Stacy Iannone, DHSc, MS, CCMA(AAMA)

Springfield, PA
(215) 684-9940
Stacyi513@gmail.com

Education:

- University of Pennsylvania, Philadelphia, PA, USA
  Master of Health Care Innovation, Current
- Manor College, Jenkintown, PA, USA
  Certified Clinical Medical Assistant, 2025
- Drexel University, Philadelphia, PA, USA
  Doctorate - Health Science, June 2023
- Philadelphia College of Osteopathic Medicine, Philadelphia, PA, USA
  Master of Science – Forensic Pathology, June 2015
- East Stroudsburg University, East Stroudsburg, PA, USA
  Bachelor of Science - Psychology, June 2008

Experience:

ADJUNCT PROFESSOR, DELAWARE COUNTY COMMUNITY COLLEGE, AUGUST 2024–CURRENT

Responsible for designing and delivering comprehensive coursework in human anatomy and physiology, incorporating lectures, laboratory instruction, and interactive learning strategies to enhance student comprehension. Develops engaging curricula that integrate theoretical knowledge with practical applications, including dissections, histological analysis, and physiological experiments. Provides academic advising and mentorship, guiding students in their educational and career pursuits within healthcare and life sciences. This contributes to curriculum development and interdisciplinary collaborations to strengthen the institution's science programs. Implements innovative assessment methods to evaluate student learning and ensure mastery of anatomical and physiological concepts.

ASSOCIATE DIRECTOR E, AI-4-AI LAB, UNIVERSITY OF PENNSYLVANIA, JULY 2024–CURRENT

Associate Director (AD) oversees projects bridging SEAS, PSOM and Annenberg, and is directly involved with planning, funding, and initial pilot projects between the School of Medicine and the School of Engineering and Applied Sciences. AD is responsible for assisting with grant preparation, staff hiring and training and mentoring staff, IRB submissions, student recruitment, pilot projects, presentations, and overall management of people and time to program milestones. AD facilitates communication among several research teams—initially just at the University of Pennsylvania, but eventually at other health systems nationally. AD develops relationships with internal and external international project partners and is expected to extend beyond existing projects over time. The position requires work within standardized PMP project management frameworks and actively works on outreach, and other activities to foster scientific collaboration and utilization of the developed resources in collaboration with partners. AD oversees abstract and manuscript processes in collaboration with the Principal Investigator. AD serves as a liaison between the PI and the rest of the team (including internal and external lab/project advisors), managing and monitoring operations and timelines, and working with the PI and grants manager to manage the grant budget. AD has a high level of independence, attention to detail, familiarity with medicine, engineering, NIH and NSF funding, and strong communication skills are expected. Perform tasks with minimal supervision. Directs and oversees one or more aspects of the clinical research program. Directs clinical research team and resources to accomplish specific goals and objectives. Provides guidance on data management, implementation, procedures, study feasibility, ethics, accountability, host and schedule meetings, provide training and onboarding support. The main point of contact for study issues is to respond to data requests, respond to budget inquiries. Lead IRB submissions, guidance and grant support. Directs clinical research team and resources to accomplish specific goals/objectives. Provide training to study staff on protocol compliance, and guidance on study specifications. Develop efficient recruitment strategies. Ensure all staff have completed required training and certifications. Provide

onboarding support, equipment set up. Create and maintain accurate study documentation. Collaborate with other departments within the organization and externally. Manage competing priorities to meet study deadlines. Implement strategies for retention of study participants.

