

Academic Senate – December 3, 2007  
Executive Committee – November 19, 2007



2 October 2007

A. Lorris Betz  
Senior Vice President for Health Sciences  
Building 550, 5<sup>th</sup> Floor  
Campus

Dear Vice President Betz:

At its meeting of 24 September 2007, the Graduate Council voted to approve a proposal to create a Master of Science in Clinical Investigation degree within the School of Medicine.

The Master of Science in Clinical Investigation will train students in research methods for independent investigation, primarily targeting junior faculty, fellows and residents, as well as clinical doctoral students in areas such as Nursing, Physical Therapy and Pharmacy.

The M.S. in Clinical Investigation is currently supported by the NIH K-Award program, and addresses a nation-wide increasing need for investigators. Additionally, funding agencies have an increasing expectation of the training standards for candidates for research awards.

A copy of the proposal is attached for your approval and transmittal to the Academic Senate.

Sincerely,

David S. Chapman  
Associate VP for Graduate Studies

The Graduate School  
302 Park Building  
201 South Presidents Circle, Room 302  
Salt Lake City, Utah 84112-9016  
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28 September 2007

Matt Samore, MD  
Chief, Division of Epidemiology  
AC226 SOM  
Campus

Dear Dr. Samore,

I am pleased to inform you that in its meeting on 24 September 2007, the Graduate Council unanimously approved your proposal to create a Master of Science in Clinical Investigation degree in the School of Medicine.

The Council asks for two minor revisions to the proposal: 1) consolidate courses (see pages 10 and 11); and 2) address sustained funding should the K-Award funding cease.

Once the revisions have been made, please forward the proposal to Lisa Blair in the Graduate School for transmittal to Senior Vice President Betz.

Sincerely,

David S. Chapman  
Dean

cc: Carol Sweeney  
James Kushner  
Donald McClain  
David Bjorkman

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Request for Program Approval  
Master of Science in Clinical Investigation (MSCI)

Submitted by

School of Medicine  
University of Utah

May 2007  
Revised October 2007

## **SECTION I: The Request**

The School of Medicine at the University of Utah requests approval to offer the Master of Science in Clinical Investigation (MSCI) effective autumn, 2007.

## **SECTION II: Program Description**

The MSCI degree program provides classroom and mentored research experience in clinical research, preparing its trainees for careers in clinical investigation, both in academic medicine and the allied health sciences. The program prepares trainees to be competitive investigators capable of gaining extramural funding for their clinical research projects. The curriculum of the MSCI focuses on the theories, models, methods, and tools used by investigators who conduct bench-to-bedside and bedside-to-community translational research. Candidates for the MSCI degree will elect one of two areas of emphasis or “tracks”. The first track emphasizes the inherited basis of human disease, mechanism-oriented clinical research, and bench-to-bedside translational research. The second track emphasizes epidemiology, health services research, and bedside-to-community translational research. The program is designed to support a mentored research experience for fellows and junior faculty members at the University of Utah School of Medicine and allied health science fields.

### **Purpose of Degree**

Well-trained clinical investigators represent a vital resource for the advancement of scientific knowledge and the development of improved treatments for human disease. The goal of the MSCI is to provide superior, coordinated didactic and practical training for individuals interested in academic careers in clinical investigation. The program prepares trainees to be competitive investigators capable of gaining extramural funding for their clinical research projects. The program is designed to prepare the next generation of effective clinical investigators in academic departments and academic medical centers. This degree program addresses the need for research training for individuals seeking careers in academic medicine. The M.S. degree program represents an extension of an existing program at the School of Medicine that has been funded by the National Institutes of Health (NIH) for the past seven years through a mechanism designated the K-30 Clinical Research Curriculum Award.

### **Institutional readiness**

A Masters Degree program for participants in the K-30 program was first considered several years ago. We have already implemented many of the procedures required to be eligible to offer a degree granting program. Through the K-30 award, we established the Training Program in Clinical Investigation (TPCI), a two-year curriculum suitable for a Master’s Degree. The courses that make up the didactic portion of the program are listed in the current University catalog. Courses specific to our program carry the designation “MDCRC”, a designation indicating that the General Clinical Research Center (GCRC) is the organization within the School of Medicine sponsoring the courses. Some of the courses in the didactic curriculum are graduate level courses sponsored by other departments, particularly Medical Informatics, Biochemistry and Human Genetics.

The MSCI is complementary to a number of NIH-funded training programs in the School of Medicine. These NIH K-12 and T-32 programs support training in specific areas of medicine; the coursework in the MSCI provides the didactic classroom curriculum in research methods required for trainees in these programs. All of these peer-reviewed programs provide evidence of the existing capacity for providing research training within the University of Utah's School of Medicine. The NIH-funded training programs are the following:

Training in Cardiovascular Research (T32HL007576-22, Benjamin, Ivor PI)  
Genetic Models of Cardiovascular Renal & Pulmonary (T32HL079874-02 Capecchi, Mario, PI)  
Research Training In Hematology (T32DK007115-32 Kushner, James, PI)  
Research Training in Inherited Neurological Disease (T32NS007493-05 Leppert, Mark, PI)  
Developmental Biology Training Program (T32HD007491-11 Mango, Susan, PI)  
Training Program in Genetics (5T32GM007464-30 Stillman, David, PI)  
Multidisciplinary Cancer Research Training Program (T32CA093247-05 Virshup, David, PI)  
Training Program in Microbial Pathogenesis (T32AI055434-03 Weis, Janis, PI)  
Utah BIRCWH Career Development Program in Women's Health (5K12HD043449-05 Bjorkman, David, PI): provides training and career development for four scholars from three departments in the School of Medicine (Neurology, Pulmonary Medicine and Plastic Surgery) and one from the College of Health (Physical Therapy)  
Genetic and Developmental Mechanisms of Pediatric Disease (5K12HD001410-04 Clark, Edward, PI): has four trainees, one each in Pediatric Hematology/Oncology and Pediatric Critical Care and two in Neonatology  
Pediatric Critical Care Scientist Development Program (5K12HD047349-03 Dean, Jonathan, PI): supports research career development for junior faculty in pediatric critical care (currently there are seven participating scholars).

