**CURRICULUM VITAE**

**PERSONAL DATA:**

Name: JoAnn P Pfeiffer, DrSC

Address: 6311 S Wilson Drive, Chandler, AZ 85249

Telephone: Office (602) 496-0547 Cell (510) 909-3801

Email: [jpfeiff4@asu.edu](mailto:jpfeiff4@asu.edu)

**ACADEMIC AND PROFESSIONAL PREPARATION:**

|  |
| --- |
| **Major Area of Study Year Institution Degree** |
| Community Health 1981 University of Utah Bachelor of Science  Public Health 1983 University of Utah Master of Science  Alternative Dispute 1997 Denver University Graduate Certification  Resolution  Regulatory Science 2010 University of Southern Master of Science  California  Regulatory Science 2013 University of Southern Doctorate of Science  California |

**PROFESSIONAL EXPERIENCE**

|  |
| --- |
| **Year Institution Position** |
| 2016 - Present Arizona State University Director  Clinical Research Management  2015 – 2016 Arizona State University Associate Director  Clinical Research Management  2014 – Present Arizona State University, College Faculty Associate  of Nursing and Health Innovation  2014 – 2015 Thomas Edison State College Graduate Student Mentor  School of Science and Technology  2014 – 2015 George Washington University Adjunct Assistant Prof.  Translational Research and Regulatory  Affairs, School of Medicine and Health  Sciences  2014 – Present Collaborative Institutional Training Curriculum Development  Initiative (CITI) at the University of Clinical Trial Agreements  Miami  2010 – 2013 Velos Medical Informatics, Inc. Product Mgr/Compliance  Officer  2008 – 2010 University of Southern California Program Manager  Clinical and Translational Science  Institute  2006 – 2008 Boling Clinical Trials Director of Research  2000 – 2006 University of Denver at Colorado Research Manager/Director  Center for Human Nutrition Industry-Sponsored  Research  1993 – 2000 Colorado Department of Public Program Manager/Training  Health and Environment Specialist – CVD, Diabetes,  Arthritis  1985 – 1993 Parks and Recreation Districts Manager, Fitness &  Metro Denver, CO Wellness  1983 – 1985 Denver University, Sports for Program Supervisor  People Program |

**PROFESSIONAL CERTIFICATIONS**

|  |
| --- |
| **Organization Certification** |
| Association of Clinical Research Associates Certified Clinical Research Associate  (Active)  Regulatory Affairs Professional Society Regulatory Affairs Certified (Active) |

**MEMBERSHIP IN PROFESSIONAL ORGANIZATIONS:**

|  |  |  |
| --- | --- | --- |
| **Year** | **Organization** | **Role** |
| 2018 - Present  2018 - 2020  2017 - Present  2016 – Present  2016 - Present  2015 - Present  2006 – Present  2010 – Present  2011 - 2013  2012 – 2014  2014 – Present  2015 – Present  2015 – Present  2016 | CAAHEP  Association of Clinical Research Professionals  Association of Clinical Research Professionals  CoAPCR  ISBER  PRIM&R  AGRE  Association of Clinical Research Professionals  Regulatory Affairs Professional Society  Society of Clinical Research Associates  National Association of Professional Women  Embracing Change Conference Committee  Association of Graduate Research Education  Association of Professional Clinical Research  Embracing Change Conference Committee | Accreditation Site Evaluator  Regulatory Affairs Committee Member  Mentor  Committee Member/Co-chair Website  Member at Large  Member at Large  Committee Member  Member at Large; Member Local Chapter  Member at Large  Member at Large  Member at Large  Speaker Review Committee  Member  Member  Chair |

