BioSolutions Clinical Research Center

CURRICULUM VITAE

SIGNATURE:		DATE:	165P222
NAME:	Roy C. Brownlow	DATE	Sep 2020
TITLE:	Principal Investigator	UPDATED:	Sep 2020

RESEARCH SITE ADDRESS & PHONE:

Main	Office:	

BioSolutions Clinical Research Center 5565 Grossmont Center Dr. Bldg. 3 Suite 253

La Mesa CA 91942

Office: (619) 637-0770 Fax: (619) 713-0156

Email: drbrownlow@biosolutionsresearch.com

EDUCATION/TRAINING:

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
North Carolina Baptist Hospital Winston-Salem, NC	Residency	1988-1991	Anesthesia
North Carolina Baptist Hospital Winston-Salem, NC	Internship	1987-1988	General Surgery
Wake Forest University Winston-Salem, NC	Doctor of Medicine	1982-1987	M.D.
East Carolina University Greenville, NC	Master's	1978-1982	Education
East Carolina University Greenville, NC	B.S.	1974-1978	Biology

BOARD CERTIFIED:

BOARD CERTIFIED/ELIGIBLE	YEAR(s)	SPECIALTY
Board Certified	1991	Physician and Surgeon

POSITIONS AND EMPLOYMENT:

2020-Present	Investigator, BioSolutions Clinical Research Center, La Mesa, CA
2018-Present	Physician/Anesthesiologist, California Pain and Spine Care., La Mesa, CA
2015-Present	Physician, Newnan Plaza Pharmacy, Newnan, GA
2013-Present	Physician/Anesthesiologist, White Oak Surgery Center, Newnan GA
2013-Present	Physician, Care Plus Pharmacy, Newnan, GA

2008-Present	Physician/Pain Management Specialist, Georgia Pain and Spine Care, Inc., Newnan, GA
2008-Present	Principal Investigator, Better Health Clinical Research, Inc., Newnan, GA
2005-2008	Sub-Investigator, Drug Studies America, Marietta, GA
1999-2008	Pain Management Specialist, Pain Solutions Treatment Centers, Marietta, GA
1998-1999	Pain Management Specialist, Coast Pain Management, San Diego, CA
1996-1998	Staff Anesthesiologist and Pain Management Specialist, Northside Hospital, Atlanta, GA
1996-1996	Staff Anesthesiologist and Pain Management Specialist, Kaiser Permanente, San Diego, CA
1994-1996	Anesthesiologist and Pain Management Specialist, JLR Anesthesia Group, Orlando, FL
1991-1994	Anesthesiologist and Pain Management Specialist, U.S. Naval Medical Center, San Diego, CA

PROCEDURAL SKILLS:

Spinal Cord Stimulation

DRG Stimulators

IT Pumps

Vertiflex

MILD

Radiofrequency Ablation

Epidural Steroid Injections

Ultrasound Diagnostics

Ultrasound Guided Injections

Peripheral Nerve Blocks

Discography: Cervical, Thoracic, and Lumbar

Joint Injections

CERTIFICATIONS:

Certified Principal Investigator (CPI), Association of Clinical Research Professionals

Diplomate, American Board of Anesthesiology

ABA Certificate of Added Qualifications in Pain Management

Diplomate, American Academy of Pain Management

Diplomate, American Academy of Pain Medicine

Fellow in Interventional Pain Practice, WIP & ASIPP

Certified in American Acupuncture

CLINICAL RESEARCH EXPERIENCE:

- 1. "A Study of the Efficacy and Safety of XXXX Extended Release (XXER) Compared to Placebo in Patients with Chronic Pain." (Sub-Investigator)
- 2. "A Randomized, Double-Blind, Two-Period Crossover Study Comparing the Efficacy, Safety, and Tolerability of XXXX (XXXX, controlled release) and XXXX (XXXX, controlled release) in Cancer Patients Who Require Opioid Treatments." (Sub-Investigator)

