

**BIOGRAPHICAL SKETCH**

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NAME: Nachman, Sharon Appelbaum

eRA COMMONS USER NAME (credential, e.g., agency login): snachman

POSITION TITLE: Division Chief, Pediatric Infectious Diseases, Professor of Pediatrics

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
CCNY/CUNY, New York, NY	BS	06/1981	Biomedical
Stony Brook School of Medicine, Stony Brook, NY	MD	05/1983	Medicine
Long Island Jewish Medical Center	Internship Residency	06/1986	Pediatrics
New York Medical College	Fellowship	06/1987	Pediatric Infectious Diseases
Rockefeller University	Post- Doctoral Fellowship	12/1990	Microbiology

**A. Personal Statement**

I am a senior clinical researcher with more than 30 years of continuous NIH support, and am currently serving as the PI of a U01 grant; International Maternal Pediatric and Adolescent Clinical Trials Network; IMPAACT. I have served in this position for the past 9 years and have expertise in managing domestic and international clinical trials sites, developing a robust and diverse clinical trial scientific agenda, collaborating with different NIH institutes and pharma and getting new therapies for pregnant women and children licensed. This diverse expertise includes having served as either chair or vice chair for over 20 protocols, working to develop them from concept sheet to protocol, to writing guidelines for HIV+ populations worldwide. I have also developed studies helping to define the dose and PK for new antibiotics, evaluate new vaccines and understand the long-term issues including neurodevelopment outcomes that develop in infants born to HIV+ women worldwide.

With the COVID-19 pandemic epicenter in New York, and as Chair of the Stony Brook Medicine's COVID Research Committee, I have been at the front lines of care and research for patients with COVID-19. I am currently serving as the PI of our institution's multiple CoVPN/NIH funded studies for treatment of COVID-19 and vaccination to prevent COVID-19, as well as serving as the site PI for all of the COVID-19 vaccine studies in children. Our site successfully enrolled over 250 adults and over 150 children on these studies and is poised to now investigate novel therapies including antivirals and monoclonals for children.

I am very excited to be serving several key functions in the LINCATS proposal. These include being part of the leadership group of the proposal, Lead in the Hub Liaison Team and Co-Lead on the Resources and Services Team. My current expertise includes serving on FDA and NIH study sections, working with and advising several key NIH networks including AIDS Clinical Trial Group (ACTG), HIV Vaccine and HIV Prevention Networks (HVTN and HPTN) as well as the Infectious Disease Clinical Research Consortium (formerly the Vaccine Treatment Evaluation Network), and mentoring faculty across the lifespan. This combined expertise demonstrates that I am well suited to the tasks at hand. I will work to bidirectionally link LINCATS studies to TIN studies, evaluate and review performance of the Resources and Services linked to LINCATS and work

closely with leadership of LINCATS to identify emergent needs along with developing plans to accomplish its goals.

Ongoing and recently completed projects that I would like to highlight include:

**UM1AI068632-08** Nachman (PI) 12/01/2020– 11/30/2027  
International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT)  
The major goal of this project is for S. Nachman to serve as Chair and PI of the IMPAACT Network.

**HHSN2752018000011** Nachman (Site PI) 11/30/2020- 11/30/2021  
NICHD International and Domestic Pediatric and Maternal HIV Studies Coordinating Center  
The major goal of this project is to serve as a site for enrolling subjects on IMPAACT studies. Renewed annually (established 1992, annual re-funding)

**3UM1AI068632-14S2** Nachman (PI) 11/30/20-11/30/22  
Pharmacokinetics and Safety of Remdesivir for Treatment of COVID-19 in Pregnant and Non-Pregnant Women in the United States. This study will support the licensure for use of this antiviral during pregnancy

**1H12HA248800100** Nachman (PI) 08/01/2018 – 07/31/2021  
Ryan White Title IV Women, Infants, Children, Youth and Affected Family Members AIDS Healthcare  
The major goal of this project is to provide outpatient or ambulatory family-centered primary medical care for women, infants, children, and youth with HIV/AIDS in Suffolk County. Renewed annually (established 1997)

## **B. Positions, Scientific Appointments, and Honors**

### **Positions and Employment**

2021- Editorial Board Lancet HIV  
01/2014- PI and Chair, IMPAACT Network  
2007- Director Clinical Trials Office at Stony Brook  
2006- Associate Dean for Research, Stony Brook University  
2006-2012 Chair, Complications Scientific Committee, IMPAACT Network, NIAID  
2003- Professor of Pediatrics, Stony Brook University  
1997-2003 Associate Professor of Pediatric, Division Pediatric Infectious Disease, SUNY @ Stony Brook  
1993- Division Chief, Pediatric Infectious Disease, SUNY Stony Brook School of Medicine  
1990-1997 Assistant Professor Pediatric, Division Pediatric Infectious Disease, Stony Brook University

