

## **Course Descriptions**

### ***Master of Science in Clinical Investigation and Translational Science (MSCI-TS)***

#### **TSCI 5050 Introduction to Data Science**

1.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: Alex Bokov, PhD

This elective course is designed to train participants to use programming languages such as R and SQL to extract, prepare, and analyze data. This course is designed to be self-contained: statistical methods and theory relevant to analyzing large datasets will be covered with the computer-related course content providing tangible applications and motivating examples. In addition, the course will include organizational skill training and best practices needed to run a successful collaboration between researchers conducting patient oriented clinical research and the researchers in the computational fields.

#### **TSCI 5070 Responsible Conduct of Research**

2.0 Semester Credit Hours (SCH)

Course Director: Kimberly Summers, PharmD and Babatunde Oyajobi, MD, PhD

This interdisciplinary course is designed to train participants in the responsible conduct of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) delineate a history of hallmark abuses of humans enrolled in clinical research, (2) describe the evolution of national and international codes and regulations guiding inclusion of human subjects in clinical investigations, (3) list the elements of informed consent and describe procedures and precautions for enrolling special populations into clinical investigation, (4) write a consent form in understandable language, (5) recognize different forms of scientific misconduct, (6) describe the role and processes of a peer review board to judge violations in research ethics, (7) develop strategies for self-assessment and validation of scientific objectivity in one's own research, and (8) recognize the ethical responsibilities and consequences of whistle blowing.

#### **TSCI 5071 Patient-Oriented Clinical Research Methods-1**

2.0 Semester Credit Hours (SCH)

Course Director: Byeongyeob Choi, PhD

This interdisciplinary course is the first in a two-semester sequence designed to train participants in the conduct of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) define a research question, (2) effectively conduct a systematic review of the scientific literature, (3) design strategies for recruitment into a study, (4) delineate strategies for minimizing bias in cross-sectional and retrospective studies, and (5) read and interpret research reports of cross-sectional and case control investigations.

## **TSCI 5072 Patient-Oriented Clinical Research Biostatistics-1**

2.0 Semester Credit Hours (SCH)

Course Directors: Jonathan Gelfond, MD, PhD

This interdisciplinary course is the first in a two-semester sequence designed to train participants in the analysis and biostatistics of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) identify and summarize different categories of data; (2) set up and perform tests of hypotheses; (3) estimate sample sizes for survey and case-control studies; and (4) use statistical software packages to enter, summarize, graph, visualize, and analyze data.

## **TSCI 5073 Integrating Molecular Biology with Patient-Oriented Clinical Research**

1.0 Semester Credit Hours (SCH)

Course Directors: Teresa L. Johnson-Pais, PhD

This interdisciplinary course is designed to train participants on integrating molecular biology methods into patient-oriented clinical research. Students will have the opportunity to learn to: (1) appropriately use molecular terms in clinical investigation; (2) describe the events involved in protein synthesis; (3) describe the principles involved in molecular techniques (e.g., polymerase chain reactions, Southern blots); (4) identify the appropriate specimens, collection, and handling requirements for each molecular technique; (5) identify and correct common sources of error in performing molecular techniques; (6) cite examples of clinical applications of molecular techniques in clinical medicine; and (7) apply molecular techniques in the laboratory to specific clinical problems.

## **TSCI 5074 Data Management, Quality Control, and Regulatory Issues**

2.0 Semester Credit Hours (SCH)

Course Director: Schmidt, Susanne, PhD

This interdisciplinary course is designed to train participants in the necessary data management and quality control procedures required for the conduct of patient-oriented clinical research.

### **By the end of this course, each student should be able to:**

1. Understand the principles of data management as they pertain to clinical research
  - a. Using and Defining meta data
  - b. Research logistics
  - c. Data Security
  - d. Randomization
2. Understand supporting principles
  - a. Data management and Analysis ethics
  - b. Compliance
  - c. Quality Control
  - d. Program Evaluation

3. Using the REDCap Electronic Data Capture (EDC) tool
  - a. Design and build a data collection instrument
  - b. Design and build a survey
  - c. Design and build a longitudinal study
  - d. Build a report
  - e. Import external data from Excel
  - f. Export data to Excel
4. Be able to identify individuals and resources within the institution that can provide guidance in all areas covered.

### **TSCI 5075 Scientific Communication**

2.0 Semester Credit Hour (SCH)

Course Directors: Bandana Chatterjee, PhD

This interdisciplinary course is designed to train participants to write effectively in all aspects of conducting patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) recognize and avoid errors in grammar, punctuation, and usage that are common in scientific writing; (2) construct units of writing whose structure, style, and logical continuity allows instant and clear comprehension; (3) construct concise, informative titles; (4) develop clear, comprehensive, abstracts for papers and grant proposals; (5) construct complete, well-rationalized sets of specific aims for grant proposals; and (6) effectively apply the 4-Point Rule (What is the question? How did we approach it? What happened? What does it mean?) to all forms of scientific writing.

