

ADAPT

Addressing Disparities in Asian Populations through Translational Research (ADAPT)

Course description: The ADAPT seminars aim to raise awareness of Asian health disparities and facilitate community-engaged translational research that targets the health of Asian-Americans. These presentations are for the research and clinical communities, public health and policy makers, and community leaders.

- 1. Together Strengthening the Health of Chinatown: Advancing Asian American Health Research and Health Equity
 - Carolyn Rubin EdD, MA, Chau Trinh-Shevrin, DrPH, Vivien Wu, and Giles Li
- 2. Together Strengthening the Health of Chinatown: Community Assessment of Freeway Exposure and Health (CAFEH)
 - Doug Brugge, PhD, MS
- 3. Public Health and Health Disparities Career Discussion
 Aviva Must, PhD, Chau Trinh-Shevrin, DrPH, and Carolyn Rubin EdD, MA
- 4. Together, Strengthening the Health of Chinatown: An Asian Health Symposium, Introduction
 - Alice Rushforth, PhD, Carolyn Rubin, EdD, MA, Harris Berman, MD, Mei-Hua Fu, MS, MEd
- Using Data to Advance Health in Chinatown
 Giles Li, Susan Koch-Weser, ScM, ScD, Mengxi Du, Kaiyan Jew, Yuao Liu, Tina Wang,
 Meng Zhang
- 6. Results of a Healthy Chinatown Needs Assessment: Healthy Eating and Active Living Among Pre-School Aged Children in Chinatown Early Education Programs Virginia R. Chomitz, PhD, MS, Bernadette Davidson
- 7. ADAPT and Chinese Church Head Start: How a Head Start Center Benefits From Academic-Community Collaboration
 - Mei-Hua Fu, MS, MEd, Merieka Torrico, MPH, Moussa Cisse, Risha DeLeon
- 8. Increasing Utilization of Preventative Care in Asian American Women in MA Lisa Gualtieri, PhD, ScM, Tam H. Nguyen, PhD, MSN/MPH, RN
- 9. Community Engagement to Promote Healthy Aging for Older Adults in Chinatown Kieran Reid, PhD, MPH

ВΙ

Biomedical Informatics

Course description: How can you best capture the data for your study? Which electronic data capture software is best for you? Tufts CTSI's biomedical informatics seminars review leading software applications and describe their potential for streamlining clinical trials, patient registries, surveys, and more.

Using REDCap[™] to Build a Database or Survey
Karen M. Switkowski, MS, MPH



CER

Comparative Effectiveness Research (CER) Survey Course

Course description: This groundbreaking course tackles one of the most opportune and relevant topics in medicine: Comparative Effectiveness Research (CER). Nationally renowned CER experts describe the current state of CER, define CER tools, and explain state-of-the-art CER methodologies in a series of 15 captivating 2-hour lectures. Each lecture has been professionally videotaped and combined with slides and other learning materials to provide interactive presentations.

1. Unit 1: Introduction

Part 1: Comparative Effectiveness Research: Recent History and Role in Healthcare Reform

Part 2: Rationale for CER

Harry P. Selker, MD, MSPH

Peter J. Neumann, ScD

2. Introduction: A Review of Evidence-Based Medicine (EBM) and a Framework for Understanding the CER Agenda

Thomas W. Concannon, PhD

3. Unit 2: Evidence Generation

Part 1: Comparative Effectiveness Trials

Part 2: Assessing Pharmacogenetic Information in Clinical Trials

David M. Kent. MD. MSc

Thomas A. Trikalinos, MD, PhD

4. Personalized Medicine, Heterogeneity of Treatment Effect, and Implications for Comparative Effectiveness

David M. Kent. MD. MSc

5. Retrospective and Observational Comparative Effectiveness Studies

Dana Gelb Safran, ScD

Peter K. Lindenauer MD, MSc

6. Unit 3: Evidence Synthesis

Systematic Review and Meta-Analysis

Joseph Lau, MD

Christopher H. Schmid, PhD

7. Unit 4: Evidence Integration

Decision Modeling – Cost-Effectiveness

Stephen G. Pauker, MD

John B. Wong, MD

8. **Decision Modeling – Simulations**

Joshua T. Cohen, PhD

9. Unit 5: Use of Evidence in Decision Making

Community Engagement and Input into CER

Laurel K. Leslie, MD, MPH

10. Clinical Practice Guidelines

Katrin Uhlig, MD, MS

11. Clinical Effectiveness Trials and Predictive Instruments as Decision Support for Implementing CER

Harry P. Selker, MD, MSPH



12. Drug Development in the CER Era

Kenneth I. Kaitin, PhD

- 13. Using Comparative Effectiveness Research to Reach Employers and Employees Debra J. Lerner, MS, PhD
- 14. Economic and Policy Implications of CER

