

HIRA SHRESTHA, MA, BS

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PROFESSIONAL SUMMARY

Experienced Research Project Manager with 13 years in the field, including 7 years in research oversight and project management. Expertise spans diverse therapeutic areas, such as Oncology, Neurology, OB/GYN, and Pediatrics/Neonatology. Skilled at leading cross-functional teams to achieve project goals within urban academic hospital settings. Currently pursuing PMP certification, expected in July 2025.

Key Experiences:

<ul style="list-style-type: none">• Clinical Trials & Projects Management• CBER and CDER application• Regulatory responsibilities management• Research budget development and oversight• Vendor selection and management• Contract review and oversight• Database development and management• Line Management• Internal/External site start-up/Close-out	<ul style="list-style-type: none">• Grant application preparation and submission – Federal, Foundation, Industry, Institutional• Trial Protocol and operational documents development• ClinicalTrials.gov profile creation and reporting• Skilled in various administrative, management, and clinical software
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CURRENT POSITIONS

MASS GENERAL HOSPITAL (MGH) – NEUROLOGY DEPARTMENT, Boston, MA

Sr. Clinical Research Program Manager – McCance Center for Brain Health

April 2023 – Present

I joined McCance Center for Brain Health in April 2023 to support center's newly formed Clinical Trials Unit with setting up clinical trials infrastructure to run platform trials targeting prevention of Alzheimer's disease using repurposed market drugs and natural product combinations. This effort involved identifying internal/external stakeholders and resources that could be leveraged to efficiently and cost-effectively run these trials using federal, foundation, and institutional grants. Majority of my time at McCance so far has been devoted to understanding ever-evolving institutional research infrastructures; developing center's trial management plans and SOPs; biomarker and investigational product vendor identification, communication, and contracting; IRB submissions; several grants submission; trial budgets development; trial start-up activities under Mass General Brigham regulatory guidelines; and bi-weekly faculty seminar management.

Key contributions & responsibilities:

- Working with leadership to develop clinical research infrastructure and portfolio development including brain nutrition and Alzheimer's Disease prevention trials
- Supporting staff development efforts
- Putting together detailed clinical trials budget as well as grant application packets for several federal, foundation, and institutional grants with amount ranging in 2 to 28 million for 3-5 years trials.
- Selecting and setting up internal and external Alzheimer's Disease and nutrition biomarkers vendors
- Leading trial start-up activities in compliance with federal and institutional guidelines
- Overseeing and assisting with development of trial documents such as CRFs and implementing them.
- Developing integrated study management plans with the core project team.
- Collaborating with other functional groups within the institution where necessary to support milestone achievement and to manage study issues and obstacles.
- Developing trial regulatory management plan and supervising regulatory activities
- IRB submission and assistance with FDA correspondence as needed
- Managing trial database development and implementation in collaboration with team.
- Managing all aspects of bi-weekly McCance Center Faculty seminar series that involved developing detailed SOP for effecting management of the seminar workflows that included generating seminar dates a year in

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advance, managing speakers, maintaining distribution list, collaborating with institutional communication department to post videos, etc.

- Aiding with trial dissemination efforts and delivering any other administrative assistance as needed.

BRIGHAM AND WOMENS HOSPITAL - PEDIATRIC NEWBORN MEDICINE, Boston, MA Oct 2019 – Present

Research Specialist - Newborn Assessment Examiner

I am a certified NICU Network Neurobehavioral Scale (NNS) examiner. I joined BWH to work as a Newborn Assessment specialist to train qualified study staff to conduct NNS and also serve as a backup NNS examiner for NIMH funded study investigating postpartum developmental outcomes of infants born to mothers experiencing some level of psychiatric conditions such as depression or psychosis. I also provide NNS related consultation as needed.

PAST POSITIONS

DANA-FARBER CANCER INSTITUTE – MEDICAL ONCOLOGY, Boston, MA Nov 2021 – April 2023

Sr. Clinical Research Program Manager - Center for Early Detection and Interception of Blood Cancers

I joined the Center for Early Detection and Interception of Blood Cancers of Dana Farber Cancer Institute to lead operational management of Investigational New Drug (IND) trials portfolio that included 7 ongoing and 2 new single- and multi-site trials. These trials were initiated with a goal to prevent progression of Multiple Myeloma by intercepting at earliest pre-symptomatic stages of disease progression namely Monoclonal Gammopathy of Undetermined Significance (MGUS) and high-risk Smoldering Multiple Myeloma (SMM) by using immunotherapies including monoclonal antibodies and adoptive cell therapies that have been approved for Multiple Myeloma treatment. Under this role, I was responsible for all aspects for trial management including trial documents development; SOPs development; oversight of regulatory activities, patient-facing activities, vendors communication, meetings management, internal/external stakeholders communications, investigational product workflows and more.