### **Other Experience and Professional Memberships**

2001- AAHIVM certified (Recertified: 03, 05, 07, 09, 11)  
2001- Fellow, Society for Pediatric Research  
1995- Board Certified Pediatric Infectious Disease #280891. Recertified 2001, 2008  
1990- Fellow Pediatric Infectious Disease Society, and American Academy of Pediatrics  
1987- Board Certified in Pediatrics #36212  
1986- New York State License in Medicine and Surgery #161895

### **Honors/Awards**

2017 Senior Research Excellence Award, Stony Brook Medicine  
2016 23rd Annual Herman and Gertrude Silver Award and Lectureship, CHOP  
2007 Clinical Trial Exceptional Service Award, PhRMA  
2004 Alumni of the Year: Stony Brook University School of Medicine  
2001/02/03/06 Excellence in Teaching Pediatric Residents, Stony Brook University

## **C. Contributions to Science**

Overview: I have spent the last several decades developing clinical trials that would help to decrease the morbidity and mortality in HIV infected populations from infancy through the post-partum period. These studies have included (as chair or vice chair) over 20 clinical trials, crossing multiple scientific committee's research agendas. With the COVID pandemic my research interests have expanded to include treatment and prevention of this pathogen in women and children.

**COVID:** With the start of the COVID pandemic, recognizing the need to address the effects of the pandemic on women and children, working with leaders in the Pediatric ID world, I coauthored the following papers.

1. Shane A, Sato A, Kao C, Adler-Shohet F, Vora S, Auletta J, **Nachman S**, Raabe V, Inagaki K, Akinboyo I, Woods C, Alsulami A, Kainth M, Santos R, Espinosa C, Burns J, Cunningham C, Dominguez S, Larru B, Zhu F, Crews J, Kitano T, Saiman L, Kotloff K. A Pediatric Infectious Disease Perspective of SARS-CoV-2 and COVID-19 in Children. *J Pediatric Infect Dis Soc.* 2020 Aug 25:piaa099. doi: 10.1093/jpids/piaa099. Online ahead of print. PMID: 32840614
2. Garcia-Prats AJ, Salazar-Austin N, Conway JH, Radtke K, LaCourse SM, Maleche-Obimbo E, Hesselning AC, Savic RM, **Nachman S**. COVID-19 pharmacologic treatments for children: research priorities and approach to pediatric studies. *Clin Infect Dis.* 2020 Jun 29:ciaa885. doi:10.1093/cid/ciaa885. Online ahead of print. PMID: 32594142
3. Anderson EJ, Campbell JD, Creech CB, Frenck R, Kamidani S, Munoz FM, **Nachman S**, Spearman P. Warp Speed for COVID-19 Vaccines; Why are Children Stuck in Neutral? *Clin Infect Dis.* 2020 Sep 18:ciaa1425. doi: 10.1093/cid/ciaa1425. Online ahead of print. PMID: 3294533

### Treatment of children with HIV

With the advent of antiretrovirals to treat HIV infection in adults in the mid-1990s, came specific questions for their use in children. Studies developed under my guidance have evaluated safety of new ARVS including licensure of first in class novel therapy (Raltegravir, Integrase Inhibitor). These papers, cited several hundred times, have helped develop US and WHO guidelines for HIV infected youth

1. **Nachman S**, K. Stanley, R. Yogev, S. Pelton, A. Wiznia, S. Lee, L. Mofenson, S. Fiscus, M. Rathore, E. Jimenez, W. Borkowsky, J. Pitt, M.E. Smith, B. Wells, K. McIntosh. A Randomized Trial of One or Two Nucleoside Analogues Plus Ritonavir Versus Dual Nucleoside Analogue Therapy in Stable Antiretroviral-Experienced HIV-Infected Children. *JAMA* 2000;283(4):492-498, PMID: 10659875
2. **Nachman S**, Zheng N, Acosta EP, Teppler H, Homony B, Graham B, Fenton T, Xu X, Wenning L, Spector SA, Frenkel LM, Alvero C, Worrell C, Handelsman, E, and Wiznia A; for the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) P1066 Study Team. Pharmacokinetics, Safety, and 48-Week Efficacy of Oral Raltegravir in HIV-1-Infected Children Aged 2 Through 18 Years. *Clin Infect Dis* 2014 Feb;58(3) 413-22, PMID: PMC3890333
3. **Nachman S**, Alvero C, Teppler H, Homony B, Rodgers AJ, Graham BJ, Fenton T, Frenkel LM, Browning RS, Hazra R, Wiznia AA, and the IMPAACT 1066 study team. Safety and efficacy at 240 weeks of different raltegravir formulations in children with HIV-1: a phase 1/2 open label, non-randomised, multicentre trial. *Lancet HIV.* 2018 Dec;5(12):e715-e722. PMID: PMC6537590
4. **Nachman S**, Townsend CL, Abrams EJ, Archary M, Capparelli E, Clayden P, Lockman S, Jean-Philippe P, Mayer K, Mirochnick M, McKenzie-White J, Struble K, Watts H, Flexner C. Long-acting or extended-release antiretroviral products for HIV treatment and prevention in infants, children, adolescents, and pregnant and breastfeeding women: knowledge gaps and research priorities. *Lancet HIV.* 2019 Aug;6(8):e552-e558. doi: 10.1016/S2352-3018(19)30147-X. Epub 2019 Jul 1

