



**Office of Management and Budget  
Division of Purchasing  
Non-Competitive Contract Request Form**

Department	Public Health and Wellness	Department Contact	Briana Lyddane
Contact Email	briana.lyddane@louisvilleky.gov	Contact Phone	502-574-6690

Contract Type: check one	<b>New</b>	<b>Amendment</b>		
		Additional Funds	Time Extension	Scope
Professional Service	✓			
Sole Source (goods/services)				
	<b>Start</b>	<b>End</b>		
Requested Contract Dates (MM/DD/YYYY)	10/01/2020	09/30/2021		

**VENDOR INFORMATION**

Vendor Legal Name	University of Louisville on behalf of its Division of Infectious Diseases				
DBA					
Point of Contact	Tina Hembree	Email	Tina.Hembree@louisville.edu		
Street	323 E Chestnut Street				
Suite/Floor/Apt	208	Phone	502-852-7881		
City	Louisville	State	KY	Zip Code	40202
Federal Tax ID#		SSN# (If sole proprietor)			
Louisville Revenue Commission Account #					
<a href="#">Human Relations Commission Certified Vendors</a>	Certified Minority Owned Business	Certified Woman Owned business	Disabled Owned business		
Select if applicable					

**FINANCIAL INFORMATION**

Not to Exceed Contract Amount	<b>\$51,079</b>	(including reimbursement expenses, if applicable)			
Fund Source: General Fund	✓				
Federal Grant		Federal Granting Agency			
Other		Describe:			
Account Code String #	1101	605	4130	411401	521344
Payment Rate	per hour		per day		per service
	\$4,256.50	per month	Other		
Payment Frequency	✓	Monthly	Upon Completion / Delivery		
		Quarterly	Other		



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**CONTRACT SCOPE and PURPOSE** (Attach additional documentation if necessary)

**Amendments:** Describe the circumstances under which a time extension or scope change is needed.

**New:** Be specific about the work to be performed / product to be purchased including but not limited to: scope of work; description of service; work product created; why the service / product is necessary; and benefit to Louisville Metro Government.

The Louisville Metro Department of Public Health and Wellness (LMPHW) operates a public health laboratory and a few clinical laboratories and is in need of a qualified Laboratory Director to oversee the lab's operations for 20 hours per week. The Lab Director will perform all duties as outlined in Exhibit A which includes, but is not limited to the following: carry out the responsibilities established by the Clinical Laboratory Improvement Amendments (CLIA); ensure the proper operation of the lab including development and implementation of a sustainable business plan; ensure that the physical plant and environmental conditions are appropriate for the testing performed; and ensure testing systems provide quality lab services for pre-analytic, analytic, and post-analytic phases of testing.

**JUSTIFICATION FOR NON-COMPETITIVE GOOD/SERVICE** (Attach additional documentation if necessary)

Provide justification including but not limited to: a description of the unique features that prohibit competition; research conducted to verify the vendor as the only known source (sole source); why the service (PSC) is not feasible to be provided by LMG staff or expertise does not exist; known compatibility, proprietary and/or timing issues.

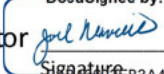
The University of Louisville employs Dr. Leslie Wolf full time as a Clinical Assistant Professor. Dr. Wolf has served as the LMPHW Lab Director since July 2013, and LMPHW would like to continue its relationship with the University of Louisville for 20 hours of Dr. Wolf's time per week. Dr. Wolf's laboratory expertise is unparalleled, as is her experience running LMPHW's lab. UofL is uniquely qualified to provide Dr. Leslie Wolf as the LMPHW Lab Director because UofL is the sole source employer of Dr. Leslie Wolf.

The Lab Director's annual compensation shall be \$79,500 plus fringe benefits for a total compensation package of \$102,157 paid by UofL. Metro Government will contribute \$51,078.60 for salary/fringe to UofL. UofL shall invoice monthly for \$4,256.55.

**AUTHORIZATIONS:** Per KRS 45A.380, I have determined that competition is not feasible for the above described good / service and there is a single source within a reasonable geographical area of the good / service to be procured; or the resulting contract is for the services of a licensed professional, technician, artist, or other non-licensed professional service.

Department Director  Date 7-22-2020  
Signature

Sarah S. Moyer  
Printed Name

Purchasing Director  Date 7/28/2020  
DocuSigned by:  
Signature

Joel Neaveill  
Printed Name

Exhibit A - Lab Director Scope of Work

- Carry out the responsibilities established by the Clinical Laboratory Improvement Amendments (CLIA) that can only be assumed by a qualified laboratory director.
- Represent the LMPHW with other agencies and programs such as the Kentucky State Laboratory, Region 6 Emergency Response District, and the Louisville Metro Medical Subgroup Emergency Response subcommittee.
- Function as the Laboratory Director for the Specialty Clinic and other small clinic laboratories that operate under a separate CUA certificate from the 430 East Gray Laboratory.
- Ensure the proper operation of the laboratory; including the development and implementation of a sustainable business plan. Be accessible to the lab to provide onsite, telephone or electronic consultation as needed.
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed.
- Ensure the environment for employees is safe from physical, chemical, and biological hazards and that safety and biohazard requirements are followed.
- Establish and participate on a performance improvement committee and a safety committee which meet monthly, at a minimum.
- Ensure testing systems provide quality lab services for pre-analytic, analytic, and post-analytic phases of testing.
- Establish a performance improvement program to include employee health and safety, pre-post analytical evaluations, quality control practices, proficiency evaluations, corrective actions, environmental assessments and other monitors consistent with CUA.
- Ensure test methods selected have the capability of providing quality results.
- Ensure verification procedures used are adequate to determine accurate precision, and other pertinent performance characteristics of the method.
- Ensure that reports of test results include pertinent information required for interpretation.
- Ensure that consultation is available to the lab's clients on matters relating to the quality of the test results reported and their interpretation concerning specific tests.
- Ensure that an appropriate procedure manual is available and routinely updated to reflect procedures based on best practice and changes in the field.
- Ensure that prior to testing patients' specimens, all personnel have the appropriate

education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

- Ensure that lab personnel are performing the test methods as required for accurate and reliable results.
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical and post-analytical phases of testing to verify that they maintain competency.
- Ensure that the lab is enrolled in a proficiency testing (PT) program.
- Ensure that PT results are returned on time to the PT program.
- Ensure that PT samples are tested in the same manner as patient samples.
- Ensure that quality control and quality assurance programs are established and maintained to identify failures in quality as they occur.
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
- Ensure that remedial actions are taken and documented whenever any deviations from the lab's established performance characteristics are identified and patient test results are correctly reported.

