

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Hagensee, Michael E.	POSITION TITLE Professor
eRA COMMONS USER NAME (credential, e.g., agency login) MHAGEN	

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of Illinois, Urbana, IL	BS	1980	Biochemistry
Baylor College of Medicine	Ph.D.	1986	Cell Biology
Baylor College of Medicine	M.D.	1988	Medicine
University of Washington	Resident	1991	Internal Medicine
University of Washington	Fellow	1994	Infectious Diseases

A. Personal Statement

The goal of this proposal is to continue enrollment and participation of minorities into clinical research trials. Over the 16 years that I have been at LSUHSC, my research focus has been examining human papillomavirus (HPV) infection of HIV+ and HIV-negative individuals and the body's immune response against HPV. These studies have focused on low-income populations of New Orleans which have been over 80% African American over this time period. I have performed studies focusing on the prevalence of HPV in HIV+ women, the role of multiple HPV infections in the HIV+ women, and the role of HPV variants in the progression of cervical Pap smears in HIV+ women. Most of this initial work was utilizing cross-sectional study design and these studies enrolled over 2,000 individual HIV+ and HIV-negative individuals into these projects. I have been the New Orleans' site Principle Investigator for the Centers for Disease Control sponsored study Sentinel Survey for HPV infection (total of 6 sites). The New Orleans site enrolled the most HIV+ women (n=194) which was over 40% of the whole. More recently, my laboratory has focused on investigating a fascinating interaction between Epstein-Barr virus (EBV) infection and HPV in the development of cervical cancer where EBV serves as a co-factor to HPV in this process. These studies have utilized a cross-sectional design again enrolling over 80% African-American women. A total of 323 women have been enrolled into these longitudinal studies with a 85% retention rate at 1 year and over 1,000 total clinical visits. In addition, I serve as a HIV provider following over 200 individuals in my clinical practice. In addition, I am the leader of the anal cancer prevention project and in charge of performing high resolution anoscopy to detect pre-cancerous lesions and remove them. My experience as a translational research and physician in the New Orleans area has demonstrated the availability and enthusiasm of these minority individuals to participate in clinical research and the ability to retain these individuals in clinical studies. I feel qualified, enthusiastic and privileged to participate in this proposal and feel that LSUHSC is well-positioned to continue its leadership role in recruiting minority individual into clinical trials.

B. Position and Honors

1994-1996	Acting Instructor in Medicine, University of Washington, Seattle, WA.
1996-2001	Assistant Professor of Clinical Medicine with joint appointment in Microbiology, Louisiana State University Health Science Center, New Orleans, LA.
2001-2011	Associate Professor with tenure, LSUHSC, New Orleans, LA
2011-present	Professor, LSUHSC, New Orleans, LA
2012-present	Head of the Translational Tumor Virology Group
2013-present	Vice Chair of Research, Department of Medicine

Honors/Memberships

Board certified in Infectious Disease 10/96

Member – Stanley Scott Cancer Center – 9/98
Named to AIDS Clinical Trials Group (ACTG), HPV PSG 11/97- 1/1/01
Named to AIDS Clinical Trials Group (ACTG), WHC- Woman's Health Committee, 2/99 –1/01
Named to AIDS Clinical Trials Group (ACTG), Mucosal focus group, 3/99 – 1/01
Named to the Institutional Review Board of LSUHSC, 6/99 - present
Named as ancillary member of Vaccine Study Group, study section for NIAID, 7/00-present
Recertified Internal Medicine, 11/01
Infectious Disease Society of America, IDSA, 8/00 – current
American Association of Immunologist, AAI, 8/00-9/05
American Society of Virologists, ASV, 10/00 –present
Named to the Dental School Center of Excellence, 01/02
Named as Adjunct Assistant Professor in the Department Epidemiology of the Tulane University School of Public Health and tropical Medicine, 3-15-02 – current
Recertified Infectious Disease, 11/06
Named to NCI-J, K award review panel, NCI, 7/09-present
Named to the School of Medicine Promotion and Tenure committee, 1/12 – present
Credentialed in colposcopy and anoscopy, 5/13 – present