University of Utah faculty members are principal investigators of more than 200 current investigator-initiated research awards (R01) from the National Institutes of Health in diverse fields, an indication of a thriving environment for biomedical research and of opportunities for mentorship of MSCI students. Trainees in the existing K-30 program and in the proposed MSCI will benefit from several multi-investigator research programs that are in place at the University of Utah School of Medicine.

*The Human Molecular Biology and Genetics (HMBG)* program, created in 1987 with funds from the Eccles Foundation and from the Lucille P. Markey Charitable Trust, has been a highly successful program that supplies funding and space for young faculty recruits, most whom are physician-scientists with research interests in human molecular biology. Twenty-four current and past faculty members at the University have been recruited through the HMBG program. The HMBG program is located in the Eccles Institute of Human Genetics and is directed by Dr. Guy Zimmerman. The HMBG Program has also established and administers a second interdisciplinary initiative termed

The Fellowship to Faculty Transition (FTFT) Program. The subsidiary FTFT Program provides a structure for mentorship and financial support that permits carefully selected junior faculty members a period of development and training before requiring them to assume the full responsibilities of a tenure-track faculty member. Since its establishment in 1995, the FTFT Program has supported sixteen new faculty investigators, all of whom have been M.D. or M.D./Ph.D. scientists.

*The Informatics, Decision Enhancement, and Surveillance (IDEAS) Center*, directed by Matthew Samore, M.D. and housed at the Salt Lake Veteran's Affairs Medical Center, focuses on implementing and evaluating informatics tools and interventions that integrate decision support and surveillance in order to improve outcomes.

*Integrated Clinical Research Networks* are inter-institutional systems established by the NIH to ensure that high-quality clinical studies and trials can be conducted effectively and efficiently. The University of Utah has been selected to participate in three: The Heart Failure Clinical Research (PI: David Bull, MD and Co-PI: Dean Li, MD, PhD) The Stillbirth Research Collaborative Networks (PI: Robert Silver, MD) The Myeloproliferative Diseases Research Network (PI: Josef Prchal, MD). The inclusion of the University of Utah in these networks provide a rich resource for physician-scientists and Ph.D.-scientists to participate in clinical trials of novel diagnostics and therapeutics, and offers access to data throughout these national networks.

*The Utah Population Database (UPDB)* is a unique source of information for genetic and health studies. The UPDB is based on an extensive set of Utah family histories, traced back over generations, in which demographic and medical information of family members are linked can be traced back through pedigrees. This database has been drawn upon for 30 years of groundbreaking genetic research at the University of Utah and continues to be a resource for novel studies.

## **Faculty**

The Master's Degree in Clinical Investigation will be awarded by the School of Medicine rather than by a particular department within the School of medicine. The Program will be supervised by an Executive Oversight Committee consisting of John Hoidal, M.D., The Clarence M. and Ruth N. Birrer Presidential Endowed Chair, Chairman of the Department of Internal Medicine, Donald McClain, M.D., Ph.D., Program Director of the GCRC, Matthew Samore, M.D., Ph.D., Professor of Medicine and Director of the track two curriculum, James Kushner, M.D., M.M. Wintrobe Distinguished Professor of Medicine, Director of the track one curriculum and Associate Program Director of the GCRC, Carrie Byington, M.D., Professor of Pediatrics and Associate Program Director for Pediatric Research of the GCRC and Lynn Jorde, Ph.D., Professor of Human Genetics.

Existing faculty in the School of Medicine are well-qualified to conduct both the classroom teaching and research mentoring for this program. Faculty mentors are regular

full-time faculty at the School of Medicine and in several other schools and colleges. Most individuals are tenured faculty and have been awarded the appropriate terminal degree for their field and specialty. The average teaching load of faculty participating is generally restricted to one course per semester. There are no immediate plans for additions to the faculty.

Current faculty are listed in Appendix C.

### **Staff**

The MSCI will require staff support for administrative tasks of overseeing course scheduling and registration, handling student applications, and maintaining student records. A staff member funded by the K30 award and the GCRC provides this support.

### **Library and Information Resources:**

The Eccles Health Sciences Library provides print and on-line access to biomedical journals and other bibliographic materials for students and faculty from all health sciences programs at the University of Utah. This existing resource will meet the needs of students in the Clinical Investigation program.

### **Admission Requirements**

The MSCI is a post-graduate program intended for clinicians who have completed a MD, DO, or DMD degree. The program is also open to individuals with other training such as a clinical doctoral degree in areas such as Nursing, Physical Therapy and Pharmacy. Because the training program does not provide stipends, candidates will generally be chosen from among those individuals who have been accepted into a fellowship training program at the University of Utah School of Medicine. Applicants must fill out an application form for the Clinical Investigation program and provide three letters of reference. One letter must be from a mentor in the applicant's home department, stating that the applicant, if accepted, will have protected time to participate in the program. Each applicant must submit a statement of intent, describing his or her career status, areas of interest in clinical investigation, reasons for applying to the program, and career development objectives. Students must apply and be accepted to the University of Utah.

### **Student Advisement**

A student starting the program will identify a mentor within his or her department or area of clinical expertise. Students will be responsible for identifying two University of Utah faculty members to serve with their mentor on their thesis advisory committee. The primary responsibility for monitoring the progress of students through the program will lie with the research mentor and the Thesis Advisory Committee members. Semi-annual reports from the research mentor will be required.

### **Justification for Number of Credits**

Thirty-three credit hours will be required to graduate from the program. Track one students must take 20 credits of required core courses in addition to the 13 credits for their mentored clinical research projects. Track two students must take 18 credits of

required core courses and two credits of elective courses in addition to the 13 credits for the mentored clinical research project. The expected time to completion of the MSCI degree is two years.

The curriculum for our current K-30 program begins with a six-week intensive block of didactic courses and workshops. This block begins in July for new students entering the program. Students in both tracks take a group of common core courses in epidemiology, data management, bioethics, biostatistics and they participate in a longitudinal research seminar series. In addition, students from both tracks participate in weekly workshops covering a broad range of topics. Students enrolled in track one (the Inherited Basis of Human Disease) also take introductory didactic courses in Biochemistry for Clinical Investigators and Genetics for Clinical Investigators. Students in track two (Epidemiology and Health Services Research) take track specific courses in epidemiology and study design.