**Leslie A. Wolf, Ph.D.**

511 S. Floyd St. MDR 113 (Work)

Louisville KY, 40292

(502) 582-1523 (work phone)

(502) 582-1512 (work fax)

lesliewolf8@gmail.com (personal); [lawolf07@louisville.edu](mailto:lawolf07@louisville.edu) (work)

**EDUCATION**

8/1986-5/1990 B.S. in Microbiology (With High Distinction), University of Kentucky, Lexington, KY

8/1990-5/1996 Ph.D., Immunology/Microbiology, University of Colorado, Denver, CO

9/1997- 9/1999 CDC/APHL Emerging Infectious Disease Postdoctoral Research Fellow, North Carolina State Laboratory of Public Health, Raleigh, NC (competitive selection process)

**ACADEMIC APPOINTMENTS**

2002 Adjunct Faculty, North Carolina Central University, Durham, NC. Research director and member of thesis committee for Masters of Science in Biology student Annissa D. Royal

2016-present Clinical Assistant Professor, Division of Infectious Diseases, Department of Medicine, University of Louisville. Laboratory Director for Infectious Diseases Laboratory

2019-present Adjunct Faculty, School of Public Health, Department of Environmental and Occupational Health, University of Louisville

**OTHER POSITIONS AND EMPLOYMENT**

9/1995-8/1997 Research Associate, North Carolina State University, Raleigh, NC

10/1999-11/2002 Public Health Scientist, North Carolina State Laboratory of Public Health, Raleigh, NC

11/2002-7/2009 Assistant Public Health Laboratory Director, North Carolina State Laboratory of Public Health, Raleigh, NC

8/2005-7/2006 Acting Laboratory Director, North Carolina State Laboratory of Public Health, Raleigh, NC

8/2006-6/2012 Laboratory Director, North Carolina State Laboratory of Public Health, Raleigh, NC

10/2012-10/2016 Laboratory Director, Galaxy Diagnostics, Inc., Research Triangle Park, Durham, NC

7/2013-present Laboratory Technical Director, Louisville Metro Public Health and Wellness Laboratory, Louisville, KY

#### **CERTIFICATION AND LICENSURE**

July 2003-present High Complexity Laboratory Director, American Board of Bioanalysis, with a specialty in Molecular Diagnostics

#### **PROFESSIONAL MEMBERSHIPS AND ACTIVITIES**

2002-present Association of Public Health Laboratories (APHL). Member of Food Safety Committee 2009-2012. Workgroup leader to develop guidelines for foodborne outbreaks of undetermined etiology. Member of Local Laboratory Committee 2015-2017. Member of Dues Task Force and Lab Director Certification Working Group in 2017. Member of Finance Committee 2017-2020.

2009-2012 Council to Improve Foodborne Outbreak Response (CIFOR) Member. Represent the Association of Public Health Laboratories, serving on various workgroups including development of Toolkit to disseminate "Guidelines to Improve Foodborne Outbreak Response" published in 2009, a law project, and development of guidelines for outbreaks of unknown etiologies.

#### **HONORS AND AWARDS**

1986-1987 Commonwealth Scholarship, University of Kentucky  
 1987-1990 Academic Excellence Scholarship, University of Kentucky  
 1990-1991 University of Colorado Health Sciences Center Doctoral Fellowship  
 1991-1994 National Science Foundation Graduate Fellowship  
 April 2002 PulseNet PulseStar Award  
 December 2004 Outstanding Leadership Project Award, Southeastern Public Health Leadership Institute  
 May 2008 APHL Emerging Leader Award

#### **COMMITTEE ASSIGNMENTS AND ADMINISTRATIVE SERVICES**

2008-2011 Consultant, Association of Public Health Laboratories Global Public Health Program. Provide on-site and remote mentoring and guidance

for quality assurance, biosafety, and molecular assay development for twinning project with the National Public Health Reference Laboratory, Georgetown, Guyana.

2015-2016	Accreditation Team for LMPHW Public Health Accreditation Board process.
2016-2019	Quality Improvement Team, Louisville Metro Public Health and Wellness
2018	LMPHW Project Director, Undergraduate Capstone Program for UofL School of Public Health and Information Sciences

## EDUCATIONAL ACTIVITIES

Mentored two Emerging Infectious Disease Undergraduate Fellows, 2000-2002, on public health research projects related to arboviral disease surveillance in North Carolina (Virginia M. Wood) and development of a molecular diagnostic assay for *Bordetella pertussis* (William A. Glover).

Research Advisor, Anissa D. Royal, MS Biology, 2000-2002, North Carolina Central University, Durham, NC. Directed research project to implement plaque reduction neutralization assay for isolation and identification of arboviruses.

Research Advisor, Katherine E. Volpe Sperry, MS Biology, 2007-2009, St. Joseph's College, West Hartford, CT. Directed research to develop variable number tandem repeat assay for *Listeria monocytogenes* to aid in molecular epidemiology of foodborne illness.

Contributed to development and review of on-line training courses for public health professionals related to the role of state and local public health laboratories in the public health system. See links to University of North Carolina at Chapel Hill Center for Public Health Preparedness and North Carolina Institute for Public Health at the following websites: [https://nciph.sph.unc.edu/tws/HEP\\_SLPH2/certificate.php](https://nciph.sph.unc.edu/tws/HEP_SLPH2/certificate.php), and [https://nciph.sph.unc.edu/tws/HEP\\_SLPH1/certificate.php](https://nciph.sph.unc.edu/tws/HEP_SLPH1/certificate.php).

