Deborah R. Tunick, RN, CCRC
Curriculum Vitae

EDUCATION:

Undergraduate: Abilene Christian University
Abilene, Texas
Bachelor of Science in Nursing
Minor in Child Psychology
2001

Nursing School: Abilene Intercollegiate School of Nursing
Abilene, Texas
Registered Nurse
2001

Certifications: NIH, GCP Certification
2004
ACRP, CCRC
2007
CITI Good Clinical Practice, 2010 – present
Health Information Privacy and Security, 2010 – present
Coordinators Basic Research Training, 2010 – present

WORK EXPERIENCE:

2004-Present **Director, Clinical Operations/Site Manager**
Chesapeake Research Group L.L.C.
Pasadena, Maryland

2003-2004 **Clinical Research Nurse**
Scirex
Cockeysville, Maryland

2003-2004 **Staff Registered Nurse**
InteliStaf Travel Nursing
Baltimore, Maryland

2001-2003 **Staff Registered Nurse on Oncology/Surgical Unit**
Anne Arundel Medical Center
Annapolis, Maryland

CLINICAL TRIAL EXPERIENCE:

Protocol HTX-011-301 (2017)
A Phase 3, Randomized, Double-Blind, Saline Placebo- and Active-Controlled, Multicenter Study of (the study drug) via Local Administration for Postoperative Analgesia and Decreased Opioid Use Following Unilateral Simple Bunionectomy

Protocol AVE-901-102 (2017)
A Phase 3, Multicenter, Randomized, Double Blind, Three-Arm Study to Evaluate the Efficacy and Safety of (the study drug) versus Placebo in the Management of Postoperative Pain Following Bunionectomy

Protocol CLCT-018 (2017)
A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Determine the Efficacy and Safety of (the study drug) as a Treatment for Moderate-to-Severe Acute Pain and the Prevention of Opioid-Induced Nausea and Vomiting (OINV) Following Orthopedic Surgery

Protocol MOB015B-IV (2017)
A Multi-Centre, Double-Blind, Randomized, Vehicle-Controlled Study of Efficacy and Safety of (the study drug) in the Treatment of Mild to Moderate Distal Subungual Onychomycosis

Protocol ESTEVE-SUSA-01 (2017)
A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel Groups, Phase 3 Clinical Trial to Establish the Efficacy of (the study drug) for the Management of Moderate to Severe Post-Surgical Pain After Bunionectomy

Protocol AFT-MXIV-07 (2016)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol CP130-3002 (2016)
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Acute Pain After Abdominoplasty

Protocol CP130-3001 (2016)
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Acute Pain After Bunionectomy

Protocol HTX-011-C2015-203 (2016)
A Phase 2, Randomized, Controlled Evaluation of the Efficacy and Safety of (the study drug) for Post-Operative Analgesia Following Abdominoplasty Surgery

Protocol HTX-011-C2016-208 (2016)
A Phase 2, Randomized, Controlled, Multicenter, Evaluation of the Efficacy and Safety of Locally Administered (study drug) for Postoperative Analgesia Following Bunionectomy

Protocol REC-15-016 (2016)
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Efficacy and Safety of (the study drug) Following Bunionectomy

Protocol INS005-16-062 (2016)
A Phase 3, Randomized, Double Blind, Multiple Dose, Parallel Group, Placebo Controlled Study of (the study drug) for the Treatment of Moderate to Severe Pain

Protocol 4975-MN-203 (2015)
An Open-Label, Multiple-Dose Extension Study to Evaluate the Safety and Efficacy of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

Protocol TV46763-CNS-30031 (2015)
A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Analgesic Efficacy and Safety of (study drug) Every 4 to 6 Hours in Patients with Moderate to Severe Pain Following Bunionectomy

Protocol REC-15-014 (2015)
A Phase 2, Single-Center, Randomized, Double-Blind Placebo-Controlled, Evaluation of Safety, Efficacy, and Pharmacokinetics of (study drug) Following Bunionectomy

Protocol ELI-200-003-2014 (2015)
A Multi-Center, Randomized, Multiple-Dose, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of (the study drug) for the Treatment of Adults with Moderate to Severe Pain Following Bunionectomy Surgery

Protocol INS-14-026 (2015)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Placebo-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Pain

Protocol 4975-MN-202 (2014)
A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of CNTX-4975 in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

Protocol CP130-2001 (2014)
A Phase 2, Multicenter, Randomized, Double-Blind, Multiple-Dose, Adaptive, Placebo-and Active-controlled Study of (the study drug) for the Treatment of Acute Post-Operative Pain After Bunionectomy

Protocol MN-201 (2014)
An Open Label, Ascending Dose Study to Evaluate the Safety and tolerability of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

