

### **Educational Background**

I graduated as valedictorian of Durham High School in 19XX, but one of my proudest achievements at that time was not academic, but athletic. I was an excellent student, but succeeded as a statewide competitive swimmer and it was only through effort and resilience – traits that I have maintained as core values throughout my career. I entered Duke University as a Merit Scholar, National Merit Scholar and Leadership Scholar. Majoring in biology, I graduated *summa cum laude* as salutatorian of my class at Duke, completing my studies a semester ahead of schedule. While I had focused my efforts on the foundation for my career in medicine, I challenged myself to learn other skills, from computer science to SCUBA. Between college and medical school, I developed new experience as an educator, teaching science to students from around the globe at the Duke Talent Identification program, while also challenging myself physically as a volunteer at a National Park.

My career path to academic medicine started at Duke University, where I had my first experience in research, under the mentorship of Dr. John Doe. I completed my medical education at Duke University School of Medicine (20XX) and went to Vanderbilt University for my internal medicine training.

### **Training, Clinical Activities**

I came to back Duke with a goal: to become the best physician I could be and to use that knowledge and skill to excel as both an educator and a clinician. Having gained clinical experience in the care of people with HIV infection during my medical training in Raleigh, North Carolina, my interest in infectious diseases (ID) and in particular HIV-infection would guide my early decision making to pursue a fellowship in infectious diseases. During my year as a Chief Resident at the Durham VA medical center, I recognized the burden of HCV infection in our veteran population and developed an interest in HCV infection, particularly in people with HIV infection. My interest in the care of people with HIV infection and viral hepatitis would lead me to pursue cross-disciplinary training during my fellowship, working closely with both ID and hepatology mentors, including weekly clinics that focused on HIV in the ID clinic at Duke and HCV in the hepatology clinic at Duke. This cross-disciplinary training has been critical to my success as a clinician-scientist and is a model that I encourage mentees to pursue in their training.

After my residency training, I worked for one year as an Associate in Hospital Medicine at Duke University Hospital (20XX). During that year I received the **General Medicine Teaching Award**, an award given by the Duke Internal Medicine house staff to the ward service attending that excelled in bedside teaching. In 20XX I started my chief residency at DVAMC, which was a year that I cannot summarize in words but that I truly cherish to this day. Functioning in a hospital administration position and being both a confidant and supervisor for trainees provided me many opportunities to grow as a physician, educator, and mentor. The additional two years of general medicine following my training allowed me to hone my clinical and teaching abilities, which have served me well over my career. In 20XX, I chose to stay at Duke for ID fellowship training, due in large part to the excellent mentorship and research infrastructure, which I knew was critical for success if I wanted to pursue a career as a clinician-scientist. Under the mentorship of Drs. John Doe and Jane Doe, I would begin the personal journey of becoming a recognized national expert in the management and treatment of the people with HIV and viral hepatitis. As I transitioned from fellow to faculty, Dr. Jane Doe served as my mentor and continues to do so today. I feel fortunate to have had such excellent mentorship, guiding me into this career path, because I have had the opportunity to be part of a paradigm shift in the treatment of hepatitis C infection, one of the greatest accomplishments in recent modern medicine.

Upon completion of my training in 20XX, I joined the faculty at Duke University as an Assistant Professor in Medicine in the Division of Internal Medicine. In 20XX, I was promoted to Associate Professor in Medicine and in 20XX I achieved tenure. I also have dual appointments at the Duke Clinical Research Institute and the Durham VA Medical Center. One of my early clinical achievements was to develop multidisciplinary, HIV/HCV co-infection and liver disease clinics at both hospital sites with the goal to provide comprehensive care to this complex patient population. Partnering with GI/Hepatology at both sites, we started the clinics

in 20XX, both of which now serve as large regional referral clinics for the management and treatment of viral hepatitis (HBV and HCV) and liver disease (cirrhosis, portal hypertension, abnormal liver enzyme elevation) in patients with HIV. We receive referrals from states spanning California to Washington, DC as well as across the state of North Carolina. In addition to leading the HIV-liver disease clinics, I also attend on the ID consult (6-8 weeks) and general medicine (2-4 weeks) services at the DVAMC. This provides me the opportunity to interact with house staff and students (medical, physician assistant, pharmacy), one of the greatest rewards of being an academic faculty member. In January 20XX I accepted the position of Director, Internal Medicine, DVAMC. In this role I have developed new clinics to improve patient flow and consultation turn-around times and to develop or improve on existing clinical protocols including HIV post-exposure prophylaxis and pre-exposure prophylaxis protocols and most recent guiding approaches to the care of people with COVID-19.