Because the Master's program is intended to train individuals intending to pursue careers as independent clinical investigators, the preferred culmination of the mentored clinical research project will be the preparation and submission of an NIH career development application (K-23, K-08) or an equivalent federal or foundation career development grant. The career development application must pass the review of the senior Executive Oversight Committee. With the approval of this committee, a peer-reviewed research paper in a leading journal may be accepted as an alternative culminating graduate project.



### **External Review and Accreditation**

The program has received external peer review through the process of application for and renewal of the NIH K-30 Clinical Research Curriculum Award.

### **Projected Enrollment:**

On average, twelve students and ten auditors have participated in the K-30 curriculum each year since July 2001 when the program began accepting students. The current pool of potential applicants is large. In the School of Medicine, there are currently 143 assistant professors and instructors who are within two years of their initial appointment and 128 clinical fellows. The College of Nursing has 56 pre-doctoral students. The College of Pharmacy has 93 pre-doctoral students and 38 post-doctoral fellows. Over sixty individuals are currently T32 trainees in the School of Medicine. We anticipate that enrollment in the MSCI will be 10-15 new students per calendar year.

### **Expansion of Existing Program**

The proposed MSCI is an extension of the existing Training Program in Clinical Investigation, which has been a functional entity for the past seven years. The faculty is already delivering a quality didactic program. Most of the courses for the MSCI (Appendix A) have been taught in the past.

## **SECTION III: Need**

### **Program Need**

Recent studies from the Institutes of Medicine, the National Research Council, the National Academy of Sciences and the NIH have documented deficiencies in the ability of American Medical Schools to produce qualified clinical investigators capable of combining clinical observations with knowledge generated in the laboratory. Opportunities for productive clinical research that have been generated by advances in genetics, molecular biology and epidemiology have not been adequately capitalized upon. Fostering the translation of new discoveries to practical health benefits for the population is a high priority for the NIH. Successful translational research depends upon a bi-directional flow of ideas between basic science laboratories and the clinical environment but impediments to the development of productive research programs have occurred at two stages. The first is translation from basic science discoveries to clinical trials in humans, the “bench-to-bedside” stage. The second is the translation of new knowledge to clinical practice, the “bedside-to-community” stage. These impediments are due in large part to failure to teach the methods required to perform scientifically rigorous clinical research during medical school and post-graduate medical training. Furthermore, in many academic centers, basic and clinical investigators are housed in separate facilities and have limited opportunities for collaboration. Other obstacles, such as issues of intellectual property and patient confidentiality, have also limited interactions between clinicians, basic scientists, and industry.

Most clinicians, even those with Master Degrees, are not adequately trained in research design and quantitative methods in order to apply or supervise the use of these methods in their own research projects and thus are not able to develop competitive

proposals as principal investigators for external grant funding. The MSCI will prepare clinicians for the transition to clinical investigator status. In recognition of the challenge of translational research and need for research training for clinicians, many universities have developed a Master of Science in Clinical Investigation or a comparable graduate degree in clinical research; these include Vanderbilt University, Northwestern University, University of Texas, New York University, the University of Minnesota, Emory University, the University of Pittsburgh, Washington University, Cornell University, University of California Los Angeles, Boston University, and Johns Hopkins University.

In response to this need for translational research training for clinicians, the University of Utah's School of Medicine, with support from an NIH K-30 Clinical Research Curriculum Award, developed a Training Program in Clinical Investigation. Our Clinical Investigation curriculum was focused, at first, on the inherited basis of human disease, an area of clear strength of the faculty of the School of Medicine; this emphasis continues as track one of the MSCI curriculum. Many prospective students are interested in clinical epidemiology and health services research, a need addressed by track two.

### **Labor Market Demand**

This program is designed to prepare medical fellows and medical school junior faculty members with the research skills needed to advance their careers in academic medicine. Recruitment of young faculty in clinical departments of Schools of Medicine around the country remains a challenge. On the website of the American Association of Medical Colleges there are 2,590 listings describing available junior faculty positions. The need for new faculty members is unlikely to diminish. At the University of Utah's School of Medicine, the average number of junior faculty positions advertised each year is 35. Faculty applicants with career development funding are intensively recruited by schools of medicine around the country and because the proposed Master's Degree in Clinical Investigation is designed to create individuals well qualified to apply for career development awards, the market demand for our graduates is predicted to remain high. Among students who have participated in the University of Utah's Training Program in Clinical Investigation in recent years, 32 have become faculty members at the University of Utah or elsewhere and 17 have already received independent awards from the NIH or professional societies to support their research efforts as young faculty members.

### **Student Demand**

Since the initiation of didactic course work in the K-30 program in July 2001, 235 trainees have participated. Of these, 72 were full-time K30 trainees, while 163 were part-time participants in selected K-30 courses. Most of the part-time participants were individuals already holding junior faculty positions in the clinical departments of the School of Medicine. Because of the program's success in generating successful career development applicants, Division Chiefs and Department Chairs continue to direct fellows and junior faculty to the program. In addition, Drs. Kushner and Samore give presentations to diverse School of Medicine departments to recruit students to the program. This has ensured a steady stream of applicants.

### **Similar Programs**

No other didactic curriculum or degree program exists at the University of Utah, nor in the intermountain region, that is specifically directed toward clinicians seeking research skills for clinical investigation. Only the MSCI focuses directly on translational research and is specifically linked with the NIH funded K-30 Clinical Research Curriculum Award.

Track one emphasizes research methods for studies of the inherited basis of human disease. Track two offers training in study design and research methods in epidemiology, health services research, clinical decision-making, cost effectiveness, and implementation science. The track one curriculum is complementary to the M.S. in Genetics whereas track two is complementary to the graduate programs in Public Health and Biomedical Informatics.

A key distinction between the MSCI and these other programs is that they target students with different goals and have dissimilar culminating activities. The Masters of Public Health degree requires a public health practicum and capstone as culminating activities, whereas the Master of Science in Clinical Investigation requires a master's thesis based on mentored clinical research project. The Informatics program emphasizes application of computer and information science, whereas training in Clinical Investigation focuses on study design and data analysis methods appropriate for clinician investigations.