Protocol JN-NM-002 (2013)
A Phase 2, Randomized, Controlled, Double Blind Multi-Center Study to Evaluate Safety and Immunogenicity of (the study vaccine) compared with Menactra

Protocol TCO2-2012-01 (2012)
A Prospective, Randomized, Double-Blind Multicenter Study Comparing (the study device) standard Moist Wound Therapy (MWT) in the Treatment of Diabetic Foot Ulcers

Protocol COV15010232-US (2012)
A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of (the study drug) in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open-Label Extension

Protocol RBI.2012.003.P.2 (2012)
A Multicenter, Randomized, Sham-Controlled, Double-Blinded Study to Evaluate the Analgesic Efficacy and Safety of (the study device) in Bunionectomy Surgery for the Treatment of Post-Operative Pain

Protocol IND3-10-06 (2012)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol IND3-08-04b (2012)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Active- and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol COV15000182-US (2011-2012)
A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of COV795 ER Tablets in Moderate to Severe Post-Operative Bunionectomy Pain followed by an Open Label Extension

Protocol DIC3-08-04 (2011)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Active- and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol Q8003-022 (2011)
A Randomized, Double-Blind, Multicenter, Repeat-Dose Comparison of the Effects of Q8003 to the Morphine-Equivalent Doses of Oxycodone and of Morphine on the Opioid-Related Adverse Events of Moderate to Severe Nausea, Emesis, and Dizziness in Subjects with Acute Moderate-to-Severe Postoperative Pain Following Bunionectomy

Protocol F1J-US-HMGL (2010)
A Randomized, Placebo-Controlled Trial of XXX added to Nonsteroidal Anti-Inflammatory Drugs in Patients with Knee Pain due to Osteoarthritis who have had Suboptimal Response to Anti-inflammatory Drug Treatment

Protocol KD-PV01 (2010)
A Multi-Center, Randomized, Double-Blinded, Pivotal Study of the Safety, Local Tolerability, and Efficacy of UVC-Rich Wide Spectrum Phototherapy for the Treatment of Onychomycosis

Protocol Q8003-008 (2010)
A Randomized, Double-Blind, Multicenter, Repeat-dose, Comparison of Analgesic Efficacy and Safey of Q8003 with Oxycodone and Morphine for the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery

Protocol BK15 (2009)
Evaluation of a Medical Food for Chronic Wounds

Protocol Q8003-021 (2009)
A Double-Blind, Randomized, Multi-Center, Repeat Dose, Comparison of the Analgesic Efficacy and Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone and Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery

Protocol M10-277 (2009)
A Phase 3, Open-Label Period Followed by a Randomize, Double-Blind, Placebo-Controlled Study of the Analgesic Efficacy of (the study drug) Compared to Placebo in Subjects with Chronic Low Back Pain

Protocol DFC-005 (2008)
A randomized, double-blind, active- and placebo-controlled study of the analgesic efficacy and safety of repeated dosing of DIC075V relative to parenteral ketorolac and placebo in patients with acute moderate to severe post-surgical pain following mixed elective general orthopedic surgery

Protocol M10-421 (2008)
A Randomized, Multicenter, double-blind Study comparing the Analgesic Efficacy and Safety of (the study drug) to Placebo in Subjects with Acute Pain Following Bunionectomy

Protocol HKT-500-US10 (2008)
A Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of HKT-500 in the Treatment of Pain Associated with Grade I or Grade II Ankle Sprain

Protocol KET-017 (2008)
A randomized, multiple-center, double-blind, placebo-controlled study of the safety and analgesic efficacy of repeated dosing of PMI-150 to treat acute post-operative pain following orthopedic trauma, injury or surgery

Protocol PRD R331333PAI3018 (2008)
A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of (the study drug) in the Treatment of Acute Pain From Bunionectomy

Protocol INN-TOP-002 (2008)
A Phase II, Randomized, Parallel, Double-blind, Placebo-controlled Study to Assess Prevention of Infection Using (the study drug) in Diabetic Patients with Uninfected Lower Extremity Skin Ulcers

Protocol INN-TOP-001 (2007)
A Randomized, Controlled, Open-Label Study to Investigate the Safety and Efficacy of (the study drug) Compared to Levofloxacin in Diabetic Patients with a Mild Infection of a lower Extremity Skin Ulcer

Protocol SKY2028-1-003 (2008)
A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel Group, 6-Week Study to Evaluate the Effect of Multiple Doses of (the study drug) twice daily, Prednisone and Placebo on the Hypothalamic-Pituitary-Adrenal Axis in Adult Subjects with Mild to Moderate Asthma

Protocol Q8003-010 (2007)
A Double-Blind, Multi-Center Extenstion Study to Evaluate the Safety and Efficacy of Q8003 in Patients with Acute Moderate to Severe Pain

Protocol Q8003-007 (2007)
A Placebo-Controlled, Randomized, Double-Blind Study of the Safety and Efficacy of Q8003 in the Management of Post-Bunionectomy Pain

