

RICHARD D. BERKOWITZ, MD, FAAOS, CCRP

Phoenix Clinical Research, LLC
7171 North University Drive, Suite 100
Tamarac, Florida 33321
(954) 722-9993

EMPLOYMENT

President - Phoenix Clinical Research, LLC, Tamarac, Florida
October 2006 – Present

Solo Practitioner – Richard Berkowitz, MD, PA, Tamarac, Florida
May 2001 – Present

Medical Director of Joint Replacement Services, University Hospital, Tamarac, Florida
January 2013 - Present

Director of Joint Replacement Services, Coral Springs Medical Center, Coral Springs, Florida
January 2007 – June 2015

Director of Orthopedic Research, University Hospital, Tamarac, FL
August 2009 – December 2013


Employed Physician - Park Place Orthopedics & Rehabilitation, Tamarac, Florida
October 1996 – May 2001

Research Fellow - McGill University, Department of Orthopedic Surgery, Montreal, Quebec
July 1990 – June 1991

FACULTY APPOINTMENTS:

Nova Southeastern University, College of Osteopathic Medicine
Clinical Assistant Professor, April 2016 - June 2019

Palm Beach Consortium for Graduate Medical Education
Teaching Physician, Clinical Instructor / Preceptor, July 2015 - June 2019



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RESEARCH AFFILIATIONS

Phoenix Clinical Research, LLC
President, Principal Investigator, September 2006 – Present

Richard Berkowitz MD, PA
Principal Investigator, 1998 - 2004

Gold Coast Research
Sub-Investigator, 1999 – 2001

MEDICAL TRAINING

Kerlan-Jobe Orthopedic Clinic, Inglewood, California
Fellow, Total Joint Arthroplasty
September 1995 – August 1996

McGill University, Montreal, Quebec, Canada
Orthopedic Surgery Resident
July 1991 – June 1995

Boston City Hospital, Boston, Massachusetts
Junior Orthopedic Fellow
July 1989 – June 1990

Albert Einstein Medical Center, Philadelphia, Pennsylvania
General Surgery Resident
July 1988 – June 1989

EDUCATION

Hahnemann University, Philadelphia, Pennsylvania
Doctor of Medicine
August 1984 – June 1988

University of Rochester, Rochester, New York
Bachelor of Arts in Biology
September 1980 – May 1984

LICENSURE

Florida – Medical Licensure
Federal – DEA Licensure

CERTIFICATIONS

Certified Clinical Research Professional
Board Certified by the American Board of Orthopedic Surgery
Fellow of the American Academy of Orthopedic Surgeons
Board Certified by the Royal College of Physicians and Surgeons of Canada
Fellow of the Royal College of Physicians and Surgeons of Canada

PROFESSIONAL MEMBERSHIPS

1990 - present American Academy of Orthopedic Surgeons
1996 - present Florida Orthopedic Society
1996 - present Broward Orthopedic Society
2004 - present American Association of Hip and Knee Surgeons
2007 - present Society of Clinical Research Associates

HOSPITAL AFFILIATIONS

Coral Springs Medical Center, Coral Springs, Florida
University Hospital and Medical Center, Tamarac, Florida

RESEARCH TRAINING & CERTIFICATIONS

CITI-Good Clinical Practice Course
August 2017

2016 Site Solutions Summit
Morehouse School of Medicine, Office of Extended Professional Education
14-16 October 2016

CITI-Biomedical Research Course-Human Subjects Research
Stage 3
August 2016

9th Annual Site Solutions Summit
Amelia Island, FL – October 2014

Collaborative IRB Training Initiative
Basic Course – Human Subjects Research
Broward County, FL – March 2008, September 2012

Certified Clinical Research Professional,
Society of Clinical Research Associates
October 2008, Recertified October 2011, October 2014

7th Annual Site Solutions Summit
Palm Beach Gardens, FL – October 2012

6th Annual Site Solutions Summit
Palm Beach Gardens, FL – October 2011

MAGI's Clinical Research Conference
Las Vegas, NV – October 2011

20th Annual Partnerships in Clinical Trials
Phoenix, AZ – March 2011

GCP Training - Pfizer
On-Line - December 2010

5th Annual Site Solutions Summit
St. Petersburg, FL – October 2010

18th Annual Society of Clinical Research Associates Conference
Nashville, TN – September 2009

Site Operations and SOPS
Western Institutional Review Board, Inc.
Orlando, FL - April 2010

Standard Operating Procedures; Development and Implementation
Society of Clinical Research Associates
Clearwater Beach, FL - February 2010

