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Appendix A: Principal Investigator Credentials	Version 1.0

Appendix A:

Principal Investigator Credentials

Please find on the following pages details about principal investigators and their credentials.

Confidentiality Statement

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PRINCIPAL INVESTIGATOR CREDENTIALS

NAME	Address
Hui Cheng	601 E Jackson St, Richmond, VA 23219
POSITION TITLE	Email:
Principal Scientist I	Phone:

(b) (6)

A. Education/Training

INSTITUTION	DEGREE	FIELD OF STUDY
Michigan State University, USA	Postdoctoral Fellow	Drug Dependence Epidemiology
Michigan State University, USA	Ph.D.	Epidemiology
Peking University, China	Bachelor of Medicine	Preventive Medicine

B. Positions and Experiences

- 2017- Research Scientist Altria Client Services, USA
- + Serve as principal investigator of an ongoing nationwide population-based survey on underage tobacco use
 - + Author product applications (PMTA and MRTP) to FDA
 - + Design and conduct analysis of existing data to understand current tobacco use landscape
 - + Develop and manage the data analysis system to document tobacco-related analysis of existing data
- 2015-2017 Postdoctoral Fellow Michigan State University, USA
- + Serve as the chief fellow to provide day-to-day supervision and coordinate projects of the team
 - + Conduct epidemiologic studies using existing data
 - + Lead a project on psychoactive drug use among college students
 - + Mentor undergraduate students and summer interns
- 2011-2015 Research Scientist Shanghai Mental Health Center, China
- + Serve as principal investigator of a project on health burden associated with alcohol drinking in China
 - + Serve as the Chinese lead author of landscaping papers about disease burden associated with mental disorders as part of the China-India Alliance in Mental Health project
 - + Serve as core member of study teams of various surveys:
 - Knowledge and attitude about mental health in Ningxia province
 - Wellbeing of electronic factory workers in China
- 2010-2011 Research Scientist Peking University Institute of Mental Health, China
- + Serve as core member of study teams of population-based surveys on mental disorders in three Chinese cities
 - Chifeng
 - Xi'an
 - Beijing
- 2005-2009 Research Assistant Michigan State University, USA
- + Serve as lead analyst of the Drug Dependence Workgroup of the World Mental Health Survey Initiative
 - + Participate in study design and data collection of multiple surveys on drug use among college students

C. Statistical Skills

Efficient in multiple statistical software including Stata, Mplus, SAS

Experienced in a range of statistical models including descriptive analysis, generalized linear models, survival analysis, longitudinal data analysis, and structural equation models.

D. Honors

- 2017 Director's Travel Award, NIDA
- 2016 Early Career Travel Award, American College of Neuropsychopharmacology
- 2016 Director's Travel Award, NIDA
- 2011 Runner-up of Young Scholars Award, of the International Society of Addiction Journal Editors (ISAJE)/World Health Organization
- 2008 Women and Gender Junior Investigator Travel Award, NIDA

E. Selected Peer-reviewed Publications

a. Journal articles

A more complete list of publications on PubMed is available at
<https://www.ncbi.nlm.nih.gov/myncbi/hui.cheng.1/bibliography/public/>