The University of Utah's Public Health graduate program, Biomedical Informatics graduate program, Biostatistics track of the Master of Statistics program, and MSCI Track 2 program, although distinct in their goals and targeted student populations, do have areas of subject matter that are in common in their didactic curricula. The track 2 program faculty initiated a meeting with faculty from these other programs in Spring 2007 to discuss improving coordination across the programs. As follow-up to the meeting, the faculty compiled information about courses of potential common interest; these lists of selected courses were distributed to help students to identify relevant electives from the other programs. The faculty from the four programs agreed to meet twice a year to discuss future steps such as cross-listing of courses and adjusting curricula to address potential overlap.

### **Collaboration With and Impact on Other USHE Institutions**

The proposed MSCI degree is a medical school program, with the University of Utah being the only Utah state higher education institution with a medical school. No other Utah state higher education institution already offers a degree that is similar to, or competitive with, the proposed MSCI degree. Specifically, no other institution has a graduate degree in human genetics or a graduate degree oriented towards health care research. The only even remotely similar degrees are the MS in nursing offered by BYU and the Master of Science in Nurse Education offered by Westminster College. Although students in these two programs might take research oriented classes, such as statistics, the programs are not oriented towards research training. In summary, there will be no impact

on or opportunities to collaborate with the other institutions in offering the proposed MSCI degree.

### **Benefits**

Students enrolled in the MSCI program have made commitments to careers as academic investigators and will participate in the discovery, creation and transmittal of knowledge through the educational and training programs in which they will participate. It is expected that the majority of the students completing the proposed Master's program will do independent research and contribute to the field of biological sciences and clinical medicine both locally, at the state-wide level and at the national level. Because many enrollees will be fellows or junior faculty in the School of Medicine, the program will support the School of Medicine and Health Sciences Center in developing and sustaining a research-productive faculty.

### **Consistency with Institutional Mission**

The University of Utah and its various schools, colleges and graduate programs is designated a type one university (doctoral/research university) according to policy R312 entitled: "Configuration of the Utah System of Higher Education and Institutional Missions and Roles". The proposed Master's Program in Clinical Investigation fits well with the described mission. The program is designed to train independent clinical investigators who, through their research, will improve the health of the citizens of Utah.

This program is closely consistent with the mission of the School of Medicine, supporting it in its missions of education and research, most notably, its mission of postdoctoral training of biomedical scientists.

## **SECTION IV: Program and Student Assessment**

### **Program Assessment**

The success of the MSCI will be evaluated using multiple indicators. The number of new students enrolled each year will be an indicator of continued need for the program and of the program's reputation. Course evaluations by students will be used to assess success of individual courses and as a basis for continuing to improve the curriculum to meet student needs. The success of the degree program overall will be evaluated by monitoring the number of students completing the degree each year, the number of former students awarded research funding for proposals submitted through peer-reviewed, competitive mechanisms, and the progress of former students in their academic careers.

### **Expected Standards of Performance**

Students will be expected to make timely progress toward completion of the degree. Mastery of material addressed in individual courses will be assessed through performance on written assignments, exams, and presentations. The Master's Thesis will be expected to be of a standard comparable to peer-reviewed grant proposals or to manuscripts submitted to peer-reviewed biomedical journals.

## **SECTION V: Finance**

The program is currently funded at a level of \$300,000 per year through the award from the NIH. The School of Medicine is currently preparing an application for a Translational Science Award in response to a request for applications from the NIH. The K-30 program and the proposed Master's Degree Program in Clinical Investigation represent a central element in the Clinical Translational Science Award application. The budget for the educational component for that application is approximately \$500,000 annually. No internal reallocation of University funds will be required for the proposed Master's Degree in Clinical Investigation program.

### **Budget**

Salaries and Wages:	196,165
Benefits:	61,544
Travel	3,000
Course materials:	10,900
Other:	<u>3,250</u>
 TOTAL:	 274,859

### **Funding Sources**

Our competing renewal application to the NIH for the K-30 program was successful and we obtained funding for an additional five year period. We are now prepared to move forward with a Master's Degree program. We currently receive approximately \$300,000 annually from the NIH to support this program. No University funds will be required to establish the proposed new Master's Degree program in Clinical Investigation. Looking further into the future, we anticipate ongoing support for this training program through the NIH Clinical Translational Science Award mechanism. If external funding for the program is lost in future, the number of courses that can be offered specific to the MSCI degree will have to be reduced. In this situation, the degree program may continue to be offered by revising the curriculum requirements to include more courses taken through other programs such as Public Health and Biomedical Informatics.

### **Reallocations**

None.

### **Impact on Existing Budgets**

None.

## **Appendix A: Program Curriculum**

The MSCI degree will provide two tracks, or areas of emphasis. The first track emphasizes the inherited basis of human disease, mechanism-oriented clinical research, and bench-to-bedside translational research. The second track emphasizes epidemiology, health services research, and bedside-to-community translational research.

The course requirements for graduation are listed below. In addition to required and elective courses offered specifically for the MSCI degree, which are designated MDCRC, students may select electives from other graduate programs such as Biomedical Informatics (BMI), Public Health (FPMD), and Master of Statistics (STAT).

