

### MSCI Leadership

**T. Alp Ikizler, MD, Program Director**  
Professor of Medicine, Catherine McLaughlin Hakim Chair in Vascular Biology  
**Satish R. Raj, MD, MSCI, Associate Program Director**  
Assistant Professor of Medicine and Pharmacology  
**Arnita L. King, MEd, Interdisciplinary Program Coordinator**



**Founders of the MSCI program**  
Thomas A. Hazinski, MD  
Nancy J. Brown, MD  
**PI of the founding grant**  
Robert S. Dittus, MD, MPH



### MSCI Biostatistics Faculty

**Ayumi Shintani, PhD, MPH**  
Associate Professor of Biostatistics and Medicine  
• *Biostatistics II, 2004-2012*  
• *Epidemiology, 2008-2009*  
• Vanderbilt Academy for Excellence in Teaching 2012  
• MSCI Teaching Award 2005



**Daniel Byrne, MS**  
Senior Associate in Biostatistics and Medicine  
• *Biostatistics I, 2000-2012*  
• *Medical Writing for Clinical Investigators, 2000-2012*  
• Vanderbilt Academy for Excellence in Teaching 2010  
• MSCI Excellence in Teaching Award 2002-2005



**Yu Shyr, PhD**  
Professor of Biostatistics, Biomedical Informatics, Cancer Biology and Preventive Medicine  
• *Clinical Trials, 2000-2012*  
• Jack Hawiger Teaching Award 2012  
• MSCI Excellence in Teaching Award 2002-2004



### Abstract

Traditional research skills courses, especially statistical courses, are often ineffective and poorly rated by students. Since 2006, VICTR has provided the MSCI program invaluable infrastructure to support an enriched environment for patient-oriented clinical research. The MSCI courses focus on essential skills in conducting clinical investigation including but not limited to, biostatistics, clinical trials, medical writing, clinical epidemiology, drug and device development and database management and creation. All courses are based on applied clinical research data and taught by experienced VICTR-supported instructors who favor real-life examples over complex didactics. Courses use feedback loops for continuous quality improvement based on trainees' inputs and evaluation of long-term retention. Multiple statistical software packages are introduced. MSCI students were the first to test the VICTR supported "Expert Studios", Biostatistics Clinics and vouchers. Currently trainees present their work early in their 1<sup>st</sup> year through VICTR-Studios to multidisciplinary experts for critique, improvements in design and building collaborations. In their 2<sup>nd</sup> year, trainees take advantage of VICTR-Studios for manuscript or grant writing. Future VICTR-supported innovations for MSCI will include the use of VICTR applications REDCap and ROCKET to provide experience in an up-to-date IT environment that employs an automated grading system, interactive learning and video workshops. Since its inception, 68 MSCI alumni are currently managing 44 awards totaling \$16,185,278 and have published more than 700 manuscripts in peer reviewed journals. The exemplary synergy between the MSCI program and VICTR is producing the next-generation leaders in patient-oriented research.

### VICTR support has enhanced the MSCI program

- **Studios** - Trainees present their study design early in their 1<sup>st</sup> year through VICTR-Studio for multidisciplinary review and input. In their 2<sup>nd</sup> year, they will present manuscripts and grants to VICTR-Studios.
- **VICTR Funding** - 54 trainees have received funding from VICTR since 2006 with total awards of \$1,764,682.
- **StarBRITE** - Research resources are organized into this single web portal.
- **Daily Biostatistics Clinics** - All trainees are introduced to Clinics.
- **REDCap** - will provide automated grading and real-time monitoring of classwork.
- **ROCKET** - provides a course website to organize lecture notes and datasets and also for trainees to post their questions.