### **TSCI 5077 Practicum in Translational Science**

1.0–3.0 Semester Credit Hours (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: TBN (To Be Named)

This *elective* course provides an opportunity for participation in unique clinical and translational research activities that are highly individualized for each student on the basis of prior experience and research interests.

### **TSCI 5080 Integrating Molecular Biology with Patient Oriented Clinical Research Practicum**

1.0 Semester Credit Hour (SCH)

*Prerequisite: Consent of the Course Director*

Course Director: Goutam Ghosh-Choudhury, PhD

This is the required practicum to TSCI 5073 (Integrating Molecular Biology with Patient-Oriented Clinical Research Practicum). This practicum is designed to provide the opportunity for highly individualized research activities for integrating molecular biology methods into patient-oriented clinical research.

## **TSCI 5201 Advanced Statistics for Machine Learning Methods: Statistical Principles of Machine Learning Applied to Biomedical Data**

3.0 Semester Credit Hour (SCH) (elective)

Course Director: Zhu Wang, PhD

This class offers a hands-on approach to machine learning and data science. The class discusses the application of supervised and unsupervised techniques for machine learning including random forests, support vector machines, boosting, deep learning, K-means clustering and mixture models. The course focuses on real data application with open-source implementations in Python and R.

## **TSCI 5230 Programing for Biomedical Data Science**

3.0 Semester Credit Hour (SCH) (elective)

Course Director: Alex Bokov, PhD

This class offers a hands-on approach to data science programming for biomedical research. We will introduce R, Python, SQL, and the software tools that interoperate with them. We will also cover cross-cutting best practices for organizing one's work to facilitate collaboration, reproducibility, and portability. Students who already have data they want to analyze are encouraged to use it in their assignments.

## **TSCI 6001 Introduction to Translational Science**

1.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: Bertha E. "Penny" Flores, RN, PhD

This *elective* course provides an in-depth overview of the essential components encompassed by translational science. Content is provided through a series of lectures, assigned readings, literature reviews, class presentations, and discussions with faculty

## **TSCI 6060 Patient-Oriented Clinical Research Methods-2**

2.0 Semester Credit Hours (SCH)

*Prerequisite: Patient-Oriented Clinical Research Methods-1*

Course Director: Byeongyeob Choi, PhD

This interdisciplinary course is the second in a two-semester sequence designed to train participants in the conduct of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) define criteria for inferring causation from observational studies; (2) design strategies for subject retention in a prospective study; (3) design strategies for monitoring progress in a randomized control trial; (4) delineate strategies for minimizing bias in cohort studies and randomized control trials; (5) compare and contrast the uses, strengths, and weaknesses of different clinical trial designs; (6) read and interpret research reports of cohort studies and randomized control trials; and (7) describe the steps in conducting a meta-analysis.

## **TSCI 6061 Patient-Oriented Clinical Research Biostatistics 2**

2.0 Semester Credit Hours (SCH)

*Prerequisite: Patient-Oriented Clinical Research Biostatistics - 1*

Course Director: Jonathan Gelfond, MD, PhD

This interdisciplinary course is the second in a two-semester sequence designed to train participants in the biostatistical analysis of patient-oriented clinical research. Students will have the opportunity to learn to and, by the end of the course, be required to: (1) perform a two-way analysis of variance and explain the results; (2) perform survival analysis; (3) compare and contrast the purpose and characteristics of different forms of interventional trials; and (4) plan the sample size, analysis, and stopping rules of a randomized clinical trial.

## **TSCI 6065 Health Services Research**

2.0 Semester Credit Hours (SCH)

*Prerequisite: Patient-Oriented Clinical Research Methods-1 and Patient-Oriented Clinical Research Methods-2*

Course Director: Helen P. Hazuda, PhD

This course focuses on concepts and methods used in research focusing on health care quality, utilization, access, and safety. The seminar will utilize skills-based learning, small group activities, and outside assignments. By the end of the course, candidates will be required to:

- articulate underlying core concepts
- describe basic methods used in health services research
- identify relevant databases and data sources for health services research
- critically appraise and interpret published reports of health services research
- discuss current issues in HSR
- understand how to incorporate health services concepts, methods, or tools, into current research

## **TSCI 6067 Genomic Healthcare**

1.0 Semester Credit Hour (SCH) (elective course)

Course Director: Donna Lehman, PhD

This *elective* course prepares students to integrate genomic and other omics technology into patient care and clinical research. It begins with an introduction to genomics and overview of omics technologies. Students will explore the different resources of genomic information and have opportunities to apply these resources to keep abreast of current knowledge in their health topic of interest including the ethical individual and societal challenges ahead. Genomics in cancers is an active area in personalized medicine, and this topic will be discussed by a local cancer genomics expert. The course will also provide an introduction and overview of current applications of gene therapeutics to a variety of disorders. By the end of the course, students will have a working knowledge of the human genome and the tools for integrating this information into clinical research as well as conveying it to patients.