### *Required Core Courses (credits)*

#### *Both Tracks 1 and 2*

- MDCRC 6000 Introduction to Biostatistics (1)
- MDCRC 6010 Introduction to Epidemiology (1)
- MDCRC 6020 Data Management (1)
- MDCRC 6040 Design and Implementation of Clinical Trials (2)
- MDCRC 6410 Research Seminar Series (summer 1)(Fall 0.5)(spring 0.5)
- MDCRC 6430 Bioethical Issues in Clinical Research (1)
- MDCRC 6450 Grant Writing (2)
- MDCRC 6970 Mentored Clinical Research Project (13 hours)

#### *Track 1 Specific*

- MDCRC 6400 Medical Genetics for Clinical Investigators (1)
  
- MDCRC 6420 Genetics of Complex Diseases (2)
- MDCRC 6500 Gene Localization-Principles and Practice (2)
- MDCRC 6510 Molecular Biology for Clinical Investigators (1)
- MDCRC 6520 Biochemistry for Clinical Investigators (2)
- MDCRC 6530 Utilization of Animal Models in the Development of Clinical Research Projects (2)

#### *Track 2 Specific*

- MDCRC 6030 Computer Practicum (1)
- MDCRC 6100 Epidemiology Seminar (1)
  
- MDCRC 6110 Intermediate Epidemiology (2)
- MDCRC 6120 Cost-Effectiveness Analysis (1)
- MDCRC 6130 Introduction to Decision Analysis (1)
- MDCRC 6210 Regression Models (2)

#### *Elective Courses – Track 2 Specific*

MDCRC 6140 Intermediate Decision Analysis (1)  
MDCRC 6200 Meta Analysis (1)  
MDCRC 6220 Survey Methods (1)  
MDCRC 6230 Health Services Research (1)  
MDCRC 6250 Epidemiology of Infectious Diseases (1)  
MDCRC 6430 Implementation Science (1)  
MDCRC 6440 Intervention Research (2)  
MDCRC 6450 Grant Writing (2)

*New Courses to be Added in Next Five Years – Track 2 Specific*

MDCRC 6150 Molecular Epidemiology (1)  
MDCRC 6160 Pharmacoepidemiology (1)  
MDCRC 6240 Clinical Research with Diverse Populations (1)  
MDCRC 6260 Behavioral and Community Interventions (1)  
MDCRC 6270 Case Studies in Clinical Decision Support Systems (1)  
MDCRC 6280 Clinical Epidemiology (1)  
MDCRC 6290 Nutritional Epidemiology (1)

*Suggested Electives in Other Health Sciences Programs*

BMI 6040 Foundations of Genetic Epidemiology (1.5)  
BMI 6700 Public Health Informatics (2)  
BMI 6560 Familiality Methods (2)  
STAT 6969 Special Topics in Statistics (1 – 6)  
FPMD 6530 Global Health (3)  
FPMD 7140 Applied Multivariate Data Analysis (3)

*Course Descriptions for Both New and Existing Courses*

MDCRC 6000 Introduction to Biostatistics (1)

Basic statistics with emphasis on medical and epidemiologic research problems, including description of data, theoretical distributions, hypothesis testing, multiple comparisons, correlation, confidence intervals, basic regression models, and sample size estimation.

MDCRC 6010 Introduction to Epidemiology (1)

This course covers the basics of epidemiology including: measures of disease frequency, measures of effect, basic study designs, confounding bias, stratification, and causal reasoning.

MDCRC 6020 Data Management (1)

The course materials cover managing databases for research including: problems and solutions for data management, database design, table linkage, confidentiality issues and data security.

MDCRC 6030 Computer Practicum (1)

This course is designed to afford hands-on practice with statistical software (Stata). Students learn to merge databases, generate and modify variables, scientific graphing, and simple programming.

#### MDCRC 6100 Epidemiology Seminar (1)

Key papers describing epidemiological methods are discussed, followed by critical reviews of representative studies illustrating the application of these methods. Causal reasoning and causal graphs are introduced. This course is presented in two two-hour blocks each week for the first three weeks of the intensive introductory course. 1 credit.

#### MDCRC 6040 Design and Implementation of Clinical Trials (2)

This course defines clinical trials and reviews drug registration trials, phase I, II and III trials, clinical endpoints, surrogate endpoints, pharmacokinetics, drug-drug interactions, data and safety monitoring, criteria for closure and single versus multi-institutional trials. Case-based sessions covering clinical trials in occlusive heart disease, arthritis, asthma and oncology emphasize informative examples of trial design and potential pitfalls.

#### MDCRC 6110 Intermediate Epidemiology (2)

Students enrolling in this course must have completed MDCRC 6010, Introduction to Epidemiology. The course considers in some depth the epidemiologic study designs: cohort, case-control, cross-sectional, ecological. Goals are that students will be able to: 1) design epidemiologic studies; 2) understand causal inference and potential sources of bias in observational studies; 3) recognize and address confounding and effect modification in data; and 4) critically read epidemiologic papers.

#### MDCRC 6120 Cost Effective Analysis (1)

The material presented covers concepts used in the economic evaluation of health care programs, foundations of cost effectiveness analysis, interpreting and critiquing the literature of cost-effective analysis, and constructing these analyses.

#### MDCRC 6130 Introduction to Decision Analysis (1)

This course serves as an introduction to the subject of decision analysis related to health care and includes: concepts, creation and evaluation of decision trees, Markov chains, sensitivity analysis and incorporation of patient preferences with utility analysis.

#### MDCRC 6140 Intermediate Decision Analysis and Modeling (1)

This course is a practicum in designing and constructing a decision analysis model to solve an actual health care problem. A problem is provided and students are instructed in methods to solve the problem utilizing decision analysis.

#### MDCRC 6150 Molecular Epidemiology (1)

The molecular epidemiology course will prepare students to conduct multidisciplinary studies using biological samples from humans. Students will become familiar with epidemiologic and data quality considerations for molecular epidemiology studies, for example studies of intermediate markers of disease, studies of genetic susceptibility to disease, and pharmacogenetics studies.



#### MDCRC 6160 Pharmacoepidemiology (1)

Pharmacoepidemiology joins the fields of clinical pharmacology and epidemiology, and it is the study of the use and effects of drugs in large groups of people.

Pharmacoepidemiologic methods are also used to conduct and evaluate programmatic efforts to improve medication use on a population basis. The aim of the course is to introduce students to the most important issues in pharmacoepidemiology. To this end, the course will emphasize pharmacovigilance, surveillance methods, and follow-up studies. The course will present an overview of observational study designs, including drug utilization studies, case reports, and case-control and cohort studies. Description and measurement of drug exposures and outcomes, biases, and confounders as well as their implications in pharmacoepidemiological research will be included. The course contains lectures as well as exercises, and group discussions

#### MDCRC 6200 Meta Analysis (1)

The material covered focuses on the meta-analysis approach of combining quantitative data. Subjects covered include statistical methods, eligibility criteria of studies, tests of homogeneity, summary measures, sources of variation and sensitivity analysis

#### MDCRC 6210 Regression Models (2)

The course in regression models covers linear regression, logistic regression, Poisson regression, Cox regression, and includes: methods for correlated data (generalized estimating equations and mixed models), testing model assumptions, and assessment of model fit.