Guest Lecturer, North Carolina State University, Department of Microbiology, GPH 201, Global Public Health course, Fall 2010 and Fall 2011. Provided overview of NC State Laboratory of Public Health and global public health laboratory project with Guyana.

Guest Lecturer, One Health Intellectual Exchange, March 2011, about the role of public health laboratory in foodborne disease investigation and surveillance during a session entitled, "Ensuring National and International Food Safety." The One Health Intellectual Exchange was a collaborative effort between North Carolina State University, University of North Carolina at Chapel Hill and Duke University to provide a series of seminars on various health topics to students, professors and other interested members.

Practicum Advisor, Sadaf J. Warraich, MPH Epidemiology 2015-2016, University of Louisville School of Public Health and Information Sciences. Directed research project to identify both clinical and non-clinical risk factors for active TB cases in Jefferson County, KY, 2013-2015.

Practicum Advisor, Raven Robbins, MPH Candidate, University of Kentucky School of Public Health. July 2017 to Jan 2018. Directed research project to identify both awareness of and barriers to implemented 2010 CDC guidelines regarding screening pregnant women for blood lead levels.

Served as first-round and second-round Judge for Research!Louisville September 2017, Medical Students and Medical Students-Distinction Track.

Served as Project Manager for Capstone Experience at LMPHW for Public Health majors at UofL SPHIS, 2018. Developed process for selecting Capstone students, assigning tracks for a broad experience at LMPHW, and generating projects for students to complete in Spring 2019 semester.

Served as judge for student research and clinical vignette posters at KY ACP Conference, October 2018, UofL Shelby Campus.

Served as mentor for Public Health major Kendall Streible on her Capstone project involving screening pregnant women for risk of lead exposure at Louisville Metro Public Health and Wellness January through April 2019.

Guest Lecturer, University of Louisville PHEH-440 Biology for Population Health course, April 10, 2019, entitled *"Surveillance for Foodborne Pathogens: Laboratory Aspects:"*

Served as mentor for Public Health major Lilyan Bryan on her Capstone project involving mosquito surveillance at Louisville Metro Public Health and Wellness June through July 2019.

Primary Instructor, University of Louisville PHEH-440 Biology for Population Health course, Spring 2020 and Fall 2020 semesters.

Served as mentor for Heather Ness, a senior Public Health major at UofL, for the 2019-2020 academic year through the UofL Board of Overseers Mentoring Program.

Served as mentor for Heather Ness, a senior Public Health major at UofL, for the 2019-2020 academic year through the Summer Research Opportunity Program (SROP). She earned an \$800 scholarship on top of the SROP award for her excellent work.

## **CLINICAL ACTIVITIES**

Laboratory Director for CLIA accredited laboratories performing a variety of clinical tests for diagnosis of sexually transmitted diseases, blood lead levels, and other infectious diseases of public health significance, such as vector-borne diseases. I ensure compliance with federal clinical laboratory regulations by giving direction and providing oversight to facility, safety, general laboratory quality, testing personnel, specimen types, test systems, and reporting requirements.

Provide training to nurses, medical assistants who perform waived testing at various LMPHW clinic sites and oversee quality of laboratory testing at main laboratory, TB Clinic, Specialty Clinic and WIC locations.

Provide in service training as needed to the Infectious Diseases Laboratory, 550 and Travel Clinic staff regarding proper specimen collection, storage and test request form completion.



## GRANTS AND CONTRACTS

### CURRENT GRANTS

1. Principal Investigator, KBRIN NextGenSeq Pilot Study, May 2019, "*Urine Microbiome of Persons with Pneumococcal Pneumonia Using NGS*"
2. Project Manager, Association of Public Health Laboratories, April 2019, "*Expanding Access to Childhood Blood Lead Testing*," \$60,000. One of two proposals awarded funds to replace aging analytical equipment, scientific supplies and collection kits to at-risk populations in Jefferson County.

### PAST GRANTS

3. Principal Investigator, Association of Public Health Laboratories and CDC grant "*DNA-Based Subtyping of Listeria monocytogenes*", 2003-2009, \$85,000-110,000/annually. Project funded one full-time Medical Laboratory Specialist to develop a multi-locus variable number tandem repeat analysis method to augment the PulseNet gold-standard method of pulsed-field gel electrophoresis. Additionally, grant funded scientific supplies, office supplies and travel to CDC meetings. A publication resulted from this project in the *Journal of Clinical Microbiology*.
4. Principal Investigator, Association of Schools of Public Health grant entitled "*Pathways to Public Health*", January 2010 through December 2010, \$30,000. Project funded four paid student internships through a competitive selection process of rising juniors and seniors at North Carolina State University. Research projects were provided in four distinct laboratory areas for an eight-week internship for four students in summer 2010.
5. Principal Investigator, Association of Public Health Laboratories grant entitled "*Expanded Access to Interferon Gamma Release Assays*", January 2016 through October 2016, \$37,000. Project funded to implement IGRA testing at the main Laboratory to support the Regional TB Clinic both within the Louisville Metro Public Health and Wellness Department.

### CURRENT CONTRACT

1. Serve as local representative on Institutional Biosafety Committee for Western Institutional Review Board (WIRB), February 2017 to present. Review protocol changes, attend annual webinar meeting and perform site visits as necessary at local clinic where the clinical trial is ongoing.

### PAST CONTRACTS

1. Technical Writer, McKing Consulting/Centers for Disease Control and Prevention Newborn Screening August-September 2012. Provided white paper on perceived issues related to state mandated newborn screening programs. These issues related to privacy, public benefits and other ethical considerations.

2. Laboratory Systems Improvement Project (L-SIP) Coordinator, North Carolina State Laboratory of Public Health (NCSLPH), June 2014-December 2015, \$4000. Lead the L-SIP team to prepare for public health laboratory system assessment based on toolkit provided by the Association of Public Health Laboratories (APHL).
3. Laboratory Systems Improvement Project (L-SIP) Coordinator, Louisville Metro Public Health and Wellness Department, January 2015-June 2015, \$4000. Lead the L-SIP team to prepare for public health laboratory system assessment based on toolkit provided by the Association of Public Health Laboratories (APHL).