Protocol M06-850 (2007)
A Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of ABT-894, Duloxetine and Placebo in Subjects with Diabetic Neuropathic Pain

Protocol KF5503/37 (2007)
A Phase 3, Randomized, Double-Blind, Parallel-Group, Multi-Center, Active- and Placebo-Controlled Trial to Evaluate the Analgesic Efficacy and Safety of Multiple Doses of (the study drug) for Postoperative Pain Following Bunionectomy

Protocol 2005-005 (2006)
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of (the study drug) for Sedation During Monitored Anesthesia Care

Protocol H7U-MC-IDAW (2006)
A Phase 3, Open-Label, Parallel Group Treatment Concordance Study to Compare Insulin Use and Its Effect on Glycemic Control in Patients with Type 2 Diabetes Mellitus: Two Populations with Different Insulin Treatment Options

Protocol 2005-008 (2006)
A Phase 2, Randomized, Double-Blind, Parallel Group, Multicenter Lock-out Determination Study of (the study drug) Administered by a Patient-Controlled Analgesia (PCA) Pump for the Treatment of Postoperative Pain Following Elective Bunionectomy Surgery

Protocol PRD R331333PAI3018 (2008)
A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of (the study drug) Immediate Release Formulation in the Treatment of Acute Pain From Bunionectomy Followed by a Voluntary Open-Label Extension

Protocol M04-697 (2007)
A Phase III, Randomized, Multi-center, Double-Blind Study Comparing the Analgesic Efficacy of (the study drug) to Placebo in Subjects With Osteoarthritis

Protocol XP21L-301 (2006)
A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of the Analgesic Efficacy of (the study drug) in Subjects with Pain Following Bunionectomy Surgery

Protocol VGF3554g (2006)
A Phase II, Double-Blind, Randomized, Placebo-Controlled Study to Assess the Effect of (the Study drug) for Induction of Healing of Diabetic Foot Ulcers

Protocol EN3269-301 (2006)
A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase III Study of the Efficacy, Tolerability, and Safety of (the study drug) in the Treatment of Pain Associated with Grade 1 or Grade 2 Ankle Sprain or Strain

Protocol 3000-0523 (2006)
A Phase III, Open Label, Single Arm Study to Assess the Safety of (the study drug) for Minimal to Moderate Sedation in Patients undergoing Minor Surgical Procedures

Protocol M05-790 (2006)
A Phase III, Open-Label period followed by a Randomized, Double-Blind, Placebo-Controlled Study of the Analgesic Efficacy and Safety of (the study drug) Compared to Placebo in Subjects with Chronic Low Back Pain

Protocol HKT-500-US05 (2005)
A Randomized, Multi-center, Double-Blind, Placebo-Controlled, Two-Week Study to Assess the Safety and Efficacy of HKT-500 in Subjects with pain from Moderate Lateral Epicondylitis

Protocol SB767905/014 (2005)
A Randomized, Double-Blind, Placebo-Controlled, Multi-center Phase III Study to Evaluate the Long-Term Safety of (the study drug) for 12 Months for the Treatment of Opioid-Induced Bowel Dysfunction in Adults taking Opioid Therapy for Persistent Non-Cancer Pain

Protocol HKT-500-US06 (2005)
An Open Label Safety Study with Intermittent Use of HKT-500 in Subjects with Lower Back Pain, Pain from Osteoarthritis of the Knee, Shoulder Pain or Lateral Epicondylitis Pain

Protocol M03-666 (2005)
An Open Label Study Evaluating the Safety and Tolerability of Long Term Administration of (the study drug) in Subjects with Moderate to Severe Chronic Non-Malignant Pain

Protocol 3000-0412 (2004)
A Phase III, Randomized, Open Label Study to Assess the Safety and Efficacy of (the study drug) Versus Midazolam HCL for Sedation in Patients Undergoing Minor Surgical Procedures

Protocol M03-643 (2004)
A Randomized, Multi-Center, Double-Blind Study Comparing the Analgesic Efficacy of (the study drug) Extended Release and Placebo in Subjects with Osteoarthritis

Protocol 4975-2-003-1(2004)
Randomized, Double-Blind, Placebo-Controlled Dose Ranging Trial of (the study drug) in Subjects Undergoing Bunionectomy with First Metatarsal Osteotomy Surgery

Protocol U10-03-02-005 (2003)
A Double-Blind, Randomized Comparison of the Analgesic Activity of M40403 + Morphine Versus Morphine alone in a post-surgical dental pain model

Protocol M03-609 (2003)
A Randomized, Double-Blind, Placebo-Controlled Study Comparing the Analgesic Activity of (the study drug) Extended Release and Placebo in Subjects with Pain Following Bunionectomy Surgery