Device Research and GCP Regulations and Guidelines
Society of Clinical Research Associates
Chicago, IL - May 2009

Clinical Science Course for Clinical Research Professionals
Society of Clinical Research Associates
Fort Worth, TX - March 2008

Good Clinical Practices for Clinical Research Professionals
Association of Clinical Research Professionals
Malvern, PA - November 2007

RESEARCH EXPERIENCE

Regulation of Coagulation in Orthopedic Surgery to Prevent DVT and PE; a Controlled, Double-Blind, Randomized Study of XXX in the Prevention of VTE in Subjects Undergoing Elective Total Knee Replacement

A Randomized, Double-Blind, Active and Placebo Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of XXX Immediate-Release Formulation in the Treatment of Acute Pain from Total Hip Replacement Surgery Followed by a Voluntary Open-Label Extension

A Phase 2, Randomized, Active Comparator-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of XXX in Subjects Undergoing Total Knee Replacement

A Phase 3, Randomized, Double-Blind, Active-Controlled, Parallel-Group, Multi-Center Study to Evaluate the Safety and Efficacy of XXX in Subjects Undergoing Elective Total Hip Replacement Surgery (The ADVANCE-3 Study XXX Dosed Orally Versus Anti-Coagulation with Injectable Enoxaparin to Prevent Venous Thromboembolism)

A Multinational, Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of XXX With Enoxaparin For The Prevention of Venous Thromboembolism in Patients Undergoing Elective Knee Replacement Surgery

A Multinational, Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of XXX with Enoxaparin For The Prevention of Venous Thromboembolism in Patients Undergoing Elective Total Hip Replacement Surgery

A Randomized, Double-blind, Placebo-and Active-Controlled, Parallel-Arm, Multicenter Study in Subjects With End-Stage Joint Disease to Compare the Frequency of Constipation Symptoms in Subjects Treated With XXX and XXX Using a Bowel Function Patient Diary

A Randomized, Double-Blind, Double-Dummy, Parallel Group Study to Compare XXX BID and QD Doses and Enoxaparin for Prevention of Venous Thromboembolism in Subjects Undergoing Elective Hip Replacement Surgery

Prospective Multicenter Post Approval Study of the XXX Mobile Bearing Knee

XXX High-Flex Knee Used Within the Knee Registry Protocol

XXX Hip Stem Prosthesis Used Within the Hip Registry Protocol

An Open-label Pharmacodynamic Study of Initiation of XXX following Low Molecular Weight Heparin (LMWH) for Venous Thromboembolism (VTE) Prophylaxis After Total Joint Replacement: The Safe Simple Transitions (SST) Study

A Double-Blind, Randomized, Placebo-Controlled, 12 Week Treatment Period, Pivotal Trial. This Study Will Consist of XXX and XXX Active Treatment Arms and Placebo Control Arms.

A Double-Blind, Randomized, Placebo-Controlled, 12 Week Treatment Period, Extension Study. Patients that Complete Study XXX Will be Invited to Participate in this Extension Study. Patients will be Re-Randomized to an Assigned Treatment Arm, XXX or Placebo.

A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation

A Randomized, Double-Blind, Placebo-Controlled 12-Week Extension to Assess the Safety and Tolerability of XXX in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation

A Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety In Osteoarthritis or Rheumatoid Arthritis Patients With or at High Risk for Cardiovascular Disease Comparing XXX with XXX and XXX

An Open-Label 52-week Study to Assess the Long-Term Safety of XXX in Opioid-Induced Constipation (OIC) in Patients with Non-Cancer-Related Pain

A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Active-Controlled, Parallel-Group, Multicenter Trial of XXX Controlled-Release Tablets (XXX) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-Induced Constipation (Compared to XXX Controlled-release Tablets (XXX) In Opioid-Experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-Induced Constipation who Require Around-the Clock Opioid Therapy

A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy and Safety of the XXX System to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Acute Post-Operative Pain

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of The XXX System/15 mcg for the Treatment of Post-Operative Pain in Patients after Knee or Hip Replacement Surgery

Sensitivity and Specificity of XXX PET-CT Scanning in Detecting Prosthetic Joint Infection in Patients Presenting with Pain in a Prosthetic Knee or Hip Joint

Psychometric Validation of Performance Based Measures for Use with Hip Fracture and Elective Hip and Knee Replacement Populations

A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Active-Controlled, Parallel-Group, Multicenter Trial of XXX Controlled-Release Tablets (XXX) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-Induced Constipation (Compared to Placebo) and the Management of Opioid-Induced Constipation (Compared to XXX Controlled-Release Tablets (XXX) in Opioid-Experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-Induced Constipation who Require Around-the Clock Opioid Therapy

