Submitted to Amentum for ARPA-H STATS

NAME	JOB TITLE	PWS Tasks
Leah White	DSPR - Intermediate Program Coordinator	7.1.7; 7.1.18; 7.3.1-7.3.7; 7.5.4; 7.5.9

Job Responsibility	Qualifying Skills
Project & Deliverable Coordination: Oversee work product development, track deadlines, and ensure seamless execution of projects across multiple offices.	· Led multi-million-dollar federally funded clinical research initiatives at NIH, USAID, and The Ohio State University, ensuring timely completion of deliverables. · Managed 70+ clinical research protocols at Henry M. Jackson Foundation, tracking program activities, deadlines, and dependencies. · Implemented Agile project management practices, improving operational efficiency across NIH and government-funded programs.
Resource Allocation & Compliance: Monitor resource needs and ensure government-funded initiatives align with federal requirements.	· Oversaw the $78M AMP AD 2.0 and $400M ADNI research initiatives, managing financial reporting, grants, and regulatory compliance at FNIH. · Developed internal audit processes and SOPs, ensuring regulatory compliance for multi-site clinical trials. · Monitored government research funding allocations, ensuring compliance with NIH, FDA, and international clinical trial regulations.
Stakeholder Collaboration & Reporting: Engage with internal and external stakeholders, track program priorities, and provide data-driven updates to leadership.	· Served as a primary liaison between NIH leadership, principal investigators, and private-sector partners, aligning research goals with policy objectives. · Provided strategic reporting to government agencies, including HHS, FDA, and CMS, summarizing trial progress and regulatory compliance. · Developed and managed executive briefings, status updates, and project reports, ensuring alignment with government policies.

Education

Masters of Public Health **August 2005**
Masters of Public Health Administration
Northwest Ohio Consortium for Public Health (CEPH Accredited) Toledo, OH - Medical College of Ohio

Bachelor of Science **May 2004**
Bachelor of Applied Health Sciences, Bowling Green State University, Bowling Green, OH

Experience

Senior Project Manager **Nov-2022 – Present**
Veranex (Contract Research Organization) Rockville, MD

· Managed multiple Pharma Phase 1 and Phase 2 Clinical Trials Projects from start-up to close-out.

Senior Project Manager **Sep2021- Oct 2022**
Foundation for the National Institute of Health Rockville, MD

· Managed the Accelerated Medicine Partnerships Alzheimer's Disease 2.0 (AMP AD 2.0), a public-private partnership of $78 million target discovery engine

- Managed the Alzheimer's Disease NeuroImaging (ADNI) Private Partners Scientific Board, a $400 million private-public funded cohort study.

Senior Project Manager **Sept 2020- Aug2021**
Technical Resources International (TRI), a Clinical Research Organization Rockville, MD

- Managed Laboratory testing requirements for ACVTI-2, an NIH-funded outpatient COVID-19 platform trial
- Managed the international regulatory submission for ACTIV-4, an NIH-funded international COVID-19 platform trial

Director of Quality Improvement and Publications **Jun 2019- Mar 2020**
American Society of Addiction Medicine Rockville, MD

- Translated clinical research into clinical practice guideline recommendations
- Oversaw 10 different publications, from textbooks to the Journal of Addiction Medicine
- Managed the completion and publication of two clinical practice guidelines
- Oversaw the completion and launch of the Level of Care Certification program

Chief of Clinical Research Operations **Mar 2018- Jan 2019**
Infectious Disease Clinical Research Program/ Henry M Jackson Foundation Bethesda, MD

- Oversaw all aspects of Clinical Research Operations
- Develop program-wide quality management protocol
- Improved cooperation with IRB, reducing review timelines by more than 70%
- Managed a staff of 20 employees, 10 at remote sites internal and external to the United States
- Oversaw 70 clinical research protocols in various stages
- Conducted trial master file audits.

