A. ADVANCED DEGREE OPTIONS

Trainees have the opportunity to complete a Master of Science Degree. The five most relevant degrees to our program are:

1. **Masters of Public Health (MPH)**
2. **Master of Science in Clinical Investigation (MS-CLI) Degree**
3. **Master of Science in Medical Statistics (MS-MS) Degree**
4. **Master of Science in Clinical Translational Research (MS-CTR) Degree**
5. **Masters of Data Science Degree**

The courses are offered in collaboration with the Department of Public Health Sciences and the Clinical and Translational Science Institute.

B. DIDACTIC CURRICULUM

In partial fulfillment of the MS degree options noted above, fellows will focus on training in three focus areas: **patient-oriented research, biostatistics and informatics research, and health outcomes research** as part of the UR CCRTP. These include courses, seminars, and workshops sponsored by the R25, Wilmot Cancer Institute, the Clinical and Translational Science Institute, the URCC NCORP Program, the Department of Public Health Sciences, and URMC.

Patient-Oriented Research Curriculum

1. **REQUIRED PROGRAM LECTURE:**

   "Biobehavioral Research in Cancer Prevention and Control" (G. Morrow and M. Janelsins)

   Topics: Issues of recruitment, sampling, design, assessment points, primary and secondary endpoints, patient assessment burden, forms design, database development, aspects of implementing and conducting cancer control clinical trials in a medical setting.

2. **REQUIRED CORE COURSES:**

   (1) Social and Behavioral Medicine (PM 426) The course will focus on: 1) the application of behavioral, sociological, and anthropological science approaches to the etiology, prevention, treatment, and management of physical disease and illness; and 2) the identification of relationships among behavioral, sociological, anthropological, and biological factors in health. Students will acquire a familiarity with current theoretical and methodological issues in social and behavioral medicine, develop an understanding of evidence-based health promotion/disease prevention interventions in different content areas,

consider cross-cultural perspectives, and develop critical thinking skills necessary to evaluate the research literature in these areas. **(D. Ossip-Klein is course coordinator, G. Morrow, J. Roscoe, K. Mustian, M. Janelsins, L. Peppone, C. Kamen)**

(2) Design of Clinical Trials (BST 465) Design, conduct, and analysis of clinical trials. Sample size, power, and randomization. Coordination, data management, compliance, interim analysis, and reporting procedures.

(3) Ethics and Professional Integrity in Research (IND 501) This course covers conflict of interest, plagiarism, animal and human experimentation, copyright, fair use, intellectual property among other topics.

3. ELECTIVE COURSE OPTIONS (SELECTED):

- Biopsychology of Social and Clinical Behaviors (PSY 113)
- Social Psychology and Individual Differences (CSP 161)
- "He said...She said...:" Gender Differences in Communication (PSY 192Q)
- Neuropsychology (BCS 242)
- Behavioral Medicine (CSP 283)
- Exploring Research in Family Psychology I (PSY 377)
- Research in Motivation (PSY 398)
- Psychology of Health (CSP 568)

4. REQUIRED CORE SEMINARS:

Introduction to Clinical Research at the University of Rochester (July of 1st year)

This series constitutes four one-hour seminars, which will introduce the trainee to opportunities for transdisciplinary investigation within the University of Rochester and its Medical Center. These initial seminars will provide an overview of the types of clinical research taking place at the University, including patient oriented research, epidemiology, behavioral sciences and health services research. The goal of these sessions is to initiate the planning for each trainee's individual curriculum and research project as early as possible, and facilitate the identification of local research resources, populations, and databases. **(CTSI Faculty)**

Enhancing Clinical and Translational Research Skills

This seminar provides practical guidance for designing randomized trials and longitudinal studies with cancer control outcomes involving biomarkers (eg. How to determine which biomarkers to choose, biospecimen type, how to pilot test methods, quality control methods, working with diverse laboratories, and validation studies. **(M Janelsins, Select UR Core Resources Faculty)**

Wilmot Cancer Institute Grand Rounds

Invited speakers from around the country discuss cancer prevention, treatment, cancer control, and cancer care delivery. Seminars occur weekly.

Health Outcomes Research Curriculum

1. REQUIRED PROGRAM LECTURE:

(1) "Health Outcomes Research in Cancer Prevention and Control" (Public Health

Sciences Faculty and Staff)
Topics: Issues of population based studies, sampling, design, assessment points, forms design, database development, aspects of implementation and conducting a health outcomes trial in the community.