### Courses and Instructors

#### Core Courses

- Biostatistics I (Daniel Byrne)
- Biostatistics II (Ayumi Shintani)
- Case-Studies in Clinical Investigation I, II (T. Alp Ikizler, Satish R. Raj)
- Clinical Scientist Career Seminars (T. Alp Ikizler and William Cooper)
- Clinical Trials (Yu Shyr)
- Drug and Device Development (Satish Raj)
- Epidemiology I: Clinical Epidemiology (Karel G.M. Moons)
- Grant Writing (Wayne Ray)
- Master's Research (T. Alp Ikizler, Satish R. Raj)
- Medical Writing for Clinical Investigators (Daniel Byrne)
- Molecular Medicines (Chae Lim)
- Research Ethics and Scientific Integrity (Elizabeth Heitman)

#### Elective Courses

- Cancer Biology (Fiona Yull)
- Data Management (Paul Harris)
- Epidemiology II (Wayne Ray)
- Human Genetics Epidemiology (Scott Williams, Dana Crawford)
- Molecular and Cellular Immunology (Sebastian Joyce)
- Proteomics (Lorraine Ware)
- Research Skills (Carlos Orozco)

### Financial Assistance

- Vanderbilt Physician Scientist Development Program
- Vanderbilt Clinical and Translational Research Scholars Program
- Vanderbilt Clinical Oncology Research Career Development Program
- Building Interdisciplinary Careers in Women's Health (BIRCWH) Career Development Program
- Vanderbilt Environmental Health Science Scholars Program
- MSCI-CTSA Scholarship
- MSCI Minority Scholarship
- MSCI Hazinski Scholarship

\* MSCI helps candidates with identifying funding opportunities.

### How to Apply

#### Required Application Materials

1. Letter from mentor documenting commitment to candidate's career development. Please include a copy of the mentor's CV.
2. Three letters of recommendation (may include mentor).
3. Letter from Division Director or Department Chair assuring 80% protected time for research.
4. Research Plan: The three to five page proposal should describe Specific Aims, Background and Significance, Experimental Methods, Procedures, and Long-Term Objectives. Plans exceeding the five-page limit will be returned. Be sure to provide a title for your project.
5. Curriculum Vitae of applicant.
6. Statement of how this proposed research plan fits into your career objectives.
7. Letter stating confirmation of tuition payment from responsible person or department.
8. Undergraduate and medical school transcripts.

#### Proposals will be evaluated on the following criteria:

Proposals must outline patient-oriented research that is hypothesis-driven and mechanistic. Performance of the project must be feasible within a two-year period. Project mentors must have extramural research grant funding that is assured for the duration of the project. Sponsoring departments will be expected to guarantee that 80% of the candidate's professional time will be devoted to the goals and objectives of the MSCI program.

### Number of Trainees, Publications and Funds

- 122 trainees completed the MSCI program.
- 29 trainees are currently enrolled.
- 68 MSCI alumni are currently managing 44 awards totaling \$16,185,278.
- MSCI trainees have published more than 700 manuscripts in peer reviewed journals.