**Teaching and Mentoring Contributions** (please also refer to the Tabular Summary of Teaching)

One of the greatest benefits of being faculty at an academic institution is the opportunity to interact with learners, students, trainees, and junior faculty.

As a resident I was recognized for my dedication to teaching as a nominee of the Golden Apple Resident Teaching Award. As an ID fellow I was nominated for the Favorite Fellow by internal medicine house staff. As a hospitalist attending, I was again nominated for the Golden Apple Attending Teaching Award and received the AMA/WPC Physician Mentor Recognition, both nominations by medical students. I received the General Medicine Teaching Award for the Duke Ward service, which is awarded by internal medicine residents. Now as a subspecialist attending, I continue to interact with trainees and student in many ways. I round on general medicine wards at the Durham VA where I love giving "Talks" on any topic of interest to the teams and taking the teams on radiology and pathology rounds. In fact, my evaluations by medical students and residents are excellent and comment on their enjoyment of these teaching activities. In addition to the 10-12 weeks of inpatient activities, I continue to supervise students, interns, residents, and fellows in my subspecialty HIV-liver disease clinics at Duke University and DVAMC, where they get to experience first-hand the collaborative, multidisciplinary approach to patient care that our clinic fosters.

One of the greatest rewards for a clinician-scientist is mentoring the next generation of investigators. Over the past 10 years I have served as research mentor for undergraduate and graduate students (7), residents (5), fellows (9), and junior faculty (7) including serving as the primary mentor for two K23 awardees. These mentoring relationships have resulted in 21 publications and numerous abstract presentations at national meetings, for which I support travel for mentees to attend these meetings and present their projects. These mentoring relationships include primary and secondary scientific mentorship, service on mentorship committees, and life mentorship. I was nominated for the Duke School of Medicine Clinical Research Mentoring Award in 20XX.

In addition to bedside teaching and mentoring I am also involved in other teaching activities locally, regionally, and nationally. Locally, I have served as faculty lecturer for the Duke School of Medicine Capstone Program, the Internal Medicine and Surgery Resident and Fellowship Conference Series as well the Nurse Practitioner program for the SoN. I served as an Internal Medicine Stead Teaching Attending and in 20XX accepted the invitation from the Internal Medicine Residency leadership to serve as Leader. In my position as Leader, I provided career mentorship to approximately 20 medical interns/residents per year and worked with the society to develop a Faculty Meet-and-Greet Series that highlights the diverse backgrounds and careers of our faculty here at Duke. In addition, our S.S. developed a collaborative relationship with the DICM Academy, serving as medical content experts for multiple classroom activities. Most recently from 20XX-20XX, I served on the C.C. Committee for the Internal Medicine Fellowship Program.

Regionally and nationally, I am grateful to have the opportunity to work with many groups including the North Carolina Area Health Education Center and the IDSA to develop and participate in continuing medical education activities across North Carolina and the US. I have given over 100 regional, national, and

international invited lectures on HIV and liver disease. As the Chair of the IDSA HCV Curriculum Working Group, I worked with ID Fellowship Program Directors to develop a core curriculum for ID specialist including ID fellows. We developed a free, online curriculum that utilizes multiple mediums of education and provides a path for self-learners to navigate to gain knowledge and competence in the treatment and management of HCV infection. I also served on the IDSA HCV ABIM MOC Development Panel. Education is truly a passion, so I was humbled when I was awarded the **ID Fellow Award for Distinguished Faculty Educator** by the ID fellows at Harvard University of in 20XX. In 20XX, I was thrilled to join the faculty supporting the Annual Southwestern Fellows Retreat Skills and Training Workshop.