Christopher P. Tompkins, PhD

15. Unit 6: Future Directions in CER

Part 1: The IOM 100 Priorities and AHRQ 14 Priority Conditions and Populations

Part 2: The USPSTF Breast Cancer Screening Guidelines (Mammography) and CER: A

Panel Discussion

CERS

Comparative Effectiveness Research (CER) Seminars

Course description: The comparative effectiveness research (CER) seminars add to the content already in the CER Survey Course. They use research examples to explain each step of the Translational Spectrum of Comparative Effectiveness Research at Tufts CTSI. The seminars also discuss the current state of CER, explain state-of-the-art CER methodologies and the importance of CER.

- 1. Why Comparative Effectiveness Research Matters John B. Wong, MD
- 2. **Methods for Prioritizing Research in Comparative Effectiveness Research**Peter Neumann, ScD, Ethan M. Balk, MD, MPH, and Joshua T. Cohen, PhD
- 3. Demystifying Pragmatic Clinical Trials

Thomas W. Concannon, PhD, Harry P. Selker, MD, MSPH, Karen Freund, MD, MPH, and Robin Ruthazer, MPH

4. Systematic Review and Meta-Analysis of Diagnostic Test Studies

Ethan Balk, MD, MPH and Norma Terrin, PhD

5. Making Research Useful: Dissemination and Application of Findings from Comparative Effectiveness Research

Dominic Hodgkin, PhD

6. Feedback & Assessment: An Essential Ingredient in Comparative Effectiveness Research

R. Christopher Sheldrick, PhD

7. Comparative Effectiveness Research: Where are We Going? John B. Wong, MD

8. 2016 Comparative Effectiveness Research Symposium: Introduction and What's Next, CTSI 3.0

John Wong, MD, and Harry P. Selker, MD, MSPH

- The HELPS-HD Trial: A Cluster Randomized Pragmatic Trial of Oral Protein Supplements by DCI and Demystifying Pragmatic Clinical Trials Daniel Weiner, MD, MS and Thomas Concannon, PhD
- 10. 2016 Comparative Effectiveness Research Symposium: Theory and Charge for the Day

Thomas Concannon, PhD, and John Wong, MD



11. Improving Screening for Diabetes in Asian Americans

Susan Koch-Weser, PhD; Anastassios G. Pittas, MD, MS; and William F. Harvey, MD, MSc, FACR

CIV

Civic Life & Health Research

Course description: What is civic life, and why is it important to consider in clinical research? Understand the relevance of civic engagement to clinical and other health research at Civic Life and Health Research, a seminar by Peter Levine, PhD, Associate Dean and Lincoln Filene Professor of Citizenship and Public Affairs at Tufts University's Jonathan M. Tisch College of Civic Life. Get oriented to current research and debates about civic engagement in the US; challenge the frequent definition of civic engagement as professionals consulting stakeholders; and instead begin to see medical researchers and health professionals as citizens who should relate to other people as fellow citizens. By the end of this seminar, participants will be able to: Define the concept of civic life and related terms such as civic engagement, social capital, democratic participation, and community engagement from social science perspectives. Value civic engagement as relevant to the clinical research process. Explore differences in theory and practice depending on whether one thinks in terms of clients, patients, stakeholders, communities, publics, or citizens. Illustrate exemplary actions that investigators can take that involve civic life.

1. Introduction to Civic Life (12 min)

Peter Levine, PhD

2. Social Capital (16 min)

Peter Levine, PhD

3. Collective Efficacy (6 min)

Peter Levine, PhD

4. Common Pool Resource (8 min)

Peter Levine, PhD

5. Public Sphere (13 min)

Peter Levine, PhD

6. Importance in Health Research (6 min)

Peter Levine, PhD

7. Idea of "Stakeholders" (13 min)

Peter Levine, PhD

8. Common Tools for Civic Engagement in Research (2 min)

Peter Levine, PhD

CMI

Common Metrics Implementation

Course description: In order to maximize the CTSA Program's impact, the National Center for Advancing Translational Sciences (NCATS) is implementing the Common Metrics Initiative, which employs a set of common metrics for use in collaborative management based on the principles of the Results-Based Accountability (RBA) framework. The videos and activities outlined below are intended to teach you about the RBA framework, the Scorecard software and



their use/application. The materials are broken up into units that correspond with each training session and should be followed sequentially.