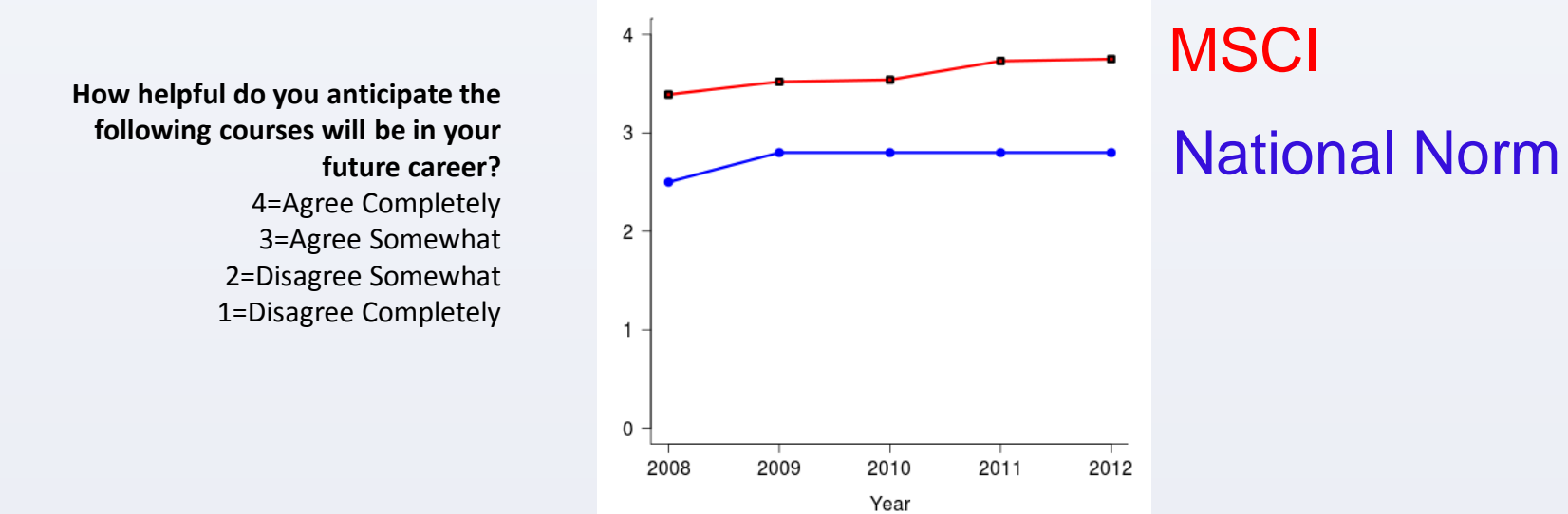


2012 MSCI Biostatistics I Class

### Trainees by Specialty Area

Specialty Area	Number
Clinical Pharmacology	16
Nephrology	11
Hematology/Oncology	10
Surgery	10
Pediatric Cardiology	9
Allergy, Pulmonary, Critical Care	8
Industry	8
International/Global Health Scholars	7
Pediatric Hematology/Oncology	7
Cardiovascular Medicine	6
Pediatric Critical Care and Anesthesia	6
Pediatric Gastroenterology	5
Diabetes, Endocrinology, Metabolism	4
Medicine Other	12
Pediatrics Other	10
Other	2
<b>Total</b>	<b>151</b>

### Quality of the Training

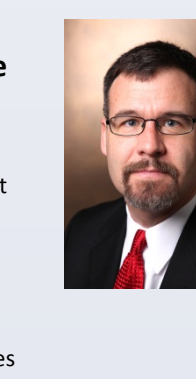


MSCI indicates average rating of the following courses (Biostatistics I, II, Clinical Trials, Epidemiology I) National Norm indicates average rating for Biostatistics and Epidemiology from 2012 Medical School Graduation Questionnaire, All Schools Summary Report & Individual School Report, Association of American Medical Colleges, Administrative Summary

### Testimonials



**Timothy Girard, MD, MSCI, Assistant Professor Allergy/Pulmonary & Critical Care**  
Vanderbilt's MSCI Program has an indispensable part of my training to become a clinical investigator. The courses I completed as well as the mentorship and hands-on experience I received during the two-year program came at a pivotal time in my career young investigator. Formal training in statistics, epidemiology, clinical trials, research ethics, medical writing, grant preparation and many other areas important to the successful conduct of clinical research prepared me on the path to become an NIH-funded investigator, completing and publishing large clinical studies that can make a difference to patients throughout the world. Upon completing the MSCI Program, I was able to publish the results of my MSCI project in a high-impact medical journal and successfully compete for funding from a private foundation and the NIH. I highly recommend the program to anyone whose goal is to have a career as an independent clinical investigator.