PROJECT MANAGER C, AI-4-AI LAB, UNIVERSITY OF PENNSYLVANIA, OCTOBER 2022–JULY 2024

Managed complex, high-impact, multidisciplinary research initiatives bridging SEAS, PSOM, and the Annenberg School, driving collaboration across diverse academic and clinical domains. Spearheaded the planning, execution, and oversight of pilot projects, securing funding and aligning strategic objectives with institutional goals. Directed comprehensive grant development processes, including NIH and NSF submissions, and maintained strict compliance with evolving regulatory frameworks. Led cross-functional teams, managing recruitment, onboarding, and mentorship of staff, while fostering an innovative, high-performance culture. Navigated complex IRB submissions, ensuring ethical standards and protocol adherence across studies. Developed and executed strategic timelines and milestones, managing competing priorities within tight deadlines. Acted as the primary liaison between PIs and multidisciplinary teams, coordinating resources and facilitating seamless communication across national and international research partners. Oversaw budget management and allocation, balancing financial constraints with project demands. Designed and implemented robust participant recruitment and retention strategies, driving successful study outcomes. Managed data integrity and reporting processes, including abstract and manuscript preparation, leveraging PMP frameworks to ensure project deliverables were met with precision and minimal supervision.

PROJECT MANAGER, LABCONNECT (BIOSPECIMAN DIVISON), FEBRUARY 2022–DECEMBER 2022

Responsible for oversight of assigned clinical studies. Performed duties associated with day-to-day oversight of ongoing clinical trial study projects, throughout the life of the trial to ensure quality deliverables on time and within budget. Provided ongoing oversight for clinical trial projects assigned, including client meetings and communications, report development and review, issue resolutions, and budget oversight. Participated in the handover process between Business Development (BD) and the Project Initiation Services team (PIS), and in the training process of internal staff and handover from PIS to the PM. Primary project contact with Sponsors and Contract Research Organizations to ensure appropriate communication channels are maintained and reporting schedules adhered to. Serves as the first point of contact for management issues related to clinical trials. Worked closely and in coordination with clinical laboratory management and directors in support of clinical trials. Review of reports and documents, including enrollment logs, pending test reports, reporting from other laboratories, issue logs, shipping manifests, and other documents that assist with study oversight. As needed, interfaced with laboratories(ies), BD, Operations, and Data Management. Liaised with Project Coordinators to ensure study-related tasks have been performed, and with the assigned data manager to ensure data is delivered on time by SOW. Review and analyze operational and performance-related metrics to assess the success of study oversight activities. Liaised with managers/supervisors in other departments to stay informed of operational changes. Collaborated with project managers in partner laboratories to provide a global overview of study management. Coordinated requests for shipment of stored samples as directed at the SOW. Ensured that all laboratory requirements outlined in the protocol are managed to meet expectations and in compliance with laboratory practices.

PROJECT MANANGER - COUNTRY APPROVAL SPECIALIST, PPD (3 MONTH CONTRACT), NOVEMBER 2021–FEBRUARY 2022

Prepared, reviewed and coordinated, under guidance, local regulatory submissions (MoH, EC, additional special national local applications if applicable, e.g. gene therapy approvals, viral safety dossiers, import license) in alignment with global submission strategy. Provided, under guidance, with local regulatory strategy advice (MoH &/or EC) to internal clients. Provided project specific local SIA services and coordination of these projects. May have contact with investigators for submission related activities. Key-contact at country level for either Ethical or Regulatory submission-related activities. Coordinated, under guidance, with internal functional departments to ensure various site start-up activities are aligned with submissions activities and mutually agreed upon timelines; ensure alignment of submission process for sites and study are aligned to the critical path for site activation. Achieved PPD's target cycle times for site. May work with the start-up CRA(s) to prepare the regulatory compliance

review packages, as applicable. Develop country specific Patient Information Sheet/Informed Consent form documents. Assisted with grant budgets(s) and payment schedules negotiations with sites. Supported the coordination of feasibility activities, as required, in accordance with agreed timelines. Enters and maintains trial status information relating to SIA activities onto PPD tracking databases in an accurate and timely manner. Ensured the local country study files and filing processes are prepared, set up and maintained as per PPD WPDs or applicable client SOPs. Maintained knowledge of and understand PPD SOPs, Client SOPs/directives, and current regulatory guidelines applicable to services provided.