- 1. Tufts CTSI Common Metrics Implementation Session One Pre-Work
- 2. Tufts CTSI Common Metrics Implementation Session Two Pre-Work
- 3. Tufts CTSI Common Metrics Implementation Session Three Pre-Work
- 4. Tufts CTSI Common Metrics Implementation Session Three Post-Work

CR Clinical Research

Course description: How is research designed, conducted, evaluated, and applied to patient care? The Clinical Research seminar series provides a comprehensive overview of clinical research methodology, from writing a research question to publishing findings. No matter what your experience, if you are interested in learning about the basic principles of research, you are encouraged to view these exciting one-hour sessions.

- Clinical & Translational Research: An Overview and Basic Principles Karen M. Freund, MD, MPH
- 2. **Developing and Writing Research Questions, Aims & Hypotheses**Jonathan M. Davis, MD
- 3. Experimental & Observational Study Designs
 Daniel E. Weiner, MD, MS
- 4. Research Using Existing Data
 Tara Lagu, MD, MPH & Mihaela Stefan, MD, MS
- 5. Calculating Sample Size and Power Farzad Noubary, PhD
- 6. Research Ethics of Clinical Investigation Susan K. Parsons, MD, MRP
- 7. Why Studies Fail: Bias and Confounding Jessica Paulus, ScD
- 8. **Developing a Research Study Protocol** Tammy Scott, PhD
- 9. **IRB and Regulatory** Ashley Hicks, CIP
- 10. **Data Analysis**Lori Lyn Price, MAS
- 11. **Evaluating Medical Journal Articles**Paul Visintainer, PhD
- 12. **Research Data Management**Brian Wilson, BSc
- 13. **Managing Multicenter Clinical Trials**Patricia Sheehan, RN, MS, MPH



DMRC

Developing and Managing Your Research Career

Course description: New and seasoned researchers will benefit from this outstanding professional development series that covers diverse topics such as team science, mentoring, submitting a manuscript, managing a research laboratory, and getting grant funding. These seminars are co-sponsored by the Tufts University-wide Committee for Teaching and Faculty Development.

- 1. The Team Science Balancing Act: Independent Research vs. Collaborations Karen M. Freund, MD, MPH
- 2. Defining the Mentoring Relationship

Karen M. Freund, MD, MPH, Susan K. Parsons, MD, MRP, Diana W. Bianchi, MD, Michael J. Kelly, MD, MPH, and Jill L. Maron, MD, MPH.

3. What Editors Look For in a Manuscript

Karen M. Freund, MD, MPH, Andrew S. Levey, MD, and Nijsje Dorman, PhD

4. Managing a Research Laboratory

Karen M. Freund, MD, MPH, Sarah L. Booth, PhD, and Meghan Faherty, MS, MPH

5. Time Management Tools and Strategies

Karen M. Freund, MD, MPH, Claire Weigand, and Linden T. Hu, MD

6. Mutual Mentoring

Karen M. Freund, MD, MPH and Donna Qualters, PhD, MEd

7. How to Conduct Research as a Busy Clinician

Karen M. Freund, MD, MPH, Eric Smith, MD, and Laura K. Snydman, MD

- 8. **Building a Culture of Feedback: Giving and Receiving Constructive Feedback** Karen M. Freund, MD, MPH, and Maria Blanco, EdD
- 9. How to Manage a Large Clinical Trial

Susan K. Parsons, MD, MRP, Christine Wanke, MD, and Kim Dong MS, RD

10. How to Get a K Award

Karen M. Freund, MD, MPH, Tara Lagu, MD, MPH, Mihaela S. Stefan, MD, and Peter K. Lindenauer, MD, MsC

11. What To Do When You Receive Your First Grant

Karen M. Freund, MD, MPH, Andrew M. Hoffman, DVM, DVSc, and Robert M. Blanton, MD, MA

12. How to Work with Industry: Insights from Experts

Karen M. Freund, MD, MPH, Gillian Black-Noller, MD, Jeffrey B. Blumberg, PhD, FASN, FACN, CNS, John Cosmopoulos, MSc, MBA, CLP, and Daniel G. Jay, PhD