**Todd W Rice, MD, MSCI, Assistant Professor Allergy/Pulmonary & Critical Care**  
My MSCI degree has been invaluable. I have used the knowledge I gained in the program to design multiple multi-center clinical trials and it has afforded me instant credibility in dealing with some of the most experienced investigators in these endeavors. I have applied the statistical knowledge that I learned to numerous projects and many investigators seek me out to collaborate because of my ability to undertake and understand statistics. In my role as Assistant Professor, my MSCI has been great for passion for teaching. I have used the degree to better understand the literature in my field which has resulted in me hosting an informal journal club for our fellows. This is one of the endeavors that I enjoy the most.



**Edward D Siew, MD, MSCI Assistant Professor, Nephrology**  
The MSCI program has helped me since the beginning of my research career at Vanderbilt. Bringing in an initial project to be used as a substrate for the coursework helped focus my efforts on how to design, conduct, and write about my findings. The MSCI course also provided encouragement from other peers at the same stage in their careers and helped me to make new and collaborative relationships with some of the instructors beyond the coursework itself. I was excited to see how applying the skills learned in the MSCI towards publishing my first quality manuscript snowballed into invitations to give talks on the topic and author reviews. That productivity has enabled me to remain at Vanderbilt on faculty, compete successfully for career development funding, and has positioned me well to compete for independent level funding.



**E. Wes Ely, MD, MPH, Professor (Mentor) Allergy/Pulmonary & Critical Care**  
We have been fortunate enough to attract mentees whom I consider among the best and brightest. And yet before the MSCI program, it was extremely laborious to train those who did not have a formal tool box regarding clinical investigation skills. After my mentees took MSCI courses, there was a night-and-day difference in their abilities as scientists. MSCI course were so key in helping to develop their research tool box. They went from clinicians to clinician-scientists. Now they have designed and conducted investigations published in the highest impact journals such as Lancet and JAMA, studies that others look at as a template by which to design future research. They went from a very rudimentary stage of scientific development into true expertise.



**Kelly A Birdwell, MD, MSCI, Assistant Professor, Nephrology**  
MSCI immediately helped me to get VPSD and K23 grant awards, which I feel would not have been competitive for me without MSCI training. Reviewers of these grants commented how well I was clearly qualified as an applicant, and that was likely to be successful with my MSCI preparation. Through my training I can now identify challenges in conducting certain types of clinical trials and I have solutions for that. My colleagues now look at me differently, and they expect me to know more about conducting clinical trials. At national meetings, I am prepared to answer comments on study design and statistical methods, raising the quality of my research. I now have the tools to do quality work in medical writing, including but not limited to grants and manuscripts, which is highly valuable. Finally, the MSCI experience places one at the forefront of a network of research opportunities for novel science and networking - rarely are such opportunities readily available to fellows and junior faculty otherwise. In trying to be a successful clinical translational physician scientist, the MSCI truly positioned me in an excellent manner. The training and research experience also helped to form the foundation of my K23 award and helped to hasten my development as a valuable team member to my research group.



**Eric D Austin MD, MSCI, Assistant Professor Pediatric Allergy, Immunology and Nephrology**  
I came to Vanderbilt for fellowship in part because of MSCI program. For a variety of reasons, the MSCI provides a number of very important things to augment one's training as a physician-scientist. First, mentors and the entire scholarship oversight committee are required to be very involved in our career development experience. The MSCI created a great framework by which that was established early on as I transitioned from a 1st year of clinical fellow to a fellow doing a research. The assurance of an engaged mentor who nurtures your career development is incredibly valuable. Second, the MSCI training creates a terrific framework in a number of vital disciplines, including biostatistics, epidemiology, and clinical design. Third, the MSCI program provides in depth training in medical writing and presentation, including but not limited to grants and manuscripts, which is highly valuable. Finally, the MSCI experience places one at the forefront of a network of research opportunities for novel science and networking - rarely are such opportunities readily available to fellows and junior faculty otherwise. In trying to be a successful clinical translational physician scientist, the MSCI truly positioned me in an excellent manner. The training and research experience also helped to form the foundation of my K23 award and helped to hasten my development as a valuable team member to my research group.



