**CURRICULUM VITAE**

**PERSONAL DATA:**

Name: JoAnn P Pfeiffer, DrSC

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**ACADEMIC AND PROFESSIONAL PREPARATION:**

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| **Major Area of Study Year Institution Degree** |
| Community Health 1981 University of Utah Bachelor of SciencePublic Health 1983 University of Utah Master of ScienceAlternative Dispute 1997 Denver University Graduate CertificationResolutionRegulatory Science 2010 University of Southern Master of Science California Regulatory Science 2013 University of Southern Doctorate of Science California  |

**PROFESSIONAL EXPERIENCE**

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| **Year Institution Position** |
| 2016 - Present Arizona State University Director Clinical Research Management2015 – 2016 Arizona State University Associate Director  Clinical Research Management2014 – Present Arizona State University, College Faculty Associate of Nursing and Health Innovation2014 – 2015 Thomas Edison State College Graduate Student Mentor School of Science and Technology2014 – 2015 George Washington University Adjunct Assistant Prof. Translational Research and Regulatory Affairs, School of Medicine and Health Sciences2014 – Present Collaborative Institutional Training Curriculum Development Initiative (CITI) at the University of Clinical Trial Agreements Miami2010 – 2013 Velos Medical Informatics, Inc. Product Mgr/Compliance Officer2008 – 2010 University of Southern California Program Manager Clinical and Translational Science Institute 2006 – 2008 Boling Clinical Trials Director of Research2000 – 2006 University of Denver at Colorado Research Manager/Director Center for Human Nutrition Industry-Sponsored  Research1993 – 2000 Colorado Department of Public Program Manager/Training Health and Environment Specialist – CVD, Diabetes,  Arthritis1985 – 1993 Parks and Recreation Districts Manager, Fitness &  Metro Denver, CO Wellness 1983 – 1985 Denver University, Sports for Program Supervisor People Program  |

**PROFESSIONAL CERTIFICATIONS**

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

**MEMBERSHIP IN PROFESSIONAL ORGANIZATIONS:**

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| **Year** | **Organization** | **Role** |
| 2018 - Present2018 - 20202017 - Present2016 – Present2016 - Present2015 - Present2006 – Present2010 – Present2011 - 20132012 – 20142014 – Present2015 – Present2015 – Present2016 | CAAHEPAssociation of Clinical Research ProfessionalsAssociation of Clinical Research ProfessionalsCoAPCRISBERPRIM&RAGREAssociation of Clinical Research ProfessionalsRegulatory Affairs Professional SocietySociety of Clinical Research AssociatesNational Association of Professional WomenEmbracing Change Conference CommitteeAssociation of Graduate Research EducationAssociation of Professional Clinical Research Embracing Change Conference Committee | Accreditation Site EvaluatorRegulatory Affairs Committee MemberMentorCommittee Member/Co-chair WebsiteMember at LargeMember at LargeCommittee MemberMember at Large; Member Local ChapterMember at LargeMember at LargeMember at LargeSpeaker Review Committee MemberMemberChair |

**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**

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| **Year Organization Committee** |
| 2018 Benthamscience Journal Review Panel Journals 2017 CONHI Grievance Committee2017 exl Pharma Conference Planning Committee2017 International  Conf. on Clinical  Trials Conference Committee2017 ASU College of Law Conference Planning Committee  Chair2017 Embracing Change Chair, Marketing Committee2017 Conference Chair Clinical Trial Financial Mgt. Summit 2016 - 2017 Planning Comm. Society of Clinl. Ops. Profl. Exec.2016 NIH/NIAID Scientific Review Group2015 – Present CoAPCR Member/Website Committee2015 – 2017 CONHI Clinical Track Faculty Hiring Comm.2016 Embracing Change Chair2014 - Present Embracing Change Conference Planning |

**RESEARCH AND GRANTS:**

**Completed:**

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| **Year Title Funding** |
| 2003 LOOK AHEAD: Action for Health in Diabetes National Institutes of  Research Manager (12 yr. study) Health: $2 million/year2004 Fiber in Weight Loss Johnson & Johnson Research Director/Author $840,0002005 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:**

