science (C.4.iv.) or molecular translational research (C.4.v.). At the conclusion of the program, Scholars will complete another self-assessment to determine whether they have achieved their goals.

### B.3. Design and Execution of Hypothesis-Driven Clinical Trials

All Scholars will write at least one protocol for a clinical trial that tests hypotheses and preferably includes translational correlates. Scholars will be required to obtain institutional approval for scientific merit through Sylvester's Protocol Review and Monitoring Committee (PRMC) and approval for ethical concerns through the Institutional Review Board (IRB). These processes should be complete by the end of year one of the program, with protocol initiation in year two (or earlier). Scholars will accrue and treat patients on the protocol, analyze the results, and prepare abstracts and manuscripts on the findings.

#### **B.4. Monthly Scholars Forum**

All Scholars will come together monthly with K12 leadership to share insights with each other and learn from distinguished clinical investigators from within and outside Sylvester regarding development of clinical and translational research to improve cancer care.

#### **B.5. Annual Paul Calabresi Symposium**

All Scholars will attend and present at the annual Paul Calabresi Symposium. The one-day event will bring together current and former Calabresi Scholars to share their experiences and learn from and network with clinical trial leaders. The day will feature a keynote speaker, as well as presentations and panels on research, mentorship, and career development.

#### **B.6. Clinical Trials Courses, Workshops, and Seminars**

To assist with the design and execution of clinical trials, Scholars will participate in all of the following required courses and workshops.

##### **Design and Management of Clinical Cancer Trials Workshops**

*Sep-Oct, 5 weeks, Fri 8:00 AM - noon*

Modeled after the AACR-ASCO Methods in Clinical Cancer Research Workshop, this course includes 20 hours of lectures and discussion over five weeks. Participants complete weekly homework assignments leading to the development of a clinical trial LOI ready for submission by the end of the course. Lectures teach the basic research concepts and principles that underlie the design and day-to-day conduct of cancer clinical trials, setting the foundation for in-depth coursework pursued by each Scholar as laid out in their IDP, and as detailed in course descriptions throughout this document. Topics include:

- Study design for phase I, phase II, and population science studies
- Considerations in special trial design
- Appropriate statistics to use
- Incorporating biomarkers into clinical trials
- Role of the PI
- Clinical trial ethics and valid consent
- Mentorship and career path of a clinician-investigator
- Regulatory aspects of cancer clinical trials
- Patient-reported outcomes in clinical research

##### **Clinical Trials Biostatistics Journal Club**

Scholars take turns presenting the statistical approaches of published cancer clinical trials during this bimonthly journal club facilitated by faculty from the Sylvester Biostatistics and Bioinformatics Shared Resource. Scholars.

##### **External Workshop/Instruction in Clinical Trials**

To complement program activities and ensure comprehensive instruction, all Scholars will attend at least one external clinical trials conference or workshop over the course of their two-year term. E.g.:

- [FDA Accelerating Anticancer Agent Development and Validation Workshop](#)
- [AACR-ASCO Methods in Clinical Cancer Research Workshop](#)
- [SOCRA Annual Conference](#)
- [ACRP Certification](#)

##### **Site Disease Group Clinical Trials Working Groups**

Each SCCC Site Disease Group has a weekly or monthly clinical trials review meeting. Scholars will participate in the SDG meeting relevant to their career plan.

### **Study Start-up Workshop**

Too little preparation for complex studies is a recipe for non-compliance. This 3.5-hour workshop is offered by the Office of Research Compliance and Quality Assurance (RCQA) for clinical investigators to get information and tools to be prepared prior to enrolling their first subject. Participants learn how efforts put towards the study start-up phase can save time and frustration down the line.

### **Sylvester Precision Medicine Molecular Tumor Board**

*First Thur, 8:00 - 9:00 AM*

The Precision Medicine Tumor Board is a monthly forum to discuss patient cases from a molecular level, bringing insights from across disciplines and cancer types. The attendees discuss precision medicine clinical trials that are open at SCCC. Patient cases are presented monthly accompanied by next-generation sequencing data and other molecular diagnostic information for discussion.

## **B.7. Instruction in the Responsible Conduct of Research (RCR)**

Scholars will complete the following modules required for University of Miami clinical researchers:

### **CITI Modules**

*Online, self-guided activity*

PI completion of courses on [Conflict of Interest](#), [Good Clinical Practice](#), and [Human Subjects Research](#) are required for PRMC approval of a protocol.