2. REQUIRED CORE COURSES:

(1) Principles of Epidemiology (PM 415) This course provides an introduction to epidemiological concepts of disease and interventions to ameliorate them. The course will discuss population-based aspects of disease, morbidity and mortality statistics, basic study designs (cross-sectional, case-control, cohort and clinical trials), and the use of epidemiological data to draw conclusions about disease causation. At the end of the course, students should have a broad view of denominator-based medicine and be prepared for higher level courses in epidemiological methods. **(Public Health Sciences Faculty and Staff)**

(2) Epidemiologic Methods (PM 416) This course is designed to provide an in-depth coverage of the quantitative methodological issues associated with population-based epidemiological research. Issues specific to study design and analysis are emphasized. Topics to be covered include: optimal study design, methods of data collection and data management, confounding and effect-modification, and multivariate analytic techniques, including linear and logistic regression, Kaplan-Meier survival techniques and Cox proportional hazards modeling. **(Public Health Sciences Faculty and Staff)**

(3) Molecular/ Cancer Epidemiology (PM 466) The purpose of this course is to provide the student with a basic understanding of the biology, prevention, treatment and burden of malignancy in the U.S. The course will include discussions of patterns of cancer incidence, etiologic factors, individual risk assessment, stages of neoplastic development, recent laboratory techniques for measurement of biomarkers, and interventional approaches related to prevention, screening and treatment. Seminars will be generated from a series of selected papers from the literature, each representing either a seminal contribution or a new strategy in cancer research. In depth critiques of the research design and statistical approaches of each paper will also be included. **(Public Health Sciences Faculty and Staff)**

3. ELECTIVE COURSE OPTIONS (SELECTED):

- Cancer Screening & Prevention (PM 467)
- Epidemiology of Mental Disorders (PM 468)
- Multivariate Models for Epidemiology (PM 469)
- Politics & Policies in US Health Care (PM 420)
- Intro to US Health Care System (PM 421)
- Field Epidemiology (PM 413)
- Clinical Evaluation & Outcomes Research (PM 482)
- Cost Effectiveness Research (PM 484)
- Nutritional Epidemiology (PM 442)
- Infectious Disease Epidemiology: Prevention & Control (PM 451)
- Qualitative Health Care Research (PM 458)

4. REQUIRED SEMINARS:

Working with funding agencies. In the first semester of year 2, the trainees will attend a series of

14 seminars on technology transfer and protection of intellectual property. The trainee will be introduced to types and sources of research funding, including the University of Rochester's computerized database on sponsored research, the SMART system. These are designed to supplement the broad experience of the program mentors in obtaining cancer control research. These seminars will also include legal issues in clinical research, working with industry including copyright, patenting, licensure, and other intellectual property issues, and program management and marketing by industry. Invited speakers from local biotechnology and pharmaceutical firms will present their views on key topics. Roles of regulating agencies such as the FDA will be discussed. Federal policies and regulations in clinical research, including the inclusion of women, minorities and children and a discussion of assurances will constitute additional sessions. (Office of Human Subject Protection).

Health Services Research Seminar Topics in health services are of growing importance in health care and cancer care delivery research. Topics covered include population-based studies, sampling, database analyses and other related topics. (Surgical Outcomes Faculty)

Biostatistics and Informatics Research Curriculum

The statistical group has active, grant-supported research in developing, testing and implementing various techniques of statistical analyses. There is a focus on mathematical modeling applicable to cancer research. Individual projects focus on how to incorporate quality of life measures into survival models. There is an ongoing series of RO-1 supported investigations of models for extending and predicting results of expanded clinical trials in the clinical arena.

1. **REQUIRED LECTURE:**

   "Biostatistics in Cancer Control"

   Topics: Issues of recruitment, sampling, design, assessment points, primary and secondary endpoints, patient assessment burden, forms design, database development, aspects of implementing and conducting cancer control clinical trials in a medical setting. **(Cancer Control Core Biostatistics Faculty and Staff)**

2. **REQUIRED CORE COURSES:**

   (1) Introduction to Biostatistics (BST 463) Review of basic statistical and data-analytic methods in medical and clinical research. Topics include summarizing and displaying data, diagnostic tests, hypothesis tests and confidence intervals, methods for comparing means and proportions, and regression analysis. The StataQuest computer software package is introduced and used. The course is strongly use-oriented, stressing practical understanding and interpretation not mathematical derivation. **(Biostatistics Faculty and Staff)**

   (2) Statistical Methods for Biomedical Applications (BST 464) Statistical analysis of clinical trials and observational studies. Analysis of covariance, multiple regression, logistic regression, log-linear analysis, and survival analysis. (Kaplan-Meier curves and the Cox models). Measurement Error. **(Biostatistics Faculty and Staff)**