A Prospective, Randomized, Controlled, Single-Blinded, Multicenter Study to Evaluate the Efficacy and Safety of XXX for Hemostasis in Primary Unilateral Total Knee Arthroplasty (TKA)

Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of a Single Injection Femoral Nerve Block with XXX for Postsurgical Analgesia in Subjects Undergoing Total Knee Arthroplasty

An Open-Label, Multi-Center, Randomized Study to Evaluate the Safety and Efficacy of Oral XXX in Combination with Oral Rifampin for Prosthetic Joint Infection, in Comparison with Standard of Care Intravenous Antibiotic Treatment Regimens, during Two-Stage Prosthesis Exchange

A Multi-Center, Randomized, Double-Blind, Phosphate Buffered Saline-Controlled Study to Evaluate Effectiveness and Safety of a Single Intra-Articular Injection of XXX for the Treatment of Osteoarthritis of the knee with Open-Label Safety Extension

Efficacy, Immunogenicity, and Safety Study of Clostridium difficile XXX in Subjects at Risk for Clostridium difficile Infection

A 56-week, Randomized, Multi-Center, Double Blind, Placebo-Controlled, Phase IIa / IIb Study to Evaluate the Safety and Efficacy of IV XXX on Total Lean Body Mass and Physical Performance in Patients After Surgical Treatment of Hip Fracture

Assessing the Association between Patients' Perceptions of Success with Post-Operative Pain Management and Overall Experience with Care A Post-Market, Multi-Center, Prospective, Double-blind, Randomized, Controlled Study to Evaluate the XXX Device in Treating Pain Associated with Total Knee Arthroplasty

A Randomized, Double-Blind, Parallel-Group, Dose-Ranging Study of the Efficacy and Safety of XXX in Patients with Osteoarthritis of the Knee/Hip who have an Inadequate Response to NSAID and Opioid Therapy

A Phase 3, Open-Label Study to Evaluate the Safety of XXX in Patients with Acute Pain for Which Parental Opioid Therapy is Warranted

A Randomized, Double-Blind, Multi-Dose, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Patients with Pain due to Osteoarthritis of the Knee or Hip

Assessing the Association between Patients Perceptions of Success with Post-Operative Pain Management and Overall Experience with Care

A Randomized, Double-Blind, Double-Dummy, Active-Controlled, Repeated-Dose, Multicenter Study to Compare Intravenous and Oral XXX for the Treatment of Acute Moderate to Severe Pain in Combination with Patient-Controlled Analgesia With Morphine in Adults Following Elective Total Knee Arthroplasty

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Evaluation of the Safety of XXX Following Major Surgery

A Phase 1, Open-Label Pharmacokinetic Study to Investigate Drug Penetration in the Bone after Repeated Oral Administration of XXX to Patients Undergoing Hip Replacement Surgery

Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of the Analgesic Efficacy and Safety of a Dose Titration Regimen for the Subcutaneous Administration of XXX in Subjects with Osteoarthritis of the Hip or Knee

A Post-Market, Multi-Center, Prospective, Double-Blind, Randomized, Controlled Study to Evaluate the XXX Device in Treating Pain Associated with Total Knee Arthroplasty

A Phase 3, Multicenter, Long-Term Observational Study of Subjects From XXX Studies who Undergo a Total Knee, Hip, or Shoulder Replacement

An Open-Label, Non-Randomized, Single-Arm Multi-Center Study to Evaluate Oral XXX for the Treatment of Staphylococcal Bone or Joint Infections in Subjects for whom Chronic Antibiotic Suppressive Therapy is Indicated

A Phase 2 Randomized Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of a Single Intrathecal Preoperative Administration of XXX Injection in Patients Undergoing Unilateral Total Knee Replacement

A Phase 2b, Randomized, Double-Blind, Saline Placebo- and Active-Controlled, Multicenter Study of XXX via Infiltration for Postoperative Analgesia in Subjects Undergoing Total Knee Arthroplasty

Phase 3 Randomized, Double-Blind, Active-Controlled, Multicenter Study of the Long-Term Safety and Efficacy of Subcutaneous Administration of XXX in Subjects with Osteoarthritis of the Hip or Knee

Retrospective Multi-Center Clinical Survey of the XXX Longevity Constrained Liner & XXX 40mm ID Standard Longevity Liner

A Randomized, Double-Blind, Double-Dummy, Multicenter, Adaptive Design, Dose-Escalation (Part 1) and Dose-Response (Part 2) Study to Evaluate the Safety and Efficacy of Intravenous XXX Versus Oral Apixaban in Subjects Undergoing Elective Total Knee Replacement Surgery