### **Office of Research Compliance and Quality Assurance (RCQA) Courses**

*1- to 1.5-hour courses, offered at least once per semester*

Two RCQA courses, “Protocol Compliance from Start to Finish” (one hour) and “Coercion and Undue Influence in Research” (1.5 hours), are required for Scholars. RCQA offers 14 additional courses on compliance, corrective and preventive action in clinical research, and clinical trials disclosure.

### **Clinical Research Operations and Regulatory Support (CRORS) New Investigator Training**

*2 hours, offered twice per month*

This training, which covers Good Clinical Practice and associated responsibilities, is required for all new principal investigators at the institution. CRORS is notified when a new PI submits a study to IRB, and the PI must complete the training prior to beginning their study.

## **B.8. Instruction in Grant Writing and Scientific Presentations**

Scholars will participate in the activities below to help develop their grant writing and scientific presentation skills. During the period of K12 support, Scholars will submit one or more grant applications for peer-reviewed funding, in addition to contracts from pharma and support from foundations. To facilitate Scholars' applications for funding, the SCCC Grants and Contracts Team will help identify grant opportunities and assist with budget, proofing, and submission of applications. It may take more than the two years of support to obtain funding, but this is a long-term expectation, so Scholar's career trajectories will be tracked.

### **Specific Aims Review**

Scholars will participate in the Specific Aims review process through the Sylvester Faculty Development Program. 3-4 months before grant submission, Scholars will submit their Specific Aims for review by a panel including two senior faculty members and one junior faculty peer. Scholars will receive a summary statement and individual reviewer comments. Specific Aims for upcoming grant submissions will also be reviewed and discussed during the Monthly Scholars Forum.

### **Presentation Skills Training**

The ability to verbally communicate research results is an essential career skill in academic medicine. Scholars will attend a workshop with a presentation coach and will also have the opportunity to work 1:1 with the coach in advance of oral presentations at external academic/professional society meetings.

### **Experience in Scientific Presentations**

Scholars will have several formal and informal opportunities to present their research throughout the program. Scholars will regularly provide updates as part of the Monthly Scholars Forum, receiving critiques and tips from K12 leadership and fellow Scholars. Scholars will present each year as part of the agenda for the Annual Paul Calabresi Symposium. In year two of the program, Scholars will present hour-long seminars as part of the Sylvester Junior Faculty Lecture Series.

### **Sylvester Faculty Development Program First Fridays**

Sylvester's Assistant Director for Faculty Development hosts this monthly series dedicated to research-focused networking. This is an opportunity to get feedback from leadership and peers on topics related to academic advancement. Past and planned sessions have addressed Specific Aims, dissecting study section comments, crafting the biosketch personal statement, writing a strong introductory letter for grant resubmission, and how and when to reach out to a PO or journal editor.

### **B.9. Introduction to Shared Resources**

To further understanding of how SCCC core resources, listed below, may be applied in clinical trials, Scholars will participate in a series of presentations by core leaders highlighting their resources and technologies, with attention to how they can be used for correlative studies for clinical trials and for molecular and other aspects of population research projects. Other University of Miami shared resources will also be covered.

- Analytical Imaging Shared Resource
- Behavioral and Community-Based Research Shared Resource
- Biospecimen Shared Resource
- Biostatistics and Bioinformatics Shared Resource
- Cancer Modeling Shared Resource
- Flow Cytometry Shared Resource
- Molecular Therapeutics Shared Resource
- Onco-Genomics Shared Resource

### **B.10. Committee Observation**

To gain greater familiarity with trials infrastructure, Scholars are required to observe at least one meeting of each of the following committees that review cancer-related trials:

#### **Protocol Review and Monitoring Committee (PRMC)**

Scholars will gain an appreciation for clinical protocol implementation by shadowing the PRMC chair and auditing meetings. The PRMC 1) reviews scientific merit of all cancer research protocols; 2) prioritizes protocols; and 3) monitors trial progress. The PRMC also reviews protocols regularly to evaluate scientific progress, accrual rates, and completion of scientific aims per the timeframe of the protocol. The function of the PRMC is complementary to that of the IRB (see below), which focuses on protection of human subjects.