### **Academic Achievements and Scholarship**

Over the ten years since joining the Duke faculty, I have transitioned from an NIH K12 Mentored Patient-Oriented Career Development Award, which was funded in 20XX, to independent funding with multiple R-level NIH awards. The focus of my research program is to improve the health of people living with HIV and liver disease, with particular interest in viral hepatitis co-infection. I lead a clinical and translational research program that spans clinical trials and partnerships with basic scientists to address unique pathogenesis related to fibrosis in people with HIV. To date I have published **100 (30 first or senior author, h-index 35)** peer reviewed articles and **5** other non-referred publications or book chapters, including the HCV chapter for the premier Infectious Diseases textbook, Harvey, Wayne, and Amelia's Principles and Practice of Infectious Diseases. I have served on multiple editorial boards and currently serve as the Associate Editor for Clinical Infectious Diseases, the flagship journal for the Infectious Diseases Society of America. I serve as a journal reviewer for numerous scientific journals including JAMA, Lancet and Lancet Infectious Diseases. I previously served as a Board Member for NewPath, a non-profit organization that provides access to HIV and HCV medications for uninsured people. From 20XX-20XX, I also served as a consultant for the Health Access Initiative with a focus on providing guidance on the development of national guidelines and country specific protocols for the roll-out of HCV therapies in low- and middle-income countries. I have served on numerous NIH special emphasis and ad-hoc review panels, am now a standing member on the HIV Clinical Studies Study Section. In addition, I have served on 4 national guideline committees, including serving on the inaugural American Association for the Study of Liver Disease/IDSA HCV Practice Guideline Panel, for which I served on from 20XX-20XX.

In July 20XX I completed a Master of Health Sciences, with a focus on Translational Medicine, through the Clinical Research Training Program at Duke University.

### **Scholarly Research Activity**

Since completing my fellowship training just over a decade ago I have developed a vibrant clinical and translational research program at Duke focused on people living with HIV and liver disease. People living with HIV have more rapid progression of liver fibrosis in the setting of liver injury, particularly in the setting of viral hepatitis co-infection. When I started my fellowship, liver disease was the leading cause of non-AIDS related death for people with HIV and this was primarily attributable to concomitant hepatitis C (HCV) and hepatitis B (HBV) infection. I focused my early career on investigating novel mechanisms of liver fibrogenesis in the setting of HIV-infection and developing novel biomarkers to predict treatment response and end-stage liver disease events in this very high-risk clinical population. The impact of my research on the field was recognized in 20XX at the annual Infectious Diseases Society of America meeting, where I was awarded an **Award**, which recognizes outstanding early achievement in infectious diseases by individuals 45 or younger.

The research program that I have developed over the past decade has been multipronged, leveraging multiple unique resources across the Duke campus and nationally, to address the multiple gaps in the field, particularly in HIV/HCV co-infection. I completed my training during a time that direct acting antivirals (DAA) were being developed as targeted treatments for chronic HCV infection. These treatments have now been in the clinics for over 8 years and have had significant impact on the lives and health of our patients. I am proud that my work in clinical trials supported the FDA approval of these regimens in people with HIV and

informed national guidelines for the treatment of people with HIV infection and more recently the treatment of acute hepatitis C infection in people with and without HIV infection. In my role as the Chair of the AIDS Clinical Trials Group, I continue to lead national clinical trials that will inform national and international guidelines in viral hepatitis C and hepatitis B.

Early in my career, the standard of care for treatment of HCV infection was interferon-based therapies. Interferon exogenously boosts the innate immune response of the patient and people with HIV had significantly lower therapeutic response rates when compared to people without HIV co-infection. In addition, the tolerance of interferon and ribavirin was poor, thus predictors of response or tolerance to therapy was highly relevant. I spent several years (funded by the K12 award) focused on discovering and validating pharmacogenomic biomarkers of treatment response and regimen tolerance in people with HIV/HCV and follow-up studies to investigate potential biologic mechanisms. I worked with collaborators in Italy to complete the first investigation of the predictive value of the *IL20B* single nucleotide polymorphism in interferon treatment, which was discovered at Duke, although initially in people without HIV infection. To further improve the ability to predict treatment response to interferon-based therapy I led an innovative study combining stepwise pharmacogenomics and proteomics and discovered a multi-omic model that improved the accuracy of predicting treatment response in patients with HIV/HCV co-infection. I also led a study investigating the biologic mechanism of the *IL20B* polymorphism and reported that the unfavorable genotype was associated with dysregulated innate immune response, particularly of natural killer cells, in the setting of interferon-based therapy ((Name) *et al*, *Hepatology* 20XX). Lastly, I led the study investigating variants in the *ITPA* gene, which are protective of ribavirin-induced hemolytic anemia, a significant treatment limiting toxicity, particularly for people with HIV ((Name) *et al*, *J Infect Dis* 20XX). The body of work described above had impact that directly translated to clinical practice, as the *IL20B* polymorphism became a baseline test used in HIV practices until interferon was replaced by DAAs as the standard of care.