13. Translational Research: It's About Time

Karen M. Freund, MD, MPH and Harry P. Selker, MD, MPH



GCP

Good Clinical Practice for Social and Behavioral Research

Course description: The following e-Learning Course, Best Practices in Social and Behavioral Research Course, provides researchers with an overview of Good Clinical Practice (GCP) principles specific to social and behavioral clinical trials. This interactive learning resource is available courtesy of the National Center for Advancing Translational Sciences (NCATS) and the Clinical and Translational Science Awards (CTSA) Consortium. There are 9 modules in total, and each module takes approximately 25 minutes to complete. Completing the entire course is expected to take 3-4 hours. Please note that this is a self-learning tool, and may not satisfy GCP training requirements at your institution. Please check your institutional GCP training policy before completing any GCP coursework to ensure you are in compliance with NIH requirements. To receive a certificate of completion, check with your IRB office about taking this course through the "Collaborative Institutional Training Initiative (CITI) Program.

Module 1 – Introduction

Module 2 - Research Protocol

Module 3 - Recruitment and Retention

Module 4 - Informed Consent Communication

Module 5 - Confidentiality and Privacy

Module 6 - Participant Safety and AE Reporting

Module 7 - Quality Control and Assurance

Module 8 - Research Misconduct

Module 9 - Conclusion & Wrap Up

GW Grant Writing

Course description: Looking for grant writing advice? Need help strengthening your proposals? Investigators in the process of writing a grant proposal should not miss Tufts CTSI's grant writing seminars. With small class sizes and targeted discussions, these workshops teach participants how to attract reviewers to the significance, innovation, and approach of their studies, right from the very first page.

- Grant Writing Strategies for Successful Research Proposals Amy Gantt, MA
- 2. Strategies for Developing a Team Science Grant Proposal Amy Gantt, MA
- 3. Writing Clearly and Concisely Amy Gantt, MA



HL Health Literacy

Course description: The Tufts Medical Center Floating Hospital for Children partnered with Tufts CTSI and the American Board of Pediatrics (ABP) to implement a department-wide quality improvement (QI) project targeting residents, fellows, and faculty called "HEALERS" (Harnessing Efforts to Address Health Literacy and Enhance Relationships and Service). The project built off of materials developed by the Agency for Healthcare Quality and Research (AHRQ) and the ABP. The presentations and associated materials review what we know about Health Literacy, the purpose and operationalization of the HEALERS project, overviews of the two change strategies implemented, and a summary of HEALERS as a QI project.

- 1. Addressing Health Literacy and Improving Healthcare Quality Sabrina Kurtz-Rossi, MEd and Laurel Leslie, MD, MPH
- 2. Introduction to the HEALERS Project
 Laurel Leslie, MD, MPH, Priya Garg, MD, and Supriya Shah, BA
- 3. **HEALERS Change Strategy 1: Encouraging Questions**Laurel Leslie, MD, MPH, Priya Garg, MD, and Supriya Shah, BA
- 4. **HEALERS Change Strategy 2: Teach Back**Laurel Leslie, MD, MPH, Priya Garg, MD, and Supriya Shah, BA
- 5. **HEALERS: Putting it All Together** Laurel Leslie, MD, MPH
- 6. **Maintenance of Certification (MOC) Overview**Laurel Leslie, MD, MPH and Virginia Moyer, MD, MPH

MM

Survey, Qualitative, and Mixed Methods

Course description: What are the differences between qualitative and quantitative research, how do you decide which to use in your study? The seminars in our Survey, Qualitative, and Mixed Methods series define each research approach, explain how different methods are used in clinical and basic research, show how to design a study using qualitative and quantitative methods, and demonstrate how mixed methods can be successfully applied.

- An Introduction to Mixed Methods
 Tom Mackie, MA, PhD
- 2. **Mixed Methods Approaches for Health Services Research: An Introduction** Justeen Hyde, PhD and Tom Mackie, MA, PhDc
- 3. The Qualitative Research Process: Study Designs for Health Services Research Justeen Hyde, PhD and Tom Mackie, MA, PhDc
- Designing a Mixed Methods Study
 Justeen Hyde, PhD and Tom Mackie, MA, PhDc
- 5. **Applying Mixed Methods Effectively**Justeen Hyde, PhD and Tom Mackie, MA, PhDc
- 6. **An Overview of Survey Design**Susan Koch-Weser, ScD
- 7. **Item Response Theory** Barbara Gandek, PhD



NIH

NIH Biosketch, Policy and Guidance Changes

Course description: How do you implement the recent NIH/ARHQ policy and guidance changes into your grant application? Resources such as My Bibliography and SciENcv can help you to properly format your biosketch and ensure that it is compliant with NIH policies. Experts will discuss the changes to rigor and transparency in research, inclusion reporting, data safety monitoring, vertebrate animals, definition of child, research training, appendices, biosketch clarifications, font requirements and post-award changes.

