



Curriculum Vitae

Amy Kelley, RN, CCRC

Research Affiliation

Arkansas Center for Sleep Medicine, PLLC
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(501) 661-9191 x.104
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Research Affiliation

Preferred Research Partners, Inc.
11219 Financial Center Parkway
Suite 320
Little Rock, AR 72211
(501) 553-9987 x.104
(501) 553-9986 FAX

Signature: _____

A handwritten signature in black ink, appearing to read "Amy Kelley", written over a horizontal line.

Date: _____

05 MAY 2016

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Office

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Preferred Research Partners, Inc.
11219 Financial Centre Parkway, Suite 320
Little Rock, AR 72211
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Education

May 2002: Bachelor of Science in Nursing, University of Central Arkansas
Conway, AR

Work Experience

January 2009-present: Vice President, Preferred Research Partners, Inc.- Little Rock, AR
Position entails training and supervising team of research coordinators, establishing contacts with sponsors & CROs, recruiting new studies, initiating & maintaining investigator relationships, feasibility assessment, source document creation, AP & AR, regulatory, budget & contract negotiation, marketing, recruiting study participants, AE/SAE reporting, laboratory collection and processing.

May 2005-present: Research Director, Arkansas Center for Sleep Medicine, PLLC & Paul E. Wylie, MD, PA- Little Rock, AR
Responsibilities include negotiating budgets and contracts, IRB submissions, marketing, recruiting patients, recruiting new studies, ensuring all equipment functional & calibrated, creation of study ads, patient safety monitoring, profit analysis, informed consent process, oversight of research staff, establishing contacts with sponsors & CROs, patient care, CRF and source documentation completion, creation of ICFs & source documents, regulatory, filing, invoicing, scheduling, AE/SAE reporting, laboratory collection and processing.

April 2003-May 2005: Study Coordinator, Research Solutions, LLC- Little Rock, AR
Position involved conducting study visits & ensuring patient safety, AE/SAE reporting, facilitating informed consent process, collection of IRB correspondence, patient recruitment, CRF and source documentation completion, laboratory collection and processing.

June 2002- April 2003: Medicare Manager, Chenal Healthcare & Rehabilitation- Little Rock, AR
Duties included screening patients for admission to the skilled nursing facility, staffing for nurses & CNAs, supervision of nursing personnel, documentation & nursing care for Medicare & long-term care residents including formation of immediate plan of care, admission assessments, body audits, discharge planning, patient teaching, administration of medications & treatments/wound care.

Certifications/Licensures

RN license #R68675 (AR)

ACRP CCRC certification number: FDA-C-0306-214

Professional Affiliations

2009-present: MAGI

2009-present: Drug Information Association (DIA)

2005-present: Association of Clinical Research Professionals (ACRP)

1998-2002: National Student Nurses Association (NSNA)

1999-2001: ANSA Conventions

Presentations & Academic Research

2/2010: "Effective Subject Recruitment & Retention Strategies" presentation to all RLS sites on A0081185 for United Biosource Corporation

2007: "Recruitment & Retention Strategies for Insomnia Study" presented to all insomnia sites at coordinator meeting

2001-2002: Special study on "Treatment strategies for Alzheimer's Disease"

2000: "Effective Interventions to Decrease Caregiver Role Strain" - Poster Presentation at UCA Student Research Colloquium

Research Experience

Pharmaceutical:

- 2003: Pain due to Osteoarthritis of the Knee. Labopharm- MDT3-002/MDT3-003
- 2003: "A Double-Blind, Placebo-Controlled, Randomized, Multicenter Study to Investigate the Safety and Efficacy of 2 mg TID of Cilansetron Over 12 Weeks Followed by a 4-Week Re-randomized Treatment Period in Diarrhea-Predominant Irritable Bowel Syndrome Subjects" Solvay- S2413011
- 2003: GSK, Epilepsy- LAM40117