- 3. "An Open-Label Extension study to evaluate the Long-Term Safety, Tolerability, and Analgesic Efficacy of XXXX (XXXX, controlled release) in Subjects with Cancer Pain or Chronic Lower Back Pain." (Sub-Investigator)
- 4. "A prospective, Open-Label, Multicenter Study of the Effectiveness and Safety of XXXX as Add-on Treatment in Patients with Post-herpetic Neuralgia, Diabetic Neuropathy, or Low Back Pain." (Sub-Investigator)
- 5. "A Prospective, Multicenter, Open-Label Study of the Effectiveness and Safety of XXXX and Add-on or Mono-therapy in Patients with Pain from Osteoarthritis in One or Both Knees." (Sub-Investigator)
- 6. "A Study of the Efficacy and Safety of XXXX (XXXX, extended release) Compared to Placebo in Subjects with Persistent Pain." (Sub-Investigator)
- 7. "A phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of Extended Release XXXX Tablets (XXXX) to Placebo in Subjects with Osteoarthritis." (Principal Investigator)
- 8. "A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Multiple Dose, Parallel Design, Dose Ranging Study of the Safety and Efficacy of XXXX in Painful Diabetic Peripheral Neuropathy." (Sub-Investigator)
- 9. "XXXX Phase III Clinical Trial: A Twenty Four Week, Randomized Double-Blind, Placebo Controlled, Safety and Efficacy Trial of XXXX 50 and 100 Milligrams Each Evening in Premenopausal Women With Hypoactive Sexual Desire Disorder." (Sub-Investigator)
- 10. "An Open Label, 12-Month Study to Evaluate the Safety, Tolerability, and Efficacy of XXXX for the Management of Breakthrough Pain in Opioid Tolerant Patients with Chronic Non-cancer Pain." (Sub-Investigator)
- 11. "A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXX for the Management of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Neuropathic Pain." (Sub-Investigator)
- 12. "A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXX for the Management of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Low Back Pain." (Sub-Investigator)
- 13. "A 12-Week, Open-Label Study With 3 Within-Patient Double-Blind Placebo-Controlled Periods to
 Evaluate the Efficacy and Safety of XXXX Treatment for the Management of Breakthrough Pain in
 Opioid-Tolerant Patients With Non-Cancer-Related Chronic Pain." (Sub-Investigator
- 14. "A Multi-Center, Double-Blind, Placebo-Controlled Randomized Study of XXXX 200 mg, XXXX 300 mg, and XXXX 400 mg in the Treatment of Chronic Low Back Pain."

 (Sub-Investigator)
- 15. "A Multi-Center, Standard of Care-Controlled Study to Evaluate the Long Term Safety of XXXX for the Treatment of Chronic Low Back Pain." (Sub-Investigator)
- 16. "A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of XXXX for Treatment of Breakthrough Pain In Opioid Tolerant Cancer Patients Followed by an up to 12

 -Month, Non-Randomized, Open-Label Extension to Assess Long-Term Safety." (Sub-Investigator)
- 17. "A randomized, multi-center, double blind, parallel-group study assessing the analgesic efficacy and safety of different dosages of XXXX bid compared to active comparator bid and placebo bid in subjects with chronic knee-joint osteoarthritis." (Sub-Investigator)

