

Rhonda Washington-Lewis
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Professional Experience

Clinical Research Manager/Lab Instructor

University of Maryland
June 2016 to Present

Funding: DARPA/BARDA/Prometheus/CDC/Flu Lab
Research Studies: C.A.T.C.H. the Virus, StopCOVID UMD
Vaccine Clinical Trial: Novavax and Moderna
Medical Devices: Spire Health Tag, BioBeat Watch

Management

- Manage overall clinical operations and study startup
- Create and maintain clinic SOPs
- Create, develop and implement all clinical training material
- Provide leadership and guidance to clinical and administrative staff
- Develop strategic plans and timelines to implement protocols safely in a clinic setting
- Hiring manager for clinical and administrative positions
- Develop risk assessment plans for staff conducting home visits/field research
- Directly supervise and train research assistants, phlebotomists, medical assistants, research coordinators, recruitment team and drivers
- Initiate partnerships with local urgent care facilities, firehouse, churches, and community centers
- Develop and coordinate community outreach/recruitment activities

Budget

- Create and manage study budget for clinical operations, staffing, and human subjects' compensation
- Create clinical feasibility and throughput reports
- Manage and disperse participant's compensation via Greenphire System

Human Subjects

- Screen, enroll and consent subjects in accordance with GCP and ICH guidelines
- Collaborate with human subjects' office to ensure guidelines are followed
- Distribute medical devices and maintain accountability log
- Ensure the safety for all participants by following the minimal risks guidelines
- Complete study visits and collect biological samples and data

Study Development

- Meet with sponsors to gain understanding of request and create study implementation
- Collaborate with PI, Sub Investigator on study design
- Develop the clinical logistics to ensure safety of human subjects and staff
- Collaborate with Medical Director to write protocols and associated documents (e.g., informed consent forms, data collection forms, eligibility screening, marketing material)
- Collaborate with Data Management teams on programming study in REDCap

Undergraduate Development

- Lab Instructor for MIEH325
- Independently created, developed, instructed phlebotomy and clinical skills course for undergraduates
- Develop field research safety and emergency response plans
- Directly supervised and trained >80 undergraduate research assistants

Senior Clinical Research Coordinator

University of Maryland
December 2014 to June 2016

Funding: NIH/NIDA and VA
Clinical Trial: Smoking Cessation (Phase II)

- Screen, enroll, consent and randomize human subjects
- Conduct study visits and collect biological samples and EKGs
- Managed and dispensed cash compensation to study participants
- Managed and dispensed investigational drugs (ID) and maintained accountability logs
- Work with medical monitor during RMV and close-out visit
- Completed study visits progress reports
- Internal monitor of regulatory document to maintain audit-ready files
- Created and executed recruitment campaigns
- Managed vendor activities
- Performed investigational drug compliance test and illicit drug screening
- Work directly with PI on recruitment strategies
- Conduct feasibility assessments and produce reports
- Create and submit IRB documents
- Enter, audit, and resolve queries in MediData
- Administer CSSRS to subjects
- Label, centrifuge and aliquot samples per protocol

Clinical Research Coordinator

Lockheed Martin NIH/NIAID/Vaccine Research Center
January 2007 to January 2013

Funding NIH/NIAID

Clinical Trials: VRC012, VRC015, VRC304, VRC305, VRC306, VRC505, VRC310, VRC205, VRC101, VRC700, VRC701, VRC703, VRC704, VRC-AVIDNA036-00-VP, VRC-FLUDNA063-00-VP (Phase I, II, III)

- Liaison to NVITAL and Vaccine Research Center
- Lead Study Coordinator for Apheresis and HIV/AIDS Therapeutic Protocol w/3000 volunteers
- Developed the project plan and managed multiple satellite clinics and mobile clinic
- Assisted with the development of the VRC special EBOLA unit
- Collaborated with internal and external PI's on sub studies
- Collaborated with international colleagues on vaccine trials
- Liaison and host to international colleagues during visits to the United States
- Facilitated sample transport with contractors and resolve sample discrepancies
- Reconciled Study Manager and EMMES database
- Conducted pre-screen interview with study volunteers for multiple NIAID protocols
- Review medical records and lab results to confirm enrollment eligibility for all new enrollments
- Developed recruitment routes for mobile clinic advertising
- Abstracted medical information from medical history commitment medications and preexisting conditions for follow up visits and data analysis
- Create and organize research data for clinical presentations
- Arrange community outreach events with local governments, radio stations, magazines, and metro campaign
- Managed phlebotomy lab and ensured GCL guidelines are followed
- Train new staff on procedures and protocols
- Collect biological samples and vital signs for all visits on multiple protocols
- Perform quality assurance test and maintain logs on products used for procedures