CLINICAL RESEARCH COORDINATOR III (ONCOLOGY: BONE MARROW/TRANSPLANT/BONE MARROW/CELL THERAPY), UNIVERSITY OF PENNSYLVANIA, NOVEMBER 2019–AUGUST 2021

Obtained consent of research participants in accordance with the IRB-approved protocols and all applicable regulations including HIPAA. Identified, scheduled, and/or conducted participant study visits, interviews, and tests. Maintained all regulatory documentation, including local or central IRB and study data. provided data/support to study investigators, sponsors and/or external monitors/auditors. identified issues with protocol compliance. kept principal investigator and manager aware of any issues regarding compliance. Documented and collected data and/or samples for research-related procedures performed during participant study visits. Tracked and maintained study-related information in the data management system within the required timeframe. Responsible for monitoring the inventory of study-related data and collection tools, (e.g. questionnaires, treatment data, and/or therapeutic checklists). Maintained strict adherence to all study protocols, including all regulatory requirements adhering to appropriate federal, local, and institutional guidelines. Adhered with established policies, health and safety regulations and requirements, procedures, and department objectives. Adhered to good clinical practice (GCP) guidelines and all human subject protection practices. initiated and managed clinical projects in accordance with all relevant guidelines, legislation and SOPs. Monitored the progress of the clinical trial against the project plan and performance indicators for quality and budget. Identified risks, and developing and implement plans to mitigate risks in collaboration with team members and other stakeholders. Acted as a daily point of contact for the sponsor and members of the project team, developed research-specific documents, trial master files (TMF) and electronic trial master files (eTMF), reported progress to the internal project team and stakeholders; negotiated contracts with research centers and suppliers. Managed project finances in accordance with the sponsor contract and budget, provided input for proposals and budgets. Trained all new staff and managed clinical research coordinators (I and II) on the team.

CLINICAL RESEARCH COORDINATOR III (ONCOLOGY: OTOLARYNGOLOGY/LUNG), THOMAS JEFFERSON UNIVERSITY, JUNE 2016– NOVEMBER 2019

Reviewed and developed a familiarity with the protocol, e.g., study proceedings and timelines, inclusion and exclusion criteria, confidentiality, privacy protections. Assisted PI in communication of study requirements to all individuals involved in the study. Provided appropriate training and tools for study team members. Documented date of training and signatures of study personnel trained on study specific training log. Collected documents needed to initiate the study and submit to the sponsor (e.g., FDA Forms 1572, CVs, etc.). Worked with the PI to develop and implement recruitment strategies in accordance with IRB requirements and approvals. Conducted or participated in the informed consent process including interactions with the IRB and discussions with research participants, including answering any questions related to the study. Obtained appropriate signatures and dates on forms in appropriate places. Assured that amended consent forms are appropriately implemented and signed. Screened subjects for eligibility using protocol specific inclusion and exclusion criteria, documenting each potential participant's eligibility or exclusion. Registered participants to the appropriate coordinating center (if multi-site study). Registered each participant in the billing matrix to ensure billing of study procedures to the appropriate funding source. Coordinated participant tests and procedures. Collected data as required by the protocol. Assured timely completion of Case Report Forms. Maintained study timelines. Maintained adequate inventory of study supplies. Maintained required records of study activity, including case report forms, drug dispensation records, or regulatory forms. Monitored study activities to ensure compliance with protocols and with all relevant local, federal, and state regulatory and institutional policies. Managed subject enrollment to ensure that informed consent is properly obtained and documented. Assessed eligibility of potential subjects through methods such as screening interviews, reviews of medical records, and discussions with physicians and nurses. Recorded adverse event and

side effect data and conferring with investigators regarding the reporting of events to oversight agencies. Prepared for or participated in quality assurance audits conducted by study sponsors, federal agencies, or specially designated review groups. Identified protocol problems, informing investigators of problems, and assisting in problem resolution efforts such as protocol revisions. Prepared study-related documentation such as protocol worksheets, procedural manuals, adverse event reports, institutional review board documents, and progress reports. Participated in the preparation and management of research budgets and monetary disbursements. Participated in the development of study protocols including guidelines for administration or data collection procedures. Instructed research staff in scientific and procedural aspects of studies including standards of care, informed consent procedures, or documentation procedures. Communicated with laboratories or investigators regarding laboratory findings. Reviewed scientific literature, participated in continuing educational activities, or attending conferences and seminars to maintain current knowledge of clinical supplies affairs and issues. Provided regular updates to internal teams as well as stakeholders, including trial sponsors.