- 18. A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase 3 Study to Evaluate the Efficacy and Safety of XXXX 0.5mg Once Daily and 0.5mg Twice Daily for 12 Weeks for the Treatment of Opioid-Induced Bowel Dysfunction in Adults taking Opioid Therapy for Persistent Non-Cancer Pain." (Sub-Investigator)
- 19. "A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase 3 Study to Evaluate the Long-Term Safety of XXXX 0.5mg Twice Daily for 12 Months for the Treatment of Opioid-Induced Bowel Dysfunction in Adults taking Opioid Therapy for Persistent Non-Cancer Pain." (Sub-Investigator)
- 20. "An observational study to characterize the burden of illness associated with laxative use in subjects using opioids for the management of persistent pain." (Sub-Investigator)
- 21. "A Randomized, Double-Blind, Active-Control, Parallel Group, 90-Day Safety Study of XXXX Immediate Release in Subjects With Chronic Pain From Low Back Pain or Osteoarthritis of the Hip or Knee." (Sub-Investigator)
- 22. "A Double-Blind, Randomized, Placebo-Controlled Study of XXXX and XXXX in Patients with Excessive Daytime Sleepiness Due to Opioid Therapy." (Sub-Investigator)
- 23. "A Randomized, Double-Blind, Controlled Study of XXXX for the Treatment of Postherpetic Neuralgia." (Sub-Investigator)
- 24. "A Multicenter Randomized, Double-Blind, Controlled Study of XXXX for the Treatment of Post herpetic Neuralgia." (Sub-Investigator)
- 25. "A multi-center, Open Label, Phase 2 Study of XXXX For the Treatment of Neuropathic Pain in Patients with Painful HIV-Associated Neuropathy (HIV-AN) or Post herpetic Neuralgia (PHN)." (Sub-Investigator)
- 26. "An Open-Label Safety Study With Intermittent Use of XXX in Subjects with Lower Back Pain, Pain From osteoarthritis of the Knee, Shoulder Pain or Lateral Epicondylitis Pain." (Sub-Investigator)
- 27. "A Long-Term, Open-Label, Safety Study of XXXX and Low-Dose XXXX in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee." (Sub-Investigator)
- 28. "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Phase III, Efficacy & Safety Study of XXX in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee." (Sub-Investigator)
- 29. "A Long-Term, Open-Label, Safety Study of XXXX in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee." (Sub-Investigator)
- 30. "A Multi-center, Open-label, Follow-on Trial to Assess the Long-term Safety and Efficacy of XXXX in Subjects with Painful Distal Diabetic Neuropathy." (Sub-Investigator)
- 31. "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial to Assess the Efficacy and Safety of XXXX (200, 400, and 600 mg/day) in Subjects with Painful Distal Diabetic Neuropathy." (Sub-Investigator)
- 32. "A Randomized, Double Blind, Placebo-Controlled, Parallel Group Study to Demonstrate the Subjective Treatment Effects of XXXX on Sleep using a Post Sleep Questionnaire-Interactive Voice Response System (PSQ-IVRS) in an "At-Home Setting" in an Adult Population with Chronic Insomnia." (Sub-Investigator)

- 33. "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of Oral XXXX for the Treatment of Opioid-Induced Bowel Dysfunction in Subjects with Chronic Non-Malignant Pain." (Sub-Investigator)
- 34. "A Double-Blind, Placebo-Controlled, Multiple Crossover Proof-of-Concept Study to Evaluate the Efficacy of XXXX Applied over a XXXX for the Treatment of Breakthrough Pain in Patients with Moderate to Severe Non-malignant Chronic Pain." (Sub-Investigator)
- 35. "An Open-Label, Long-Term Safety Study to Evaluate the Safety of the XXXX for the Treatment of Moderate to Severe Non-Malignant Chronic Pain." (Sub-Investigator)
- 36. "Opioid Utilization Study in Chronic Non-Cancer Pain" 2008 (Principal Investigator)
- 37. "Open-label, Multi-center Safety Trial of XXXX for the Treatment of Breakthrough Cancer Pain" 2008. (Principal Investigator)
- 38. "A Randomized, Double-Blind, Active Controlled Crossover Study to Evaluate the Efficacy and Safety of XXXX Compared With XXXX for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Pain, Followed by a 12 Week Open Label Extension to Evaluate the Impact of XXXX on Patient Outcomes." 2009 2010. (Principal Investigator)
- 39. "A Multicenter, Randomized, Placebo-Controlled, Crossover Study for the Evaluation of the Safety,

 Tolerability, and Efficacy of XXX-XXX Compared to Placebo in the Treatment of Cancer Breakthrough
 Pain." 2009 2010. (Principal Investigator)
- 40. "A Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Evaluate the Safety and Efficacy of XXXXXXXX Sublingual Spray (XXXXXXXX SL Spray) for the Treatment of Breakthrough Cancer Pain," 2010. (Principal Investigator)
- 41. "A Prospective, Multi-Centered Clinical Evaluation of the Eon™ Mini 16-Channel Implantable Pulse Generator (IPG) in Combination with Paddle Lead(s) for the Management of Chronic Pain of the Trunk and/or Limbs," 2010 2014. (Principal Investigator)
- 42. "A Phase 3B Multicenter, Double-Blind, Randomized Withdrawal Efficacy and Safety Study of XXXXXXXXX in the Treatment of Patients with Inadequately Treated Painful Diabetic Peripheral Neuropathy," 2010 2011. (Principal Investigator)
- 43. "A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of XXXXXXXXX (XXX Patch) in Patients with Chronic Low Back Pain," 2010 2011. (Principal Investigator)

- 47. "Evaluation of the EMBEDATM Risk Evaluation and Mitigation Strategy (REMS) Education and Communication Program: Patients," 2010. (Principal Investigator)