- 2003: Neurocrine, Insomnia- NBI-34060-IR-0215
- 2003: Takeda, Insomnia- 01-01-TL-375-020
- 2003: AstraZeneca, Hypercholesterolemia (ARIES)- 4522US/0002
- 2003: GSK, Restless Legs Syndrome- 101468/249
- 2003: Takeda, Sleep Disorders- 01-02-TL-375-022
- 2003: Takeda, Insomnia- 01-02-TL-375-025
- 2003: Bertek, Hypertension in African Americans- NEB-202
- 2003: BMS, Type II Diabetes Mellitus- CV168-025
- 2003: Aventis, Type II Diabetes Mellitus- HOE901/4022
- 2003: Eli Lilly, Stress Urinary Incontinence- F1JUSSBCD
- 2003: Boehringer-Ingelheim, Hypertension- 502.421
- 2004: Takeda, Type II Diabetes Mellitus- 01-00-TL-OPI-506
- 2004: AstraZeneca, Hypertension- 324A
- 2004: Schering-Plough, Hypercholesterolemia- P0337-21
- 2004: Takeda, Type II Diabetes Mellitus- 01-03-TL-559-016
- 2004: CellTech, Crohn's Disease- CDP-870-031
- 2004: AstraZeneca, Cardiac Prophylaxis (JUPITER)- 4522US/0011
- 2004: ISIS, Ulcerative Colitis- 2302CS22
- 2004: Targacept, Ulcerative Colitis- TC-2403-12-CRD-00
- 2004: AstraZeneca, Type II Diabetes Mellitus (GALLANT 6)- D616C00030
- 2004: Cephalon, Excessive Sleepiness- C10953/3023/ES/MN
- 2004: BMS, Hypercholesterolemia- 800-01-01
- 2004: Sankyo, Type II Diabetes Mellitus- WEL-303
- 2004: NovoNordisk, Type II Diabetes Mellitus- NN304-1431
- 2004: Mead Johnson, Formula- 3371-2
- 2004: Roche, Osteoporosis- ML18056
- 2004: Sankyo, Type II Diabetes Mellitus- CS-011-202
- 2004: Yamanouchi, Overactive Bladder- 905-UC-007
- 2004: Takeda, Dyslipidemia- 01-04-TL-475-002
- 2004: Sankyo, Type II Diabetes Mellitus- CS-011-203
- 2004: Berlex, HRT in Essential Hypertension- 306743
- 2005: Arena, Obesity- APD356-003
- 2005: Merck, Primary Insomnia in Adults (polysomnography)- MK-0928/004
- 2005: Merck, Primary Insomnia in Elderly (polysomnography)- MK-0928/002
- 2005: Sankyo, Type II Diabetes Mellitus- 917-203
- 2005: Sankyo, Hypertension- CS8663-A-U301
- 2005: CellTech, Crohn's Disease- CDP-870-034
- 2005: Somaxon, Primary Insomnia in Elderly (polysomnography)- SP-0503
- 2006: GSK, Primary Insomnia in Adults (polysomnography)- MAD103894
- 2006: Xenoport, Restless Legs Syndrome – XP060
- 2006: Boehringer-Ingelheim, Pediatric PK Restless Legs Syndrome – 248.600
- 2006: Takeda, Sleep Maintenance Insomnia (polysomnography)– 01-05-TL-375-067
- 2006: GSK, Restless Legs Syndrome (polysomnography)– RRL103660
- 2007: Xenoport, Restless Legs Syndrome (PK)– XP081