1. **Cheng HG***, Shidhaye R*, Charlson FJ, Deng F, Lyngdoh T, Nanda S, Chen S, Baxter A, Whiteford HA. Public health challenge of mental, neurological and substance use disorders in China and India. *Lancet Psychiatry*. 2016; 3(9):882-99. *Joint first authors
2. Charlson F J., Baxter A J., **Cheng HG.**, Shidhaye R, Whiteford HA. The Burden of Mental, Neurological and Substance use Disorders in China and India. *Lancet*. 2016 May 17. pii: S0140- 6736(16)30590-6.
3. **Cheng HG**, McBride O, Phillips MR. Relationship between knowledge about the harms of smoking and smoking status in the 2010 Global Adult Tobacco China Survey. *Tobacco Control*. 2015;24:54- 61. doi: 10.1136/tobaccocontrol-2013-051163.
4. **Cheng HG**, Kaakarli H, Breslau J, Anthony JC. Assessing Changes in Alcohol Use and Alcohol Use Disorder Prevalence in the United States: Evidence from National Surveys From 2002 Through 2014. *JAMA Psychiatry*. 2018 Feb 1;75(2):211-213. doi: 10.1001/jamapsychiatry.2017.4008.
5. **Cheng HG**, Phillips MR, Li X, et al. Co-occurrence of DSM-IV mental disorders and alcohol use disorder among adult Chinese males. *Psychological Medicine*. 2017 May 29:1-12. doi: 10.1017/S0033291717001337
6. **Cheng HG.**, Chen S, McBride O, Phillips MR. Prospective relationship of depressive symptoms, drinking, and smoking among middle-aged and elderly community-dwelling adults: results from the China Health and Retirement Longitudinal Study (CHARLS). *Journal of Affective Disorders*. 2016; 195: 136-143
7. **Cheng HG**, Phillips MR; Zhan, Y; Wang Z. Psychometric properties of the Drinking Motive Questionnaire-Revised among community dwelling current drinkers in the Ningxia autonomous region of China. *Drug and Alcohol Review*. 2015 Jul 21. doi: 10.1111/dar.12310
8. **Cheng HG**, Deng F, Xiong W, Phillips MR. Prevalence of alcohol use disorders in mainland China: a systematic review. *Addiction*. 2015 May;110(5):761-74. doi: 10.1111/add.12876.

b. Book Chapters

1. Anthony J., **Cheng H.**, Fairman B., Romer D., & Wenk G. (In press). The neurobiology, characteristics, and prevalence of substance use. In D. W. Evans, E. B. Foa, R. E. Gur, H. Hendin, C. P. O'Brien, M. E. P. Seligman, & B. T. Walsh (eds.). Treating and preventing adolescent mental health disorders: What we know and what we don't know, 2nd edition. New York: Oxford University Press.
2. **Cheng, H.**, Radovanovic, M., Wilcox, H.C., Anthony, J.C. Global Epidemiology: Trends in Suicide Behavior. In: Amresh Shrivastava (Ed.): In Press Handbook of Suicide Behavior. Royal College of Psychiatrists. London, UK. 2008

Richard Brendan Noggle

Principal Scientist II
Altria Client Services LLC



(b) (6)

Summary

- + 17 years of public health related surveillance and study of human subjects
- + 12 years of grant management as a principal investigator
- + Experience in conducting tobacco-related perception, behavior and health research
- + CITI Human Subjects Research Trained

Relevant Experience

Epidemiologist, Principal Scientist II
Altria Client Services LLC, Richmond, VA

April 2017 - Current

- + Served as the principal investigator on a tobacco-related intentions survey
- + Served as the study manager and IRB liaison for a tobacco-related secondary analysis of behaviors and urinary biomarkers
- + Develop tobacco-related research on perception, behavior and health
- + Manage planning, documentation, study execution and other responsibilities within an FDA regulated environment
- + Provide epidemiological support and consultation

Epidemiology Manager
Virginia Department of Health, Richmond, VA

February 2013 - April 2017

- + Oversee grant progress, proposals, and requirements including the Early Hearing Detection and Intervention Information System, and support State Public Health Actions to Prevent and Control Chronic Diseases CDC grants
- + Coordinate novel research projects designed to improve the health of Virginia
- + Create new surveillance systems and pioneer data sharing with health systems in Virginia
- + Manage and provide technical mentorship to cancer, chronic disease, tobacco prevention, injury, maternal and child health, newborn screening, population survey, and social determinant epidemiology staff and projects
- + Epidemiology team provides data support to inform Agency strategic direction and everyday work
- + Create community health assessments and present methods to engage communities with data

Newborn Screening and Birth Defects Epidemiologist
Georgia Division of Public Health

2007-2013

- + Co-Principal Investigator – Surveillance and Health Promotion for Sickle Cell Disease
 - Characterize the burden of sickle cell disease by combining multiple data sources and determine valid baselines for new Healthy People 2020 Blood Disorders objectives
- + Georgia Principal Investigator – Registry and Surveillance System for Hemoglobinopathies (RuSH) grant
 - Oversee the collaborative effort and direction among multiple stakeholders to collect population-based data on people with sickle cell disease and thalassemia, including data linkage
- + Principal Investigator – Early Hearing Detection and Intervention (EHDI) systems advancement grant. Build, deploy, evaluate, and improve a web-based data system for the identification, diagnosis, and intervention of children with congenital hearing loss

- + Manage the design and deployment of SendSS Newborn, a web-based method for conducting identification, referral, and follow-up for the state of Georgia's EHDI program, the Early Intervention program, and the Newborn Genetic Screening (NBS) Program. Integrate health surveillance, tracking, epidemiology, and evaluation of multiple programs.