**Satish Raj, MD, MSCI, Assistant Professor Clinical Pharmacology**  
Like many of the MSCI students, I came to the MSCI program with excellent clinical training and an interest in clinical research, but without the skills necessary to carry out clinical investigation. The MSCI was a critical component of my research training. Courses such as Biostatistics and Clinical Trials gave me practical skills that have applied in writing up research protocols of my own. Drug & Device Development gave me insights into the Drug Development process that is entirely absent in medical training. Importantly, the MSCI was not just about theory but about applying knowledge gained from the classes to patient-oriented research projects. The skills gained from MSCI positioned me to be a great first author on a NIH Clinical Research Early Career Development Award (K23).



**Ingrid Mayer, MD, MSCI Assistant Professor, Hematology-Oncology**  
This program provides a very comprehensive curriculum that I designed and implemented. Another important part of the MSCI training focused on how to successfully apply and get grants. My MSCI thesis project became my Career Development K23 award, and I have also been awarded a highly competitive Breast Cancer Research Foundation - American Association for Cancer Research (AACR) Grant for Translational Breast Cancer Research. I currently serve as the Clinical Core Director and co-Leader in two translational research projects in the Vanderbilt Breast Cancer SPOC. The MSCI training was incredibly valuable in assisting all these endeavors, and I strongly recommend it to anybody considering an academic career in Clinical Research!



**Madan Jagasia, MD, MSCI, Associate Professor Section Chief, Hematology & Stem Cell Transplant**  
Hi Dan, Ayumi, and Yu,  
I wanted to let you both know that I recently got promoted to Associate Professor. I could not have done without MSCI and specifically the three of you. I am currently leading a national multicenter randomized double blind study in primary prevention of ocular GVHD. The lessons I learned in MSCI have been invaluable. I still open my binders when I have questions and looking at the notes brings back old memories. (2009)  
With being 6 years post-MSCI, I am now guiding students, residents, fellows as they start their research careers. The principles, attention to detail, and knowledge that I acquired during MSCI has been instrumental. MSCI has defined my career. I apply the principles of MSCI even in my daily administrative duties. My only regret - wish I had done MSCI 5 years earlier! (2012)

### Requirements for completion

- **Didactic Work** - 36 credit-hours of courses comprising 20% of time commitment.
- **Mentored Research Apprenticeship** - Completion of a mentored research project with 80% of time commitment mentored by an established physician-scientist.
- **Career Path Development** - Seminar series to meet successful patient-oriented researchers and to learn academic "rules of the road".
- **Final Project Submission** - Submission of a manuscript to peer-reviewed journals or completed proposal for a federal grant or major foundation.

### Key Factors for Successful Classroom Learning

- The MSCI courses use **modern statistical methods and technology**.
- The MSCI courses teach students to become statistically multilingual via applied knowledge to several state-of-the-art **statistical software packages**.
- All courses are taught with advanced concepts **without an overwhelming amount of technical jargon**.
- All lectures blend concept with **hands-on exercises on laptops** to reinforce learning.
- **Continuous Quality Improvement** methods are used to improve the courses including (1) **Feedback loop** during the courses, (2) **Expanded course evaluations**, (3) **6-month follow-up of retention**.

- All courses are based on **applied clinical research data and projects**; and are taught by experienced instructors who de-emphasize didactics in favor of **medical research examples**.
- 1 to 1 tutoring is provided by **teaching assistants**.
- Exposure to **statistical guidelines** from high-profile medical journals.
- **Experience-based learning** - e.g., a random number predictive modeling project, a logistic regression modeling contest.

### Conclusions

VICTR's financial and resource support have provided MSCI trainees with invaluable real-world exposure to research applications, leading clinical researchers in multiple disciplines, and opportunities to develop collaborative relationships. Trainees will graduate ready to participate in the competitive fields of research, publishing, and grantsmanship.