STUDENT LIFE AND ENGAGEMENT COORDINATOR, THOMAS JEFEFRSON UNIVERISTY, AUGUST 2016–JUNE 2019

The Student Life Engagement Coordinator spearheaded creating and supporting a high-quality student life experience for all students. They implemented and facilitated opportunities for co-curricular learning and student leadership development. Proactive retention activities and student engagement were promoted under their guidance. Various initiatives were undertaken to enhance student life, including organizing events, clubs, and societies that catered to diverse interests and promoted social interaction. Academic and personal development workshops were conducted to equip students with essential skills and knowledge beyond the classroom. Moreover, the Coordinator provided mentorship programs, counseling services, and peer support networks to ensure students' holistic well-being and success. Strategies such as orientation programs for new students, academic advising, and career counseling were implemented under their leadership to support students throughout their educational journey. Additionally, they established feedback mechanisms to gather student input and continually improve the student life experience. Overall, the Student Life Engagement Coordinator was pivotal in creating a vibrant and inclusive campus environment conducive to learning, growth, and community engagement.

CLININCAL RESEARCH COORDINATOR I (NEUROLOGY), THOMAS JEFFERSON UNIVERSITY, AUGUST 2016 – AUGUST 2017

The Clinical Research Coordinator I was responsible for data entry, administering A1C blood draws, and conducting standardized cognitive assessments to evaluate participants' cognitive function under the supervision of Dr. Barry Rovner. The study aimed to examine the relationship between cognitive impairment and elevated A1C levels. Participants who met the study criteria—exhibiting both cognitive impairment and high A1C levels—were provided with an electronic medication bottle that recorded the frequency of medication access. This device enabled researchers to monitor adherence patterns and assess the impact of cognitive impairment on medication adherence behaviors.

CLININCAL RESEARCH COORDINATOR I (TRANSPLANT), NATIONAL DISEASE INTERCHANGE, JUNE 2015–JULY 2016

The Clinical Research Coordinator I collaborated with tissue banks, organ procurement organizations, and hospitals to collect donor records, charts, or other social medical information promptly so that the organ/tissue could be matched and placed with a researcher. They obtained telephonic consent for research donation as needed and filed it accordingly. Furthermore, they verified the accuracy of donor screening and data entry processes to ensure the integrity of the collected information. The coordinator liaised between multiple stakeholders, ensuring seamless communication and efficient coordination of efforts to facilitate organ and tissue donation for research purposes. They meticulously organized and managed the documentation process, adhering to regulatory requirements and ethical standards governing research involving human subjects. Throughout their role, the coordinator demonstrated a commitment to detail and accuracy, recognizing the critical importance of reliable data in advancing medical research. Their efforts contributed to the timely availability of vital research resources, ultimately supporting advancements in healthcare and scientific understanding.

Skills:

- Computer: Proficient in all aspects of Windows and Microsoft Office Proficient in biology computer software and statistical analysis software (SPSS). Advanced in CTMS, eTMF (Veeva Vault), Oracle Activate, Medidata RAVE, Redcap, Suvoda IRT, Labvantage, Advantage eClinical, Inform, Global trace and Novartis EDC.
- Laboratory: Proficient in all basic and advanced laboratory procedures and centrifugation.
- Medical: Extensive knowledge of oncological medicine. Extensive knowledge of medical terminology and clinical skills, including physical examinations.
- Others: Project planning and management, study review and design, protocol, informed consent and laboratory manual writing, knowledge of FDA guidance and regulations, physician meetings, presentations, customer support, personnel training, IRB submissions.

Teaching:

- Teaching assistant
    - Biochemistry
    - Biology 1 &2
    - Gross Anatomy
    - Physics 1 &2
    - Chemistry 2
    - Organic Chemistry 1

Languages:

Native fluency in English including translation, oral and written skills. Proficient in French.

Certifications:

- Certified Medical Assistant
- BLS