**TEACHING RESPONSIBILITIES**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Year/**  **Semester** | **Course Title** | **Course Type** | **Credit**  **Hours** | **% Course**  **Responsibility** |
| Fall 2017 | Clinical Trials Contracts & Budgets | Online | 3 | 100% |
| Fall 2017 | Medical Device Development & Regulation | Online | 3 | 100% |
| Fall 2017 | Medical Device Development & Regulations | Online | 3 | 75% |
| Fall 2017 | Clinical Trial Budgets & Contracts | Online | 3 | 100% |
| Spring 2017 | Quality in Clinical Research | Online | 3 | 100% |
| Fall 2016 | Clinical Trial Budgets and Contracts | Online | 3 | 100% |
| Fall 2016 | Medical Device Development and Regulations | Online | 3 | 100% |
| Su 2016 | Intro to Clinical Research | Online | 3 | 75% |
| Sp 2016 | Quality and Clinical Research | Online | 3 | 100% |
| Fall 2015 | Contracting and Budgeting | Online | 3 | 100% |
| Fall 2015 | Clinical Research Operations | Online | 3 | 50% |
| Fall 2015 | Medical Device Development and Regulations | Online | 3 | 75% |
| Su 2015 | Intro to Clinical Research | Online | 3 | 100% |
| Sp 2015 | Quality Assurance | Online | 3 | 100% |
| Sp 2015 | Responsible Conduct of Research | Online | 3 | 100% |
| Sp 2015 | Introduction to Global Regulatory Affairs | Online | 3 | 100% |
| Sp 2015 | Research Management | Online | 3 | 50% |
| Sp 2015 | Introduction to Clinical Research | Online | 3 | 100% |
| Fall 2014 | Medical Device Development & Regulations | Online | 3 | 100% |
| Fall 2014 | Clinical Research Operations | Online | 3 | 50% |
| Fall 2014 | Introduction to Regulatory Affairs | Online | 3 | 50% |
| Summer/Fall 2014 | Clinical Trials Research: Practice to Policy | Online | 3 | 100% |
| Summer 2014 | Capstone 1 | Online | 3 | 100% |
| Summer 2014 | Capstone 2 | Online | 3 | 100% |
| 2004 - 2006 | Colorado Weigh | Didactic Classroom (CU – Denver) | NA | 100% |
| 2004 - 2006 | Active for Life | Didactic Classroom | NA | 100% |
| 2004 - 2006 | Slim for Life | Didactic Classroom | NA | 100% |

**PROFESSIONAL/COMMITTEE SERVICE**

|  |
| --- |
| **Year Organization Committee** |
| 2018 Benthamscience Journal Review Panel  Journals  2017 CONHI Grievance Committee  2017 exl Pharma Conference Planning Committee  2017 International  Conf. on Clinical  Trials Conference Committee  2017 ASU College of Law Conference Planning Committee  Chair  2017 Embracing Change Chair, Marketing Committee  2017 Conference Chair Clinical Trial Financial Mgt. Summit    2016 - 2017 Planning Comm. Society of Clinl. Ops. Profl. Exec.  2016 NIH/NIAID Scientific Review Group  2015 – Present CoAPCR Member/Website Committee  2015 – 2017 CONHI Clinical Track Faculty Hiring Comm.  2016 Embracing Change Chair  2014 - Present Embracing Change Conference Planning |

**RESEARCH AND GRANTS:**

**Completed:**

|  |
| --- |
| **Year Title Funding** |
| 2003 LOOK AHEAD: Action for Health in Diabetes National Institutes of  Research Manager (12 yr. study) Health: $2 million/year  2004 Fiber in Weight Loss Johnson & Johnson  Research Director/Author $840,000  2005 Fiber in Weight Management Johnson & Johnson  Research Director/Author $510,000  2006 – Miscellaneous Investigational Drug Studies Amgen, Merck, BMS,  2007 Research Director (rheumatology, CVD, Genentech, Roche,  Women’s health, diabetes) Regeneron, Pfizer  Targeted Genetics,  etc. ($10 mil/yr.)  2008 – Clinical and Translation Science Institute National Institutes of  2010 Co-author Health: $11 million for  5 years |

**PUBLICATIONS:**

**Text Books/Course Packets**

Pfeiffer, J.P., Shah, K. and Wells, C. (2017). Clinical Trial Training Exercises. LAD Custom Publishing, Georgia.

Shah, K., Wells, C., and Pfeiffer, J.P. (2017) A Clinical Trial Workbook: to complement research education and training. Second Edition. LAD Custom Publishing, Georgia.

Pfeiffer, J.P. and Wells, C. (2017) A Practical Guide to Clinical Research Operations. Taylor & Francis, CRC Press, Oxford, UK and Florida, US.

Shah, K., Wells, C., and Pfeiffer, JP. (2016) A Clinical Trial Workbook: to complement research education and training. LAD Custom Publishing, Georgia.

Pfeiffer, J.P. and Windscheigl, M. (2017) Managing Clinical Trial Budgets and Contracts. LAD Custom Publishing, Georgia.

Pfeiffer, J.P. and Bilkic, D. (2016). The Investigator’s Role in the Management of the Clinical Trial Agreement. Collaborative Institutional Training Initiative. BRANY, NY.