While DAAs have had a significant impact on the safety and efficacy of HCV treatment, there remain relevant scientific gaps that are identified NIH HIV/AIDS Research Priorities related to co-infections and co-morbidities. Liver fibrosis remains a significant risk to the health of people living with HIV and viral hepatitis and liver disease remains a leading cause of non-AIDS mortality. Furthermore, it is disappointing that the majority of people living with HIV/HCV co-infection in the United States and globally have not been treated, and for those that are cured, there are studies reporting significant rates of liver disease complications following cure. This is likely due to the slow regression of liver fibrosis after HCV cure, but also the potential for ongoing liver injury unrelated to the HCV infection. Several studies have reported that approximately 20% of people with HIV continue to have abnormal liver enzymes after HCV cure, suggestive of ongoing inflammation and injury. Whether this is related to aberrant immune mediated pathways in the liver or other undiagnosed etiologies of liver injury, such as drug toxicity or fatty liver, is unclear. To address these gaps my research program has two primary lines of active investigation: (1) discovering and validating novel metabolomic biomarkers to predict end-stage liver disease events and gain mechanistic insights into etiologies of liver fibrogenesis in people with HIV-infection, during HCV infection and after HCV cure, and (2) assessing the role of NKT cell phenotype on liver fibrogenesis pathways (particularly the canonical hedgehog pathway) in patients with HIV/HCV co-infection.

Supported by an R01 through the NIDDK, we are leveraging the Duke Core Facility and working closely with Dr. John Doe and his lab to discover and validate metabolomic biomarkers that are predictive of liver disease complications in people with HIV/HCV co-infection. This work was a direct extension of my K12 award, during which we found a relationship with HCV viral load and clinical lipids markers ((Name) *et al*, *Open Forum Infect Dis* 20XX). The HCV virus interacts extensively with the host lipid pathways in the hepatocyte, thus investigating lipids and other metabolites as predictors of liver disease was a logical step in exploring this relationship. Multiple bioactive lipids and metabolites have been implicated in liver disease pathogenesis including sphingolipids and oxidized polyunsaturated fatty acids. Through this R01 funding we have discovered a novel set of lipids and other metabolites that accurately identifies patients with HIV/HCV co-infection at the greatest risk for hepatic decompensation or hepatocellular carcinoma over the

subsequent 2 years ((Name) *et al*, *J Infect Dis* 20XX). We are now validating this set of metabolites in two national cohorts of people with HIV/HCV infection. This discovery could allow for individualizing clinical care pathways for these highest-risk patients, including the potential for more frequent liver cancer surveillance and individualized education on risk reduction.

Another area of investigation for my research program is understanding the mechanisms and pathways involved in the more severe liver fibrogenesis that results in higher rates of cirrhosis in people with HIV and liver injury. Through an ABDC pilot grant I collaborated with John Doe in the Vaccine Institute and Jane Doe in the Division of Internal Medicine to investigate the role of the fetal morphogen hedgehog (Hh) signaling pathway in liver fibrogenesis in patients with HIV/HCV co-infection. The Hh pathway has been implicated in multiple metabolic diseases, including nonalcoholic steatohepatitis, obesity, and diabetes. The Hh pathway has also been implicated in HCV mono-infection, which induces hepatic steatosis and insulin resistance, but never in HIV-associated liver disease. Our data was the first to support a role for Hh activation in HIV-related liver disease. Furthermore, the evidence of Hh activation in patients with HIV-infection without HCV coinfection suggests a potential role for ongoing liver fibrosis after HCV eradication or a risk of fibrosis in the absence of HCV infection ((Name) *et al*, *Open Forum Infect Dis*, 20XX). Furthermore, we found that enrichment of NKT cells via active recruitment into liver tissue, was associated with markers of fibrogenesis, supporting a key role for NKT cells in fibrogenesis pathways in people with HIV and liver injury. This work is now the subject of an R01 application that proposes to further investigate the role of phenotypically skewed NKT cells, as has been described in the periphery in people with HIV infection, in Hh pathway activation and accelerated fibrogenesis in the liver.