## **PATENTS**

None

## **EDITORIAL WORK**

Section Editor: Clinical Microbiology, University of Louisville Journal of Respiratory Infections, 2017-present

## **ABSTRACTS AND PRESENTATIONS**

### **ORAL PRESENTATIONS**

1. Association for Molecular Pathology, Industry Workshop, November 2015, Austin, TX. Invited presentation by Microbiologics, Inc. entitled "A Practical Guide to Laboratory Developed Tests (LDTs) Validation and QC Requirements."
2. South Central Association of Clinical Microbiology, Kentucky Fall 2016 meeting, Elizabethtown, KY. Invited presentation entitled "Intersection between Public Health and the Private Clinical Laboratories."
3. South Central Association of Clinical Microbiology, Kentucky Fall 2017 meeting, Elizabethtown, KY. Invited presentation entitled "TB the Louisville KY Way."
4. American Association of Clinical Chemistry International Point of Care Testing Symposium, September 2018, Washington, DC. Invited presentation entitled "The Benefits and Challenges of Point of Care Testing for Respiratory Tract Infections."
5. Association of Schools and Programs of Public Health Undergraduate Public Health and Global Health Education Summit. "Creating a Student Centered Undergraduate Public Health Practice Experience with Your Local Health Department," March 20, 2019, Washington D.C

## **POSTERS**

1. International Emerging Infectious Disease Conference, July 2000. Atlanta, GA, "*Salmonella javiana*: an emerging serotype in NC," LA Wolf, B Jenkins.
2. American Society for Microbiology, May 2001, Orlando, FL. "The use of PFGE analysis in *Shigella sonnei* outbreak investigations," LA Wolf, B Jenkins.

3. American Society for Microbiology, May 2001, Orlando, FL. "The use of PFGE analysis in *Shigella sonnei* outbreak investigations," LA Wolf, B Jenkins.
4. Association of Public Health Laboratories, Infectious Disease Conference, March 2003. Denver, CO, "Characterization of North Carolina *Bordetella pertussis* strains by pulsed-field gel electrophoresis: 2000-2002," WA Glover, S Reid, LA Wolf.
5. American Society for Microbiology, May 2004, New Orleans, LA. "*Borrelia lonestari glpQ* gene detected in *Amblyomma americanum* ticks from southeastern Missouri and North Carolina," M. Pilgard, R. Bacon, R. Gilmore, L. Wolf, B. Engber, J. Piesman, M. Quintana, B. Johnson.
6. Infectious Disease Society of America, September 2004, Boston, MA. "Genetic Diversity of *Salmonella Enterica* Serotype Typhi and *Salmonella Enterica* Serotype Paratyphi from Nepal", Woods CW, Murdoch DR, Zimmerman MD, Glover WA, Wolf L, Belbase RH, Reller LB.
7. Association of Public Health Laboratories Annual Meeting, June 2016, Albuquerque, NM, "Review of Clinical and Non-clinical Features of Active TB Cases 2012-2014, Jefferson County, KY," Sadaf J. Warraich, Sandra Melendez, Maura E. Murphy, and Leslie A. Wolf.
8. Association of Public Health Laboratories Annual Meeting, June 2016, Albuquerque, NM, "Evaluation of reflex HIV 4<sup>th</sup> generation testing after rapid oral fluid HIV 1/2 testing for a local health department," Leslie A. Wolf, Jennifer A. Hong, Ian Santisteban, Cindy Maiorella, Teresa Fields, Matthew Johnson, and Ranjana Arora.
9. Clinical Virology Symposium, May 2017, Savannah, GA. "Multi-plexed, PCR Detection of *M. pneumoniae*, *C. pneumoniae*, and *L. pneumophila* in Broncho-alveolar Lavage and Oropharyngeal Swab Specimens, " J. T. Summersgill, L. Wolf, S. Marimuthu; Univ. of Louisville, Louisville, KY.
10. Association of Public Health Laboratories Annual Meeting, June 2017, Providence, RI, "Expanded mosquito surveillance activities, 2016, Louisville Metro/Jefferson County, KY," Leslie A. Wolf, R. Rochelle Ransom and R. Matthew Vanderpool.
11. Research!Louisville, September 2017, Louisville, KY, "Multiplexed RT PCR Detection of *Anaplasma phagocytophilum* and *Ehrlichia* spp. in Whole Blood Specimens Using the Luminex ARIES<sup>®</sup>," Subathra Marimuthu, Stephanie Lunn, Leslie Wolf, and James Summersgill.
12. Research!Louisville, September 2017, Louisville, KY, "Microbiological Work-up And Etiologies In Hospitalized Patients With CAP - Standards Of Care In Louisville, KY: Results From The University Of Louisville Pneumonia Study," Durgaprasad Gadireddi, Samreen Fathima, Praneet K.Srisailam, Thanh Van Thi Luong, Bilal Abaid, Connor L. English, Leslie Wolf, and Paula Peyrani.
13. Research!Louisville, October 2018, Louisville, KY. " Development of a Real-time PCR assay for *Pneumocystis jirovecii* on the Luminex ARIES<sup>®</sup> Platform." Subathra Marimuthu, Kuldeep Ghosh and Leslie A. Wolf.

14. Research!Louisville, September 2019, Louisville, KY. "Real-time PCR detection of *Streptococcus pneumoniae* in respiratory specimen BAL, whole blood, cerebrospinal fluid and urine using the Luminex ARIES® platform." Rocio B. Damiano, Subathra Marimuthu, Megan E. Greenwell and Leslie A. Wolf.

## PUBLICATIONS

### Non-peer Reviewed (Review article, invited)

1. **L. A. Wolf**, N.A. Cherry, R. G. Maggi, E. B. Breitschwerdt. In Pursuit of a Stealth Pathogen: Laboratory Diagnosis of Bartonellosis. *Clinical Microbiology Newsletter* March 1 2014, p. 33-39.