- 2007: Takeda, Chronic Insomnia – 01-05-TL-375-069
- 2007: Xenoport, Restless Legs Syndrome – XP053
- 2007: Takeda, Delayed Sleep Phase Syndrome (polysomnography)– 01-04-TL-375-044
- 2007: Sanofi-Aventis, Sleep Maintenance– LTE6673 (SAMS)
- 2007: Xenoport, Restless Legs Syndrome – XP055
- 2007: Organon, Chronic Primary Insomnia (polysomnography) – 176002
- 2007: Organon, Chronic Primary Insomnia – 176004
- 2007: Pfizer, Primary Insomnia – A4251037
- 2008: Pfizer, Non-Restorative Sleep (polysomnography) – A4251033
- 2008: Lilly, Primary & Secondary Insomnia – 12K-MC-ZZAD
- 2009: Pfizer, Restless Legs Syndrome – A0081186
- 2009: Pfizer, RLS Patient Reported Outcomes – PI6034A
- 2009: Pfizer, Fibromyalgia & Sleep Maintenance Insomnia – A0081165
- 2009: Pfizer, Restless Legs Syndrome (polysomnography) – A0081185
- 2009: Romark Laboratories/SGS, Acute Uncomplicated Influenza – RM01-2027
- 2010: Pfizer, Restless Legs Syndrome – A0081184
- 2010: Sepracor, Attention Deficit Disorder & Insomnia in Children (polysomnography) – 190-246
- 2010: Sepracor, Attention Deficit Disorder & Insomnia in Children (rollover & treatment naïve) – 190-247
- 2010: Romark Laboratories/SGS, Acute Uncomplicated Influenza – RM08-3001
- 2010: Eli Lilly & Company, Sickle Cell Anemia – H7T-MC-TAEK(a)
- 2010: AstraZeneca, Major Depressive Disorder – D413C00004
- 2010: Furiex Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – 27018966IBS2001
- 2011: AstraZeneca, Opiod Induced Constipation – D3820C00005 (KODIAC 5)
- 2011: AstraZeneca, Opiod Induced Constipation – D3820C00008 (KODIAC 8)
- 2011: Anchen Pharmaceuticals, Chronic Idiopathic Constipation – 71060001
- 2011: Impax Pharmaceuticals, Restless Legs Syndrome – IPX159-B11-02
- 2011: UCB, Restless Legs Syndrome in Adolescents – SP1004
- 2011: Bristol Myers Squibb, Type II Diabetes & Hypertension – MB102073
- 2012: Synergy Pharmaceuticals, Chronic Idiopathic Constipation – SP304-20210
- 2012: UCB, Restless Legs Syndrome in Adolescents – SP1005
- 2012: Bristol Myers Squibb, Type II Diabetes & Hypertension – MB102077
- 2012: Forest Research Institute, Hypertension – NAC-MD-01
- 2012: Ardea BioSciences, Gout – RDEA594-301
- 2012: Orexigen, Obesity & Cardiovascular Outcomes – NB-CVOT
- 2012: Novartis, High Triglycerides – CLCQ908C2201
- 2012: Furiex Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – 27018966IBS3001
- 2012: Lexicon Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – LX1033-1.201
- 2012: Tioga Pharmaceuticals, Diarrhea Predominant Irritable Bowel Syndrome – ASMP3001