C. Selected Peer-reviewed Publications (Selected from 50 peer-reviewed publications)

Most relevant to the current application

1. Brinkman, J.A., Jones, W.E., Gaffga, A.M., Sanders, J.A., Chaturvedi, A.K., Slavinsky, III, J., Clayton, J.L., Dumestre, J., and **Hagensee, M. E.** Detection of Human Papillomavirus DNA in urine specimens from HIV+ women. *J. Clinical Microbiology*, 40:3155-3161, 2002.
2. Palmisano, M.E., Gaffga, A.M., Daigle, J., Brinkman, J., Mire. K., Lenczyk, K., Martin, D.H, and **Hagensee, M. E.** Detection of Human Papillomavirus DNA in Self-Administered Vaginal Swabs as Compared to Cervical Swabs, *International Journal of STD and AIDS*. *International J. of AIDS and STDs* 14: 560-567, 2003.
3. Chaturvedi, A.K., Dumestre, J., Gaffga, A.M., Mire, K.M., Clark, R.A., Braly, P.S., Dunlap, K., Kissinger, P.J., and **Hagensee, M. E.** Prevalence of Human Papillomavirus Genotypes in Women from Three Clinical Settings. *J Medical Virology*, 75:105-113, 2005.
4. Cameron, J.E., Mercante, D., O'Brien, M., Gaffga, A.M., Leigh, J.E., Fidel, Jr., P.L. and **Hagensee, M. E.**, The Impact of Highly Active Antiretroviral Therapy (HAART) and Immunodeficiency on Human Papillomavirus (HPV) Infection of the Oral Cavity of HIV Seropositive Adults. *Sexually Transmitted Diseases* 32:703-709, 2005
5. Datta, S. D., Koutsky, L.A., Ratelle, S., Unger, E.R., Shlay, J., McClain, T., Weaver, B., Kerndt, P., Zenilman, J., **Hagensee M.E.**, Suhr, C.J., and Weinstock, H. Human papillomavirus infection and cervical cytology in women screened for cervical cancer in the United States, 2003-2005. *Ann. Intern. Med.* 148:493-500. 2008.

Additional recent publications of importance to the field (in chronological order)

1. Slavinsky III, J., Kissinger, P., Burger, L., Boley, A. , Di Carlo, R. and **Hagensee, M.E.** Seroepidemiology of Low and High Oncogenic Risk Types of Human Papillomavirus in a Predominantly Male Cohort of STD Clinic Patients. *Int J STD AIDS* 12:516-523, 2001.
2. Snowwhite, I.V., Jones, W.E., Dumestre, J., Dunlap, K., Braly, P.S., and **Hagensee, M. E.** Comparative analysis of methods for collection and measurement of cytokines and immunoglobulins in cervical and vaginal secretions of HIV and HPV infected women. *J. Immunological Methods*, 263: 85-95, 2002

3. Cameron, J.E., Snowwhite, I.V., Chaturvedi, A.K., and **Hagensee, M. E.**, Human papillomavirus-specific antibody in oral fluids modestly reflects serum status in Human Immunodeficiency virus-positive individuals. *Clinical and Diagnostic Immunology* 10:431-348, 2003.
4. Chaturvedi, A., Brinkman J. Gaffga, A.M., Dumestre, J. , Clark, R.A., Braly, P.S., Dunlap, K., Kissinger, P.J., and **Hagensee, M. E.** Distribution of Human Papillomavirus type 16 Variants in Human Immunodeficiency Virus-1 Positive and Negative Women. *J Gen Virol.* 85: 1237-1241, 2004
5. Chaturvedi, A.K., Myers, L., Hammons, A.F., Clark, R.A., Dunlap, K., Kissinger, P.J. and **Hagensee, M. E.**, Prevalence and Clustering Patterns of Human Papillomavirus Genotypes in Multiple Infections. *Cancer Epidemiology and Biomarkers*, 14:2439-2445, 2005
6. Lilly, E.A., Cameron, J.E., Shetty, K.V., Leigh, J.E., Hager, S., McNulty, K.M., Cheeks, C., **Hagensee, M. E.**, and Fidel, P., Lack of Evidence for Local Immune Activity in Oral Hairy Leukoplakia and Oral Wart Lesions. *Oral Microbiology and Immunology*, 20:154-162, 2005.
7. Herrel, N.R., Johnson, N.L., Cameron, J.E., Leigh, J., and **Hagensee, M.E.**, Development and Validation of a HPV-32 Specific PCR Assay. *Virology Journal* 6:90 (1-7), 2009. PMID: PMC2715387
8. Ficarra M, Ibane JS, Poretta C, Ma L, Myers L, Taylor SN, Greene S, Smith B, **Hagensee M**, Martin DH, Quayle AJ. A distinct cellular profile is seen in the human endocervix during Chlamydia trachomatis infection. *J of Repro Immunology.* 60:415-425, 2008. PMID: PMC2574558
9. Kissinger, P., Amedee, A., Clark, R.A., Dumestre, J., Theall, K.P., Myers, L., **Hagensee, M.E.**, Farley, T.A., and Martin, D.H. Trichomonas vaginalis treatment reduces vaginal HIV-1 shedding. *Sex Transm Dis.* 2009 Jan;36(1):11-6. PMID: PMC3779369
10. Chesson HW, Flagg EW, Koutsky L, Hsu K, Unger ER, Shlay JC, Kerndt P, Ghanem KG, Zenilman JM, **Hagensee M**, Weinstock H, Datta SD. Modeling the impact of quadrivalent HPV vaccination on the incidence of Pap test abnormalities in the United States. *Vaccine.* 2013 Jun 24;31(29):3019-24. PMID: in progress.