### Articles Published in Peer-Reviewed Journals

1. **L. Wolf** and R.G. Gill. "Xenoreactive T-cell lines initiate pancreatic islet xenograft destruction in vivo," *Transplantation Proceedings*, 25(1): 440, 1993.
2. R.G. Gill and **L. Wolf**. "Immunobiology of cellular transplantation," *Cell Transplantation*, 4(4): 361-370, 1995.
3. **L.A. Wolf**, M. Coulombe and R. G. Gill. "Donor antigen-presenting cell-independent rejection of islet xenografts," *Transplantation*, 60(10): 1164, 1995.
4. M. Coulombe, H. Yang, **L.A. Wolf** and R.G. Gill. "Tolerance to antigen-presenting cell-depleted islet allografts is CD4 T cell dependent," *Journal of Immunology*, 162: 2503-2510, 1999.
5. **L.A. Wolf** and S.M. Laster. "Characterization of arachidonic acid-induced apoptosis," *Cell Biochemistry and Biophysics*, 30(3): 353, 1999.
6. W.A. Gebreyes, S. Thakur, P. Dorr, D.A. Tadesse, K. Post, **L. Wolf**. Occurrence of *spvA* Virulence Gene and Clinical Significance for Multidrug-Resistant *Salmonella* strains. *Journal of Clinical Microbiology* 47(3): 777-780, 1999.
7. **L. Wolf**, T. McPherson, B. Harrison, B. Engber, A. Anderson and P. Whitt. "Prevalence of *Ehrlichia ewingii* in *Amblyomma americanum* in North Carolina," *Journal of Clinical Microbiology*, 38(7): 2795, 2000.
8. Outbreaks of *Salmonella* serotype Enteritidis Infection Associated with Eating Shell Eggs---United States, 1999-2001, *Morbidity and Mortality Weekly Report*, 51(51): 1149-1152, 2003.
9. C. Pilcher S. Fiscus, T. Nguyen, E. Foust, **L. Wolf**, D. Williams, R. Ashby, J Owen-O'Dowd, J.T. McPherson, B. Stalzer, L. Hightow, W. Miller, J. Eron, M. Cohen, P. Leone. "Detection of Acute Infections during HIV Testing in North Carolina," *The New England Journal of Medicine*, 352(18): 1873-1883, 2005.

10. C. Woods, D. Murdoch, M. Zimmerman, W. Glover, B. Basnyat, \***L. Wolf**, R. Belbase, L.B. Reller. "Emergence of *Salmonella enterica* serotype Paratyphi A as a major cause of enteric fever in Kathmandu, Nepal," *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 100(11):1063-7, 2006.
11. MacDonald PDM, Torok MR, Maillard J, Salyers M, **Wolf LA**, Nelson AL. Knowledge and practice of foodborne disease clinical specimen testing and reporting in North Carolina. *NC Med J*, 68:305-311, 2007.
12. K.E. Volpe Sperry, S. Kathariou, J.S. Edwards, \***L.A. Wolf**. Multiple-Locus Variable-Number Tandem-Repeat Analysis as a Tool for Subtyping *Listeria monocytogenes* Strains. *Journal of Clinical Microbiology*, 46(4): 1435-1450, 2008.
13. Sanders AP, Flood K, Chiang S, Herring AH, **Wolf L**, Fry RC (2012) Towards Prenatal Biomonitoring in North Carolina: Assessing Arsenic, Cadmium, Mercury, and Lead Levels in Pregnant Women. *PLoS ONE* 7(3): e31354. <https://doi.org/10.1371/journal.pone.0031354>.
14. Timothy L Wiemken, Stephen P Furmanek, William A Mattingly, Brian E Guinn, Rodrigo Cavallazzi, Rafael Fernandez-Botran, **Leslie Wolf**, Connor L English, Julio A Ramirez. Predicting 30-Day Mortality in Hospitalized Patients with Community-Acquired Pneumonia Using Statistical and Machine Learning Approaches, *University of Louisville Journal of Respiratory Infections*, 1(3), Summer 2017.
15. Subathra Marimuthu, James T. Summersgill, and **Leslie A. Wolf**. "Evaluation of a real-time *lytA* PCR assay for detection of *S. pneumoniae* in urine specimens from hospitalized patients with community acquired pneumonia," *University of Louisville Journal of Respiratory Infections*, Fall 2017, Volume 1, Issue 4; **DOI:** 10.18297/jri/vol1/iss4/5.
16. Subathra Marimuthu, **Leslie A. Wolf**, and James T. Summersgill. "PCR Detection of *Mycoplasma pneumoniae*, *Chlamydia pneumoniae* and *Legionella pneumophila* in Respiratory Specimens Using the ARIES System," *University of Louisville Journal of Respiratory Infections*, Winter 2018, Volume 2, Issue 1; **DOI:** 10.18297/jri/vol2/iss1/3.
17. Subathra Marimuthu, Kuldeep Ghosh, **Leslie A. Wolf**, "Development of a Real-time PCR assay for *Pneumocystis jirovecii* on the Luminex ARIES Platform, *University of Louisville Journal of Respiratory Infections*, Spring 2019, Volume 3, Issue 1; **DOI:** 10.18297/jri/vol3/iss1/5.
18. Marimuthu Subathra, Vidyulata Salunkhe, Stephen P. Furmanek, **Leslie A. Wolf**. "Association of Urine Levels of C-Reactive Protein with Clinical Outcomes in Patients with Pneumonia: A Pilot Study," *University of Louisville Journal of Respiratory Infections*, August 2019. **DOI:** 10.18297/jri/vol3/iss2/2
19. **Leslie A. Wolf**, Subathra Marimuthu, James T. Summersgill. "Detection of *Ehrlichia* spp. and *Anaplasma phagocytophilum* in whole blood specimens using a duplex real-time PCR assay on the ARIES instrument," *Ticks and Tickborne Infections*, in press, <https://doi.org/10.1016/j.ttbdis.2020.101387>.
20. Arnold, Forest W; Burns, Mark V; Mahmood, Kamran; Aden Darmaan; Furmanek, Stephen; Tella, Mahder; Glick, Connor; Raghuram, Anupama; Beavin, Leslie; Cavallazzi, Rodrigo; Balcom, Dawn; **Wolf, Leslie**; Palmer, Kenneth E; Carrico, Ruth; Ramirez, Julio A. and the Center of Excellence for Research in Infectious Diseases (CERID) Coronavirus Study Group (2020). "Endemic Human Coronaviruses in Hospitalized Adults with Community-Acquired Pneumonia in the City of Louisville, Kentucky," *The University of Louisville Journal of Respiratory Infections*: Vol 4, Issue 1, Article 1.