## **TSCI 6069 Statistical Issues, Planning, and Analysis of Contemporary Clinical Trials**

2.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Patient-Oriented Clinical Research Biostatistics – 1 and Patient-Oriented Clinical Research Biostatistics – 2*

Course Director: Joel Michalek, PhD

This *elective* course will serve as an in-depth survey of the various clinical trial designs, analysis, and regulatory issues. Students will learn to apply statistical principles in designing clinical trials to minimize risk to patients while maximizing generalizable discovery. Specific topics include Phase I-V studies, adaptive designs, longitudinal and survival studies. Students will learn to specify the primary outcome and to estimate the required sample size for common trial designs. Clinical trial design and analysis is often complicated by idiosyncrasies such as missing data, and the methodology for handling these will be covered.

## **TSCI 6070 Biostatistics Methods for Longitudinal Studies**

2.5 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Patient-Oriented Clinical Research Biostatistics – 1 and Patient-Oriented Clinical Research Biostatistics – 2*

Course Director: Chen-Pin Wang, PhD

This *elective* course will discuss a broad range of statistical techniques for deriving statistical inference from longitudinal studies. Main topics include design of longitudinal studies (power analyses and sample size estimation), analyses of repeated measured outcomes (continuous and discrete), analyses of time-to-event outcomes, techniques to address challenges associated with missing data and confounding data, and rigorous casual modeling approaches. Students will learn to identify feasible and efficient statistical designs for longitudinal studies and to conduct rigorous and robust statistical methods to analyze data from longitudinal studies. The goal is to develop students' biostatistical competencies in conducting high-quality longitudinal studies in medical research.

## **TSCI 6097 Research**

1.0 – 3.0 Semester Credit Hours (SCH)

*Prerequisite: An approved Supervising Professor, Supervising Committee, and research project proposal in the MSCI-TS program and submission of the Planned Activities form to the Academic Coordinator/Course Director prior to enrollment required.*

Course Director: Helen P. Hazuda, PhD

The Research Course is set up for the student to conduct their Mentored Research Project with their faculty advisor. This time is to be spent directly working on the project and includes, but is not limited to, writing consent forms, collecting data, analyzing data, and preparing a manuscript. After MSCI-TS COGS approval of the research project, students will take 3 semester credit hours of research during each semester of the Master of Science in Clinical Investigation and Translational Science Degree Program.

## **TSCI 6098 Thesis**

1.0 Semester Credit Hours (SCH)

*Prerequisite: An approved Supervising Professor, Supervising Committee, and research project in the MSCI-TS program.*

Course Director: Helen P. Hazuda, PhD

Registration for one semester is required of MSCI-TS degree candidates.

### **TSCI 6100 Practicum in IACUC Procedures**

1.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: Rodolfo Trevino, MS, CPIA

This *elective* course presents an in-depth introduction to the institutional program that provides oversight and regular review of projects that involve the care and use of animals. This includes consideration of the operational procedures of the Institutional Animal Care and Use Committee (IACUC) of the UTHSCSA. Course objectives are achieved through a combination of readings, monthly attendance at selected IACUC meetings, and discussions with faculty.

### **TSCI 6101 Topics in Translational Science**

1.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: Christopher Frei, PharmD, MSc

This *elective* course addresses selected topics in translational science through a series of lectures, assigned readings, literature reviews, class presentations, and discussions with faculty.

### **TSCI 6102 Practicum in IRB Procedures**

1.0 Semester Credit Hour (SCH) (elective course)

Course Director: Pamela Sabrsula, MS, CIP

This *elective* course presents an in-depth introduction to the institutional program that provides oversight and regular review of research projects that involve human subjects. This includes consideration of the operational procedures of the multiple Institutional Review Boards (IRB) of the UTHSCSA. Course objectives are achieved through a combination of readings, monthly attendance at selected IRB meetings, and discussions with faculty.

### **TSCI 6201 Data Science Leadership in Healthcare**

1.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: Jonathan Gelfond, MD, PhD

This offers a hands-on approach to data science operations in biomedical science. The class discusses the management of data science teams, collaboration within healthcare organizations, and the social and ethical responsibility of data scientists. The course focuses on real world applications.

## **TSCI 6202 Data Visualization and Building Applications**

2.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: Alex Bokov, PhD

This course offers a hands-on approach to data visualization for biomedical data science. The class uses R, Python and Javascript and the software tools that interoperate with them. Some cross-cutting best practices. The course focuses on real world applications.

## **TSCI 6203 Practicum in Biomedical Data Science**

1.0 Semester Credit Hour (SCH) (elective course)

*Prerequisite: Consent of the Course Director*

Course Director: Zhu Wang, PhD

This course provides an opportunity for participation in unique biomedical data science and translational research activities that are highly individualized for each student on the basis of prior experience and research interests.