KIRSTEN A. HAUGE, MPH

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EDUCATION

2009 University of Washington, Seattle, WA
Master of Public Health – Epidemiology

1998 University of Wisconsin, Madison, WI
Bachelor of Science – Medical Microbiology and Immunology

CORE QUALIFICATIONS

- 19+ years of experience in infectious disease research and vaccine trials, including 5 large-scale COVID-19 trials
- 19+ years of experience in regulatory affairs
- 10+ years developing clinical trial protocols
- 4+ years of experience supervising a clinical research team
- 3+ years of working with international partners in Kenya

PROFESSIONAL EXPERIENCE

University of Washington Virology Research Clinic, Seattle, WA **2003 to present**
Manager of Program Operations *2018 to present*

- Manage regulatory approval processes and ensure regulatory compliance for over 30 domestic and international protocols. Work includes IRB submissions, FDA IND submissions, DSMB charters, Material Transfer Agreements. Serve as main point of contact with collaborating partners at NIH, CROs, and pharmaceutical companies. Serve as a critical resource to study investigators on regulatory matters.
- Manage a $16M funding portfolio of both NIH and industry-funded research. Develop budgets, staffing projections, work with fiscal staff to ensure compliance with polices and maintenance of accurate fiscal reports, allocate fiscal resources, manage payroll distributions.
- Assist Clinic Director with strategic planning on upcoming trials and long-term funding
- Oversee start-up, implementation, and close-out of research trials, plan and allocate clinic staff and study resources, lead weekly team meetings, develop agendas and action items. Oversee the Quality Assurance program.
- Supervise 15+ employees; set clinic HR policy, develop onboarding plans, manage performance reviews and disciplinary action.
- Oversee site operations for our partner clinics in Kenya and the Lummi Tribal Health Center in Bellingham, Washington; developed an oversight and reporting plan to ensure site compliance with regulatory and sponsor policies.

Research Program Manager *2009 - 2018*

- Manage regulatory approval processes and ensure regulatory compliance for a comprehensive research program of over 30 domestic and international protocols
- Write protocols; assist in the evaluation of proposed clinical trials
- Write DSMB Charters and Data Safety Monitoring Plans; prepare clinical study reports
- Prepare and maintain investigator-initiated FDA IND applications

- Oversee study planning, implementation, and close-out; ensure follow-up on site monitoring visits
- Develop and maintain study databases including regulatory document tracking, staff training, and clinicaltrials.gov
- Develop and maintain clinic Standard Operating Procedures (SOPs)

Research Study Coordinator *2003 - 2009*
University of Washington Virology Research Clinic, Seattle, WA
- Maintain all required regulatory documents for clinical trials
- Develop study-related documents and recruitment materials; write consent forms
- Subject recruitment and tracking for multiple clinical trials; data entry

Seattle Biomedical Research Institute, Seattle, WA **2001 - 2003**
Laboratory Technician
- Developed novel transposome mutagenesis system for *M. avium*

University of Washington, Department of Genetics, Seattle, WA **2000 - 2001**
Research Technician
- Worked exclusively with yeast on experiments involving protein interactions

University of Wisconsin, Genome Center of Wisconsin, Madison, WI **1999 - 2000**
Associate Research Specialist
- Worked all areas of the bacterial pathogen genome sequencing laboratory

PUBLICATIONS

- Stankiewicz Karita HC, **Hauge K**, Magaret A, Mao C, Schouten J, Grieco V, Xi LF, Galloway DA, Madeleine MM, Wald A. Effect of Human Papillomavirus Vaccine to Interrupt Recurrence of Vulvar and Anal Neoplasia (VIVA): A Trial Protocol. JAMA Netw Open. 2019 Apr 5;2(4):e190819. doi: 10.1001/jamanetworkopen.2019.0819.

- Freeman R, Kato-Maeda M, **Hauge KA**, Horan KL, Oren E, Narita M, Wallis CK, Cave D, Nolan CM, Small PM, Cangelosi GA. Use of rapid genomic deletion typing to monitor a tuberculosis outbreak within an urban homeless population. J Clin Microbiol. 2005 Nov;43(11):5550-4.

- Philalay JS, Palermo CO, **Hauge KA**, Rustad T, Cangelosi GA. Antimicrob Agents Chemother. Genes Required for Intrinsic Multi-Drug Resistance by *Mycobacterium avium*. 2004 Sept;48(9):3412-8.

- Milan SJ, **Hauge** KA, Kurepina NE, Lofy KH, Goldberg SV, Narita M, Nolan CM, McElroy PD, Dreiswirth BN, Cangelosi GA. Expanded Geographical Distribution of the N Family of *Mycobacterium tuberculosis* Strains within the United States. J Clin Microbiol. 2004 Mar;42(3):1064-8.

- Laurent JP, **Hauge K**, Burnside K, and Cangelosi GA. Mutational Analysis of Cell Wall Biosynthesis in *Mycobacterium avium*. J Bacteriol. 2003 Aug;185(16):5003-6.

PUBLICATIONS - COLLABORATOR

- Risk of Severe Acute Respiratory Syndrome Coronavirus 2 Acquisition Is Associated With Individual Exposure but Not Community-Level Transmission. Friedman-Klabanoff DJ, et al. .J Infect Dis. 2022 Aug 24;226(2):225-235. doi: 10.1093/infdis/jiac029.

- Efficacy and Safety of NVX-CoV2373 in Adults in the United States and Mexico. Dunkle LM, Kotloff KL, Gay CL, et al. N Engl J Med. 2022 Feb 10;386(6):531-543. doi: 10.1056/NEJMoa2116185. Epub 2021 Dec 15.

- Homologous and Heterologous Covid-19 Booster Vaccinations. Atmar RL, Lyke KE, et al. N Engl J Med. 2022 Mar 17;386(11):1046-1057. doi: 10.1056/NEJMoa2116414. Epub 2022 Jan 26.

- Implementation of a fully remote randomized clinical trial with cardiac monitoring. Mayfield JJ, Chatterjee NA, et al. Commun Med (Lond). 2021 Dec 20;1:62. doi: 10.1038/s43856-021-00052-w. eCollection 2021.

- Hydroxychloroquine as Postexposure Prophylaxis to Prevent Severe Acute Respiratory Syndrome Coronavirus 2 Infection : A Randomized Trial. Barnabas RV, Brown ER, et al .Ann Intern Med. 2021 Mar;174(3):344-352. doi: 10.7326/M20-6519. Epub 2020 Dec 8.

TRAINING

- Human Subjects Protection Training; Good Clinical Practice

References available upon request.