My research program currently spans viral hepatitis (HBV and HCV) with and without HIV infection, HIV and fatty liver disease, and HIV and fibrogenesis, as well as recently clinical trials focused on COVID-19. While there remains much to do to improve treatment of HCV infection for key high-risk population and to understand the risk of liver related disease after HCV cure, there are also growing opportunities and scientific interest in HBV infection including people with HIV/HBV co-infection. I am expanding my research program to including HBV clinical trials and translational studies to develop biomarkers of disease progression.

### **Grant Support**

Since transitioning to faculty, I have maintained continuous grant funding. Early in my career, I was funded on a NIH K12 Mentored Career Development Award and in 20XX, I was successful in securing my first R01. Today I have a robust research program that spans leading national clinical trials and translational science investigations of biomarkers of liver disease. I am currently funded on >7 grants, for which I am the principal or co-principal investigator on 5 and in leadership roles on another two. These grants are run from Duke and the Durham VA Medical Center. In addition to my current grant funding, I have 2 additional grants that are either pending submission in the next few months or awaiting review/funding decisions.

### **Local, national and international leadership**

Over the past 10 years I have had great opportunities for leadership in research and administration. I am currently a member of several national and international organizations including IDSA, the American Association for the Study of Liver Disease (AASLD) and the International AIDS Society. I am entering my second year serving on the IDSA program committee and I serve on the abstract review committee for the Conference on Retroviruses and Opportunistic Infections (CROI). I have been invited to speak at >100 regional, national or international conferences.

One of the most rewarding opportunities I have had is serving, initially as a member and then as Co-chair, on the inaugural AASLD/IDSA Hepatitis C Practice Guideline Panel. The first collaboration between the AASLD and the IDSA was initiated in 20XX and today the guidelines continue to serve as a critical resource to clinicians and helped advocate for access to newly approved direct acting antivirals for the treatment of HCV infection. Since this experience, I now serve on three additional national guideline committees and

one international consensus committee. I have just agreed to serve a second term on the Guidelines for Adults and Adolescents, and I continue to serve on the CDC/NIH/IDSA-HIVMA Infections Guideline Committee. I now serve as the Viral Hepatitis lead for the DHHS Panel. Most recently, as the pace of discovery in response to the COVID pandemic has accelerated, the NIH created the inaugural COVID-19 Treatment Guideline Committee, and due to my prior experience and performance on other guidelines and my early experience in the care of people with COVID-19, I was asked to serve on this committee. In 20XX, I was one of only two Americans asked to serve on the Treatment Network, Acute Consensus Committee. These experiences have provided me the opportunity to have impact on the national and international policies and patient care and have elevated my national reputation as a thought leader in the fields of HIV.

The AIDS Clinical Trials Group (ACTG) is a NIAID funded research consortium and is the leader in developing and operationalizing clinical trials in people with HIV infection. I have served as a member of the AIDS Clinical Trials Group (ACTG) Transformative Science Group since 20XX. As a member, I served as the Co-Chair of the ABCD-1234 Study and now as the Co-Chair of the ABCD-5678 Study, both national clinical trials testing shortened treatment courses of DAA for acute HCV infection. In 20XX, I was asked to take the role of Vice-Chair of the TSG and in 20XX I transitioned to the role of Chair. In this role as Chair of the TSG, I lead the national strategy for the ACTG related to viral hepatitis. I engage leading investigators on the group to ensure our strategy is consistent with the clinical needs and that it is on the leading edge. I engage industry sponsors as we identify partners for clinical trials in people with HIV and viral hepatitis. In this role I work closely with the NIH, FDA and the ACTG leadership to ensure that we are aligned and that our trials are meeting all appropriate regulatory expectations.

### **Administrative leadership**

Since transitioning to faculty in 20XX, I have several opportunities for administrative leadership that have culminated in my current role as Senior Vice Dean for Faculty.