#### **Data and Safety Monitoring Committee (DSMC)**

The DSMC conducts data and patient safety reviews on cancer-related institutional, interventional studies (single and multi-site) that entail risks(s) to participants. The DSMC is responsible for 1) protecting participant safety, 2) ensuring the credibility and integrity of the data, and 3) providing analysis of efficacy data and interim reviews of safety monitoring.

#### **Institutional Review Boards (IRBs) Cancer Protocols**

The IRBs ensure adherence to all federal, state, local, and institutional regulations concerning the protection of human subjects in research.

## C. Optional Program Components

### C.1. Master of Science in Clinical and Translational Investigation (MSCTI)

Scholars are highly encouraged to enroll in the [Master of Science in Clinical and Translational Investigation \(MSCTI\) program](#), offered through the Miami Clinical and Translational Science Institute. The goal of the MSCTI is to help early-career investigators pursue independent careers in academic clinical and/or translational science. This highly integrated, cross-disciplinary program provides a foundation for future practitioners and leaders of translational and clinical science to identify and overcome institutional, cultural, regulatory, and other barriers that inhibit translational research.

MSCTI candidates complete 30 credits. Six (6) credits will be satisfied by Scholars' design and execution of clinical trials and grant application submission. The following core courses comprise an additional 15 of the 30 total credits:

- [CTI 602](#) - Writing for Translational and Clinical Science (2 credits)
- [CTI 603](#) - Research Ethics (2 credits)
- [CTI 605](#) - Introduction to Team Science and Entrepreneurship (3 credits)
- [EPH 604](#) - Clinical Trials (3 credits)
- [EPH 621](#) - Fundamentals of Epidemiology (3 credits)
- [HGG 630](#) - Variation and Disease (2 credits)

The remaining nine credits (9) will be made up by electives. MSCTI candidates are required to take at least one course in each of the following categories: Bioinformatics, Biostatistics, and Cultural Diversity and Community Engagement.

Course descriptions can be found below (C.4.).

### C.2. Optional Workshops and Seminars

#### **Pipelines in Cancer Research Seminar Series**

*Variable day and time*

This seminar series was developed as a resource for clinical and translational investigators at SCCC. Oncology program leaders from the pharmaceutical/ biotechnology industry discuss promising projects and products in their oncology portfolios. The goal is to facilitate collaborations between SCCC clinicians and scientists within the pharmaceutical/biotechnology industry. Scholars will have dedicated time to meet with these leaders. Examples of speakers in this series: Nancy Whiting, PharmD, BCOP, Vice President, Head of Medical Affairs, Seattle Genetics, Inc.; William Go, MD, PhD, Senior Director for Clinical Development, Kite Pharmaceuticals, Inc.

#### **Quantitative Science Clinic**

The SCCC Biostatistics and Bioinformatics Shared Resource (BBSR) hosts a weekly Quantitative Science Clinic open to all cancer center members, affiliates, and staff. At the clinics, researchers can discuss their statistical questions or issues in a group environment. The Quantitative Science Clinic staff provide expert biostatistical, bioinformatics, and computational advice to cancer researchers on all phases of research, including analysis plans, sample size calculations, statistical study design, interpretation of quantitative findings, and high throughput genomic data analysis.

#### **Biostatistics Roundtable**

The University of Miami Biostatistics Collaboration and Consulting Core (BCCC) hosts a monthly Biostatistics Clinic and a twice-monthly Biostatistics Roundtable open to the community. Participants are encouraged to bring projects for which they need advice and specific questions for discussion in a small group format (limited to 10 participants, by RSVP).

### **Sylvester Distinguished Lecture Series and Distinguished Collaboration Series**

Sylvester's Distinguished Guest Lecture Series provides a forum for outstanding clinical and translational researcher guest lecturers to interact and ultimately collaborate with Sylvester faculty. The focus of the series is to bring basic science and clinical researchers together to discuss recent advances in the understanding and treatment of human cancer – a realization of the “bench to bedside” ideal. Teams of distinguished internal speakers present as part of the Distinguished Collaboration Series. The lectures focus on different aspects of the same scientific/clinical problem and explore the interrelationships between basic cancer research and clinical medicine. The audience for both series is typically a mix of clinicians, clinical researchers, basic scientists, and physician scientists. Lectures take place almost every Friday at 1:00 PM.