- 2012: Shionogi, Inc., Opioid Induced Constipation – 1107V9221
- 2012: Tsumura Pharmaceuticals, Crohn’s Disease – TU100P2T2
- 2012: Coronado Biosciences, Crohn’s Disease – CNDO-201-003
- 2012: Shire, GERD – SPD557-206
- 2012: UCB, Healthy Adult, Phase I – SP1031
- 2012: UCB, Restless Legs Syndrome – RL0003
- 2012: GSK, Restless Legs Syndrome – RXP114025
- 2013: Ardea BioSciences, Gout – RDEA594-306
- 2013: Dr. Reddy’s Laboratories, Chronic Idiopathic Constipation – DRL-USG01-L/2012
- 2013: Purdue Pharma L.P., Chronic Low Back Pain & Opioid-Induced Constipation – ONU3705
- 2013: Cubist Pharmaceuticals, Inc., Opioid-induced Constipation – 5945-SOIC-12-05
- 2013: Cubist Pharmaceuticals, Inc., Opioid-induced Constipation – 5945-OIC-12-04
- 2013: Ferring International Pharmascience Center US, Inc., Chronic Idiopathic Constipation – 000080
- 2013: Ferring International Pharmascience Center US, Inc., Chronic Idiopathic Constipation – 000081
- 2013: Synergy Pharmaceuticals, Inc., Chronic Idiopathic Constipation (OLE CIC) – SP304203-01
- 2013: Shionogi, Inc., Opioid Induced Constipation – 1315V9232
- 2013: Menarini, Diarrhea-Predominant Irritable Bowel Syndrome – NAK-07 (IRIS-4)
- 2013: Synergy Pharmaceuticals, Inc., Chronic Idiopathic Constipation (CIC3) – SP304203-00
- 2014: Evoke, Diabetic Gastroparesis – METO-IN-003
- 2014: Evoke, Diabetic Gastroparesis – METO-IN-004
- 2014: Eisai, Long-Term incidence of MACE events & conversion to Type II Diabetes Mellitus in Obese & Overweight Subjects with Cardiovascular Disease or Multiple CV Risk Factors – APD356-G000-401
- 2014: Takeda Development Center Americas, Inc., Gout – FEB-XR_301
- 2014: Salix, Crohn’s Disease – RECD3125
- 2014: Applied Proteomics, Colorectal Cancer Biomarker Specimen Collection Study – API-CP001
- 2014: Xenon, RLS Genetic Biomarker – XEN-RLS
- 2014: Targacept, Diabetic Gastroparesis – TC6499-12-CLP-005
- 2015: Rhythm Pharmaceuticals, Diabetic Gastroparesis – RM-131-009
- 2015: Jazz Pharmaceuticals, Narcolepsy & Excessive Daytime Sleepiness – 14-002
- 2015: Jazz Pharmaceuticals, Obstructive Sleep Apnea & Excessive Daytime Sleepiness – 14-003
- 2015: Jazz Pharmaceuticals, Long-term extension study for Obstructive Sleep Apnea or Narcolepsy with Excessive Daytime Sleepiness – 14-005
- 2015: Neurocrine Biosciences, Inc., Tardive Dyskinesia – NBI-98854-1304 (KINECT3)
- 2015: Theravance, Diabetic or Idiopathic Gastroparesis – 0099
- 2015: Synergy Pharmaceuticals, Inc., Irritable Bowel Syndrome-Constipation – SP304203-04

- 2015: Forest Research Institute, Inc., Irritable Bowel Syndrome-Constipation &/or Chronic Idiopathic Constipation – LIN-MD-10
- 2015: Edgemont Pharmaceuticals, Generalized Anxiety Disorder – EDG004-003
- 2015: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3001 (TRANSFORM-1)
- 2015: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3003 (SUSTAIN-1)
- 2015: Neurocrine Biosciences, Inc., Tardive Dyskinesia – NBI-98854-1402 (KINECT4)
- 2015: Naurex Inc., Major Depressive Disorder – NRX1074-C-202
- 2015: Gilead, Ulcerative Colitis – GS-US-326-1100
- 2015: Sunovion Pharmaceuticals, Adult Attention Deficit Hyperactivity Disorder (ADHD) – SEP360-301
- 2016: Ferring International Pharmascience Center US, Inc., Ulcerative Colitis – 000174
- 2016: Ferring International Pharmascience Center US, Inc., Ulcerative Colitis – 000175
- 2016: Conatus Pharmaceuticals, Non-alcoholic Steatohepatitis (NASH) – IDN-6556-12
- 2016: Synergy Pharmaceuticals, Irritable Bowel Syndrome with Constipation (IBS-C) – SP304203-06
- 2016: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3008
- 2016: Eisai Pharmaceuticals, Elderly Insomnia – E2006-G000-304
- 2016: Luitpold Pharmaceuticals, Inc., Restless Legs Syndrome – 1VIT14037
- 2016: Braintree Laboratories, Chronic Constipation – BLI400-302
- 2016: Braintree Laboratories, Opioid Induced Constipation – BLI801-203