Education

Master of Public Health Prevention Sciences	2007
Georgia State University, Atlanta, GA	
Bachelor of Science Exercise and Sport Science	2001
University of Georgia, Athens, GA	

Published Work

- + Chinelo Ogbuanu, Goodman D, Kahn K, **Noggle B**, Long C, Bagchi S, Barradas D. Factors Associated with Parent Report of Access to Care and the Quality of Care Received by Children 4 to 17 Years of Age in Georgia. *Matern Child Health J.* 2012 Apr; 16 Suppl 1:S129-42.
- + Chinelo Ogbuanu, Goodman D, Kahn K, **Noggle B**, Long C, Bagchi S, Barradas D. Timely Access to Quality Health Care Among Georgia Children Ages 4 to 17 Years. *Matern Child Health J.* 2012 Oct 10.
- + Mary Hulihan, Feuchtbaum L, Jordan L, **Noggle B**, Young W, Pettiford B, Wang Y, Cramer W, Werner E, Grant A. Population-based Surveillance for Sickle Cell Disease: Past, Present, Future. *American Journal of Hematology.* 2013 Dec 88(12):E26-E26 (Symposium Article).
- + **Brendan Noggle**, Georgia's Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program. *Georgia Epidemiology Report.* 2009 Jan (25) 1. Available from <http://health.state.ga.us/pdfs/epi/gers/Jan09GER.pdf>
- + Ann Marie Hart, Patti A, **Noggle B**, Haller-Stevenson E, Hines L. Acute Respiratory Infections and Antimicrobial Resistance. *American Journal of Nursing.* 2008 Jun (108) 6, pgs 56-65.
- + **Brendan Noggle**, Iwamoto M, Chiller T, Klevens M, Moore MR, Wright J, Whitney C. Tracking resistant organisms: Workshop for improving state-based surveillance programs [conference summary]. *Emerg Infect Dis.* 2006 Mar. Available from <http://www.cdc.gov/ncidod/EID/vol12no03/05-1335.htm>

Selected Poster and Oral Presentations

- + Tobacco Harm Reduction Summit: Poster presentation
- + Society for Research on Nicotine & Tobacco: Multiple poster presentations
- + Council of State and Territorial Epidemiologists: Oral, roundtable and multiple poster presentations
- + Virginia Local Community Action Networks: Multiple Oral Presentations
- + Association of Maternal and Child Health Programs Conference: Oral and Poster Presentations
- + Governor's Council on Hearing Loss: Oral Presentation
- + CDC's Metropolitan Atlanta Congenital Defects Program Annual Conference: Oral Presentation

Lai Wei

Principle Scientist—Biostatistician
Altria Client Services

(b) (6)

Education

- 2017–Present **M.S. in Data Science**, *The Johns Hopkins University*, Elkridge, MD.
- 2011–2013 **Ph.D. in Biostatistics**, *State University of New York at Buffalo*, Buffalo, NY.
- 2009–2011 **M.A. in Biostatistics**, *State University of New York at Buffalo*, Buffalo, NY.
- 2005–2009 **B.S. in Mathematics and Applied Mathematics**, *University of Science and Technology Beijing*, Beijing, China.

