

Brianna Costales, BS

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EDUCATION

2017–Present **University of Florida, College of Pharmacy**, Gainesville, FL
Doctor of Philosophy (PhD) in Pharmaceutical Sciences
Concentration: Pharmaceutical Outcomes and Policy
Expected Graduation: July 2022

2009–2013 **California State University, Fullerton**, Fullerton, CA
Bachelor of Science (BS) in Health Science

WORK EXPERIENCE

Aug 2017–Present **Graduate Research Assistant/Teaching Assistant**
College of Pharmacy, University of Florida, Gainesville, FL

- Research Assistant for the Consortium for Medical Marijuana Clinical Outcomes Research: Systematic evidence review, supporting expert panel research priorities, and support for Cannabis Clinical Outcomes Research Conference supervised by Dr. Amie Goodin
- Teaching Assistant for PharmD courses: Patient Safety and Quality in Pharmacy (Fall 2017 and Summer 2018), Principles of Systems-Based Practice (Spring 2018)
- Graduate Assistant duties included assisting the Department of Pharmaceutical Outcomes and Policy with recruitment and proctoring PharmD exams

Jul 2015–Jul 2017 **Quality Assurance Coordinator**
Collaborative Neuroscience Network, LLC.
Garden Grove, Long Beach, and Torrance, CA

- Conducted internal quality assurance audits of the processes, procedures, and controls employed in the design, conduct, and analysis of phase I-IV clinical trials for central nervous system therapeutics
- Reviewed internal documentation for compliance to SOPs, ICH, GCP, and other regulatory requirements
- Reviewed essential documents such as CRFs, Informed Consent Forms, and investigational drug accountability for adequacy and compliance with GCP and FDA regulations
- Assisted with preparation of investigator site files for sponsor, regulatory agency, and FDA inspection
- Documented audit observations, prepared audit reports, and made recommendations for appropriate corrective actions
- Experienced with DSM-IV-TR, DSM-5, clinical efficacy and safety assessments/rating scales, health economics and outcomes assessments, and patient-reported outcome measurements
- *Summary of randomized clinical trials with delegated duties – see Pages 5-6*

Jul 2014–Jul 2015 **Compliance Officer**
Hartley Medical Center Pharmacy, Long Beach, CA

- Sterile and non-sterile pharmaceutical compounding facility specialized in pain management
- Ensured compliance with state pharmacy boards, FDA, DEA, HIPAA, and OSHA regulations
- Maintained data submissions and reporting to prescription drug monitoring programs for over 40 states
- Monitored federal and state legislation relative to compounding, controlled substances, and pharmacy
- Drafted SOPs, HIPAA policies, and regulatory documents
- Audited prescriptions, compounding documents, and patient records

Oct 2013–Nov 2014 **Doctor’s Assistant**, VCA West Coast Specialty and Emergency Animal Hospital, Fountain Valley, CA

Oct 2012–Oct 2013 **Clinical Research Assistant**, SDS Clinical Trials, Orange, CA

Aug 2012–May 2013 **Research Assistant**, Fibromyalgia and Chronic Pain Center, California State University Fullerton, Fullerton, CA

Jul 2009–Oct 2013 **Front and Back Office Assistant**, Neoderma (formerly Wellskin and Tattoo Removal Center), Anaheim and Torrance, CA

Aug 2009–May 2011 **Student Assistant**, College of Health and Human Development, California State University Fullerton, Fullerton, CA

GRANTS & RESEARCH SUPPORT

Current Grants and Support

Aug 2021–Aug 2022

National Institute of Mental Health (NIMH), Mental Health Research Dissertation Grant to Enhance Workforce Diversity R36 Dissertation Award

Project: Applying Big Data to Improve Mental Health Outcomes with Restless Legs Syndrome Treatment

PI: Brianna Costales

Award Amount: \$36,797

Role: PI, 100%

Aug 2021–May 2022

University of Florida, College of Pharmacy, Bonnie Avery Advancing Women in Pharmaceutical Sciences Endowment Award