- 48. "A Multi-centre, Parallel, Double-Blind, Blinded Evaluator, Randomized, Placebo Controlled Study to
 Evaluate the Safety and Effectiveness of a New Viscoelastic Hydrogel (XXXXXXXTM) in the Treatment of
 Knee Osteoarthritis with an Open-Label Extension." 2011 2012 (Principal Investigator)
- 49. "RA0056 Phase II A Randomized, Double-Blind, Placebo-Controlled, Dose Ranging Study with an active Comparator to evaluate the efficacy and safety of CDP6038 administered subcutaneously for 12 weeks to subjects with active Rheumatoid Arthritis having previously failed TNF-Blocker Therapy." 2011. (Sub-Investigator)
- 50. "A Phase II, Randomized, Double Blind, Placebo-controlled, Multicenter Study to Investigate the Inpact of NP2 in Subjects with Intractable Pain due to Malignancy." 2011-2012. (Principal Investigator)
- 51. "Long-term Allopurinol Safety Study Evaluating Outcomes in Gout Patients (LASSO)." 2011 2012. (Principal Investigator)
- 52. "A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of XXXXXXXXX and Allopurinol Compared to Allopurinol Alone in Subjects with Gout who have had an Inadequate Hypouricemic Response to Standard of Care Allopurinol." 2012 2013. (Principal Investigator)
- 53. "A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of XXXXXXXX Monotherapy Compared to Placebo in Subjects with Gout and an Intolerance or Contraindication to a Xanthine Oxidase Inhibitor." 2012 2013. (Principal Investigator)
- 54. "A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of XXXXXXXXX and Febuxostat Compared to Febuxostat Alone at Lowering Serum Uric Acid and Resolving Tophi in Subjects with Tophaceous Gout." 2012 2014. (Principal Investigator)

- 57. "APhase 3, Double-Blind, Placebo-Controlled, Multicenter, Randomized Withdrawal Study to Evaluate the Analgesic Efficacy, Safety, and Tolerability of XXXX XXXXXXXXXXXXXXX in Opioid-Experienced Subjects with Moderate to Severe Chronic Low Back Pain Requiring Around-the-Clock Opioid Analgesia for an Extended Period of Time." 2013 2014. (Principal Investigator)

- 60. "A Multicenter, Randomized, Double Blind, Placebo Controlled, Phase 3 Study of XX XXXX for the Treatment of Opioid Induced Constipation in Adults Taking Opioid Therapy for Non Cancer Pain." 2013 2014. (Principal Investigator)
- 61. "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Safety and Tolerability of XX XXXX for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain." 2013 2014. (Principal Investigator)
- 62. "A Long-Term Extension Study of XXXXXXXXX in Combination with Febuxostat for Subjects with Gout Completing an Efficacy and Safety Study of XXXXXXXXX and Febuxostat." 2013 2016. (Principal Investigator)
- 63. "A Long-Term Open-Label Extension Study for Subjects Completing a Phase 3 Efficacy and Safety Study of XXXXXXXX Monotherapy in Subjects with Gout." 2013. (Principal Investigator)
- 64. "A Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of XXXXXXX Oromucosal Spray (XXXXXXX) as Adjunctive Therapy in Relieving Uncontrolled Persistent Chronic Pain in Patients with Advanced Cancer Who Experience Inadequate Analgesia During Optimized Chronic Opioid Therapy." 2013 2014. (Principal Investigator)
- 65. "A Multicenter, Non-Comparative, Open-Label Extension Study to Assess the Long-Term Safety of XXXXXXX Oromucosal Spray (XXXXXXX) as Adjunctive Therapy in Patients with Uncontrolled Persistent Chronic Cancer Related Pain." 2013 2016. (Principal Investigator)
- 66. "A Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of XXXXXXX Oromucosal Spray (XXXXXXX) as Adjunctive Therapy in Relieving Uncontrolled Persistent Chronic Pain in Patients with Advanced Cancer Who Experience Inadequate Analgesia During Optimized Chronic Opioid Therapy." 2014 2015. (Principal Investigator)
- 67. "A Multicenter, Randomized, Double-blind, Controlled, Comparative Study of XXXXXXX in Patients with Lumbar Disc Herniation (Phase III)." 2014 2017. (Principal Investigator)
- 68. "A Multicenter, Open-label Study of XXXXXXX in Patients with Lumbar Disc Herniation (Phase III), 2015 2017. (Principal Investigator)
- 69. "A Phase 2 Randomized, Double-Blind, Placebo-Controlled Crossover Study to evaluate the safety, tolerability and preliminary efficacy of XXXXXXX in combination with Pregabalin in subjects with Painful Diabetic Neuropathy and Good Pain-Reporting Ability." 2014.
- 70. "A Phase 3, Randomized, Double Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of XXXXXXXXXX 40 mg XR, 80 mg XR, 40 mg IR and 80 mg IR in Subjects with Gout." 2014 2015. (Principal Investigator)
- 71. "A Randomized, Double Blind, Placebo- and Active-Controlled, 4 Week, Multi-Center, Parallel Group Study Assessing the Analgesic Effect, Safety and Tolerability of XX-XXXXXXXX in Subjects with Chronic Low Back Pain Using Naproxen as a Positive Control." 2014 2015. (Principal Investigator)
- 72. "A Randomized, Double-Blind, Trial Investigating the Efficacy and Safety of Intravenous XXXXXXXXX in Subjects with Complex Regional Pain Syndrome Type I (CRPS-I)." 2015 2016. (Principal Investigator)
- 73. "A Phase 3, Randomized, Double Blind, Placebo and Active-Controlled, Multicenter, Parallel-Group Study of the Analgesic Efficacy and Safety of XXXXXXXXXX in Adult Subjects with Chronic Low Back Pain." 2015 present. (Principal Investigator)