Research Interests

Population Modeling, Data Mining, Clinical Trials, Complex Survey Design and Analysis, Post-Market Safety Surveillance, Pharmacovigilance, Network Analysis, Robust Estimation, Quick Estimators Bootstrap, Order Statistics, Nonparametric Inference, ROC Curve

Experience

Working

- 2016–Present **Principle Scientist, Statistician**, *Population Science, Regulatory Affairs, Altria Client Services LLC*, Richmond, VA, USA.
 - Managing Tobacco Landscape Survey Surveillance System (SSS) to provide comprehensive and up to date view of the tobacco landscape;
 - Analyzing data from national surveys to support regulatory engagement activities;
 - Developing population modeling methodologies to study the benefits and negative impacts of new tobacco products and cohort longevity.
- 2014–2016 **Senior Survey Statistician**, *Research Development and Regulatory Affairs, Center for Research & Technology, Altria Client Services*, Richmond, VA, USA.
 - Designed and analyzed complex in-market survey studies including developing study protocols, statistical analysis plans and preparing statistical results for study reports and regulatory submissions;
 - Developed a compartmental cohort model based on national surveys to study the benefits and negative impacts of a modified risk tobacco product and cohort longevity.
- 2013–2014 **Postdoctoral Fellow**, *Center for Biologics Evaluation and Research, US Food and Drug Administration*, Rockville, MD, USA.
 - Collaborated with statisticians, medical officers and other CBER scientists to develop methods to evaluate the safety of pandemic influenza vaccines and other medical countermeasures;
 - Developed statistical data mining methods including association rule mining, biclustering, concept analysis, etc., for mining adverse event databases (e.g. VAERS, FAERS);
 - Developed and defined algorithms for network analysis on the Vaccine Adverse Event Reporting System (VAERS).
- 2012–2014 **Lead Statistician**, *Digital System, Inc.*, Chevy Chase, MD, USA.
 - Worked on the Small Business Innovation Research Program (SBIR) funded by Walter Reed Army Institute of Research (WRAIR);
 - Supervised and developed the Statistical Explorer for Epidemiology (SEE) for epidemiology statistical analysis that enables users to build a suitable model according to data structure and research hypothesis;
 - Wrote proposals of grant application for bidding projects funded by government agencies.

Publications & Presentations

Publications

- 2020 **Wei, L.** Muhammad-Kah, R., Hannel, T., Pithawalla, Y.B., Gogova, M., Chow, S., Black, R. The Impact of Cigarette and E-Cigarette Use History on Transition Patterns: A Longitudinal Analysis of the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015. *Harm Reduction Journal* (doi:10.1186/s12954-020-00386-z).
- 2020 Lee, P., Abrams, D., Bachand, A., Baker, G., Black, R., Camacho, O., Curtin, G., Djurdjevic, S., Hill, A., Mendez, D., Muhammad-Kah, R., Murillo, J.S., Niaura, R., Pithawalla, Y.B., Poland, B., Sulsky, S., **Wei L.** and Weitkunat R. Estimating the population health impact of recently introduced modified risk tobacco products: a comparison of different approaches. *Nicotine & Tobacco Research* (doi: 10.1093/ntr/ntaa102).
- 2019 Muhammad-Kah, R.S., Pithawalla, Y.B., Boone, E.L., **Wei, L.**, Jones, M.A., Black, R.A., Bryan, T.M., Sarkar, M.A. (2019). A Computational Model for Assessing the Population Health Impact of Introducing a Modified Risk Claim on an Existing Smokeless Tobacco Product. *International Journal of Environmental Research and Public Health*, 16, 1264.
- 2015 **Wei, L.** and Scott, J. (2015). Association rule mining in the US Vaccine Adverse Event Reporting System (VAERS). *Pharmacoepidemiology and Drug Safety*, 24(9), 922-933.
- 2014 **Wei, L.**, Wang, D.L., Hutson, A.D. (2014). An Investigation of Quantile Function Estimators Relative to Quantile Confidence Interval Coverage. *Journal of Communication in Statistics - Theory and Methods*, 44(10), 2107-2135.
- 2013 **Wei, L.** and Hutson, A.D. (2013). A Comment on Sample Size Calculations for Binomial Confidence Intervals. *Journal of Applied Statistics*, 40(2), 311-319.