A Randomized, Double-Blind, Multi-Dose Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Patients with Pain due to Osteoarthritis of Knee or Hip

An Open-Label Study to Evaluate the Efficacy and Safety of XXX for the Treatment of Subjects with Thrombocytopenia Scheduled for a Surgical Procedure

A Phase 2, Randomized, Controlled Study of XXX Administered Via Infiltration in Subjects Undergoing Total Knee Arthroplasty

A Phase 3b, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Evaluation of the Safety and Efficacy of XXX Administered Preoperatively in Open Unilateral Total Knee Arthroplasty

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Evaluation of the Safety of XXX Following Major Surgery

A Randomized, Open-Label, Study Drug-Dose Blind, Multicenter Study to Evaluate the Efficacy and Safety of XXX, an Oral Factor XIa Inhibitor, Versus Subcutaneous Enoxaparin in Subjects Undergoing Elective Total Knee Replacement Surgery

A Phase 2b, Randomized, Double-Blind, Saline Placebo - and Active-Controlled, Multicenter Study of XXX Administered Via Infiltration for Postoperative Analgesia in Subjects Undergoing Total Knee Arthroplasty

A Phase 3b, Open-Label Study of XXX as part of a Scheduled Non-Opioid Multimodal Analgesic Regimen in Subjects undergoing Total Knee Replacement

A Phase 4, Open-Label Study of Liposomal Bupivacaine Admixed With Bupivacaine HCL in Subjects Undergoing Total Knee Arthroplasty

PUBLICATIONS

Safety, Tolerability, and Effect on Opioid Use of Meloxicam IV Following Orthopedic Surgery

Journal of Pain Research, January 2020, 221-229

ATHENA: A Phase 3, Open-Label Study Of The Safety and Effectiveness of Oliceridine (TRV130), A G-Protein Selective Agonist at The μ -Opioid Receptor, In Patients With Moderate To Severe Acute Pain Requiring Parenteral Opioid Therapy

Journal of Pain Research - Volume 12, November 2019, 3113-3126

Liposome Bupivacaine Femoral Nerve Block for Postsurgical Analgesia after Total Knee Arthroplasty

Anesthesiology – Vol. 124 (6), June 2016, 1372-1383

FIAU: Human Dosimetry and Infection Imaging in Patients with Suspected Prosthetic Joint Infection

Nuclear Medicine and Biology – Vol. 43, May 2016, 273-279

Initiation of Rivaroxaban Following Low Molecular Weight Heparin for Thromboprophylaxis After Total Joint Replacement: The Safe, Simple Transitions (SST) Study

Thrombosis Research – Vol. 130 (5), November 2012, 709 - 715

Rehabilitation After Total Knee Arthroplasty

Vital Signs, Vol. 7, No. 4, February 1997

Cemented Femoral Reconstruction in Revision Total Hip Arthroplasty

Current Opinions in Orthopedics, Vol. 7, No.1, February 1996

Magnetic Resonance Imaging Evaluation of Calcaneal Fat Pads in Patients with Os Calcis Fractures Due to a Fall from a Height

Foot and Ankle, Vol. 13, No. 2, February 1992

JBJS (B) Orthopaedic Proceedings, Vol. 73B, Supp. II, 1991

JBJS Orthopedic Proceedings, 1991

Hawkins Type III Fracture-Dislocation of the Talus and Diastasis of the tibiofibular Joint without Concomitant Fracture of the Malleoli – A Case Report

Clinical Orthopedics and Related Research, #279, June 1992

Intra-Articular Administration of 5-Bromo-2-Deoxyuridine to Label Meniscal and Synovial Cells

Transactions of the 38th Annual Meeting of the Orthopaedic Research Society, Vol. 17, Sec. 2, February 1992

JBJS Orthopedic Proceedings, 1992

INVITED LECTURER

How to Prepare a Person for Total Joint Arthroplasty

National Association of Rehabilitation Professionals in the Private Sector
Fort Lauderdale, Florida – February 1999

Management of the Infected Total Knee Replacement from Excision to Revision

Revision Total Knee Seminar
Clearwater, Florida – May 1998

Inflammatory Conditions in the Ambulatory Patient

Annual Meeting of the Tennessee Pharmacists Association
Perido Beach, Alabama – July 1997

PRESENTATIONS

HTX-011 Combined with Multimodal Analgesia as Pain Management after Total Knee Arthroplasty: Results from a Phase 3b Open-Label Study

Canadian Anesthesiologists' Society 2020 Annual Meeting
Halifax, NS, Canada - June 2020