(3) Introduction to SAS for Windows (PM 429): This six-week course will present an introduction to the SAS system for Windows. The focus of the course will be on data management and statistical analysis using SAS. The student will gain an understanding of SAS as a research tool through the completion of a research project of their own design. Prerequisites: BST 463 or equivalent and knowledge of MS Windows. **(Biostatistics Faculty and Staff)**

3. ELECTIVE COURSE OPTIONS (SELECTED):

- Global Public Health Informatics (PM 454)
  Structural Equation Modeling (CSP 514)
- Data Analysis: General Linear Applications II (CSP
- 519) Applied Multivariate Analysis
  (BST 441) Statistical Modeling
  Techniques (BST 479)

4. REQUIRED CORE SEMINARS:

Introduction to Medical Informatics - The levels of expertise among clinical research trainees with regard to computers and telecommunications are expected to be highly variable. The goal of this four-session seminar in Year 1 is to orient the trainee to computer and communication resources available to them at the University of Rochester. An overview of the University's computer resources and telecommunications network including the trainees' access to information on the Intranet, Internet, etc will be provided. **(Biostatistics Faculty and Staff)**

Advanced Research Informatics - In Year 2, a second series of workshops on Advanced Medical Informatics will be held. These will expand upon the use of the Internet and introduce the concept of the "Virtual Research Center," based in the NCORP web site. This innovation will be used by the trainee to collaborate with other scientists, working as a team, who may be at great distances. This is an approach being used by investigators in the NCORP research base to develop manuscripts/concepts/protocols. At the end of this workshop, the trainee should be comfortable with technologies needed to participate in a worldwide network of clinical researchers. **(G. Morrow)**

Department of Statistics and Computational Biology Seminar Series - This bi-weekly series has included seminars on the following among the recent presentations: "Nonparametric Regression Methods for Longitudinal Data Modeling with Applications in AIDS Clinical Trials", "Functional Response Models and their Applications to Psychosocial Research", "Interval-censoring, Medical Researches and Statistical Methods", "Modeling Breast Cancer Screening" **(Biostatistics Faculty and Staff)**

C. OTHER EDUCATIONAL EXPERIENCES AND PROFESSIONAL DEVELOPMENT

Practical Skills in Grant Writing *(PM 438)*

- Semester-long seminar to increase skills in writing an NIH research grant. The final exam is a mock peer review of a grant application. We feel it qualifies for the grant preparation requirement of the R25T program

Professional Scientific Editing

R25 Tuesday Professional Development Meeting

Presentation and Networking Opportunities

- Attendance at national meetings
- Mini-sabbaticals with other research groups
- Receptions at national meetings for past UR R25T trainees and faculty
- NCORP Breakfast meeting specifically for R25T trainees

In the second semester of Year 1 (16 weeks) and the fall of Year 2 (14 weeks), weekly workshops will be held to improve the trainee's skills in clinical research. In Year 1, the skills of scientific communication will be the focus of the seminars. Trainees will initiate a writing project (e.g., a literature review, scientific proposal, case study, manuscript of prior research) which will be reviewed for clarity, organization, and content. Skills in critiquing a manuscript will also be taught at this time. Trainees will learn the principles of presentation of scientific work, including public speaking, working with the media, preparation of abstracts, preparation of slides, and the development of posters.

Techniques of computer-based presentation, including an introduction (or more advanced instruction, as befits the individual trainee) to software programs such as PowerPoint will be included. At the end of this series, the trainee will be able to prepare and present his/her results in written, visual, or oral form clearly and concisely. Under the supervision of their mentors, they will prepare and submit an abstract of some aspect of their ongoing research for presentation at a relevant scientific meeting such as the Society of Behavioral Medicine (SBM), Multinational Association for Supportive Care in Cancer (MASCC), American Society of Clinical Oncology (ASCO) or another.

D. MENTORED RESEARCH OPPORTUNITIES

- Research opportunities and mentorship from 9 Cancer Control Research Training Program Core Mentors who have NCI funding and 15 other NCI or NIH-funded investigators working in cancer research who are affiliated with our Cancer Control Program.
- Fellows have the opportunity to develop and lead their own pilot study.
- As part of our unique training environment, our mentors have experience in several areas including:
    - Diverse areas of Cancer Control Research and Cancer Care Delivery Research
    - Clinical Trials Experience (Phase I to III)
    - Longitudinal Study Design
    - UR NCI Community Oncology Research Program (NCORP) Research Base
    - Behavioral Interventions
    - Geriatric Oncology
    - Exercise Oncology
    - Nutraceuticals
    - Cognitive Function
    - Patient-Reported Outcomes

- Mobile Health
- Health Equity
- Translational Science
- Biostatistics