Key Contributions and Responsibilities:

- Provided management and regulatory oversight for a portfolio of 7 active single/multi-site IND trials: [NCT04775550](#), [NCT03236428](#), [NCT05469893](#), [NCT02279394](#), [NCT03301220](#), [NCT04270409](#), [NCT00422799](#)
- Prepared and submitted 3 new IND applications to FDA's Center for Biologics Evaluation and Research (CBER) in 1 year, of which 2 were approved ([Immuno-PRISM: NCT05469893](#) and [CAR-PRISM: NCT05767359](#)) and 1 was in review at the time of my departure
- Assisted the PIs with FDA correspondence by preparing extensive response letters while establishing efficient communications with stakeholders to get responses back to FDA within deadlines as tight as 3 hours from response receipt.
- Led all regulatory processes under federal and institutional guidelines for new trials from IND approval through trial activation and operational phase.
- Handled ClinicalTrials.gov responsibilities under institutional guidelines by setting up profile for new trials, reporting trial updates for ongoing trials, reporting final data
- Led trial staffing and line management – hiring, onboarding/offboarding, payroll, promotion, performance reviews, conflict resolution
- Provided oversight and guidance for trial billing and finances in collaboration with research finance and billing team.
- Coordinated and facilitated trial databases development and management
- Developed and implemented center's research portfolio resource management plan to support Clinical Trials Office's department-wide initiative to manage portfolio-specific effort allocation needs
- Provided oversight of investigational product (IP) procurement and management in collaboration with trial IP sponsors and investigational pharmacies.

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- Involved in contract negotiations, review/approval of vendor agreements in collaboration with contract and agreement department.
- Provided oversight and facilitated trial monitoring and auditing activities in support with core operations team.
- Maintained trial regulatory binders ensuring trials were conducted under strict federal and institutional guidelines.
- Closely monitored and supervised data collection to ensure study activities adhered to trial protocol and made sure deviations/violations and adverse events were reported and documented appropriately and timely.
- Energized and supervised operational team to build their own functional workflow to efficiently carry out day-to-day patient/clinician facing trial activities

BOSTON MEDICAL CENTER (BMC) – DEPARTMENT OF PEDIATRICS, Boston, MA

Feb 2015 – Nov 2024

Neurodevelopmental Assessment Examiner (Seasonal)

Dec 2021 – Nov 2024

Clinical Research Manager

Aug 2017 – Nov 2021

Clinical Research Coordinator

Dec 2016 – Jul 2017

Senior Research Assistant

Feb 2015 – Nov 2016

Key Contributions-

Project Management and Coordination:

- Administrative Responsibilities: Overseeing day-to-day operations, ensuring project timelines are adhered to, and handling logistical support.
- Staff Supervision and Training: Leading, mentoring, and training research staff involved in ongoing projects to ensure proper execution and adherence to protocols.
- Patient Contact and Enrollment: Engaging with patients for study participation, ensuring smooth enrollment processes, and addressing patient inquiries.
- Media Coordination: Managing communication and outreach regarding the study, possibly involving press releases, social media updates, or public relations efforts.
- Inter-Departmental Collaboration: Facilitating communication among different departments, ensuring alignment and collaboration on shared objectives.
- Financial Transactions: Handling financial aspects of the study, including participant compensation, study-related billing, and managing research finances through systems like ClinCard and VelosCT.

Research and Regulatory Responsibilities:

- IRB Regulation and Reviews: Ensuring adherence to ethical and legal guidelines by preparing and submitting IRB applications, facilitating audits, and reviewing protocols for compliance.
- Biospecimen Collection: Overseeing the collection of biological samples (blood, saliva, hair, placenta) from participants, ensuring proper handling, storage, and documentation.
- Developmental Assessments: Performing neurodevelopmental assessments on participants, such as the NICU Network Neurobehavioral Scale (NNS) and Bayley Scales of Infant Development (BSID-III).
- Medical Record Abstraction: Supervising data collection from patient medical records using systems like Citrix and ensuring that data is accurately entered into research databases (e.g., StudyTrax, RedCap, eClinical).

Database and Publications Management:

- Database Creation and Management: Designing, maintaining, and managing research databases that support the study.
- Assistance with Publications: Supporting the dissemination of research findings through manuscripts,

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posters, and other formats for publication or presentation.

- Study Dissemination: Coordinating the preparation and dissemination of study-related documents, including treatment protocols, research posters, and other media for sharing findings.