In 20XX, I assumed the Director position of Research at the DCRI. In this position I interacted with industry partners who had investigational compounds or devices of scientific interest to our faculty. I supervised and supported all proposals and bid defenses. I worked closely with business development and clinical operations teams to develop scientific and innovative proposals. The learning curve in the position was steep, because it is less clinically related; however, I gained critical skills in working across multiple groups in a research organization as well as in more granular skills including clinical protocol writing and trial design.

In 20XX, I was asked by the Chair of Research in the Department of Pathology to serve in the role of Director of the Departmental Clinical Research. At that time the Clinical Research had 5 staff supporting over 1000 research protocols. Under my leadership the Clinical Research staffing and support team grew to 15 staff, including an Associate Director, supporting >1,100 protocols and ~375 faculty and >100 operational staff. In addition to recruiting an excellent operational support team and managing out ineffective staff, under my leadership in the Clinical Research, we developed a new allocation plan for cost recovery for the department and a new residual distribution policy for the Department, ensuring an equitable distribution of residual project funds across divisions. I interacted closely with division chiefs, served on the executive team of the chair, and worked closely with a faculty advisory board to drive new initiatives in clinical research for the department. During the 3 years that I served in the role as Director, I also managed multiple difficult faculty relationships including developing a resolution management plan for a very difficult faculty dispute.

In February of 20XX, I was asked by the Dean of Research, Dr. John Doe, to serve in the role of Associate Vice Dean for Clinical Research. This role would move me from a departmental wide vision to a school wide platform by which I could enable clinical research and push forward initiatives to support clinical research in innovative and novel ways. In this new role I would oversee the Duke ABC, working closely with the Director of the ABC to ensure appropriate and timely review of protocols while identifying bottlenecks created by old policies and working to manage research teams with repeated deviations or determinations

of noncompliance. Under my leadership the ABC created a review board focused solely on non-compliance determinations to ensure a consistent approach to non-compliance reviews and decisions. In addition, in this new role I would oversee the Office of Affairs, which is an office that provides support for regulatory submissions to the FDA and training and oversight for Good Practice facilities at Duke. Under my leadership we created a shared position with the Investigational Drug Service in Duke Pharmacy to support best-practice drug compounding and to ensure ORAQ oversight of these processes. We have also restructure ORAQ to support the growing portfolio in GP and quality. In addition, Dr. Doe asked me to lead an initiative to address needs for biobanking across our Duke Research community. An ongoing initiative, over the past year I have worked to sunset an inefficient and redundant biobanking shared resource with an annual budget deficit of ~\$150K and have partnered with successful Duke shared resource biobanks to develop a plan for TwoDuke Bio, a cross-cutting virtual Duke biobank that will leverage existing biobanking partners at Duke to ensure Duke School of Medicine investments translate to the greatest benefit for investigators and scientific discovery. It is also in this role that I led the SoM at the start of the COVID pandemic to safely manage non-COVID clinical research by creating a plan for maintaining essential research activities and pausing non-essential research activities. As our community gained better control of the virus spread, I led planning for re-opening non-COVID research activities. This effort involved working closely with the Duke Office of Clinical Research and Clinical Research Units across all departments, centers and institutes as well as working closely with colleagues across the country leading similar efforts, as we all worked to manage this crisis at our institutions.

In May of 20XX, I was asked by Dean Klotman to take over the role of Senior Vice Dean for Faculty, as Dr. Doe transitioned to a new role as the Director of Duke Regional Hospital. This was not an easy decision, primarily due to my goal of maintaining my own research program, which I intend to do. This role includes four direct reports including an Executive Director, Assistant Dean, and Associate Dean. In this role, I provide oversight for the Duke Office of Clinical Research, Duke Early Phase Research Unit, and Duke ORAQ with a total budget of \$2 million. Since taking on this role in May I have been heavily focused on bringing up a large COVID clinical research program. While we were pausing non-essential research programs, we were simultaneously rapidly developing the infrastructure and operational support for an inpatient, and more recently an outpatient, COVID research program. In January, I created the Duke SoM Task Force, with the primary mission of providing central coordination of human subject research protocols that propose to enroll participants with COVID-19 or Persons Under Investigation (PUI) for COVID-19. This Task Force has ensured the safety and training of research staff working on COVID studies as well as has developed institutional priorities for clinical research study commitments, to ensure that Duke contributes to studies that will ultimately answer the most important scientific questions. In under 6 months, Duke has opened approximately 300 clinical research protocols and performed >3000 individual consents. Duke has been a top enroller nationally for multiple multicenter clinical trials, which is in part attributed to the strategic prioritization of key studies and of the central organization of recruitment and enrollment activities. One of my most significant accomplishments since taking on this role is the opening of the new Duke University School of Medicine Clinical Research @ Erwin Road site. In just under 8 weeks, we have converted an empty building, previously used as an outpatient primary care clinic, into a fully staffed and stocked COVID clinical research unit, that will support multiple outpatient trials that range from prevention trials of vaccines in healthy volunteers to infusions of investigational monoclonal antibodies in patients with mild COVID-19 who do not require hospitalization. This is truly unbelievable and represents the dedication and countless hours of work from many people across the Duke community.