- Navigating the New 2015 NIH Biosketch Format
 Tyler Manoukian, BA, Busra Ozturk, MEd, and Laura Schmidt, PhD
- Planning for NIH and AHRQ Grant Application Changes
 Zoya Davis-Hamilton, EdD, CRA, Amy Gantt, MA, Kathleen Benoit, CRA and Debbie Slater, MHA
- Uniform Guidance (UG) Implementation
 Zoya Davis-Hamilton, EdD, CRA and Joyce Ferland, BS, MBA

OH One Health

Course description: One Health is an integrative, multi-disciplinary effort to optimize health for people, animals, and the shared environment at the local, national, and global level. The CTSI One Health program seeks to harness the synergies of diseases shared by people and animals, as well as the benefits of human-animal interactions, to advance collaborative and interdisciplinary solutions for important medical issues. This united approach will translate research into practice more effectively to optimize the health and well-being of animals, humans, and the environment. One Health incorporates expertise from diverse fields, such as human and veterinary medicine, environmental and biological sciences, engineering, public health, political science, urban planning, sociology, and statistical modeling.

- 1. One Health Overview
 - Deborah T. Kochevar, DVM, PhD, DACVCP
- 2. Natural Animal Models: Beyond Rats and Mice
 Andrew Hoffman, DVM, DVSc, DACVIM, Elizabeth McNiel, DVM, PhD, DACVIM,
 DACVR, and Nicholas Frank, DVM, PhD
- 3. Healthy Pets Helping People: the Healthcare Community's Role in Safe and Effective Animal-Assisted Therapy
 - Deborah Linder, DVM, DACVN and Megan Mueller, MA, PhD
- 4. **Zoonotic Diseases: Learning from Yesterday, Planning for Tomorrow** Sam Telford, III, Ms, SD and Felicia Nutter, DVM, PhD
- 5. **Environmental Aspects of One Health**Christine L. Rioux, PhD, MS, and Antje M. F. Danielson, PhD
- 6. What the CTSI One Health Program Offers Lisa Freeman, DVM, PhD, DACVN



7. Zoobiquity Boston Keynote Session 1: Personalizing Cancer Care for Pets and People

Bruce Chabner, MD

8. Zoobiquity Boston Session 2: Obesity in a 12-Year-Old Female Domestic Shorthair Cat and a 64 -Year-Old Female Pharmacist

Lisa Freeman, DVM, PhD, and Caroline Apovian, MD

9. Zoobiquity Boston Session 3: Anterior Cruciate Ligament Injury in a 3-Year-Old Labrador Retriever and a 21-Year-Old Competitive Skier

Randy Boudrieau, DVM, and Paul Weitzel, MD

10. Zoobiquity Boston Session 4: Autism in a 15-Month-Old Male Bull Terrier and a 10-Year-Old Boy

Nicholas Dodman, BVMS, and Jean Frazier, MD

11. Zoobiquity Boston Session 5: Peripheral T-Cell Lymphoma in a 10-Year-Old Boxer Dog and a 56-Year-Old Nurse

Kristine Burgess, DVM, and Andreas Klein, MD

PACE

PACE Symposium: Using Group Data to Treat Individuals

Course description: What is Patient-Centered Outcomes Research and how can we improve our methods of conducting it? This Accelerating Patient-Centered Outcomes Research and Methodological Research seminar provides an overview of the Patient-Centered Outcomes Research Institute (PCORI), and the appropriate methods to implement when conducting patient-centered research.

- 1. Accelerating Patient-Centered Outcomes Research and Methodological Research Jessica Paulus, ScD, Harry Selker, MD, MSPH and Emily Evans, PhD, MPH
- Introduction to Heterogeneity of Treatment Effect (HTE)
 David Kent, MD, MSc
- 3. Risk and Treatment Effects

Peter Rothwell, MD, PhD

4. Genetic Prediction of Common Diseases

A. Cecile J.W. Janssens, PhD

5. Risk-Based Heterogeneity of Treatment Effect in 30 Large RCTs David Kent, MD, MSc

6. Person-Level THE

Issa J. Dahabreh, MD, MS

7. Discussion on Heterogeneity Treatment Effects

Jessica Paulus, ScD, Ravi Varadhan, PhD, Douglas Altman, DSc, A.Cecile J.W. Janssens, PhD, and David Kent, MD, MSc