#### MDCRC 6220 Survey Methods (1)

This course provides an overview of the effects of survey design decisions on data quality. It focuses on the design of surveys used in research and practical issues related to their development, application, and interpretation. Topics include methods of data collection, sampling strategies, measurement error, and error associated with sampling and non-response. Additional topics include questionnaire format, interviewer effects and training, survey evaluation, and other strategies for ensuring survey quality.

#### MDCRC 6230 Health Services Research (1)

This course is focused on measurements of clinical outcomes and includes scale development, reliability and validity, study design, misclassification bias, co-morbidity, severity of illness scores and quality of life measurements.

#### MDCRC 6240 Clinical Research with Diverse Populations (1)

This course will focus on conducting observational and intervention research with diverse populations that are traditionally underserved, including people classified by age, gender, sexual orientation, geography, race and ethnicity. Students will critically examine recruitment and retention methods, data collection instruments, research interventions, and study implementation strategies. There will be an emphasis on cultural competency and disparities in health indicators in diverse populations.

#### MDCRC 6250 Epidemiology of Infectious Diseases (1)

This course covers the epidemiology of infectious diseases and the dynamics of transmissible agents, including: outbreak investigation, mathematical models of host-microorganism interactions, and statistical methods for detection of disease clusters.

#### MDCRC 6260 Behavioral and Community Interventions (1)

This course provides an overview of social and behavioral science theories, community health assessment and planning models, social and behavioral determinants of health, and applying these to the design and implementation of inter-disciplinary community interventions. Research methods for program evaluation will be covered, including study designs and statistical models.

#### MDCRC 6270 Case Studies in Clinical Decision Support Systems (1)

This course will provide an overview of clinical decision support systems (CDSS) and methods, including implementation of CDSS and study designs for CDSS evaluation in clinical settings. Several case studies of actual CDSS implementations will be used to illustrate the issues and concepts.

#### MDCRC 6280 Clinical Epidemiology (1)

This course focuses on methods to study the determinants for variation in outcomes of illness, such as diagnostic and therapeutic interventions. Statistical methods for diagnostic and screening tests are presented, including test characteristics, comparisons and regression models for test characteristics, and correcting these for bias. Study designs for evaluating therapeutic efficacy and measuring natural history of disease are discussed.

#### MDCRC 6290 Nutritional Epidemiology (1)

This course focuses on application of epidemiological methods to current studies of diet, nutrition, and chronic disease. A discussion of current issues and controversies enable students to plan studies in nutritional epidemiology and disease prevention. The broad aim of the course is to expose students to the principles of nutrition epidemiology and arm them with tools to evaluate nutrition epidemiology in the literature. At the end of the course students will be able to discuss the basic principles used in nutrition epidemiology and critically evaluate nutrition epidemiology in the literature.

#### MDCRC 6400 Medical Genetics for Clinical Investigators (1)

This course provides a broad overview of medical genetics with an emphasis on issues most relevant for clinical investigators, including the formal genetics of Mendelian traits. Cytogenetics and new molecular techniques are covered. Gene mapping through linkage analysis, positional cloning and candidate gene analysis are reviewed.

#### MDCRC 6410 Research Seminar Series (1 summer, 0.5 fall, 0.5 spring)

Each seminar begins with the presentation of a case representing an inherited human disorder or a clinical issue related to health care delivery or epidemiology. Discussions follow based on the methods used for cloning responsible genes or defining

epidemiologic and other health care issues. The seminars are designed to illustrate the process of scientific discovery in clinical investigation, provide examples of how innovative approaches and methods were applied and to discuss obstacles that impeded progress.

#### MDCRC 6420 Genetics of Complex Diseases (2)

This key course addresses issues relevant to the identification of genes underlying susceptibility to complex disorders. Subjects covered include advantages and disadvantages of isolates versus large populations, utilization of affected sibling pairs, discordant sibling pairs and extended families. Traditional case-control association methods and family-based methods are covered. Other subjects include locus and allelic heterogeneity, phenotypic heterogeneity, gene-gene and gene-environmental interactions and density of polymorphic markers.

#### MDCRC 6430 Bioethical Issues in Clinical Research (1)

Ethical issues and standards for scientific investigation are covered in depth. Course-work emphasizes the history and evolution of research norms and practices, institutional expectations and standards, and the process of review and oversight for experimental protocols. Additional material covers ethical issues and public policy linked to genetic research. Case-based problem solving is used to cover interactions with the Institutional Review Board.

#### MDCRC 6440 Intervention Research (2)

Interdisciplinary approaches to bedside-to-community translational research will be covered. Strategies will be presented for designing and implementing field intervention studies and cluster randomized trials. Methods of analysis will include time series analysis. This course will also encompass health information technology interventions, such as clinical decision support systems. Behavior change models will be discussed.

#### MDCRC 6450 Grant Writing (2)

This course covers the entire preparation of a grant, including funding sources, letter of intent, aims and hypotheses, background, specific projects, sample size and statistics, budgets, biosketches, and supporting appendices. Students will write an actual grant and critique classmates' grants.

#### MDCRC 6500 Gene Localization-Principles and Practice (2)

This course offers detailed coverage of methods of linkage analysis including LOD scores, estimation of pedigrees, non-parametric methods including sib-pair analysis and affected pedigree member analysis. Efficient study design is presented, with emphasis on the importance of accurate phenotyping with an introduction to the use of the GCRC phenotyping core. Basic statistical issues central to linkage analysis are covered extensively.

#### MDCRC 6510 Molecular Biology for Clinical Investigators (2)

This course focuses on modern prokaryote and eukaryote genetics, eukaryote gene structure with an emphasis on mammalian systems and cell biology emphasizing

mammalian model systems. Subjects covered include DNA replication, control of replication, transcription, transcription factor networks, signal transduction, pathways in cancer biology, bacterial phage genetics, bacterial genomics and gene targeting. Methods utilized in laboratory-based investigations utilizing molecular biology are covered in detail.