21. Ramirez, Julio A.; Carrico, Ruth; Cavallazzi, Rodrigo; Beavin, Leslie; Raghuram, Anupama; Burns, Mark V; Mahmood, Kamran; Aden Darmaan; Prabhu, Angeline; Balcom, Dawn; Furmanek, Stephen; **Wolf, Leslie**; Palmer, Kenneth E; Tella, Mahder; Glick, Connor; Arnold, Forest W and the Center of Excellence for Research in Infectious Diseases (CERID) Coronavirus Study Group (2020). "Community-Acquired Pneumonia Due to Endemic Human Coronaviruses Compared to 2019 Novel Coronavirus: A Review," *The University of Louisville Journal of Respiratory Infections*: Vol 4, Issue 1, Article 2.
22. Julio A. Ramirez, Kenneth E. Palmer, Ruth Carrico, Forest W. Arnold, Donghoon Chung, **Leslie Wolf** (2020). "Louisville Coronavirus Surveillance Program," *The University of Louisville Journal of Respiratory Infections*, Vol. 4: Iss.1, Article 3.

## AGREEMENT

**THIS PROFESSIONAL SERVICE CONTRACT**, made and entered into by and between the **LOUISVILLE/JEFFERSON COUNTY METRO GOVERNMENT**, by and through its **DEPARTMENT OF PUBLIC HEALTH AND WELLNESS** and the **LOUISVILLE METRO BOARD OF HEALTH** herein referred to as “**METRO GOVERNMENT**”, and the **UNIVERSITY OF LOUISVILLE** on behalf of its **SCHOOL OF MEDICINE, DEPARTMENT OF MEDICINE, DIVISION OF INFECTIOUS DISEASES** (“**UNIVERSITY**”), 501 East Broadway, Suite 100, Louisville, KY 40202.

### WITNESSETH:

**WHEREAS**, the Metro Government desires to employ a Laboratory Director (“Director”); and

**WHEREAS**, pursuant to K.R.S. 45A.380 the Metro Government has determined that competition is not feasible and that this Agreement is for the services of a professional; and

**WHEREAS**, Dr. Leslie Wolf is employed by the University pursuant to an employment contract (the “Employment Contract”) and has the requisite qualifications and experience; and

**WHEREAS**, University possesses the requisite experience and qualifications to provide the unique nature of the services desired by the Metro Government;

**NOW, THEREFORE**, it is agreed by and between the parties hereto as follows:

**I. SCOPE OF PROFESSIONAL SERVICES**

- A.** The parties agree that Dr. Leslie Wolf shall be appointed as Director as of the effective date of this Agreement.
- B.** University agrees as follows:
  - 1. Director’s responsibilities and duties, as Director of the LMPHW Laboratory, shall be decided by the LMPHW Health Director and shall include but not be limited items listed in Attachment A.

**C. ACCOUNTABILITY OF THE DIRECTOR**

1. Director shall be a University employee assigned to the LMPHW; and
2. With regard to Director's responsibilities to University, Director will be accountable to the appropriate Dean.

## **II. FEES AND COMPENSATION**

**A.** The Metro Government shall contribute to University one half of the Director's compensation (a sum of **THIRTY NINE THOUSAND SEVEN HUNDRED FIFTY DOLLARS (\$39,750)**), and shall provide payment to University on a monthly basis after receipt of a detailed invoice from University. The parties agree that the Director's annual compensation shall be **SEVENTY NINE THOUSAND FIVE HUNDRED DOLLARS (\$79,500)**, which may be adjusted in accordance with UofL policies and applicable laws, and which shall be paid by U of L.

University shall generate a University paycheck to Director. University further agrees that Director shall receive all usual and ordinary faculty benefits including fringe benefits through University.

In the event that the Metro Government terminates this Agreement, the Metro Government shall not be responsible for any further contribution to University for the University employee and the employee shall no longer hold the Director position. University shall then solely determine the employee's wage and duties.

In the event that University terminates Director, University shall not be responsible for any further compensation of the employee; provided, however, the Metro Government shall then have the opportunity to hire the terminated University employee. The Metro Government shall then solely determine the employee's wage and duties.

In the event a Director terminates her employment with University for any reason or if Metro Government is unable to directly hire a Director that has been terminated by



University (as outlined above), the parties will work together to identify, recruit and hire a replacement Director that is satisfactory to both parties (provided that no payments shall be due under this Agreement from Metro Government during the period when the Director position is vacant).

In the event that University were to increase its portion of the Director's salary, that will in no way increase the obligation of Metro Government.

The Metro Government shall contribute to University upon receipt of an invoice for same **ELEVEN THOUSAND THREE HUNDRED TWENTY EIGHT DOLLARS AND FIFTY CENTS (\$11,328.50)** toward payment of Director's fringe benefits.

Total annual payments to University by Louisville Metro under this Agreement shall not exceed **FIFTY ONE THOUSAND SEVENTY NINE DOLLARS (\$51,079.00)**, which amount reflects Louisville Metro's obligation to pay one half of the Director's salary and its contribution toward payments of Director's fringe benefits provided by University.

**B.** The Metro Government shall reimburse out-of-pocket expenses if they are reasonable in amount and necessary to accomplish the scope of services of this Agreement. The Metro Government will not reimburse first class air fare, personal phone calls, short-term parking expenses, or other premium type expenses. The Metro Government reserves the right to reduce or disallow expenses considered excessive or unnecessary under this contract.