### **Cancer Center Retreat**

Annually, Sylvester Comprehensive Cancer Center hosts a two-day retreat for all of our Cancer Center members, post docs, and trainees. The retreat agenda includes a poster session, which provides an opportunity for members, post docs, and trainees to learn about each other's work, network, and share ideas with cancer center leadership. Additionally, the retreat focuses on strategic planning sessions to help shape long term and short-term goals for the Center and provides a venue for team building.

### **Cancer Survivorship Lecture Series**

Sylvester developed the Survivorship Program to enhance and expand cancer survivorship care and translational behavioral research in cancer survivors, their families, and the community.

## **C.3. Committee Memberships/Shadowing of Clinical Research Services (CRS) Staff**

While Scholars are required to attend at least one meeting of the Protocol Review and Monitoring Committee (PRMC), Data and Safety Monitoring Committee (DSMC), and Institutional Review Board (IRB; described in B.10), Scholars have the option to gain even greater familiarity with trials infrastructure by shadowing clinical trials coordinators within CRS and spending three months as ad hoc members of the PRMC, DSMC, and the relevant IRB committees that review cancer-related trials.

## **C.4. Optional Courses**

The following optional courses have been identified as potentially useful for K12 Scholars and may be taken formally toward the MSCTI. When developing their Individual Development Plans (see B.2.) or their MSCTI curriculum, Scholars may select from the following coursework that aims to provide the tools needed for independent clinical research leadership.

### **C.4.i. Additional Instruction in Clinical Trials/Biostatistics**

***Please note that course availability, date, time, and format may change as a result of COVID-19 remote learning.***

#### **EPH 604 – Clinical Trials**

##### ***MSCTI core requirement***

*3 credits, May - June, 6 weeks, asynchronous online*

This course covers planning, design, analysis, and data management for clinical therapeutic and prophylactic trials. Illustrations are provided through case examples.

#### **BST 605 – Statistical Principles in Clinical Trials**

*3 credits, Jan - May, 14 weeks, Thur 2:00 - 4:30 PM*

This course is designed for individuals interested in the statistical aspects of clinical trials. Topics include types of clinical research, study design, treatment allocation, randomization and stratification, quality control, sample size requirements, patient consent, and interpretation of results. This course will additionally cover strengths and limitations of alternative study designs such as quasi-experiments and observational studies. Common sources of bias in these alternative study designs will be described along with design approaches to minimize bias.

**EPH 751 – Survival Analysis in Clinical Trials**

***MSCTI elective, Bioinformatics***

3 credits, Jan - May, 14 weeks, Thur 9:00 - 11:30 AM

This course covers statistical methods for analysis and interpretation of survival data arising from clinical trials. Topics include survival curves, estimation of sample size, survival curves, proportional-hazard models, time dependent variables, and prognostic indices.

**EPH 601 – Medical Biostatistics I**

***MSCTI elective, Biostatistics***

4 credits, Aug - Dec and Jan - May, 14 weeks, Wed 1:00 - 4:30 PM

This course is an introduction to probability and statistics, including descriptive statistics, tests of hypothesis, regression analysis, contingency tables, nonparametric tests, and life tables. Students gain hands-on experience in the analysis of medical data using several computer systems and at least one of the different statistical packages, such as BMDP, SAS, PSTAT, SYSTAT, and Minitab.

**EPH 602 – Medical Biostatistics II**

***MSCTI elective, Biostatistics***

3 credits, Jan - May, 14 weeks, Wed 1:00 - 3:30 PM

This course is a continuation and elaboration of EPH 601. Topics include design of factorial experiments, analysis of variance and variance components, multiple linear regression, and life tables.

**BST 625 – Survey of Statistical Computing**

***MSCTI elective, Biostatistics***

3 credits, Aug - Dec, 14 weeks, Mon/Wed 9:00 - 10:30 AM

This course aims to familiarize students with the basic use of SAS and R for routine statistical analysis and prepare them for more advanced courses and/or thesis research. Statistical computation will be illustrated with examples in medical research, biological study, and business. The focus of the course is on the computing environment, therefore a thorough discussion of statistical theories will not be provided. It is expected that students will already be prepared statistically.