Digital Therapeutics Site Engagement Specialist- Per Diem Consultant **Sep 2015- Mar 2020**
Responsive Health New York, NY

- Coordinate clinical site participation in Mt Sinai healthcare apps
- Developed clinical and research databases, testing, & implementation
- Synthesized non-profit coalition governance
- Represented as App Lab point of contact for sites for all needs
- Assessed sites for areas of training, support or infrastructure improvements

Director, Appropriate Use Criteria Policy **Apr 2015- Jan 2018**
American College of Cardiology, Washington, DC

- Translated clinical research into clinical practice guideline recommendations
- Synthesized application to Centers for Medicare & Medicaid Services that led to the American
- College of Cardiology being a Qualified Provider-Led Entity
- Strategic management of the Appropriate Use Criteria (AUC) Task Force led to a 40% increase in volunteer membership participation & activities while decreasing costs
- Assembled AUC Summit, a national meeting, a relationship-building conference attended by over
- 60 external stakeholders, including Centers for Medicare & Medicaid Services
- Formed multiple working groups with partnering organizations that attended the AUC Summit
- Generated the content licensing structure for AUC content
- Negotiated & executed all AUC contracts
- Scrum style- Reduced timeline to publication by 40% by utilizing technology to update methods
- Synthesized multiple Quality Improvement tools, & coordinated with National Cardiovascular Data
- Registries & Advocacy divisions
- Led Science & Quality Committee as staff liaison, oversight for all ACC clinical quality initiatives

- Evaluated practices to refine processes for efficiencies, including the utilization of cloud-based software for surveys & project management
- Evolution of the AUC development process to include project scope development, creation of serial documents, refined recommendations for activities of volunteer members
- Developed & promoted the Statin Intolerance App (currently in app stores)

Director of Research Development & Integrity **Aug 2013- Apr 2015**
American Gastroenterological Association Bethesda, MD

- Executed the startup of the first AGA Clinical Research Division
- Identified & rectified errors in an existing budget proposal, which saved the association over $ 1 million
- Wrote, budgeted, & submitted a grant to the National Institutes of Health
- Managed, monitored, audited, & evaluated all clinical research protocols to ensure compliance with federal & state laws & ethical considerations
- Utilized Agile project plans which established department-wide infrastructure & timelines
- Implemented new technology standards & programs to manage projects & clinical research
- Set standards and developed QA process for clinical trial partners and subcontractors
- Audited clinical/investigator sites, partners, and subcontractors
- Negotiated the execution of multiple contracts, from sites to CROs to Sponsors
- Acted as liaison for four volunteer physician groups ,including all meetings & activities
- Onboarded 20 sites to 3 studies
- Prepared submissions to local & national regulatory agencies
- Developed/ensured electronic case report forms met CDISC requirements
- Evaluated site data entry to ensure quality
- Wrote a new manual of standard operating procedures
- Created & edited ClinicalTrials.gov listings
- Developed & managed a publication process
- Coordinated with Communications & Marketing to promote registry activities & relationships
- Wrote & edited articles for all appropriate AGA multimedia communication vehicles

Regulatory Project Manager **Jun 2012- Aug 2013**
Westat, (Contract Research Organization) Rockville, MD
Assistant to Deputy Chief of Party, USAID program, Feed the Future FEEDBACK project.

- Collaborated with multiple international coordinators
- Managed & trained staff and developed SOPs
- Managed a team in the development of the International Clinical Research Regulatory Matrix
- Provided project management & reporting structures for deliverables

Program Manager, Regulatory & Compliance **Apr 2007- Jun 2012**
The Ohio State University Columbus, OH
Department of Internal Medicine, Division of Cardiology

- Managed, monitored, audited, & evaluated all local & national clinical research protocols to ensure compliance with federal & state laws & bioethical considerations
- Prepared submissions to local & national Institutional Review Board
- Monitored 10+ NIH, multisite or Principle Investigator Initiated Trials annually
- Developed Cardiovascular Fellows Research Training Support Initiative
- Audited billing, payments, & invoices system
- Developed, implemented, & maintained internal data collection methods
- Developed/negotiated budgets & execution of contracts

- Submitted/coordinated research billing methods with the Center for Medicare & hospital
- Managed ClinicalTrials.gov listings for Principal Investigator-initiated trials

Biomedical Research Assistant **Jan 2006- Apr 2007**
University of Toledo Medical Center Department of Neurology Toledo, OH

- Protocol creation & submission to the Internal Review Board
- Data collection & analysis using SASS; survey creation, distribution & collection
- Data collection & monitoring for the Joint Commission on Healthcare Organization

Experience in multiple clinical areas, including:

- Infectious Disease
- Neurology
- Hematology
- Cardiology
- Gastroenterology
- Behavioral Health/Addiction Medicine
- Digital Therapeutics
- Pharmaceuticals
- Devices
- Biologics