### **Institutional Service**

I am a team player in my division, department, and across the medical campus. I have served on two faculty search committees: Faculty Search Committee (20XX-20XX) and the Center for Human Variation Search Committee (20XX-20XX) and two Department/Institute 5-year review committees. During my career, I have served in multiple capacities in the Internal Medicine Training Program including serving on the Internal Medicine Residency Pinnacle Committee, as a S.S. Leader, and until recently as a Residency Program Interviewer and Faculty Speaker during the interview season. In the Division of Infectious Diseases, I served

on the Faculty Advisory Board for the Duke ID Clinical Research Support Office, the Research Advisor Committee, and the Clinical Competency Committee for ID fellows. In the School of Medicine, I served on the Compensation Committee. In 20XX, I was asked to serve on the Duke University Conflict of Interest Committee and have continued to serve on this committee as its scope expanded across the entire University.

### **Vision and goals of continuing professional development**

My long-term career goal is to continue to grow my clinical and translational research program in HIV and liver disease, while continuing to grow as a research administrative leader.

My research program now has grant funding across a broad spectrum of HIV and liver disease, including HIV/HCV, HIV/HBV and HIV and non-alcoholic fatty liver disease. The projects span multicenter clinical trials and translational projects that engage partners both locally and nationally. In addition, as many have been impacted by the COVID-19 pandemic, I have engaged in projects focused on COVID-19, predominantly large national clinical trials coordinated through the Duke Clinical Research Institute.

The direction of the HCV related research program will be two pronged: one focusing on biomarker discovery and validation to improve risk stratification of liver disease events after HCV cure and one focusing on designing clinical trials that improve the implementation of DAA therapies in high-risk populations including people who inject drugs. Through my current R01, we will validate a metabolomic biosignature that predicts with high accuracy, liver-disease complications in people with HIV/HCV infection. The last aim of this grant, which will be complete in year 5 of funding, will assess modifications of this biomarker after HCV cure. I will plan a competitive renewal focused on validating this biomarker in large cohorts of patients who are cured of HCV, to improve risk stratification for liver-related events after cure. I have a VA Merit application that proposes to validate this biomarker in Veterans, which has scored 11% and am awaiting a funding decision. I am currently partnering with colleagues at the Sharp Institute in Portland, Oregon to develop a multicenter, international research protocol testing ultra-short HCV therapies in select high-risk populations of people with HCV infection. This protocol directly addresses the need per the WHO to decrease incident HCV infection and will inform HCV elimination strategies. This project builds on the trials I have led in people with acute HCV infection, including an ongoing trial that I lead through the Clinical Trials Group that is testing the efficacy of a 4-week treatment course of DAA to cure acute HCV infection. This R01 clinical trial application will go in through the DCRI in May 20XX.

As noted previously, I am also expanding my research program to including HBV infection and non-alcoholic fatty liver disease; two highly relevant etiologies of liver injury in people with HIV infection. Through a mentored small Duke CFAR grant with one of my mentees, we are developing metabolomic biomarkers that predict progression of liver fibrosis in people with HIV/HBV infection who are on HBV targeted antiviral therapies. This project is being done in partnership with the NIDDK funded Hepatitis B Research Network (HBRN) and will provide preliminary data for a future R-level grant to the NIH. Furthermore, in my role as the Chair of the ACTG TSG I am now leading a clinical trial of novel HBV therapies in people with HBV and HIV/HBV. This will continue to provide opportunity to develop a national reputation in HBV infection. I am also currently the PI on two large efforts supported by the NIDDK to improve our understanding of non-alcoholic fatty liver disease (NAFLD) in people with HIV infection. Through a combined effort with the Clinical Research Network, a multicenter R01 will support efforts to identify predictors of NAFLD and NASH and will culminate in a randomized trial of a novel anti-fibrotic therapy in people with HIV and fatty liver disease.