**EPH 703 – Statistical Methods in Epidemiology**

***MSCTI elective, Biostatistics***

3 credits, Aug - Dec, 14 weeks, Fri 1:00 – 4:30 PM

This course covers advanced statistical methods used in analyzing data from epidemiological investigations. Topics include Mantel-Haenszel chi-square, interaction, standardization of rates, incidence density, logistics regression, and other special topics.

**C.4.ii. Additional Instruction in Clinical Research Ethics**

**CTI 603 – Research Ethics**

***MSCTI core requirement***

3 credits, Aug - Dec, 14 weeks, Wed 5:00 - 7:30 PM

This course focuses on topics related to responsible conduct of research (RCR). It covers the landscape of "scientific integrity" – both the principles and day-to-day practicalities of research ethics. The course is interdisciplinary in its approach. Readings and other materials used as part of the course draw on examples from many academic fields and are intended to have application to any academic or professional area of study in which research is conducted.

**EPH 625 – Ethical Issues in Epidemiology**

3 credits, Jan - May, 14 weeks, Tues 3:40 - 6:10 PM

The course identifies and analyzes ethical issues in epidemiologic practice and research. Issues include data acquisition and management, confidentiality, valid consent, advocacy, public policy, subgroup stigma, research sponsorship, conflicts of interest, communication of risk, and international and intercultural difference.



### Florida Bioethics Network Conference

*One-day conference held annually in the spring*

The Florida Ethics: Debates, Decisions, Solutions conference is held each spring in South Florida, providing a forum for discussion and a debate of current issues in bioethics and regulatory/public policy issues raised in medical research and practice.

### Dialogues in Research Ethics Monthly Seminar Series

*Fri 12:00 - 1:00 PM*

This series is open to the university community and encouraged for Scholars. It features leading clinicians, researchers, and scholars speaking on scientific integrity and medical ethics. Topics that have been recently covered include scientific fraud and responsibilities, animal use, social implications of genetic testing, and moral hazards in funded research.

## **C.4.iii. Additional Instruction in Grant Writing**

The Miami Clinical and Translational Science Institute (CTSI) offers several opportunities to assist and mentor faculty investigators through key stages of the grant writing process.

### Grant Writing Videos

Mary Lou King, PhD, offered grant writing workshops on writing NIH R- or K-style grants. Video modules of the workshops provide practical, step-by-step advice on all critical aspects of grant writing, including the NIH review process; how grants are scored; writing clear, concise Specific Aims, Research Strategy sections, and Significance and Innovation statements; designing powerful titles; etc.

### CTI 602 – Writing for Translational and Clinical Science

**MSCTI core requirement**

*2 credits, Jan - May, 14 weeks, Tue 4:00 - 6:00 PM*

This course, taught by MSCTI program directors and guest lecturers, focuses on developing grant and manuscript writing skills in the area of clinical and translational science across the translational science spectrum. Topics include how to streamline the writing process; structure each section of an article for maximum impact; build an article around effective hypotheses or purpose statements; highlight the significance of one's work and place it in the context of scientific knowledge; and make an article stand out with an effective abstract.

## **C.4.iv. Scholar Track in Population Science**

Scholars who elect to focus on population science will develop an understanding of emerging trends in disease incidence, morbidity, and mortality by pursuing the coursework outlined below. Such understanding is necessary for informing the rationale and design of effective clinical trials and for improving cancer outcomes for diverse populations. South Florida is characterized by unparalleled multiculturalism, which provides a unique opportunity to promote trials distinctly responsive to the needs of diverse cancer patients. Scholars in this track will have the option to complete the Public Health Certificate Program or pursue a Master of Public Health degree.

### **Training in Disparities Research and Population Sciences**

The Jay Weiss Institute for Health Equity's Pathway in Social Medicine offers exposure to health disparities and intervention methods effective in improving health equity, including applications for community-based research. Four didactic sessions and two community-based experiences will provide training in delivering healthcare information using culturally appropriate strategies.

**EPH 621 – Fundamentals of Epidemiology**

***MSCTI core requirement***

*3 Credits, Aug - Dec and Jan - May, 14 weeks, Tue 1:00 - 3:30 PM*

This course covers principles and methods of epidemiology. Descriptive epidemiology, environmental and other risk factors, detection of outbreaks, basic demography, and etiologic studies.