#### MDCRC 6520 Biochemistry for Clinical Investigators (2)

This course utilizes clinical syndromes as the starting point for teaching exercises in biochemistry. Course material covers DNA synthesis and repair, lipid metabolism, cell cycle control, protein structure, biochemistry of diabetes and the interactions of biochemical pathways in complex organisms. The objective of the course is to prepare clinical investigators to be totally conversant with techniques of biochemistry, cell cycle control and protein structure that might relate directly to clinical research projects done by multidisciplinary groups.

#### MDCRC 6530 Utilization of Animal Models in the Development of Clinical Research Projects (2)

It is now possible to precisely modify any DNA sequence within the genome of the mouse. This course emphasizes the use of mouse models to dissect the genetic basis of human disease. Deletion of genes using homologous recombination are covered extensively as are other methods of gene inactivation (anti-sense constructs, inhibitory RNA, and others). New experimental systems for modeling human diseases in zebra fish and *C. elegans* are also covered.

#### MDCRC 6970 Mentored Clinical Research Project (10 to 15)

Faculty: A roster of qualified research mentors is give in Table 6, Appendix 1.

Course Description: Graduate research projects designed to extend over the two years of the program, and culminating in the writing of a NIH career development application (K-23, K-08) or equivalent are initiated at the beginning of the student's coursework.

Selection of mentors and initiation of projects occurs outside of regular class hours.

## Appendix B. Program Schedule

The suggested class schedule for completion of the MSCI degree for Track 1 (Inherited Basis of Human Disease) is:

Year 1, Summer Semester Six-Week Intensive (2<sup>nd</sup> week of July through 3<sup>rd</sup> week of August)

MDCRC 6000 Introduction to Biostatistics (1)  
MDCRC 6010 Introduction to Epidemiology (1)  
MDCRC 6020 Data Management (1)  
MDCRC 6410 Research Seminar Series (1)  
MDCRC 6430 Bioethical Issues in Clinical Research (1)  
MDCRC 6440 – Medical Genetics for Clinical Investigators (1)  
MDCRC 6510 – Molecular Biology for Clinical Investigators (1)

Year 1, Fall Semester

MDCRC 6410 Research Seminar Series (0.5)

MDCRC 6420 Genetics of Complex Diseases (2)

MDCRC 6970 Mentored Clinical Research Project (3 hours)

Year 1, Spring Semester

MDCRC 6040 Design and Implementation of Clinical Trials (2)  
MDCRC 6410 Research Seminar Series (0.5)  
MDCRC 6500 Gene Localization-Principles and Practice (2)  
MDCRC 6970 Mentored Clinical Research Project (3 hours)

Year 2, Fall Semester

MDCRC 6520 Biochemistry for Clinical Investigators (2)  
MDCRC 6970 Mentored Clinical Research Project (4 hours)

Year 2, Spring Semester

MDCRC 6450 Grant Writing (2)  
MDCRC 6530 Utilization of Animal Models in the Development of Clinical Research Projects (2)  
MDCRC 6970 Mentored Clinical Research Project (3 hours)

The suggested class schedule for completion of the MSCI degree for Track 2 (Epidemiology and Health Services Research) is:

Year 1, Summer Semester Six-Week Intensive (2<sup>nd</sup> week of July through 3<sup>rd</sup> week of August)

MDCRC 6000 Introduction to Biostatistics (1)  
MDCRC 6010 Introduction to Epidemiology (1)  
MDCRC 6020 Data Management (1)  
MDCRC 6030 Computer Practicum (1)  
MDCRC 6100 Epidemiology Seminar (1)  
MDCRC 6410 Research Seminar Series (1)  
MDCRC 6430 Bioethical Issues in Clinical Research (1)

Year 1, Fall Semester

- MDCRC 6110 Intermediate Epidemiology (2)
- MDCRC 6120 Cost Effective Analysis (1)
- MDCRC 6130 Introduction to Decision Analysis (1)
- MDCRC 6410 Research Seminar Series (0.5)
- MDCRC 6970 Mentored Clinical Research Project (3 hours)

Year 1, Spring Semester

- MDCRC 6040 Design and Implementation of Clinical Trials (2)
- MDCRC 6210 Regression Models (2)
- MDCRC 6410 Research Seminar Series (0.5)
- MDCRC 6970 Mentored Clinical Research Project (3 hours)

Year 2, Fall Semester

- MDCRC 6970 Mentored Clinical Research Project (3 hours)
- MDCRC 6230 Health Services Research (1)
- MDCRC 6220 Survey Methods (1)

Year 2, Spring Semester

- MDCRC 6450 Grant Writing (2)
- MDCRC 6970 Mentored Clinical Research Project (4 hours)

## **Appendix C: Faculty**

Current faculty who will participate in the didactic teaching for the MSCI degree include the following:

Tom Greene, Ph.D.

Professor of Medicine

Division of Epidemiology

University of Kentucky, Lexington, KY – B.S. 1980 – Mathematics and Psychology

Cornell University, Ithaca, NY – M.S. 1983 – Statistics

Cornell University, Ithaca, NY – Ph.D. 1985 – Statistics

Research interests: statistical methods for randomized clinical trials, longitudinal data analysis, and on the validation and use of surrogate endpoints. He directs the statistical analyses for several multi-center clinical trials sponsored by the National Institutes of Health, including the African American Study of Kidney Disease and Hypertension, the Focal Segmental Glomerulosclerosis Study, and the trials of the Frequent Hemodialysis Network. Dr. Greene also directs the statistical analyses for the Collaborative Study Group, which is an international consortium of investigators who conduct industry sponsored clinical trials in patients with chronic kidney disease.

Anita Y. Kinney, Ph.D.