**C.** University agrees that all outstanding invoices at the end of the fiscal year (June 30) must reach the Metro Government no later than July 15 of the following fiscal year. University agrees that original invoices that are not in Metro Government

possession by this time will not be paid and University agrees to waive its right to payment for services billed under such invoices.

**III. DURATION**

**A.** This Agreement shall begin October 1, 2020 and shall continue through and including September 30, 2021.

**B.** This Agreement may be terminated by submitting thirty (30) days' written notice to the non-terminating party of the intent to terminate. This Agreement may also be terminated by any party, without notice to the non-terminating party, because of fraud, misappropriation, embezzlement or malfeasance or a party's failure to perform the duties required under this Agreement. A waiver by either party of a breach of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

**C.** In the event of termination, payment for services complete up to and including date of termination shall be based upon work completed at the rates identified in this Agreement. In the event that, during the term of this Agreement, the Metro Council fails to appropriate funds for the payment of the Metro Government's obligations under this Agreement, the Metro Government's rights and obligations herein shall terminate on the last day for which an appropriation has been made. The Metro Government shall deliver notice to University of any such non-appropriation not later than 30 days after the Metro Government has knowledge that the appropriation has not been made.

**IV. EMPLOYER/EMPLOYEE RELATIONSHIP**

It is expressly understood that no employer/employee relationship is created by this Agreement nor does it cause University to be an officer or official of the Metro Government. By executing this Agreement, the parties hereto certify that its performance will not constitute or establish a violation of any statutory or common law principle

pertaining to conflict of interest, nor will it cause unlawful benefit or gain to be derived by either party.

**V. RECORDS-AUDIT**

University shall maintain during the course of the work, and retain not less than five years from the date of final payment on the contract, complete and accurate records of all of University's costs which are chargeable to the Metro Government under this Agreement.

**VI. DEFENSE AND INDEMNITY**

If a claim for money damages is brought against the Director, the Metro Government agrees to defend and indemnify her as if she were a Metro employee covered by KRS 65.200-.2006 and Louisville Metro Codified Ordinances Sections 35.180-35.183.

**VII. REPORTING OF INCOME**

The compensation payable under this Agreement may be subject to federal, state and local taxation. Regulations of the Internal Revenue Service require the Metro Government to report all amounts in excess of \$600.00 paid to non-corporate contractors. University agrees to furnish the Metro Government with its taxpayer identification number (TIN) prior to the effective date of this Agreement. University further agrees to provide such other information to the Metro Government as may be required by the IRS or the State Department of Revenue.

**VIII. GOVERNING LAW**

This Agreement shall be governed by and construed in accordance with the laws of the State of Kentucky. In the event of any proceedings regarding this Agreement, the Parties agree that the venue shall be Franklin Circuit Court, Frankfort,

Kentucky. All parties expressly consent to personal jurisdiction and venue in such Court for the limited and sole purpose of proceedings relating to this Agreement or any rights or obligations arising thereunder. Service of process may be accomplished by following the procedures prescribed by law.

**IX. AUTHORITY**

The University, by execution of this Agreement, does hereby certify and represent that it is qualified to do business in the State of Kentucky, has full right, power and authority to enter into this Agreement.

**X. CONFLICTS OF INTEREST**

Pursuant to KRS 45A.455:

(1) It shall be a breach of ethical standards for any employee with procurement authority to participate directly in any proceeding or application; request for ruling or other determination; claim or controversy; or other particular matter pertaining to any contract, or subcontract, and any solicitation or proposal therefor, in which to his knowledge:

(a) He, or any member of his immediate family has a financial interest therein; or

(b) A business or organization in which he or any member of his immediate family has a financial interest as an officer, director, trustee, partner, or employee, is a party; or

(c) Any other person, business, or organization with whom he or any member of his immediate family is negotiating or has an arrangement concerning prospective employment is a party. Direct or indirect participation shall include but not be limited to involvement through decision, approval, disapproval, recommendation, preparation of

any part of a purchase request, influencing the content of any specification or purchase standard, rendering of advice, investigation, auditing, or in any other advisory capacity.

(2) It shall be a breach of ethical standards for any person to offer, give, or agree to give any employee or former employee, or for any employee or former employee to solicit, demand, accept, or agree to accept from another person, a gratuity or an offer of employment, in connection with any decision, approval, disapproval, recommendation, preparation of any part of a purchase request, influencing the content of any specification or purchase standard, rendering of advice, investigation, auditing, or in any other advisory capacity in any proceeding or application, request for ruling or other determination, claim or controversy, or other particular matter, pertaining to any contract or subcontract and any solicitation or proposal therefor.

(3) It is a breach of ethical standards for any payment, gratuity, or offer of employment to be made by or on behalf of a subcontractor under a contract to the prime contractor or higher tier subcontractor or any person associated therewith, as an inducement for the award of a subcontract or order.

(4) The prohibition against conflicts of interest and gratuities and kickbacks shall be conspicuously set forth in every local public agency written contract and solicitation therefor.

(5) It shall be a breach of ethical standards for any public employee or former employee knowingly to use confidential information for his actual or anticipated personal gain, or the actual or anticipated personal gain of any other person.

#### **XI. ENTIRE AGREEMENT**

This Agreement constitutes the entire agreement and understanding of the parties with respect to the subject matter set forth herein and this Agreement supersedes any

and all prior and contemporaneous oral or written agreements or understandings between the parties relative thereto. No representation, promise, inducement, or statement of intention has been made by the parties that is not embodied in this Agreement. This Agreement cannot be amended, modified, or supplemented in any respect except by a subsequent written agreement duly executed by all of the parties hereto.

**XII. SUCCESSORS**

This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, successors and assigns.

**XIII. SEVERABILITY**

If any court of competent jurisdiction holds any provision of this Agreement unenforceable, such provision shall be modified to the extent required to make it enforceable, consistent with the spirit and intent of this Agreement. If such a provision cannot be so modified, the provision shall be deemed separable from the remaining provisions of this Agreement and shall not affect any other provision hereunder.