**CAB 714 – Cancer Epidemiology, Prevention, and Biobehavioral Oncology**

*2 credits, Jan - Mar, 7 weeks, Tues/Thur 3:30 - 5:00 PM, offered alternate years: 2022, 2024*

This course introduces learners to the basic principles of biobehavioral oncology and cancer epidemiology and cancer prevention and control. The course explores cancer epidemiology approaches used to identify the molecular and genetic mechanisms of cancer risk and progression and how these are used to develop predictive models in treatment response. Methods for identifying social, environmental, and biological reasons for cancer disparities among different populations are also covered. Sections on biobehavioral oncology include: health behavior change processes in persons at risk for and diagnosed with cancer; methods to improve adaptation to cancer diagnosis and treatment; psychosocial intervention research techniques and biobehavioral processes explaining their effects on health and quality of life; translation of behavioral and psychosocial intervention to the community; symptom/treatment side effects management approaches; predictors of late effects of cancer treatment; and development of preventative interventions.

**EPH 647 – Community-Based Participatory Research**

***MSCTI elective, Cultural Diversity and Community Engagement***

*3 credits, Jan - May, 14 weeks, Wed 3:40 - 6:10 PM*

Community-based participatory research (CBPR) is an increasingly popular methodology in public health and other disciplines that invites community collaboration throughout the research process from conceptualization of study focus to dissemination of findings. This course will provide an opportunity for students to better understand the process by which community members and academic researchers work collectively to address health disparities and influence social change.

**EPH 617 – Introduction to Disease Prevention and Health Promotion**

***MSCTI elective, Cultural Diversity and Community Engagement***

*3 credits, Aug - Dec, 14 weeks, Mon 1:00 - 3:30 PM*

This course will introduce students to the science of prevention and health promotion. More specifically, through didactic presentations, group discussions, article readings and critiques, and a term project, this course will provide students with an overview of: the top preventable causes of disease in the U.S., the etiology of disease (with a focus on the top preventable causes of disease in the U.S.) across the lifespan, the role of prevention theories in the development of preventive interventions, and the role of methodology in prevention science. The course will also provide an overview of efficacious/effective preventive interventions, including (but not limited to) family, community, and school level interventions. Examples from the fields of obesity, drug use, smoking, and HIV will be used to illustrate the course learning objectives.

**EPH 623 – Determinants of Health and Health Disparities Across the Life Course**

*3 credits May - Jun, 6 weeks Tues/Thur 10:00 AM - 1:00 PM*

This course delves into risk and protective processes related to health outcomes across the life course, from the prenatal period to older adulthood. Class readings and discussions examine examples of common risk pathways contributing to various diseases, including pathways hypothesized to be related to health inequities and disparities, such as economic and educational disadvantage, stress, sedentary behavior and poor behavioral regulation, and social isolation. Common protective pathways that promote health are also reviewed, such as positive parenting and family relations, and social support.

### **EPH 612 – Global Health**

#### ***MSCTI elective, Cultural Diversity and Community Engagement***

*3 credits, Jan, 1 week, Mon/Tue/Wed/Thur/Fri 9:00 AM - 5:00 PM*

This seminar examines current global public health issues, governance, and decision-making challenges for the 21st century across developing, transitioning, and developed countries. Topics of discussion include new actors for world health in the era of globalization; linking human development, poverty, and health inequities; social, cultural, and ethical considerations for health planning; role of industry, trade, and public health; evidence-based research for improved global health initiatives; foreign policy and health security challenges associated with emergence and re-emergence of infectious diseases, and public and private partnerships in global health.

### **EPH 632 – US Health Systems**

#### ***MSCTI elective, Cultural Diversity and Community Engagement***

*3 credits, Jan - May, 14 weeks, Mon 1:00 - 3:30 PM*

This course provides an introduction to the multiple systems that define, describe, and shape the delivery of healthcare in the United States. Using case studies and presentations of major issues, this course will give the learner an appreciation of the dilemma confronting policy makers, providers, and patients: how to balance cost, quality, and access.