Award Amount: \$4,000

Past

Aug 2017–May 2020

University of Florida, College of Pharmacy, Grinter Fellowship

Award Amount: \$2,000 annually for 3 years

RESEARCH EXPERIENCE & PUBLICATIONS

Peer-Reviewed Publications

- Brown JD, **Costales B**, van Boemmel-Wegmann S, Goodin AJ, Segal R, Winterstein AG. Characteristics of older adults who were early adopters of medical cannabis in the Florida medical marijuana use registry. *J Clin Med*. 2020;9(4):1166. [doi:10.3390/jcm9041166](https://doi.org/10.3390/jcm9041166). PMID: 32325769.
- **Costales B**, van Boemmel-Wegmann S, Winterstein AG, Segal R. Clinical Conditions and Prescription Drug Utilization among Early Medical Marijuana Registrants in Florida. *J Psychoact Drugs* 2021;53(3):185-194. [doi:10.1080/02791072.2020.1864069](https://doi.org/10.1080/02791072.2020.1864069).
- Jugl S, Okpeku A, **Costales B** et al. A mapping literature review of medical cannabis clinical outcomes and quality of evidence in approved conditions in the United States from 2016 to 2019. *Med Cannabis Cannabinoids*. 2021. doi.org/10.1159/000515069.
- **Costales B** and Goodin AJ. Outpatient off-label gabapentin utilization for psychiatric indications among United States adults from 2011-2016. *Psychiatr Serv* 2021 (published online 21 May 2021). doi.org/10.1176/appi.ps.202000338.
- Sajdeya R, Shavers A, Jean-Jacques J, **Costales B**, Jugl S, Crump C, Wang Y, Manfio L, Pipitone RN, Rosenthal MS, Winterstein AG, Cook RL. Practice Patterns and Training Needs Among Physicians Certifying Patients for Medical Marijuana in Florida. *J Prim Care Community Health*. 2021(12). [doi:10.1177/21501327211042790](https://doi.org/10.1177/21501327211042790).

Published Abstracts and Peer-Reviewed Presentations

- Goodin AJ, Huang JL, Park H, Hincapie-Castillo JM, Brown JD, **Costales B**, Lo-Ciganic WH. Trends in Controlled Substance Utilization in Arizona from 2011-2016, by Prescription Class. [Poster] The 2019 Addiction Health Services Research (AHSR) Conference. Park City, Utah.
Published in: *Substance Abuse* 2019;40(4):469-472 (Supp 151).
doi.org/10.1080/08897077.2019.1688221.
- Goodin AJ, Huang JL, Park H, Hincapie-Castillo JM, Brown JD, **Costales B**, Lo-Ciganic WH. Change in Buprenorphine Prescriptions for Opioid Use Disorder Indications in Arizona from 2011-2016. [Podium] The 2019 Addiction Health Services Research (AHSR) Conference. Park City, Utah.
Published in: *Substance Abuse* 2019;40(4):469-472 (Supp 77).
doi.org/10.1080/08897077.2019.1688221.
- **Costales B**, van Boemmel-Wegmann S, Segal R. A Descriptive Analysis of Florida Medical Marijuana Registry Patients from 2016-2017. [Poster] International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE 35th Annual Meeting). Philadelphia, Pennsylvania.
Published in: *Pharmacoepidemiology & Drug Safety*. 2019;28(S2):264.
doi.org/10.1002/pds.4864.
- **Costales B**, Brown JD, Goodin AJ. Outpatient Off-label Gabapentin Utilization from 2011 to 2015 Among United States Adults. [Poster] International Society of Pharmacoeconomics and Outcomes Research Conference (Virtual ISPOR), May 18-20, 2020.
Published in: *Value in Health*. 2020;23(S1):S137. doi.org/10.1016/j.jval.2020.04.334.
- Goodin AJ, Huang JL, Maguire M, Park H, Hincapie-Castillo JM, Brown JD, **Costales B**, Wilson DL, Lo-Ciganic W. Changes in Prevalence of High-Risk Opioid Use Quality Measures in Arizona from 2011-2018. [Poster] AcademyHealth Annual Research Meeting [Virtual Presentation due to COVID-19]. July 2020.
- **Costales B**, Brown JD, Henriksen C, Goodin AJ. Off-label Gabapentin Utilization for Psychiatric Indications Using the Food and Drug Administration Adverse Event Reporting System Database from 1993-2019. [Poster] International Conference on Pharmacoepidemiology

and Therapeutic Risk Management (ICPE) All Access (virtual meeting). September 16-17, 2020. [doi:/10.1002/pds.5114](https://doi.org/10.1002/pds.5114).

Published in: *Pharmacoepidemiology & Drug Safety*, 2020;29(S3):4936.