D. Research Support

Ongoing Research Support

- | | | |
|--|----------------------|-------------------------|
| R01CA121979
NIH/NCI | Hagensee (PI) | 05/01/2008 – 04/30/2014 |
| Interaction of EBV and HPV in the Development of Cervical Dysplasia in HIV+ women,
This study is to explore an interaction between EBV and HPV that leads to an increase in cervical dysplasia.
Role: PI | | |
| P20MD004817
NIH/NIMHD | Dennis, Estrada(PIs) | 05/16/2010 – 02/28/2015 |
| Dillard-LSUHSC Minority Health and Health Disparities Research Center
The major goal of this project is to reduce health disparities in cancer by conducting basic and clinical research, training health care professionals to increase minority participation in clinical trials, and community engagement to promote participation in clinical research and clinical trials.
Role: PI of project #2 | | |
| P20GM103501
NIH/NIGMS | Ochoa(PI) | 07/01/2010 – 06/30/2015 |
| Center of Biomedical Research Excellence Mentoring Translational Research in Louisiana (COBRE)
The goal of this program is to mentor junior scientist to become independent translational researchers.
Role: Mentor | | |

R24MD008121 NIH/NIMHD	Estrada (PI)	01/01/2013 - 12/31/2015
Community-Academic Partnership to Address Health Disparities in New Orleans The primary objective of this project is to address specific social determinants of health identified by the Lower Ninth Ward community in New Orleans, such as access to health care, disease prevention, diet/nutrition, physical activity, and environmental factors that influence health status. Role: Co-investigator		
R21CA157263 NIH	Fontham (PI)	07/01/20012 – 6/30/2014
Feasibility of Community Based Tampon Self-Sampling To Prevent Cervical Cancer The goal of this project is to investigate the ability of home tampon testing to detect HPV DNA as a method to screen high-risk women to prevent cervical cancer Role: Co-investigator		
R01DE022815	Fidel, Griffen, Hagensee, Leys (Co-PIs)	09/21/2013 – 08/31/2018
The Oral Microbiome in HIV-associated Oral Warts and Candidiasis. The goal of this project is to examine the oral microbiome in HIV-negative versus HIV+ individuals, in those HIV+ individuals on ART and in those HIV+ individuals with oral warts and candidiasis Role: Co-Principle Investigator		

Completed Research Support

Doris Duke Clinical Research Scientist. Predictors of cervical dysplasia in HIV-infected women. Examination of the local cervical immunity against HPV as a predictor of cervical dysplasia.	Hagensee (PI)	7-1-98 - 6-30-01
American Cancer Society Prevalence of serum antibodies against HPV capsid antigens as a marker for cervical cancer Detection of human papillomavirus from stored serum of pregnant women from the 1980s	Hagensee (PI)	7/1/00 – 6-30-03
Centers for Disease Control Sentinel survey for HPV infection, Centers This study is to detect the prevalence of HPV DNA from women undergoing routine Pap smear screening, in 4 clinical settings in New Orleans.	Hagensee (Local PI)	1/02 - 12-31-05
R21DE015051-01 NIH/NIDCR Prevalence of HPV in the Oral Cavity of HIV+ Individuals, NIH- National Institute of Dental and Craniofacial Research This study is to examine the rates of HPV DNA detection from numerous oral sites in HIV+ individuals	Hagensee (PI)	9-1-02 – 8-30-04
R03CA111327-02 NIH/NCI Development of immune assays for HPV-32. This study is to develop antibody-ELISA, and T cell assays against the L1 protein of HPV-32 which is the most common type of HPV in oral warts in HIV+ individuals.	Hagensee (PI)	3-1-04 – 2-28-06
ARRA R01CA121979 NIH/NCI Interaction of EBV and HPV in the Development of Cervical Dysplasia in HIV+ Women NIH This study is to explore an interaction between EBV and HPV in anal dysplasia.	Hagensee (PI)	9/30/09 – 09/29/12