### Complications of HIV in children

Inherent in the treatment of HIV is the understanding that the virus in of itself also causes complications. The clinical trials that I co-authored included investigating complications related to ARVs, growth failure among children and more recently a long term study of the neuropsychiatric complications of HIV, comparing infected children to their uninfected siblings. Data from these studies has shown that a mix of uncontrolled virus, ongoing immune dysregulation, familial factors and other yet unknown factors that contribute to these complications. From 2013-2018 I served as a co-editor of the US Pediatric OI guidelines and helped to author, edit and publish the 25 chapters of the updated guidelines.

1. **S. Nachman**, P. Gona, W. Dankner, A. Weinberg, R. Yogev, A. Gershon, M. Rathore, J. S. Read, S. Huang, C. Elgie, K. Hudgens, and W. Hughes. The Rate of Serious Bacterial Infections Among HIV-Infected Children with Immune Reconstitution Who Have Discontinued Opportunistic Infection Prophylaxis. *Pediatrics* 2005;115:488-494, PMID: 15772172
2. **Nachman S**, Chernoff M, Williams P, Hodge J, Heston J, Gadow KD: Human Immunodeficiency Virus Disease Severity, Psychiatric Symptoms, and Functional Outcomes in Perinatally Infected Youth. *Arch Pediatr Adolesc Med.* 2012 Jun 1;166(6):528-35 PMID: 22312169 PMID: PMC3407294
3. Siberry GK, Abzug MJ, **Nachman S**, editors: Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services.

- Chernoff M, Angelidou KN, Williams PL, Brouwers P, Warshaw M, **Nachman S**; IMPAACT P1055 Study Team: Assessing Psychiatric Symptoms in Youth Affected by HIV: Comparing a Brief Self-Administered Rating Scale with a Structured Diagnostic Interview. *J Clin Psychol Med Settings*. 2018 Feb 19. PMID: 29460107 PMCID: PMC6098977

### **Response to Immunization of HIV infected children**

Recognizing that HIV infected children have higher rates of infections, I sought to understand if vaccination with both routine and experimental vaccines can be used to prevent routine childhood illnesses. I developed the first study of Prevnar in HIV infected infants and set the stage for our understanding that uncontrolled viral replication and low CD4 percent and numbers are independent correlates of protection after vaccination. I have either served as leadership in over six vaccine studies, with products including Hepatitis A, Hepatitis B, Pertussis, HPV, rotavirus, and meningococcal and pneumococcal vaccines. With the pandemic H1N1 in 2009, I authored the pivotal study demonstrating that HIV+ pregnant women need two doses of a higher titer vaccine in order to develop an adequate immune response and co-authored 2 studies of H1N1 vaccine in HIV+ children. This body of work used to develop the current ACIP vaccine guidelines for HIV infected youth.