Pfeiffer, J.P. and Bilkic, D. (2016). Negotiating the Clinical Trial Agreement. Collaborative Institutional Training Initiative. BRANY Institute, NY.

Bilkic, D. and Pfeiffer, J.P. (2016). Overview of the Clinical Trial Agreement. Collaborative Institutional Training Initiative. BRANY Institute, NY.

Bilkic, D. and Pfeiffer, J.P. (2016). Understanding the Terms of the Clinical Trial Agreement. Collaborative Institutional Training Initiative. BRANY Institute, NY.

Pfeiffer, J.P. (2016 & 2017). HCR552: Medical Device Regulations and Development. Course Workbook, LAD Custom Publishing, Buford, GA.

Pfeiffer, J.P., (2015) HCR553: Quality and Clinical Research, LAD Custom Publishing, Buford, GA.

Pfeiffer, J.P. (2015) HCR575: Clinical Trial Budgets and Contracts, Course Workbook, LAD Custom Publishing, Buford, GA.

Pfeiffer, J.P. (2015) HCR565: Clinical Research Operations, Course Workbook, Custom Publishing, Buford, GA.

Pfeiffer, JP. (2014). Clinical Trial Agreements: Negotiation and Management. Scholars’ Press. ISBN: 978-3-639-71262-9.

**Refereed:**

Pfeiffer, J.P. (2017) Clinical Trial Contracts: Language and Limitations. *Pharmaceutical Outsourcing,* Vol 18, Issue 2.

Pfeiffer, JP and Wendschiegl, M. (2016) Keys to Successfully Negotiate Site Budgets and Contracts. *Pharmaceutical Outsourcing*, Vol 17, Issue 3, May-June 2016.

Pfeiffer, JP and Richmond, FJ (2015) Current Practices of US Investigators. *Therapeutic Innovation and Regulatory Science.* Vol. 49(1), 139-145.

Pfeiffer, JP. (2014). Clinical Trial Agreements. *ACRP Newsletter*, Phoenix Chapter, pp 4 – 6.

The Look AHEAD Research Group. (2003). Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for prevention of cardiovascular disease in type 2 diabetes. *Control Clin Trials.* (5) pp 610-628.

**Non-Refereed:**

Pfeiffer, JP and Napier, J. (2012). Clinical Trials Management Systems Software Compliance Requirements. *Velos Medical Informatics White Paper.*

Pfeiffer, JP. (2012). Complying with FDA and HIPAA Regulations and Guidelines: What to Look for in Clinical Trial Software Management Systems. *Velos Medical Informatics White Paper.*

Phillipp (Pfeiffer), JP and Colorado Arthritis Advisory Board. (1999 & 2000). *Colorado State Strategic Plan for Arthritis Management and Prevention*. Colorado Department of Public Health and Environment.

Phillipp (Pfeiffer), JP and State Physical Activity Advisory Board (1996, 1997, & 1998). *Colorado State Strategic Plan for Promotion of Physical Activity to Prevent and Reduce Cardiovascular Disease.* Colorado Department of Public Health and Environment.

Phillipp (Pfeiffer), JP, Jortberg, B, and Dusenbury, L. (1996). *EXERDECK.* Colorado Department of Public Health and Environment and the National Parks and Recreation Association.

**CURRICULUM BUILDING AND DEVELOPMENT:**

|  |  |  |
| --- | --- | --- |
| **Year** | **Program** | **Course** |
| 2017  2017  2017  2017  2017  2016  2016  2016  2016  2016  2016  2015  2015  2015  2015  2015  2014  2014  2014  2014 | ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  ASU, Clinical Research Management  George Washington University  School of Medicine & Health Sci.  Collaborative Institutional Training Institute (CITI) at the University of Miami  ASU, Clinical Research Management | Scientific Innovation and Biospecimen Repository Administration  Biospecimen Resource and Technology Management  Translation Research and Medicine  Legal Aspects of Clinical Research  Global Regulatory Affairs  Drug Discovery, Development & Regulation  Ethics for Biospecimen Repositories  Management of Biospecimen Repositories  Regulations of Biospecimen  Repositories  Fundamentals Regulatory Affairs  Clinical Research Operations  Research Review Boards  Biospecimen Repository Administration    Management of Biospecimen Repositories  Contracting and Budgeting  Quality Assurance and Clinical Research  Medical Device Development and Regulation  Introduction to Global Regulatory Affairs – Common Technical Doc.  Developing four (4) modules on the management and negotiation of clinical trial agreements. |