Projects Managed at BMC:

“MATernal and Infant Network (MAT-LINK) to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy” ([DCD MAT-LINK](#))

- A multi-site surveillance system to monitor maternal, infant, and child health outcomes associated with treatment for opioid use disorder during pregnancy as well as to examine the possible effects of exposure to multiple substances and other risk factors on maternal and infant outcomes

“Medication Treatment for Opioid-dependent Expecting Mothers”

(NIDA CTN0080:MOMs - [NCT03918850](#)) – at site level

- National Institute of Drug Abuse: Clinical Trial Network 0080 (NIDA-CTN0080) funded investigational pharmaceutical clinical trial evaluating the impact of treating opioid use disorder in pregnant women with extended-release buprenorphine (BUP-XR CAM2038) compared to sublingual buprenorphine (BUP-SL) on maternal-infant outcomes

“Maternal Opioid Maintenance: Naltrexone Efficacy Study (MOM NEST) (NICHD 1 R01 HD96798-01 - [NCT03718104](#))

- National Institute of Health (NIH) funded multi-center prospective observational cohort study examining the safety, efficacy, pharmacokinetics, and pharmacogenomics of naltrexone for pregnant women with opioid use disorder or alcohol user disorder

“Neonatal Abstinence Syndrome (NAS) Quality Improvement Project”

- Inter-departmental effort to reduce length of hospital stay (LOS) of newborns with NAS by implementing non- pharmacological approach as a first line of treatment before utilizing pharmacological intervention to treat opioid withdrawal in infants
- Funded in the past by Massachusetts Health Policy Commission NAS Intervention Program under Health Care Innovation Investment (HCII) Program (Dec 2016 – Jun 2018)
- Development of novel “Eat, Sleep, Console” protocol to treat neonates at risk of NAS during birth hospitalization (<https://www.neogicma.org/eat-sleep-console>)
- Collaboration with Beth Israel Deaconess Medical Center (BIDMC) initiated Perinatal-Neonatal Quality Improvement Network (PNQUIN) of Massachusetts in developing and maintaining statewide database on outcomes of mother baby dyads affected by OUD during pregnancy

“Genomics of Neonatal Abstinence Syndrome”

- Study investigating genetic and epigenetic contributors to Neonatal Opioid Abstinence Syndrome (NOWS) outcomes

“Buprenorphine Vs. Methadone Treatment for Opioid Addiction During Pregnancy: A Study of Prenatal Compliance and Neonatal Outcomes”

- Retrospective database development effort dedicated to Project RESPECT (specialized OB/GYN clinics at BMC providing care tailored to pregnant women with opioid use disorder receiving opioid maintenance therapy) patients with goals to collecting extensive inpatient/outpatient maternal-infant pregnancy and birth data, and evaluating clinical as well as social predictors of NAS outcomes

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“Improving Outcomes in Neonatal Abstinence Syndrome”

(NIH R01 DA032889; [NCT01958476](#))

- National Institute of Drug Association (NIDA) funded R01 pharmaceutical clinical trial led by Tufts Medical Center comparing methadone versus morphine for treatment of NAS in newborns exposed to maternal opioids during pregnancy, and evaluating short and long-term neurobehavioral outcomes

Key Contributions:

- Brought BMC to highest enrollment site by enrolling 40% of the total sample size out of 8 study sites
- Performed all aspects of clinical trial including recruitment, enrollment, randomization, bio specimen collection, data abstraction, database management, patient visit coordination, infant developmental assessments, participant counselling on study medication, IRB audit preparation, payments, interdepartmental communication and coordination etc. independently
- Maintained highest participant retention rate of 80% for the study period

“Provider and Parental Attitudes toward Integrating Human Papilloma Virus (HPV) Vaccination Promotion Initiative with Cervical Cancer Screening and Prevention Initiatives in Primary Care Settings”

Phase II study about integrating HPV vaccination and cervical cancer screening in Primary Care Setting

- Increased enrollment of study subject by over 50% during a short period to time
- Recruited patients from BMC family medicine and adolescent clinics
- Performed semi-structured interviews of the mothers of participating adolescent and teenage patients
- Developed study database using REDCap
- Improved organizational system of the study for smoother operation
- Created and organized study specific regulatory documents and binders
- Trained/mentored research assistants

Site Data Coordinator

“Vermont Oxford Network (VON) – Boston Medical Center NICU”

Key contributions:

- Abstracted clinical data of NICU patients using EPIC, and entering data on VON database system using eNICQ platform
- Coordinated quarterly and annual data deadlines with the sponsor site
- Collected and summarized monthly NICU admission data as well as taskforce-specific patient level data for use by BMC’s site leader and NICU taskforces
- Managed site database and produced data summary as per need
- Trained and supervised new employees