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| **Year** | **Program** | **Course** |
| 20172017201720172017201620162016201620162016201520152015201520152014201420142014 | ASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementASU, Clinical Research ManagementGeorge Washington UniversitySchool of Medicine & Health Sci.Collaborative Institutional Training Institute (CITI) at the University of MiamiASU, Clinical Research Management | Scientific Innovation and Biospecimen Repository AdministrationBiospecimen Resource and Technology ManagementTranslation Research and MedicineLegal Aspects of Clinical ResearchGlobal Regulatory AffairsDrug Discovery, Development & RegulationEthics for Biospecimen RepositoriesManagement of Biospecimen RepositoriesRegulations of Biospecimen RepositoriesFundamentals Regulatory AffairsClinical Research OperationsResearch Review BoardsBiospecimen Repository Administration Management of Biospecimen RepositoriesContracting and BudgetingQuality Assurance and Clinical ResearchMedical Device Development and RegulationIntroduction to Global Regulatory Affairs – Common Technical Doc.Developing four (4) modules on the management and negotiation of clinical trial agreements. |

**SCHOLARLY PRESENTATIONS:**

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| **Year** | **Title** | **Meeting** |
| 19951995201120112011201120122013201420142014201520152016201720172017201720172017201720172017 | Conflict ManagementPromoting Physical Activity for HealthSoftware Lifecycle and FDA Guidance on Medical Software DevicesConducting Clinical Trials in ChinaComplying with 21 CFR 11: Clinical Trial Management SystemsClinical Trial Management SystemsEvaluating and Using Clinical Trial Management SystemsClinical Trial Agreements: Important or Just One More DocumentCurrent Practice and Issues Surrounding the Clinical Trial AgreementNegotiating Clinical Trial Agreements: Common Issues and Hidden CostsNegotiating Clinical Trial Agreements and Hidden CostsManaging Clinical Trial Agreements and BudgetsCurrent Practices and Issues of Clinical Trial AgreementsKeys for Successfully Negotiating Budgets and ContractsPanel Discussion – Negotiating Site BudgetsRoundtable Discussion – Contract Language & LimitationsContract Language and LimitationsInvestigative Site Relationships: Budget & Contract Perceptions and RealitiesDevelop Advanced Budgeting Strategies to Manage Clinical TrialsManaging Clinical Trial AgreementsAn Open Dialogue With Sites About Streamlining the Start-up ProcessContracts: What You Don’t Know Can Hurt YouThe Impact of the Final Rule on Research with Biospecimens – Panel Moderator | Colorado Parks & Recreation’s Annual ConferenceNational Parks & Recreation Assn. Annual ConferenceInternational Symposium, Hangshou, KoreaSino-American Collaboration in the Healthcare Industry, Shanghai, ChinaVelos Medical Informatics Annual MeetingSociety Of Clinical Research AssociatesSociety of Clinical Research AssociatesOMICS, International Conference onPharmaceutical Regulatory AffairsAssociation for Clinical Research Professionals 2014 Global ConferenceComplion Regulatory eSystem WebinarAssociation for Clinical Research Professionals, Phoenix Chapter MeetingAllegheny-Singer Research Institute,Pittsburgh, PAAssociation for Clinical Research Professionals, National WebinarSCOPE Summit for Clinical Ops Executives, Miami, FLSCOPE Summit for Clinical Ops Executives, Miami, FLSCOPE Summit for Clinical Ops Executives, Miami, FLSCOPE Summit for Clinical Ops Executives, Miami, FLClinical Trial Budgeting and Forecasting, Philadelphia, PAClinical Trial Forecasting Management Summit, Philadelphia, PAInternational Conference on Clinical Trials, San Antonio, TXInternational Conference on Clinical Trials, San Antonio, TXEmbracing Change, Phoenix, AZEthics & Compliance in Human Subject’s Research: Challenges Under the Revised Common Rule |

**Service to the Community**

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| 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**

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