- 8. A Proposed Guideline for Reporting HTE in Large Randomized Clinical Trials Rod Hayward, MD
- 9. Panel Discussion

Ewout Steyerberg, PhD, Douglas Altman, DSc, Robert Golub, MD, Rod Hayward, MD, David Kent, MD, MSc, and Walter Kernan, MD



QIH

Quality Improvement in Healthcare

Course description: This course will provide you an overview of the Quality Improvement (QI) methods and tools, and how can you apply them to your research? These seminars begin with an overview of QI, developing your aims statement, QI tools, and then various examples of how you implement small changes, how you measure change, and how you lead change.

1. What is Quality Improvement in Healthcare

Denise Daudelin, RN, MPH

2. The Power of Quality Improvement
Laurel K. Leslie, MD, MPH and Carmina Erdei, MD

3. Quality Improvement Tools: An Overview Priva Garq, MD

4. Aims Statements: Case Examples

Denise Daudelin, RN, MPH

 Measuring Change Strategies: Decreasing Air Leaks and Testing with PDSA Cycles

Laurel K. Leslie, MD, MPH and Patoula Panagos, MD

6. Implementing Change Strategies: Patient Falls
Denise Daudelin, RN, MPH and Tricia Ide, RN, MS

7. **Using Run Charts: Readmissions**Laurel K. Leslie, MD, MPH and Alexander Pavoll, MPH

8. Statistical Process Control Munish Gupta, MD, MMSc

9. **Team Charters, Team Dynamics, and Leading Change**Laurel K. Leslie, MD, MPH and Denise Daudelin, RN, MPH

10. Creating High Reliability for Organizational Improvement
Evan Benjamin, MD, FACP and Stephanie Calcasola, MSN, RN-BC

RA Regulatory Affairs

Course description: Why do you need to provide informed consent to clinical research subjects? What are the Principal Investigator's responsibilities for a clinical research study? What are successful strategies in working with the Institutional Review Board (IRB)? Regulatory affairs seminars provide information on how clinical research studies need to ensure subject safety and welfare while complying with federal, state and institutional regulations.

Principal Investigator IRB Responsibilities
 Andreas K. Klein, MD

2. Working with the IRB: Common Myths and Successful Strategies
Ashley D. Hicks, CIP

3. **Best Practices in Clinical Trials**David R. Snydman, MD, FACP, FIDSA

4. Navigating Contracts and Agreements Frederick M. Frankhauser, JD, MBA, RPh



5. Collaborative Institutional Review Board (IRB) Agreements

Andreas K. Klein, MD, Gordon S. Huggins, MD, Ashley D. Hicks, CIP, and Jonathan M. Davis, MD

6. Master Contracts

Paul Murphy, JD, MPA

7. Data Safety and Monitoring Boards: A Brief Overview

Tamsin A. Knox, MD, MPH

8. What You Need to Know About DSMBs (But Were Afraid to Ask)

Tamsin A. Knox, MD, MPH

9. Data Safety and Monitoring Board Information for IRB Members

Tamsin A. Knox, MD, MPH

10. The Challenge of Informed Consent: A Proposal

Jonathan M. Davis, MD

RC

Research Coordinator Education

Course description: In this series for study coordinators, research assistants, and other members of the research team: the Research Coordinator Education Program. This series will outline the roles and responsibilities of the research team throughout a research project.

1. Clinical Research Lifecycle

Tamsin Knox, MD, MPH

2. Clinical Trial Lifecycle

Veronika Testa, BSN, RN, CCRC and Douglas Reichgott

3. Clinical Research Billing and Medicare Coverage Analysis

Douglas Reichgott

RDDA

Research Design and Data Analysis

Course description: How many subjects do you need for your study? What's a P-value? How do you handle missing data? These are just some of the questions answered in our statistical, epidemiological, and research-oriented seminar series. Experienced instructors from Tufts CTSI's Research Design Center/Biostatistics Research Center (RDC/BRC) will help you to avoid common pitfalls and learn to build a successful research career.