BOSTON UNIVERSITY SCHOOL OF MEDICINE - CENTER FOR MILITARY HEALTH, Boston, MA

Associate Director - Interim

Sept 2018 – Mar 2020

The CMH is built on the work of the Joining Forces Conference held annually at BUSM and includes the development of an interdisciplinary research center, clinical care initiatives, educational curricula, and outreach efforts to address medical issues affecting veterans and service members

- Assisted the Director in forging partnerships with the military community including the Department of Defense (DoD) and the Department of Veterans Affairs for the purpose of conducting joint research on women’s health in the military
- Identified research gaps in military and veteran experience, searched for potential funding resources, and facilitated partnerships between investigators and sponsors
- Employed administrative abilities including planning and coordinating meetings and travel,

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organizing and managing grant proposals, and running weekly team meetings

- Supervised updating and maintenance of the center's website on WordPress
- Led staff development efforts including job posting, hiring, interviewing, and training new staff.
- Organized and hosted regular and annual stakeholders meetings and assisted the director with writing annual progress reports.

BETH ISRAEL DEACONESS MEDICAL CENTER - DEPARTMENT OF PSYCHIATRY, Boston, MA

Neonatal Assessment Consultant

Mar 2018 – Sep 2018

“Maternal Infant Mood and Emotion Study” (MIMES - NIMH K23 MH 107714-01 A1)

- Same responsibilities as BWH position above

UNIVERSITY OF MAINE – DEPARTMENT OF PSYCHOLOGY, Orono ME

May 2011 – Aug 2014

- **Graduate Research/Teaching Assistant/Lab Coordinator** - Department of Psychology
- **Administrative Assistant Aide-V (Part-time)** – Department of Psychology
- **Individual Research Project Supervisor** - Upward Bound Math and Science (UBMS)

Key responsibilities:

- In addition to taking graduate courses full time, I also managed my mentor Dr. Marie Hayes' Developmental Neurobiology Lab conducting research on opioid dependent mother infant dyads from pregnancy through perinatal and postnatal infant developmental outcomes:
- Streamlined data management plans
- Led neonatal sleep organization project that involved 15 hours of recorded video analysis each on over 200 babies.
- supervised lab interns, created SOPs for data coding and data management, supervised intern science projects
- actively participated in videography and biological data collection, processing, and analysis for theses and publications.
- served as a teaching assistant for several undergraduate level courses
- Assisted Psychology department chair with administrative work and publication search during summer.

EDUCATION

UNIVERSITY OF MAINE, Orono ME

Master of Arts in Developmental Psychology – Psychobiological Research Track

Sep 2011 – Aug 2014

Advisor: Marie J. Hayes, PhD

Thesis: [“Sleep, wake, and arousal properties of methadone-exposed neonates: a videographic assessment on the first or second postnatal night”](#) (NIH -DA024806-01A2, M. Hayes)

HUSSON UNIVERSITY, Bangor ME

Bachelor of Science in Psychology/Clinical Track (***Magna Cum Laude***)

Sep 2006 – Dec 2010

AWARDS

- “Gage Award for Hospital Innovation and Excellence, Boston Medical Center NAS Quality Improvement Project” America's Essential Hospitals (2018)
- “Research and Teaching Assistantship for Doctoral Program in Developmental Clinical Psychology” University of Maine, Department of Psychology, Orono, ME (2011-2014)

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TRAININGS AND CERTIFICATES

- Project Management Professionals (PMP) Certification – Estimated July 2025 or before
- Brown University, Providence, RI
 - “NICU Network Neurobehavioral Scale (NNS) Certification” (2016)
- The Jackson Laboratory, Bar Harbor, ME
 - “Short Course on Genetics of Addiction” (2012)
- Collaborative Institutional Training Initiative (CITI: Ref ID # 1953676)
 - Good Clinical Practice (GCP)
 - Human Subjects Protection Training – Biomedical Research
- Institutional compliance and safety trainings
 - Health Insurance Portability and Accountability Act (HIPPA) Compliance
 - Biosafety Level I - III Lab Trainings

MEMBERSHIPS

- Project Management Institute ([PMI](#))
- Alzheimer’s Association – [ISTAART](#)

SCIENTIFIC PUBLICATIONS, POSTER PRESENTATIONS, AND ACKNOWLEDGEMENTS

Full list available upon request

- [Google Scholar \(24 Links\)](#)
- [ASCO 2022](#) (NCT04775550)
- [Alzheimer's & Dementia Vol 20, Dec 2024](#)

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