## **C.4.v. Scholar Track in Molecular Translational Research**

Calabresi Scholars with a molecular translational research interest will greatly benefit from a number of the courses offered in the Cancer Biology Graduate Program (CAB) and other courses and seminars offered through SCCC. Scholars will select from the coursework below to gain knowledge and reasoning skills essential to understanding targeted cancer therapy (precision medicine). Scholars will be introduced to the major concepts and principles of cell growth control, signaling deregulation, gene expression alternations, and genetic damage that results in cancer.

### **BMB 709 – Advanced Biochemistry and Molecular Biology**

*3 credits, Jan - May, 14 weeks, Mon/Wed 6:00 - 7:15 PM*

This course brings the student to the forefront of research in Molecular Biology. The course material is discussed exclusively in the form of original research papers. Based on this experience, students are required to propose experimental approaches to biological problems and defend them.

### **CAB 710 – Cancer Biochemistry and Molecular Biology**

*3 credits, Jan - May, 14 weeks, Tues/Thur 9:00 - 10:30 AM*

Scholars will participate in select modules of this course, designed to introduce Scholars to the major concepts and principles of cell growth deregulation in cancer with a major emphasis on molecular mechanisms. Topics include: oncogenes, tumor suppressors, mechanisms of uncontrolled cell growth, receptors, and intracellular signal transduction pathways.

### **CAB 713 – Principles of Molecular Cancer Therapeutics**

*2 credits, Mar - May, 6 weeks, Tues/Thur 3:30 - 5:00 PM, offered alternate years: 2019, 2021, 2023*

This course explores the signal transduction pathways critical for cancer cell proliferation and survival that may provide new therapeutic targets and approaches for identification and validation of molecular targets within these pathways. Scholars are introduced to the strategies used in the discovery and design of biological and drug-based therapies and the implementation of clinical trials.

### **CAB 750 – Logic and Reasoning in Translational Cancer Research: Bench to Bedside to Bench**

*3 credits, Aug - Dec, 14 weeks, Tue/Thurs 4:00 - 5:30 PM, offered alternate years: 2018, 2020, 2022*

The goal of this course is to expose Scholars to the scientific reasoning and logic underlying problem solving in clinical cancer research. This course is designed to help participants develop the thought processes necessary to critically evaluate information in the literature and experimental approaches, conceptualize problems in the field, and identify areas for scientific exploration. Participants learn how

the knowledge obtained from basic research laboratories is applied to clinical problems including prevention, diagnosis, prognosis, and therapeutic treatment of cancer. Specific examples of translational research, i.e., laboratory to clinic/clinic to laboratory, are emphasized. Participants also learn the key role of clinical observation in identifying basic research problems.

### **CTI 605 – Introduction to Team Science and Entrepreneurship**

#### ***MSCTI core requirement***

*2 Credits, Aug - Dec, 14 weeks, Tue 4:00 - 5:40PM*

This course will introduce students to fundamental topics in translational science related to team science and entrepreneurship. Through a series of lectures, participatory exercises, and guided discussions, students will learn practical strategies for engaging in team science and for developing a translational research project into an entrepreneurial endeavor.

## **C.4.vi. Molecular Correlative Studies for Clinical Trials in the Omics Age**

The following courses can help Scholars deepen their understanding of the use of molecular correlative studies accompanying clinical trials and the challenges of analysis of complex molecular correlative “omic” data.

### **EPH 651 – Research Methods**

#### ***MSCTI elective, Bioinformatics***

*3 credits, Aug - Dec, 14 weeks, Th 3:40 - 6:10 PM*

The course is designed to introduce students to applied quantitative methods through both lecture-based and experimental strategies. Emphasis will be placed on data collection, data management, and conceptual use of various analytic techniques.

### **HGG 660 – Bioinformatics Theory and Practice**

#### ***MSCTI elective, Bioinformatics***

*3 credits, Jan - May, 14 weeks, Mon/Wed 9:30 - 11:30 AM*

This course covers a gradient of basic to advanced bioinformatics theory, data mining, and analysis. Each class will include a lecture to explain the concepts, followed by a hands-on lab session with worksheets and exercises. Early lectures will cover in-depth searching of the major databases, alignments, and motif discovery. These themes will recur with the applications of these and other algorithms to gene expression analysis, next generation sequencing data and its analysis, and analysis of variation. Freely available web resources will be used wherever possible, and Scholars will learn how to use Python for some bioinformatics applications.