**SCHOLARLY PRESENTATIONS:**

|  |  |  |
| --- | --- | --- |
| **Year** | **Title** | **Meeting** |
| 1995  1995  2011  2011  2011  2011  2012  2013  2014  2014  2014  2015  2015  2016  2017  2017  2017  2017  2017  2017  2017  2017  2017 | Conflict Management  Promoting Physical Activity for Health  Software Lifecycle and FDA Guidance on Medical Software Devices  Conducting Clinical Trials in China  Complying with 21 CFR 11: Clinical Trial Management Systems  Clinical Trial Management Systems  Evaluating and Using Clinical Trial Management Systems  Clinical Trial Agreements: Important or Just One More Document  Current Practice and Issues Surrounding the Clinical Trial Agreement  Negotiating Clinical Trial Agreements: Common Issues and Hidden Costs  Negotiating Clinical Trial Agreements and Hidden Costs  Managing Clinical Trial Agreements and Budgets  Current Practices and Issues of Clinical Trial Agreements  Keys for Successfully Negotiating Budgets and Contracts  Panel Discussion – Negotiating Site Budgets  Roundtable Discussion – Contract Language & Limitations  Contract Language and Limitations  Investigative Site Relationships: Budget & Contract Perceptions and Realities  Develop Advanced Budgeting Strategies to Manage Clinical Trials  Managing Clinical Trial Agreements  An Open Dialogue With Sites About Streamlining the Start-up Process  Contracts: What You Don’t Know Can Hurt You  The Impact of the Final Rule on Research with Biospecimens – Panel Moderator | Colorado Parks & Recreation’s Annual Conference  National Parks & Recreation Assn. Annual Conference  International Symposium, Hangshou, Korea  Sino-American Collaboration in the Healthcare Industry, Shanghai, China  Velos Medical Informatics Annual Meeting  Society Of Clinical Research Associates  Society of Clinical Research Associates  OMICS, International Conference on  Pharmaceutical Regulatory Affairs  Association for Clinical Research Professionals 2014 Global Conference  Complion Regulatory eSystem Webinar  Association for Clinical Research Professionals, Phoenix Chapter Meeting  Allegheny-Singer Research Institute,  Pittsburgh, PA  Association for Clinical Research Professionals, National Webinar  SCOPE Summit for Clinical Ops Executives, Miami, FL  SCOPE Summit for Clinical Ops Executives, Miami, FL  SCOPE Summit for Clinical Ops Executives, Miami, FL  SCOPE Summit for Clinical Ops Executives, Miami, FL  Clinical Trial Budgeting and Forecasting, Philadelphia, PA  Clinical Trial Forecasting Management Summit, Philadelphia, PA  International Conference on Clinical Trials, San Antonio, TX  International Conference on Clinical Trials, San Antonio, TX  Embracing Change, Phoenix, AZ  Ethics & Compliance in Human Subject’s Research: Challenges Under the Revised Common Rule |

**Service to the Community**

|  |  |  |
| --- | --- | --- |
| 2017-2018 | Consultant, Subject Matter Expert | Treon & Shook, PLLC |
| 2017 | Faculty Research Mentor | Nursing & Health Care Innovation PhD |
| 2017 | Mentor | Association of Clinical Research Professionals |
| 2017 | Coordinate & Lead Ethics and Law Conference on Common Rule Changes / Panel Moderator | ASU Sandra Day O’Connor School of Law, Center for Law Science & Innovation, CONHI Nursing and Clinical Research Management |
| 2017 | Member, Organizing Committee | International Conference on Clinical Trials, San Antonio, TX |
| 2017 | Build Burrowing Owl Habitats | Wild at Heart – Owls |
| 2017 | Conference Chair | Clinical Trial Financial Management Summit |
| 2017 | A Day of Social Outreach – Audubon Arizona Owl Project | Arizona State University |
| 2016 - Present | Created Webinar Wednesdays, a monthly educational series for research professionals | Arizona State University |
| 2016 | Chair | Embracing Change |
| 2016 | Time Keeper | Arizona High School Science Bowl |
| 2014 - Present | Member | Embracing Change Planning Committee |

**Achievements & Awards**

|  |  |  |
| --- | --- | --- |
| 2017 | Interprofessional Team Achievement Award | Dream-Discover-Deliver  ASU, College of Nursing & Health Innovation |
| 2017 | Mentor | Association of Clinical Research Professionals |
| 2013 | Woman of the Year | National Professional Women’s Association |