Associate Professor of Medicine

Division of Epidemiology

Seton Hall, South Orange, NJ – B.S.N. 1981 – Nursing

University of Pennsylvania, PA – M.S. 1988 – Nursing (APN)

Univ. of Texas Public Health, Houston, TX – Ph.D. 1996 – Epidemiology

Univ. of North Carolina, Chapel Hill, NC – Post Doc 1997 – Cancer Prevention & Epidemiology

Research interests: to understand variation in health outcomes and attitudes, and to use this information to develop effective interventions that facilitate informed decision making and positive changes in health behaviors. Kinney is particularly interested in studying these issues in socially and geographically underserved populations.

James P. Kushner, MD

M.M. Wintrobe Distinguished Professor of Medicine and Chief of the Division of Hematology

Program Director, Center of Excellence in Molecular Hematology (CEMH)

Associate Program Director, General Clinical Research Center (CRC)

Bowdoin College, Brunswick, Maine, B.A., 1957

New York University Graduate School of Arts and Science, New York, New York, 1957-1958

University of Pittsburgh, School of Medicine, Pittsburgh, Pennsylvania, M.D., 1962

Research interests: genetic disorders of iron metabolism and genetic disorders affecting the porphyrin biosynthetic pathway. His research has been continuously funded through the National Institutes of Health (NIH) for the past 20 years. The grant supporting his research on the genetic basis of porphyric disorders was awarded merit status in its

last competing renewal. He is the M.M. Wintrobe Professor of Medicine and an Adjunct Professor of Pathology and is the Principle Investigator and Director of the University of Utah's Center of Excellence in Molecular Hematology.

Dean Y. Li, M.D., Ph.D.

Associate Professor of Medicine

Human Molecular Biol & Genetics Program

Eccles Institute of Human Genetics

B.A. University of Chicago

M.D. Washington University

PhD. Washington University

Research interests: to describe vascular development as a series of sequential and coordinated molecular events. This information is vital for understanding embryogenesis and devising strategies for the prevention and treatment of malignancies and obstructive vascular disease. Dr. Li hypothesizes that many genes implicated in human vascular disease play fundamental roles in vascular development.

Maureen A. Murtaugh, Ph.D., R.D.

Associate Professor of Medicine

Division of Epidemiology

Syracuse University, Syracuse, NY – B.S. 1983 – Dietetics

University of Connecticut, Storrs, CT – Ph.D. 1991 – Nutrition

University of Minnesota, Minneapolis, MN – Post Doc. 2002 – Epidemiology Research

interests: the role of nutrition in development of chronic disease. She is currently principal investigator of a study to establish norms for bone health for Navajo people and another to validate a dietary history questionnaire for American Indians and Alaska Natives.

Matthew H. Samore, MD

Professor of Medicine

Chief, Division of Epidemiology

Macalester College, St. Paul, MN – B.A. 1979 – Biology

University of Wisconsin, Madison, WI – M.D. 1984 – Medicine

Research interests: methods in infectious disease epidemiology, antibiotic resistance in hospitals and communities, computer-decision support for antibiotic prescribing and infection control, and surveillance of errors and adverse events. Dr. Samore is leading or participating in several randomized intervention trials that address antimicrobial resistance and other studies that apply computer-based approaches to surveillance and/or antibiotic prescribing. These include the CMS-funded RADAR (Rural Antibiotic Decision-Support and Resistance) project, the CDC-funded IMPART (Inter-Mountain Project on Antimicrobial Resistance and Therapy), an FDA sponsored study of adverse event surveillance, and the AHRQ-funded INFORM (Intelligent Network for Orders, Registry, and Management) project.



Greg Stoddard, MPH

Division of Epidemiology, Department of Medicine

Adjunct Assistant Professor in the Department of Orthopedics

University of Utah, Salt Lake City, UT – BS 1983 – Mathematics (Statistics Emphasis)

University of Phoenix, Salt Lake City, UT-MBA 1988-Business Administration

University of Utah, Salt Lake City, UT – MPH 1998-Public Health/Epidemiology

Research Interests: statistical methods in epidemiology

Carol Sweeney, Ph.D.

Associate Professor of Medicine

Division of Epidemiology

Department of Medicine

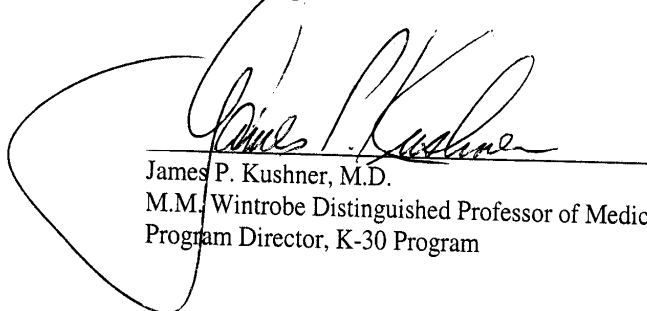
Wellesley College, Wellesley, MA – B.A. 1981 – Biological Sciences

University of Washington, Seattle, WA – M.S. 1990 – Environmental Health

University of Washington, Seattle, WA – Ph.D. 1999- Epidemiology

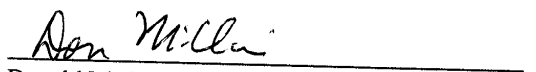
Research interests: cancer epidemiology, with specific interests in the role of common genetic variants in cancer susceptibility and survival, and in the epidemiology of cancer survivors.

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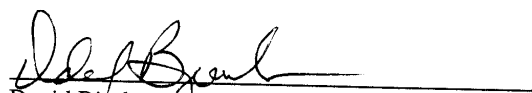
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James P. Kushner, M.D.  
M.M. Wintrobe Distinguished Professor of Medicine  
Program Director, K-30 Program



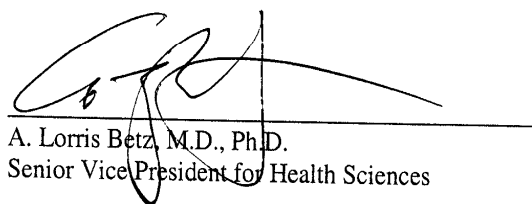
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Donald McClain, M.D., Ph.D.  
Professor of Medicine  
Program Director, General Clinical Research Center



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David Bjorkman, M.D., M.P.H.  
Dean, College of Medicine



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A. Lorris Betz, M.D., Ph.D.  
Senior Vice President for Health Sciences