- 74. "A Phase 3, Randomized, Double Blind, Active-Controlled Multicenter Study of the Long-Term Safety and Efficacy of Subcutaneous Administration of XXXXXXXXX in Subjects with Osteoarthritis of the Hip or Knee," 2016 present. (Principal Investigator)
- 75. "A Phase 3, Multicenter, Long-Term Observational Study of Subjects from XXXXXXXXX studies who undergo a total knee, hip or shoulder replacement." 2015 present. (Principal Investigator)
- 76. "A Phase 3, Multicenter, Open-Label, Single-Arm Safety Trial of Intravenous XXXXXXXXXXXXXXX in Subjects with Complex Regional Pain Syndrome (CRPS)." 2017 present. (Principal Investigator)
- 77. "A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXXXX in Patients with Moderate-to-Severe Chronic Low Back Pain and Osteoarthritis of the Hip or Knee." 2018 present. (Principal Investigator)
- 78. "A Phase 3, Multicenter, Double-Blind, Parallel-Group, 24 Month Study to Evaluate the Efficacy and Safety of XXXXXX in Subjects with Early Alzheimer's Disease." 2018 2019. (Sub-Investigator)
- 79. "A Phase 3, Double-Blind (DB), Randomized, Placebo-Controlled, Multicenter Study in Subjects with Lumbosacral Radicular Pain evaluating the Safety and Efficacy of a Single XXXXXX TF Injection compared to a Single Placebo IM Injection, followed by an Open-Label Safety Extension." 2018 present. (Principal Investigator)
- 80. "A prospective, single-arm, multi-center registry intended to collect clinical experience with the use of XXXXXX in the treatment of moderate degenerative lumbar spinal stenosis." 2018 present. (Principal Investigator)
- 81. "A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 2-Arm, Trial of Intravenous XXXXXXXXXXXXXXX in Subjects with Complex Regional Pain Syndrome (CRPS)." 2018 Present. (Principal Investigator)
- 82. "A Postmarket Registry in Subjects with Moderate Degenerative Lumbar Spinal Stenosis using the XXXXXXXX System." 2018 Present. (Principal Investigator)
- 83. "A Multi-Center, Randomized, Controlled, Double-blind Study Evaluating Safety and Efficacy of XXXXXXXXXXXXXXXX for Treatment of Lumbar, Thoracic and Cervical Discogenic Pain." 2017 2019. (Principal Investigator)
- 85. "A Phase 3, Randomized, Double-blind, Placebo-Controlled, 2-Injection, 52-Week Study to Evaluate the Efficacy and Safety of Intra-articular Injections of XXXXXXXXXXXXX in subjects with Chronic, Moderate-to-Severe Osteoarthritis Knee Pain." 2018- Present. (Principal Investigator)