Medical Technician

Walter Reed Army Medical Center
January 1998 to January 2013

- Coordinated MRI exams for Traumatic Brain Injury (TBI) research subjects returning from Operation Iraqi Freedom
- Maintained clinic schedule and secured collected data within HIPPA and OSHA regulations
- Prepared and screened patients for radiological exams
- Worked closely with Radiologists to resolve patients' concerns
- Prepared daily exam protocols with Radiologist
- Liaison between executive office and MRI department

Professional Affiliations

American Society for Clinical Pathology
Association of Clinical Research Professionals
American Medical Technologist
The Society of Clinical Research Associates
Regulatory Affairs Professionals Society
American Society of EKG Technicians

Education, Certifications and Awards

Psychology, A.A.
Psychology, B.S. (2022)
CCRC (ACRP)
PCT (ASCP)
Certified Allied Health Instructor (AMT)
Merit Award (NIAID)
Cash Awards (NIAID and Walter Reed)
NIAID Director's Award
Performance Award (NIAID and Walter Reed)

Publications

- Zhu S, Jenkins S, Addo K, Heidarinejad M, Romo SA, Layne A, Ehizibolo J, Dalgo D, Mattise NW, Hong F, Adenaiye OO, Bueno de Mesquita JP, Albert BJ, **Washington-Lewis R**, German J, Tai S, Youssefi S, Milton DK, Srebric J. (2020). Ventilation and laboratory confirmed acute respiratory infection (ARI) rates in college residence halls in College Park, Maryland. *Environment International*. Feb;137
- Ledgerwood JE, Wei CJ, Hu Z, Gordon IJ, Enama ME, Hendel CS, McTamney PM, Pearce MB, Yassine HM, Boyington JC, Bailer R, Tumpey TM, Koup RA, Mascola JR, Nabel GJ, Graham BS; **VRC 306 Study Team**. DNA priming and influenza vaccine immunogenicity: two phase 1 open label randomised clinical trials. *Lancet Infect Dis*. 2011 Dec;11(12):916-24. doi: 10.1016/S1473-3099(11)70240-7. Epub 2011 Oct 3. PMID: 21975270; PMCID: PMC7185472.

VRC 306 Study Team:

Sarah Hubka, LaSonji Holman, Laura Novik, Pamela Costner, Kathy Zephir, Floreliz Mendoza, Jamie Saunders, Brenda Larkin, Diane Johnson, Nina Berkowitz, Brandon Wilson, Sandra Sitar, Olga Vasilenko, Yesenia Merino, Joseph Casazza, Trishna Goswami, Raymond Cruz, Niraj Desai, Sheryl Young, Uzma Sarwar, Charla Andrews, Phillip Gomez, Becky Sheets, Judy Stein, Galina Yamshchikov, Hope Decederfelt, Judith Starling, LaChonne Stanford, **Rhonda Washington-Lewis**, Kathy Rhone, Hanne Andersen, Phyllis Zaia

- Ledgerwood JE, Hu Z, Gordon IJ, Yamshchikov G, Enama ME, Plummer S, Bailer R, Pearce MB, Tumpey TM, Koup RA, Mascola JR, Nabel GJ, Graham BS; **VRC 304 and VRC 305 Study Teams**. Influenza virus h5 DNA vaccination is immunogenic by intramuscular and intradermal routes in humans. *Clin Vaccine Immunol*. 2012 Nov;19(11):1792-7. doi: 10.1128/CVI.05663-11. Epub 2012 Sep 5. PMID: 22956656; PMCID: PMC3491556.