Selected Seminar Presentations (Lead Author/Presenter)

- Aug 04, 2014 Association rule mining in the US Vaccine Adverse Event Reporting System (VAERS), *Joint Statistical Meetings*, Boston, MA
- Jun 02, 2014 Association rule mining in the US Vaccine Adverse Event Reporting System (VAERS), *2014 FDA MCMi Regulatory Science Symposium*, Silver Spring, MD
- Mar 18, 2014 Robust Estimation of Scale, Dependence and Correlation Based on Quick Estimators, *International Biometric Society (ENAR) Meeting*, Baltimore, MD
- Dec 12, 2013 An Investigation of Quantile Function Estimators Relative to Quantile Confidence Interval Coverage, *U.S. Army Conference on Applied Statistics*, Alexandria, VA
- Jul 30, 2013 Introducing Statistical Explorer for Epidemiology (SEE), *Department of Preventive Medicine and Biometrics, Uniformed Services University of the Health Sciences*, Bethesda, MD
- Jul 17, 2013 A Smart, Easy and Effective Way to Do Data Analysis, *Walter Reed Army Institute of Research*, Silver Spring, MD
- Jun 10, 2013 Introducing Statistical Explorer for Epidemiology (SEE), *Department of Preventive Medicine Seminar Series, Walter Reed Army Institute of Research*, Silver Spring, MD
- Mar 12, 2013 A Comment on Sample Size Calculations for Confidence Intervals in Discrete Distributions, *International Biometric Society (ENAR) Meeting*, Orlando, FL
- Dec 14, 2012 Quantile Function Methods with Applications to Robust Estimation, *Department of Biostatistics Seminar Series*, University at Buffalo, Buffalo, NY
- Feb 18, 2011 Genetic Algorithm and PLS Regression for Variable Selection of Spectroscopic Data in Metabonomics, *Department of Biostatistics Seminar Series*, University at Buffalo, Buffalo, NY

Selected Poster Presentations (Lead Author/Presenter)

- Feb 21-24, 2018 The Impact of Tobacco Use History on e-Cigarette and Cigarette Transition Patterns - A Longitudinal Analysis of Population Assessment of Tobacco and Health (PATH) Study. *24th Annual Meeting of the Society for Research on Nicotine and Tobacco (SRNT)*, Baltimore, MD, USA
- Feb 21-24, 2018 Estimating the Population Health Impact of Authorizing the Marketing of a Smokeless Tobacco Product with a Proposed Modified Risk Claim. *24th Annual Meeting of the Society for Research on Nicotine and Tobacco (SRNT)*, Baltimore, MD, USA
- Jun 2-3, 2014 Association rule mining in the US Vaccine Adverse Event Reporting System (VAERS). *2014 FDA MCMi Regulatory Science Symposium*, Silver Spring, MD, USA
- Apr 6, 2011 GA-PLS for Biomarker Identification and Embryo Implantation Prediction: An ¹H-NMR metabonomics investigation of IVF culture media. *University at Buffalo Sigma Xi Research Day and Poster Competition*, Buffalo, NY, USA

Skills

SAS, R, Python, Matlab, SPSS, Perl, SQL, LATEX, Java, Visual Basic, Visual C++, HTML, CSS, JSP, etc.

Conferences and Workshops Attended

- Aug, 2018 ICPSR Summer Workshop: The Population Assessment of Tobacco and Health (PATH) Study Data User Workshop: Biomarker Restricted Use Files, Ann Arbor, MI
- Feb, 2018 Society for Research on Nicotine and Tobacco (SRNT) Annual Conference, Baltimore, MD
- Mar, 2016 Society for Research on Nicotine and Tobacco (SRNT) Annual Conference, Chicago, IL
- Jun, 2015 FDA Public Workshop on Electronic Cigarettes and the Public Health, College Park, MD
- Mar, 2014 International Biometric Society (ENAR) Spring Meeting, Baltimore, MD
- Dec, 2013 U.S. Army Conference on Applied Statistics, Alexandria, VA
- May, 2013 JMP for Data Mining, Predictive Modeling, and Data Visualization, Washington, DC
- Mar, 2013 International Biometric Society (ENAR) Spring Meeting, Orlando, FL
- Aug, 2012 Joint Statistical Meetings (JSM), San Diego, CA
- Apr, 2012 International Biometric Society (ENAR) Spring Meeting, Washington, DC
- May, 2011 Society for Clinical Trials Annual Meeting (SCT), Vancouver, BC, Canada
- Mar, 2011 International Biometric Society (ENAR) Spring Meeting, Miami, FL