1. Introduction to Study Design

Jessica Paulus, ScD

2. Formulating Research Questions, Hypotheses and Objectives

Kahsi A. Smith, PhD

3. Concepts of Hypothesis Testing

Lori Lyn Price, MAS

4. How Many Subjects Do I Need for My Study?

Jessica K. Paulus, ScD

5. Developing a Study Protocol

Tammy Scott, PhD



6. Pitfalls in Statistical Analysis

Lori Lyn Price, MAS

- 7. **Bias and Confounding in Clinical Research**Jessica Paulus, ScD
- 8. Linear and Logistic Regression Lori Lyn Price, MAS
- 9. **Modeling Time-to-Event Outcomes**Robin Ruthazer, MPH
- Which Statistical Test Should I Use?
 Lori Lyn Price, MAS

RPI

Research Process Improvement

Course description: Process improvement approaches (e.g. LEAN, Six Sigma, Model for Improvement) have been employed for years in industry to improve the quality, efficiency, and effectiveness of processes. What are the current trends, methods, tools and resources in process improvement and how can you apply them to your research? These seminars begin with an overview of process improvement, take a close look at tools used in process and quality improvement and how to use them, and feature a discussion with other researchers on how they addressed challenges in their research applying these approaches.

- 1. **Deconstructing Quality Improvement and Applying it to Research** Laurel Leslie, MD, MPH and Denise Daudelin, RN, MPH
- 2. **Using QI Tools for Improving Research Efficiency and Reliability**Laurel Leslie, MD, MPH and Denise Daudelin, RN, MPH
- 3. Using QI Tools for Managing Research Teams and Participant Recruitment and Retention

Laurel Leslie, MD, MPH and Denise Daudelin, RN, MPH

RRP

Research Recruitment and Participation

Course description: Why do people participate in clinical studies and trials? What are the challenges to recruiting human and animal research participants, and how can we overcome them? Find out at though this series of lectures delivered at Tufts CTSI's Translational Research Day: Innovations in Clinical Trial Participant Engagement.

- 1. Introduction, The mPower App and Using Technology for Participant Engagement in Clinical Trials
 - Harry Selker, MD, MSPH, Karl Kieburtz, MD, MPH
- 2. Participation in Clinical Research: Motivations and Perspectives
 Julia Farides-Mitchell, MA
- 3. Companion Animal Studies: Participant Engagement Andrew M. Hoffman, DVM, DVSc
- 4. Challenges in Consenting Pregnant Women, Children and Neonates Jonathan Davis, MD



- 5. **Participant Engagement Panel**Julia Farides-Mitchell, MA, Andrew M. Hoffman, DVM, DVSc, Jonathan Davis, MD
- 6. **Using Social Media for Participant Engagement in Clinial Trials: A Pilot Study** Laura Blaisdell MD, MPH, FAAP
- 7. Recruitment in Social Behavioral Research (Dear Abby and More)
 Debra Lerner, MS, PhD
- Using and Expert Panel to Randomize Patients in a Cervical Spondolytic Myelopathy Clinical Trial Zoher Ghogawala, MD
- Innovative Recruitment Strategies Panel
 Laura Blaisdell MD, MPH, FAAP, Debra Lerner, MS, PhD, Zoher Ghogawala, MD
- 10. **Using Research Process Improvement to Solve Recruitment Challenges**Denise Daudelin, RN, MPH, Donato Rivas, PhD

SE

Stakeholder and Community Engagement

Course description: Engagement of stakeholders is increasingly called for in federal and foundation-funded research. Who are these community stakeholders, and why is it important to involve them in your study? We will define patient, stakeholder, and community engagement in research, discuss national trends among funding agencies with respect to engagement of the public in research, describe the Tufts typology of stakeholder types (the 7 Ps), and provide an approach for mapping your research needs to different models of engagement of the public in research.

- 1. Stakeholder and Community Engagement: Why It's Important Laurel K. Leslie, MD, MPH
- 2. Stakeholder and Community Engagement: Lessons Learned Laurel K. Leslie, MD, MPH and Carolyn Rubin EdD, MA
- 3. Methods of Stakeholder Engagement
 Carolyn Leung Rubin, EdD, MA and Laurel K. Leslie, MD, MPH
- **4. Community Engagement to Improve Asian Health** Carolyn Rubin EdD, MA and Mei-Hua Fu, MS, MEd
- 5. Stakeholder Engagement in Patient-Centered Comparative Effectiveness Research

Thomas Concannon, PhD

- **6. Preparing for Patient-Centered and Stakeholder-Engaged Research** Thomas Concannon, PhD
- 7. Civic Life and Health Research
 Thomas Concannon, PhD and Peter Levine, PhD
- 8. Engaging Stakeholders in Community-Based Participatory Research Partnerships Thomas Concannon, PhD and Carolyn Rubin, EdD, MA