Device:

05/2005: Respironics Inc. – Efficacy of an Auto-Adjusting Bi-Level PAP Device for the Treatment of OSA. (MR-0409-AABL-XXXX)

11/2005: Respironics Inc. – Evaluation of the M-Series REMStar Auto C-Flex Device for the Treatment of OSA. (MR-0519-AUTO-MS-G/W)

05/2006: Respironics Inc. – Evaluation of the BIPAP Auto M-Series with Bi-flex Device for the Treatment of OSA (MR-0615-BASV-MS)

07/2006: Respironics Inc. – The Impact of BIPAP Auto SV on OSA and Complex Sleep Apnea (MR-0634-FASV-MS)

12/2006: Respironics Inc. – Comparison of Auto A-Flex to Auto C-flex

01/2007: Respironics Inc. – The Impact of BIPAP Auto SV on OSA and Complex Sleep Apnea.

10/2007: Respironics Inc. – The Impact of BiPAP AutoSVTM on Central Disregulated Breathing & Chronic Pain Patients (MR-0728-ASV3-MS)

10/2007: Restore Medical, Inc. – A Randomized, Placebo-Controlled Study of the Pillar Palatal Implant System with CPAP (protocol 845)

01/2008: Respiroics Inc. – Stardust Screening Study (MR-0735-SDSS-MS)

02/2008: Respiroics Inc. – Evaluation of a Positive Air Pressure Delivery Systems on Adherence & Outcomes (System One versus Better Together MR-0733-SYS1-SS)

08/2008: Respiroics Inc. – Evaluation of Software Enhancements to the Respiroics BiPAP AutoSV device (MR-0731-ASV3-MS)

04/2009: Respiroics Inc. – User Preference & Validation Evaluation of the New BiPAP autoSV3 device (ST-0906-ASV3VAL-MS)

07/2009: Respiroics Inc. – Evaluation of the Q-Series Auto Device for the Treatment of OSA (ST-0925-AQVM-MS-G/W)

2/2010: Philips-Respiroics Inc. – Engineering Evaluation of the Next Generation of autoSV Devices (ST-0937-ASV4ENG-MS)

6/2010: Philips Respiroics – Evaluation of the Philips Respiroics BiPAP autoSV devices in subjects with Sleep Disorders (ST-1007-ASV4-MS)

12/2010: Philips Respiroics – Philips Respiroics BiPAP autoSV4 User Preference Trial (ST-1030-ASV4PREF-SS)

8/2011: Philips Respiroics – BiPAP autoSV System One Advanced in Patients with Chronic Pain and Sleep Disordered Breathing (SDBPM-2011-01)

9/2011: Philips Respiroics – Automated Graduated CPAP for Improved Adherence in Newly Diagnosed OSA Patients: Multicenter Trial (AR-1112-AGPAP-MS)

6/2012: Philips Respiroics – BiPAP autoSV Advanced in Central Apnea Patients (ST-1001-ASVWO-MS)

7/2012: Philips Respiroics – User Preference/Validation Evaluation of the New Phillips Respiroics PAP Application (ST1203-APP-MS)

6/2013: Philips Respiroics – Evaluation of the OmniLab 2.0 (ST-1311-OmniLab-MS)

6/2014: Philips Respiroics – BIG4 CPAP Study (PGI-BIG4-1331-MS)

7/2014: Philips Respiroics – Evaluation of Two Servo-Ventilation Devices (ST-1431-ASV Evaluation-ARK)

5/2015: Somnarus – Comparison of the Somnarus Sleep Apnea Diagnostic Technology SomnaPatch with Polysomnography (001)

7/2015: Philips Respiroics – Servo-Ventilation In-Lab PSG Evaluation (ST-1517-ALE-MS)

