

## Principles of Clinical Research

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**Ever had an idea? A new diagnostic test? A modifiable risk factor? A cost-effective alternative? Wondering how to improve outcomes? Clinical research is for you.**

Clinical research is the key investigative method to test hypotheses that have a direct influence on our patients. The efficacy of interventions, the prognosis of patients, and the improvement in health-care delivery relies heavily on clinical research, in some cases solely.

This course, a total of 10 hours of learning, provides a foundation to assess and interpret the available orthopaedic literature, and to participate in scientific progress by providing the tools needed to initiate new or contribute to existing clinical research programs.

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## Course Curriculum

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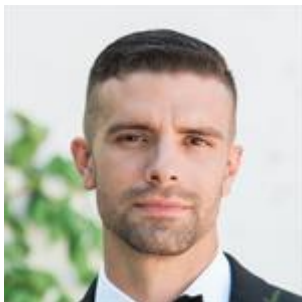
### Module 1

#### ***Principles of Clinical Research:***

#### ***An Introduction to the Understanding & Design of Clinical Research***



Kurt Spindler, MD  
Cleveland Clinic Sports Health Center



José F. Vega, MA  
Learner College of Medicine

**Learning Objectives:**

- Understand a basic approach to designing a clinical research study beginning with development of a research question and an appropriate hypothesis
- Be able to differentiate between prospective studies and retrospective studies
- Understand the advantages and disadvantages of the most common clinical research study designs
- Appreciate the role of the institutional review board (IRB) in the research process

## Module 2

### *Measurement in Clinical Research*



Joel Gagnier, ND, MSc, PhD  
University of Michigan

**Learning Objectives:**

- To understand the basics of psychometrics
- To understand the various forms of validity, reliability and responsiveness

## Module 3

### *Biostatistics for Orthopaedic Surgeons: A Practical Guide to Understanding Statistical Analysis*



Jessica Widdifield, PhD  
Sunnybrook Research Institute  
University of Toronto, Institute of Health Policy, Management & Evaluation  
Institute for Clinical Evaluative Sciences

**Learning Objectives:**

- To acquire basic biostatistics knowledge in order to effectively interpret and apply the medical literature to patient care
- To understand basic biostatistics -> terminology and common statistical methods
- To aid in the understanding of the analysis in a scientific paper

## Module 4

### *Health Services Research*



Bheeshma Ravi, MD, PhD, FRCSC  
Sunnybrook Health Sciences Centre



Jeremie Larouche, MD, MSc, FRCSC  
Sunnybrook Health Sciences Centre

#### **Learning Objectives:**

- Gain an understanding of the breadth of health services research
- Understand the advantages and disadvantages of registries
- Understand the advantages and disadvantages of administrative databases
- Gain an understanding of the importance of quality improvement
- Be able to distinguish between quality improvement and standard clinical research

## Module 5

### *Observational Studies:*

### *Cohort Studies, Case Control Studies, Cross Sectional Studies*



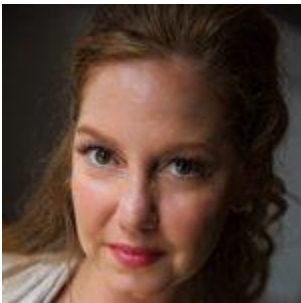
Stephen Lyman, PhD  
Hospital for Special Surgery

**Learning Objectives:**

- To understand the basic methods for designing an observational study
- To be able critically to appraise observational studies

**Module 6*****Randomized Controlled Trials:  
Structure and Management of Bias***

Roy K. Aaron, MD  
Department of Orthopaedic Surgery, Warren Alpert Medical School of Brown University



Jennifer Racine-Avila, MBA  
Department of Orthopaedic Surgery, Warren Alpert Medical School of Brown University

**Learning Objectives:**

- Learn the structure of a randomized controlled trial (RCT)
- Understand differences between RCT and other trial designs
- Recognize sources of bias in the structure of an RCT
- Learn strategies for minimizing bias
- Understand intention-to-treat method of data analysis and its weaknesses with crossover data

**Module 7*****Knowledge Synthesis: Systematic Reviews and Meta-Analyses***

Joel Gagnier, ND, MSc, PhD  
University of Michigan

**Learning Objectives:**

- To understand the basic methods for performing a systematic review and meta-analysis
- To be able to critically appraise systematic reviews and meta-analyses

## Module 8

### *Knowledge Translation & Dissemination*



David Wasserstein, MD, MSc, MPH(c), FRCSC  
Sunnybrook Health Sciences Centre

**Learning Objectives:**

- Understand the four main components of Knowledge Translation
- List issues of quality in knowledge synthesis tools
- Identify barriers to knowledge translation
- Understand a framework or approach to knowledge translation
- To be able to incorporate a strategy for KT in their own practice

## Module 9

### *Epidemiology: Musculoskeletal Injury and Disease*



Jessica Rivera, MD  
US Army Institute of Surgical Research, Extremity Trauma and Regen Medicine

**Learning Objectives:**

- To learn the terminology of epidemiology and how to study epidemiologic questions
- To describe the burden of musculoskeletal injury and disease
- To understand how injury prevention efforts aim to affect injury epidemiology
- To provide examples of how the orthopaedic community contributes to public health