VRC 304 and VRC 305 Study Teams:

LaSonji Holman, Laura Novik, Pamela Costner, Brenda Larkin, Cynthia Starr Hendel, Diane Johnson, Sandra Sitar, Olga Vasilenko, Joseph Casazza, Trishna Goswami, Raymond Cruz, Charla Andrews, Phillip Gomez, Rebecca Sheets, Hope Decederfelt, Judith Starling, LaChonne Stanford, **Rhonda Washington-Lewis**

- Ledgerwood JE, Costner P, Desai N, Holman L, Enama ME, Yamshchikov G, Mulangu S, Hu Z, Andrews CA, Sheets RA, Koup RA, Roederer M, Bailer R, Mascola JR, Pau MG, Sullivan NJ, Goudsmit J, Nabel GJ, Graham BS; **VRC 205 Study Team**. A replication defective recombinant Ad5 vaccine expressing Ebola virus GP is safe and immunogenic in healthy adults. *Vaccine*. 2010 Dec 16;29(2):304-13. doi: 10.1016/j.vaccine.2010.10.037. Epub 2010 Oct 27. PMID: 21034824.

VRC 205 Study Team:

Sarah Hubka, LaSonji Holman, Laura Novik, Pamela Costner, Kathy Zephir, Floreliz Mendoza, Jamie Saunders, Brenda Larkin, Diane Johnson, Nina Berkowitz, Brandon Wilson, Sandra Sitar, Olga Vasilenko, Yesenia Merino, Joseph Casazza, Trishna Goswami, Raymond Cruz, Niraj Desai, Sheryl Young, Uzma Sarwar, Charla Andrews, Phillip Gomez, Becky Sheets, Judy Stein, Galina Yamshchikov, Hope Decederfelt, Judith Starling, LaChonne Stanford, **Rhonda Washington-Lewis**, Kathy Rhone, Hanne Andersen, Phyllis Zaia

- Prime-Boost Interval Matters: A Randomized Phase 1 Study to Identify the Minimum Interval Necessary to Observe the H5 DNA Influenza Vaccine Priming Effect Julie E. Ledgerwood,¹ Kathryn Zephir,¹ Zonghui Hu,² Chih-Jen Wei,¹ LeeJah Chang,¹ Mary E. Enama,¹ Cynthia S. Hendel,¹ Sandra Sitar,¹ Robert T. Bailer,¹ Richard A. Koup,¹ John R. Mascola,¹ Gary J. Nabel,¹ and Barney S. Graham,¹ the **VRC 310 Study Team**

VRC 310 Study Teams:

LaSonji Holman, Laura Novik, Pamela Costner, Brenda Larkin, Cynthia Starr Hendel, Diane Johnson, Sandra Sitar, Olga Vasilenko, Joseph Casazza, Trishna Goswami, Raymond Cruz, Charla Andrews, Phillip Gomez, Rebecca Sheets, Hope Decederfelt, Judith Starling, LaChonne Stanford, **Rhonda Washington-Lewis**

- Joseph P. Casazza, Kathryn A. Bowman, Selorm Adzaku, Emily C. Smith, Mary E. Enama, Robert T. Bailer, David A. Price, Emma Gostick, Ingelise J. Gordon, David R. Ambrozak, Martha C. Nason, Mario Roederer, Charla A. Andrews, Frank M. Maldarelli, Ann Wiegand, Mary F. Kearney, Deborah Persaud, Carrie Ziemniak, Raphael Gottardo, Julie E. Ledgerwood, Barney S. Graham, Richard A. Koup, the **VRC 101 Study Team**, Therapeutic Vaccination Expands and Improves the Function of the HIV-Specific Memory T-Cell Repertoire, *The Journal of Infectious Diseases*, Volume 207, Issue 12, 15 June 2013, Pages 1829–1840, <https://doi.org/10.1093/infdis/jit098>

VRC 101 Study Team:

LaSonji Holman, Cynthia Hendel, Sarah Plummer, Laura Novik, Brenda Larkin, Steve Rucker, Pamela Costner, Trishna Goswami, Sarah Read, Susan Leitman, Hope Decederfelt, Judith Starling, Tiffany Alley, Richard Jones, Diane Johnson, Sara Jones, Sandra Sitar, La-Chonne Stanford, **Rhonda Washington-Lewis**, Ericka Thompson, Kathy Rhone, Phyllis Zaia