**XIV. COUNTERPARTS**

This Agreement may be executed in counterparts, in which case each executed counterpart shall be deemed an original and all executed counterparts shall constitute one and the same instrument.

**XVI. CALCULATION OF TIME** Unless otherwise indicated, when the performance or doing of any act, duty, matter, or payment is required hereunder and a period of time or duration for the fulfillment of doing thereof is prescribed and is fixed herein, the time shall be computed so as to exclude the first and include the last day of the prescribed or fixed period of time. For example, if on January 1, University is directed

to take action within ten (10) calendar days, the action must be completed no later than midnight, January 11.

**XVII. CAPTIONS** The captions and headings of this Agreement are for convenience and reference purposes only and shall not affect in any way the meaning and interpretation of any provisions of this Agreement.

**XVIII. MISCELLANEOUS** University agrees that, in the event it receives from the Metro Government any protected health information, it will not disclose any of that information to any third party unless the disclosure complies with the rules and regulations of the Health Insurance Portability and Accountability Act (“HIPAA”), codified in 42 U.S.C. § 1320d and 45 C.F.R. 160-164. University shall hold in strictest confidence all documentation, information, and observations gathered in the performance of this Agreement, and University agrees to negotiate and execute a mutually acceptable Health Department Business Associate Agreement, if applicable for the project. University further agrees to require any of its subcontractors to both abide by the aforementioned HIPAA prohibitions against the unauthorized disclosure of confidential and protected health information and to sign an approved Metro Government’s Business Associate Agreement that contains substantially the same terms as the Metro Government’s Business Associate Agreement.

The Metro Government and University agree to comply with Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d *et. seq.*) and all implementing regulations and executive orders, and section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 701) and the Kentucky Equal Employment Act of 1978 (K.R.S. § 45.550 to 45.640) and the Americans with Disabilities Act (42 U.S.C. § 12101 *et. seq.*). No person shall be excluded from participation in, be denied the benefits of, or be subject to discrimination in relation

to activities carried out under this Agreement on the basis of race, color, age, religion, sex, disability or national origin. This includes provision of language assistance services to individuals of limited English proficiency seeking and/or eligible for services under this Agreement.

University nor any of its employees or personnel shall speak on behalf of or as a representative of the Metro Government or the Department of Public Health and Wellness without the express authorization of the Director of that Department or his designee.

The University shall reveal any final determination of a violation by the University or subcontractor within the previous five (5) year period pursuant to KRS Chapters 136, 139, 141, 337, 338, 341 and 342 that apply to the University or subcontractor. The University shall be in continuous compliance with the provisions of KRS Chapters 136, 139, 141, 337, 338, 341 and 342 that apply to the University or subcontractor for the duration of the contract.



WITNESS the agreement of the parties hereto by their signatures affixed hereon.

APPROVED AS TO FORM AND LEGALITY CONTINGENT UPON METRO COUNCIL APPROVAL OF THE APPROPRIATION FOR THIS AGREEMENT:

LOUISVILLE/JEFFERSON COUNTY METRO GOVERNMENT

DocuSigned by:

*Paul Rutherford*

MICHAEL J. O'CONNELL  
JEFFERSON COUNTY ATTORNEY

*Sarah S. Moyer*

DR. SARAH S. MOYER  
DIRECTOR, DEPARTMENT FOR PUBLIC HEALTH AND WELLNESS

Date: 8/31/2020

Date: 9-4-2020

UNIVERSITY OF LOUISVILLE

*Toni M. Ganzel*

DR. TONI GANZEL, M.D.  
VICE PRESIDENT FOR ACADEMIC MEDICAL AFFAIRS

Date: 8/31/2020



Attachment A - Lab Director Scope of Work

- Carry out the responsibilities established by the Clinical Laboratory Improvement Amendments (CLIA) that can only be assumed by a qualified laboratory director.
- Represent the LMPHW with other agencies and programs such as the Kentucky State Laboratory, Region 6 Emergency Response District, and the Louisville Metro Medical Subgroup Emergency Response subcommittee.
- Function as the Laboratory Director for the Specialty Clinic and other small clinic laboratories that operate under a separate CUA certificate from the 430 East Gray Laboratory.
- Ensure the proper operation of the laboratory; including the development and implementation of a sustainable business plan. Be accessible to the lab to provide onsite, telephone or electronic consultation as needed.
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed.
- Ensure the environment for employees is safe from physical, chemical, and biological hazards and that safety and biohazard requirements are followed.
- Establish and participate on a performance improvement committee and a safety committee which meet monthly, at a minimum.
- Ensure testing systems provide quality lab services for pre-analytic, analytic, and post-analytic phases of testing.
- Establish a performance improvement program to include employee health and safety, pre-post analytical evaluations, quality control practices, proficiency evaluations, corrective actions, environmental assessments and other monitors consistent with CUA.
- Ensure test methods selected have the capability of providing quality results.
- Ensure verification procedures used are adequate to determine accurate precision, and other pertinent performance characteristics of the method.
- Ensure that reports of test results include pertinent information required for interpretation.
- Ensure that consultation is available to the lab's clients on matters relating to the quality of the test results reported and their interpretation concerning specific tests.
- Ensure that an appropriate procedure manual is available and routinely updated to reflect procedures based on best practice and changes in the field.
- Ensure that prior to testing patients' specimens, all personnel have the appropriate

education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

- Ensure that lab personnel are performing the test methods as required for accurate and reliable results.
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical and post-analytical phases of testing to verify that they maintain competency.
- Ensure that the lab is enrolled in a proficiency testing (PT) program.
- Ensure that PT results are returned on time to the PT program.
- Ensure that PT samples are tested in the same manner as patient samples.
- Ensure that quality control and quality assurance programs are established and maintained to identify failures in quality as they occur.
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
- Ensure that remedial actions are taken and documented whenever any deviations from the lab's established performance characteristics are identified and patient test results are correctly reported.