- S. Nachman**, S. Kim, J. King, E.J. Abrams, D. Margolis, A. Petru, W. Shearer, E. Smith, J. Moye, S. Blanchard, E. Hawkins, P. Bouquin, P. Vink, M. Benson, S. Estep Riley, F. Malinoski., for the PACTG 292 Team. Safety and immunogenicity of a heptavalent pneumococcal conjugate vaccine in HIV type-1 infected infants. *Pediatrics* 2003;112(1):66-73. PMID: 12837869
- Abzug MJ, Warshaw M, Rosenblatt HM, Levin MJ, **Nachman SA**, Pelton SI, Borkowsky W, Fenton T. International Maternal Pediatric Adolescent AIDS Clinical Trials Group P1024 and P1061s Protocol Teams. Immunogenicity and Immunologic Memory after Hepatitis B Virus Booster Vaccination in HIV-Infected Children Receiving Highly Active Antiretroviral Therapy. *JID*. 2009; 200(6):935-46. PMCID: PMC2814776
- Abzug MJ, **Nachman SA**, Muresan P, Handelsman E, Watts DH, Fenton T, Heckman B, Petzold E, Weinberg A, Levin MJ; for the International Maternal Pediatric Adolescent AIDS Clinical Trials Group P1086 Protocol team. Safety and Immunogenicity of 2009 pH1N1 Vaccination in HIV-infected Pregnant Women. *Clin Infect Dis*. 2013 May;56(10):1488-97, doi: 10.1093/cid/cit057. Epub 2013 Feb 1. PMID 23378284. PMCID: PMC3634309
- Pass RF, **Nachman S**, Flynn PM, Muresan P, Fenton T, Cunningham CK, Borkowsky W, McAuley JB, Spector SA, Petzold E, Levy W, Siberry GK, Handelsman E, Utech LJ and Weinberg A for the IMPAACT P1089 team. Immunogenicity of Licensed Influenza A (H1N1) 2009 Monovalent Vaccines in HIV-infected Children and Youth. *J Ped Infect Dis*. 2013 Dec;2(4):352-360 PMID 24363932, PMCID: PMC3869470

### **Understanding TB in children**

TB infection (and disease) is one of the most significant comorbid infections in HIV infected populations worldwide. In 2006 I brought together two groups of investigators (US and South Africa) to develop the largest TB prophylaxis study of HIV infected and exposed infants worldwide. That study, showed that INH did not prevent either TB infection or TB disease in our populations and set the current WHO guidelines and the clinical case definition of TB in HIV+ children. My consensus paper on the inclusion of children in TB clinical trials is helping to change how pharma and regulatory bodies regard children with respect to TB clinical trials. As IMPAACT Chair, I am committed to studying TB vaccines, novel diagnostics and TB therapies in our HIV infected and exposed populations worldwide.

- Nachman, S**, Ahmed A, Amanullah F, Becerra MC, Botgros R, Brigden G, Browning R, Gardiner E, Hafner R, Hesseling A, How C, Jean-Philippe P, Lessem E, Makhene M, Mbelle N, Marais B, McIlleron H, McNeeley D, Mendel C, Murray S, Navarro E, Anyalechi EG, Porcalla A, Powell C, Powell M, Rigaud M, Rouzier V, Samson P, Schaaf HS, Shah S, Starke J, Swaminathan S, Wobudeya E, Worrell C. Towards earlier inclusion of Children in Tuberculosis (TB) drugs trials: Consensus statements from an Expert Panel. *Lancet Infect Dis*. 2015 Jun;15(6):711-20. PMID: 25957923, PMCID: PMC4471052
- Madhi SA, **Nachman S**, Violari A, Kim S, Cotton MF, Bobat R, Jean-Philippe P, McSherry G, Mitchell C, P1041 Study Team: Primary isoniazid prophylaxis against tuberculosis in HIV-exposed children. *N Engl J Med* 2011 Jul 7;365(1):21-31. PMID: 21732834 PMCID: PMC3164539
- Graham SM, Ahmed T, Amanullah F, Browning R, Cardenas V, Casenghi M, Cuevas LE, Gale M, Gie RP, Grzemska M, Handelsman E, Hatherill M, Hasseling AC, Jean-Philippe P, Kampmann B, Kabra SK, Lienhardt C, Lighter-Fisher J, Madhi S, Makhene M, Marais BJ, McNeeley DF, Menzies H, Mitchell C, Modi S, Mofenson L, Musoke P, **Nachman S**, Powell C, Rigaud M, Rouzier V, Starke JR,

- Swaminathan S, Wingfield C: Evaluation of tuberculosis diagnostics in children: 1. Proposed clinical case definitions for classification of intrathoracic tuberculosis disease. Consensus from an expert panel. *J Infect Dis* 2012 May 15;205 Suppl 2:S199-208. PMID:22448023. PMCID: PMC3334506
4. Svensson EM, du Bois J, Kitshoff R, de Jager VR, Wiesner L, Norman J, **Nachman S**, Smith B, Diacon AH, Hesselning AC, Garcia-Prats AJ. Relative bioavailability of bedaquiline tablets suspended in water: Implications for dosing in children. *Br J Clin Pharmacol*. 2018 Jun 27. PMID: 29952141, PMCID: PMC6138504

**Complete List of Published Work in My Bibliography:**

<http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/46564275/?sort=date&direction=ascending>