LearnORS **an online, on demand learning platform offered by the Orthopaedic Research Society**

# Principles of Clinical Research

**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.

***LearnORS*** will maximize success by allowing the learners to control the rate at which they move forward through segmented content created by national and international content experts.

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# Course Curriculum

## 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 and RCT and others 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