- Morris EJ, **Costales B**, Jiang X, Goodin AJ, Vouri S. Evaluation of a Potential Gabapentinoid – Somnolence – Stimulant Prescribing Cascade Among Adults: A Prescription Sequence Symmetry Analysis. [Poster] International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE) All Access (virtual meeting). September 16-17, 2020. [doi:/10.1002/pds.5114](https://doi.org/10.1002/pds.5114).

Published in: *Pharmacoepidemiology & Drug Safety*, 2020;29(S3):5048.

- Jugl S, Okpeku A, **Costales B** et al. A mapping literature review of medical cannabis outcomes and quality of evidence in approved conditions in the United States from 2016 through 2019. [Poster] The Research Society on Marijuana (virtual meeting). July 24, 2020.

Published in: *Cannabis*, 2021;4(1):15-16.

<https://publications.sciences.ucf.edu/cannabis/index.php/Cannabis/article/view/95/43>.

- **Costales B**, Matthews RA, Brown JD, Goodin AJ. An analysis of adverse events reported for cannabis-derived and synthetic cannabis-related drug products using the FDA Adverse Event Reporting System (FAERS). [Poster] Cannabis Clinical Outcomes Research Conference (virtual meeting). April 8-9, 2021.

Published in: *Forthcoming*.

- **Costales B**, Matthews RA, Brown JD, Goodin AJ. A pharmacovigilance analysis of restless legs syndrome treatments and suicidality. [Poster] 37th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE)All Access (virtual conference). August 23-25, 2021.

Published in: *Forthcoming*.

[Google Scholar Bibliography](#)

[ResearchGate Profile](#)

[NCBI Bibliography](#)

[ORCID](#)

SERVICE EXPERIENCE

LEADERSHIP

Aug 2020–Aug 2021 **President**, Florida International Society for Pharmacoepidemiology (ISPE) Student Chapter

Aug 2019–Aug 2020 **Vice President**, Florida ISPE Student Chapter

Aug 2018–Aug 2019 **Secretary**, Florida ISPE Student Chapter

MENTORING

June 2020–June 2021 Rachel Matthews, PharmD PY-2 Summer research project supervisor/mentor

PROFESSIONAL SERVICE

Mar 2021 Cannabis Clinical Outcomes Research Conference 2021 (virtual), Apr 8-9, 2021
Service: Abstract Reviewer

Apr 2021 International Society for Pharmacoepidemiology (ISPE) Mid-Year Meeting 2021 (virtual), April 19-20, 2021
Service: Moderator for Oral Presentations

2021–Present *British Journal of Clinical Pharmacology*
Service: Journal Ad-Hoc Peer Review

Publons Profile Link: [Verified Reviewer Service History](#)

PROFESSIONAL MEMBERSHIPS

2017–Present	International Society for Pharmacoepidmeiology (ISPE)
2017–Present	International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

SKILLS

- **SAS Certified Specialist: Base Programming Using SAS 9.4** (Certificate verification number: JPY3MHXC1JBQ1DKZ)
- **Clinical trial management systems:** electronic data capture systems (BioClinica, Oracle, Medidata), IVR/IWRS systems (Medpace, YPrime, Bracket, ClinTrak)

AWARDS & HONORS

2020	Scholarship, 36 th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE) All Access (virtual conference)
2019	Travel grant, 35 th International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE), Philadelphia, PA, USA
2017–Present	Graduate Student Assistantship, University of Florida, College of Pharmacy
2013	Eta Sigma Gamma Distinguished Service Award
2013	Community Engagement Medal, Center for Internships & Community Engagement, California State University, Fullerton, CA
2012–2013	Eta Sigma Gamma Honors Society, Delta Rho Chapter