TRD

Translational Research Day 2017: Sensors, Devices, and Biomarkers in Medicine

Course description: How can sensor, device, and biomarker data improve health, prevent and detect disease at an earlier stage, and personalize interventions? Find out at Tufts CTSI's



Translational Research Day 2017: Sensors, Devices, and Biomarkers in Medicine. The learning objectives for Translational Research Day include that viewers of the day's talks will be able to: Recognize the different classifications of biomarkers and their potential in detecting early-stage disease and for personalizing interventions; Illustrate diverse approaches to advancing the capabilities of sensors and medical devices and their practical applications in improving health; Describe potential translational roadblocks in developing, testing, and using sensor- and device-based health prevention, detection, management, and intervention strategies; Identify Tufts CTSI resources and services that support team-based translational science.

- 1. Improving the Assessment of Functional Change in CNS Clinical Trials (15 min)
 Josh Cosman, PhD
- 2. Smart Mechanical Support Devices for Cardiac Care (11 min)
 Navin Kapur, MD
- 3. In Vivo Nanosensors and Imaging Technologies (12 min)
 Heather Clark, PhD
- 4. Improving Behavioral Measurements from Mobile Devices (15 min) Stephen S. Intille, PhD
- 5. Embedded Functioning of Nanoscale Sensors in Hybrid Tissues (13 min)
 Brian Timko
- 6. Harmonizing Biomarker Terminology: NIH-FDA BEST (Biomarkers, EndpointS, and other Tools) (22 min)

Christopher Leptak, MD, PhD

7. A Metatranscriptomic Approach to Salivary Biomarker Discovery in the Premature Newborn (13 min)

Jill L. Maron, MD, MPH

- 8. Collaborative Data Science in Health Care (14 min)
 Leo Anthony Celi, MD, Msc, PhD
- 9. The Challenge of Making Things Work Well: An Academic Perspective (10 min) Kumaran Kolandaivelu, MD, PhD
- 10. Lessons Learned from the Front Lines (24 min)

Rami Tzafriri, PhD and Michael Naimark, MS

11. Case Study Panel Discussion (12 min)

Rami Tzafriri, PhD; Michael Naimark, MS; Kumaran Kolandaivelu, MD, PhD

12. Funding Opportunities - Tufts CTSI Symposium Plus (12 min)
Graham Jones, PhD; Alysse Wurcel, MD, MS; John Leong, MD, PhD

TSS

Translational Science Seminars

Course description: This series will explore Clinical and Translational Science across its full spectrum, specific contributions of different parts of the spectrum in the overall goal of improving health, and understand topic-specific examples that one can draw upon to exemplify translational research. The seminar series will highlight current research being done cross-collaboratively between Tufts CTSI and across the Tufts campus, its community and affiliates.

1. Exploiting the Molecular Signatures of Disease: Case Studies in Bench-to-Bedside Research

Graham B. Jones, PhD, DSc



2. Bile Acids and Spore Germination: A Novel Approach to Blocking Clostridium Difficile Infection

Abraham L. Sonenshein, PhD and Yoav Golan, MD, MS

3. Translating 'Natural' Experiments into Clinical Research: Using Administrative Data for CER

Daniel E. Weiner, MD, MS

4. Spontaneous Animal Models in Translational Research: From Cardiac Cachexia to Obesity

Lisa Freeman, DVM, PhD, DACVN

TTIC

Technology Transfer and Industry Collaboration

Course description: As part of our continuing efforts to support research, innovation, translation, entrepreneurship and technology transfer within the Tufts community, Tufts Technology Transfer and Industry Collaboration (TTIC) has organized a seminar series of lectures on intellectual property management, technology transfer, start-up company formation and other relevant subjects. The topics are planned for experience at all levels and provide an overview of the role of university technology tran

 Introduction to Technology Transfer Erik Halvorsen, PhD, MBA

2. **An Introduction Into Material Transfer Agreements**Lee Tien. PhD

3. The Invention Disclosure Process

Colm Lawler, PhD

4. An Introduction Into License and Option Agreements

Martin Son, PhD

5. How to Start a Company Based on a University Technology

Paul Hartung, MS

6. **Negotiation Techniques**

Erik Halvorsen, PhD, MBA

7. Effective Marketing Strategies

Jennifer Tsai, MBA

8. The Role of Technology Development for Advancing Academic Discoveries John Cosmopoulos, MSc, MBA

9. Business Communication

Erik Halvorsen, PhD, MBA

10. How Changes to US Patent Law Impact Technology Transfer

Erika Bechtold, PhD