7/2016: Akili Interactive Labs, Inc. - A study to assess the feasibility of and to characterize Project: EVO Monitor game-play cognitive function measurements when played daily, weekly, or multiple times per day in adults 40-55 years old (Akili-026)

9/2016: Philips Respironics - In-lab PSG Evaluation of Two Philips ASV Devices (ST-PHASV-16092-JP)

Training Documentation:

August 2016	Janssen eCRF-Trial Specific Training for Site Personnel & Investigator; Patient Reported Outcomes Site Training; HRUQ; Cogstate LTM/SM Training
July 2016	Data Labs v5.4 EDC Data Entry Training
May 2016	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
May 2016	Sunovion Placebo Response Training, PRO Training (SDS, PSQI, BRIEF-A, DEQ, AIM-A, ASRS, TASS & AMSES), SMWQ & DESS Training
April 2016	IATA training
December 2015	Sunovion ICH/GCP training & CTS Database Training
November 2015	CNS Ratings LLC AIMS Certification
October 2015	Cogstate HVLTR Rater & Test Supervisor
September 2015	Clintara Rater Certification: IDS-C, CADSS, BPRS, PWC-20, MOAA/S, MCH-ATRQ, C-SSRS, MADRS, SIGH-A
July 2015	iMedidata Rave 5.6 EDC Essentials for Clinical Research Coordinators
November 2014	SIGH-A, Covi Anxiety Scale, Raskin Depression Scale, CGI training & certification
September 2014	MediData RAVE EDC & Balance
May 2014	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
November 2013	PPD Oracle OCRDC 4.6.2 training

October 2013	TrialMaster, OmniComm Systems, Inc., eClinical Solutions for Life, EDC software eLearning Course: 4.1 Study Coordinator
October 2013	COWS (Central Opioid Withdrawal Scale) training – Shionogi, Inc.
October 2013	ERT ePRO training
October 2013	Annual Bloodborne Pathogens Training – Stericycle
July 2013	Numoda Study Coordinator Single Interface Training
July 2013	Quintiles ICH GCP training for Clinical Trial Sites
August 2012	Medidata RAVE 5.6 training: Certified Clinical Research Coordinator
August 2012	Oracle OCRDC training
May 2012	National Institutes of Health web-based training on “Protecting Human Research Participants”
May 2012	American Heart Association BLS for Healthcare Providers (CPR & AED) Program
March 2012	IATA training
November 2011	Columbia- Suicide Severity Rating Scale Training/Certification
July 2011	IATA training
December 2010	IntraLinks Clinical Reviewer v1.0 training
September 2010	InForm 4.6 Phase Forward training
July 2010	Quintiles ICH GCP training for Clinical Trial Sites
June 2010	National Institutes of Health web-based training on “Protecting Human Research Participants”
May 2010	ACRP Clinical Research Coordinator Certification Maintenance
April 2010	CPR & AED training
April 2009	IATA training
April 2008	ACRP Clinical Research Coordinator Certification Maintenance

December 2008	Pfizer OC-RDC 4.5.3 training
January 2008	Stericycle Blood Borne Pathogen training
December 2007	Pfizer Investigator Site Data Capture course
June 2007	HIPAA & Clinical Trials training
May 2007	IATA training
March 2007	Third Annual Pediatric Sleep Medicine conference: Next steps in research, patient care, policy & education (Warren Alpert Medical School of Brown University)
September 2006	IntraLinks Clinical Reviewer (v1.0) training
May 2005	CPR & AED Training
March 2005	IATA training
May 2003	GCP Manual/Code of Federal Regulations Review IATA Training CD Phlebotomy Training Informed Consent Training Vital Signs Training EKG Training Coordinator Training Video Job Shadowing Blood Borne Pathogen Training CRF Training SOP Manual Review and Sign-Off Lab Processing Training HIPAA Training