Efficacy and Safety of Preoperative Meloxicam IV in Primary Total Knee Arthroplasty
American Society of Regional Anesthesia and Pain Management's 45th Annual
Regional Anesthesiology & Acute Pain Medicine

San Francisco, California - April 2020

Healthcare Resource Utilization Associated with Preoperative Meloxicam IV in Primary Total Knee Replacement

American Society of Regional Anesthesia and Pain Management's 45th Annual
Regional Anesthesiology & Acute Pain Medicine

San Francisco, California - April 2020

Lower Incidence Of Postoperative Opioid-induced Respiratory Depression With Oliceridine Compared to Morphine: A retrospective Analysis

e-Poster Presentation at Anesthesiology 2019
Orlando, Florida 2019

Safety and Opioid Use Following Total Knee Arthroplasty in a Randomized Trial of Meloxicam IV

Poster Presentation at 2018 American Academy of Hip and Knee Surgeons Annual Meeting

Dallas, Texas – November 2018

Athena: A Phase 3, Open-Label Safety Study of Oliceridine For the Treatment of Moderate-to-Severe Acute Pain

e-Poster Presentation at 2018 American Society of Anesthesiologists Annual Meeting
San Francisco, California – October 2018

A Phase 3, Placebo-Controlled Study of Meloxicam IV Following Major Surgery: Safety and Opioid Use Following Major Orthopedic Procedures

Poster Presentation at 2018 World Congress on Regional Anesthesia & Pain Medicine
New York City, New York – April 2018

Cryoneurolysis Prior to Total Knee Arthroplasty for Post Surgical Pain

Poster Presentation at Annual Meeting of the Louisiana Orthopedic Association
New Orleans, Louisiana – February 2018

Safety and Opioid Use Following Major Orthopedic Surgery in a Phase 3, Placebo-Controlled Study of Intravenous Meloxicam

Poster Presentation at 2017 Pain week Conference
Las Vegas, Nevada - September 2017

Initiation of Rivaroxaban Following Low Molecular Weight Heparin for Prophylaxis of Venous Thromboembolism: The Safe, Simple Transitions Study

17th Congress of the European Association For Haematopathology
Milan, Italy – March 2012

Initiating Thromboprophylaxis with Low Molecular Weight Heparin and Transitioning to Oral Rivaroxaban

XXIII Congress of The International Society of Thrombosis and Haemostasis
Kyoto, Japan – July 2011

Collateral Ligament Reconstruction in Difficult Primary and Revision Total Knee Arthroplasty

1997 Combined Specialty Meeting of the Knee Society and the American Association of Hip and Knee Surgeons – San Francisco, California – February 1997
1996 Knee Society Interim Meeting – Cleveland, Ohio – September 1996

Extrapelvic Compression of the Sciatic Nerve: Surgical Management

1996 Annual California Orthopedic Association Meeting, San Francisco, California – April 1996
60th Annual Western Orthopedic Association Meeting, Kauai, Hawaii – August 1996

Predicting Fat Embolism Syndrome in One Stage Bilateral Total Knee Arthroplasty:

Intraoperative Monitoring of 163 Patients with a Swan Ganz Catheter

28th Annual Eastern Orthopedic Association Meeting, Scottsdale, Arizona – October 1997

The International Society of Arthroscopy, Knee Surgery and Sports Medicine, Buenos Aires, Argentina – May 1997

3rd Congress of the European Federation of National Associations of Orthopaedic and Traumatology, Barcelona, Spain – April 1997

60th Annual Western Orthopedic Association Meeting, Kauai, Hawaii – August 1999

Magnetic Resonance Imaging Evaluation of Calcaneal Fat Pads in Patients with Os Calcis Fractures Due to a Fall from a Height

6th Annual American Orthopedic Foot and Ankle Society Meeting, Banff, Alberta, Canada – June 1990

6th Annual Orthopedic Trauma Association Meeting, Toronto, Ontario, Canada – November 1990

58th Annual American Association of Orthopedic Surgeons Meeting, Anaheim, California – March 1991

24th Annual American Orthopedic Association National Resident's Conference, Kansas City, Kansas – April 1991

25th Annual Canadian Orthopaedic Association Meeting, Calgary, Alberta, Canada – June 1991

Intra-Articular Administration of 5-Bromo-2-Deoxyuridine to Label Meniscal and Synovial Cells

38th Annual American Orthopedic Research Society Meeting, Washington, D.C. – February 1992

26th Annual Canadian Orthopaedic Research Society Meeting, Toronto, Ontario, Canada – June 1992

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