RANDOMIZED CLINICAL TRIALS EXPERIENCE

2015-2017	Phase I Clinical Trials <ul style="list-style-type: none"> ▪ A Randomized, Open-Label, Parallel Design, Multiple-Dose, Comparative Bioequivalence Study of XXX Extended-Release Injectable Suspension Versus XXX Extended-Release Injectable Suspension in Schizophrenia Patients Already Stabilized on XXX ▪ Interventional, randomised, double-blind, parallel-group, active-control, multiple-dose study investigating the effect of XXX on cardiac repolarisation in men and women with schizophrenia or schizoaffective disorder ▪ A Phase 1 Study of XXX and Oral XXX Coadministered with XXX in Adults with Schizophrenia ▪ A Multicenter, Randomized, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of XXX Using Poly (DL-lactice-co-glycolide) Polymer of Two Different Molecular Weights (Low and High Molecular Weights as Tests Treatments) Compared to Intermediate Molecular Weight (Reference Treatment) Polymer in Subjects with Schizophrenia ▪ A randomized, double-blind, placebo-controlled, parallel-group study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of XXX in healthy elderly subjects ▪ A Phase 1, Double Blind, Sponsor Open, Randomized, Placebo-Controlled, Single Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Subjects with Idiopathic Parkinson's Disease
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- A Phase 1, Placebo-controlled, Single Ascending-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Adults with Schizophrenia
- Phase 1 Combined Single and Multiple Rising Dose Study of the Safety and Pharmacokinetics of XXX Combination
- A Phase 1 Study to Evaluate the Effects of XXX on the Pharmacokinetics of XXX, A CYP3A Substrate, in Patients with Stable Schizophrenia
- A Randomized, Double-Blind, Placebo- And Active-Controlled, Multi-Center Study to Assess the Antipsychotic Efficacy of XXX After 6 Weeks of Treatment in Patients with Schizophrenia
- A Double Blind, Randomized, Placebo Controlled, Parallel Group Study to Simultaneously Qualify a Biomarker Algorithm for Prognosis of Risk of Developing Mild Cognitive Impairment due to Alzheimer’s Disease (MCI due to AD) and to Test the Safety and Efficacy of XXX to Delay the Onset of MCI due to AD in Cognitively Normal Subjects
- A Phase 1, Randomized, Open-label, Study Evaluating the Pharmacokinetics of Various Dosing Regimens of XXX in Subjects with Stable Schizophrenia
- A Phase 1 Study of an XXX Initiation Regimen in Adults with Schizophrenia
- A Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX Following Administration to the Deltoid or Gluteal Muscle in Adults with Schizophrenia or Schizoaffective Disorder

2015-2017 Phase II-IV and Observational Clinical Trials

- A Phase 1b/2a, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Subjects with Schizophrenia
- A Phase 2, Double-Blind, Placebo-Controlled Study of XXX, a Neurogenic Compound among Out-Patients with Major Depressive Disorder
- A Phase 3 Open Label Study to Evaluate the Long-term Safety and Tolerability of XXX in Adults with Relapsing Remitting Multiple Sclerosis
- A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Migraine Prevention
- A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Multiple Subcutaneous Injections of Depot XXX Over 24 Weeks in Treatment-Seeking Subjects with Opioid Use Disorder
- An Open-Label, Long-Term Safety and Tolerability Study of Depot XXX in Treatment-Seeking Subjects with Opioid Use Disorder
- A 12-week, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexibly-dosed, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Moderate to Severe Binge Eating Disorder
- Prospective Cohort Study to Describe Patient-reported Outcomes in Subjects with Migraine Eligible for Prophylaxis
- XXX for Cannabis Use Disorder in Schizophrenia
- Psychometric Testing and Validation of a Novel PRO Measure for Assessing Subjective experience of Cognitive Impairment of Schizophrenia
- Validity of an online neurocognitive test battery, the XXX, in normal healthy adults

GRADUATE COURSEWORK

PhD Coursework

Introduction to Biostatistical Methods
Regression Methods for Health and Life Sciences
Applied Survival Analysis
Data Analysis and Interpretation
Pharmaceutical Data Analysis in Health Economics and Outcomes Research Settings I
Quantitative Methods in Evidence-Based Pharmacy
Introduction to Pharmacoepidemiology
Introduction to Pharmaceutical Outcomes & Policy Research
Measurement Issues in Pharmaceutical Outcomes & Policy Research
Principles of Pharmacoeconomics
Introduction to Drug Discovery
Evidentiary Basis of Pharmaceutical Use
Epidemiology Writing Circle
Grant Writing in Population Health
Psychiatric Epidemiology
Geriatric and Age-Related Disease
Pharmaceutical Products and Public Policy
Intermediate Pharmacoepidemiology
Neurobiology of Psychiatric Disorders Journal Club (*Fall 2021*)

Short Courses/Methods Workshops

Regulatory Pharmacoepidemiology
Will Data Privacy and Confidentiality Squeeze Out Research?
Retirement of Statistical Significance Testing