Maintaining a large and diverse clinical and translational research program will ensure ongoing funding and efforts to improve the health of people with HIV infection. In addition, I will continue to leverage the funding and projects to engage trainees and junior faculty with an interest in HIV and chronic diseases. Due to the multidisciplinary approach of my research program, I continue to mentor both infectious diseases and hepatology trainees and junior faculty. Maintaining this research program will also ensure that I remain engaged in the national efforts related to these disease states, as I have done in the first twelve years of



my career.

Having recently assumed the role of Senior Vice Dean for Faculty, I am excited by the many opportunities that lay ahead in research administrative leadership. While the past 7 months have been largely focused on addressing the research needs in the setting of the pandemic, I have been able to develop my own strategic priorities and I look forward to bringing these and others to fruition over the next five years. Within the current strategic priorities I am focused on 1) developing a centralized largely virtual biobank at Duke – TwoDuke Bio- which will enable translational research and catalyze scientific discovery by connecting biospecimens from across the institution through novel and innovative IT platforms; 2) creating a centralized model for supporting outpatient phase I-IV clinical research including the creation of a free standing community based clinical research site; 3) expanding the academic clinical research enterprise and infrastructure beyond the walls of Duke University hospital, into our community and in particular our community hospitals in Durham and Raleigh; 4) ensuring equity in clinical research recruitment, enrollment and retention by recruiting and retaining a diverse clinical research work force and engaging and partnering with community leaders and members to improve outreach, education and community service involvement. To achieve these goals and others over the next 5 years I am engaging and partnering with stakeholders in departments, centers, institutes and the community to ensure alignment and collaboration with those I am meant to serve.

Duke University offers the ideal environment and infrastructure to continue to help me achieve my career goals. I appreciate your consideration of my application for promotion to Professor, with tenure.

SoM Tabular Summary of Teaching Mentoring & Educational Activities  
(Faculty Member's Name)

Activity	July 1, 20XX- June 30, 20XX (please provide at least 3 yrs.)
<b>Clinical Teaching</b>	(e.g. General Teaching Attending – DUMC)
	(e.g. Outpatient Teaching Attending – DUMC)
	(e.g. General Medicine Teaching Attending – DUMC)
<b>Lectures</b>	List name of Lecture(s), location and date.
<b>Seminars/Case Conferences</b>	(e.g. Resident Morning Report – DUMC)
	(e.g. Intern Morning Report – DUMC)
<b>Laboratories</b>	List laboratories and a brief description of your duties.
<b>Mentoring Activities</b>	Resident and Fellow Research Mentor - DUMC
	Junior Faculty: (List Mentees)
	Fellows: (List Mentees)
	Residents: (List Mentees)
<b>Research Preceptorship</b>	List Name of Preceptee(s), Year and brief description of preceptorship.
<b>CME (within Duke)</b>	List CME activities and dates
<b>Course/Curriculum Development</b>	(Course). (Event), Location (City, State). (Date). (Role, e.g. Co-Chair)
<b>Materials Development</b>	List Materials and brief description.
<b>Educational Committees</b>	List panels and committees
<b>Invited Presentations (Outside Duke)</b>	(Presentation). (Event), Location (City, State). (Date).
	(Presentation). (Event), Location (City, State). (Date).
	(Presentation). (Event), Location (City, State). (Date).
	(Presentation). (Event), Location (City, State). (Date).
	(Presentation). (Event), Location (City, State). (Date).
<b>Other:</b>	

SoM Tabular Summary of Teaching Mentoring & Educational Activities  
(Faculty Member's Name)

Activity	July 1, 20XX- June 30, 20XX
Clinical Teaching	Please see examples provided above.
Lectures	
Seminars/Case Conferences	
Laboratories	
Mentoring Activities	
Research Preceptorship	
CME (within Duke)	
Course/Curriculum Development	
Materials Development	
Educational Committees	
Invited Presentations (Outside Duke)	
Other:	

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