MEMORANDUM OF AGREEMENT
Cooperative Services Agreement during Emergency Situations

Between

Public Health Laboratory for State A

and

Public Health Laboratory for State B

Subject:

Cooperative Laboratory Services Agreement during Emergency or Critical Situations related to Variola virus (Small Pox) testing.

1. Purpose:

To establish guidance and outline the respective functions of the parties to the Memorandum of Agreement (MOA) with respect to providing laboratory testing capacity during emergency situations related to Variola virus testing.

2. Background:

Laboratory A as a member of the Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) has a mission to provide laboratory diagnostic support to the state. The Laboratory A Biosecurity Laboratory has been designated by the CDC as a Confirmatory Level Laboratory for Variola virus and as such, is uniquely equipped to respond to real or suspected biological agent attacks from this agent.

The intent of this agreement is to provide Laboratory B with a resource laboratory (Laboratory A) for testing human-source specimen(s) for Variola virus following completion of Varicella-Zoster and Vaccinia virus testing by Laboratory B. There may be occasion, based on the CDCs patient symptoms/risk criteria that initial PCR (Polymerase Chain Reaction) analysis may be required to be performed at Laboratory A.

This agreement addresses the willingness of Laboratory A to provide laboratory testing capabilities for Laboratory B during an emergency situation involving testing required for Variola virus. There is presently no laboratory diagnostic capability at Laboratory B for Variola virus in the Laboratory B’s state.

This agreement is entered on voluntary basis and describes the aid that is projected to be
available at the time of an emergency situation by Laboratory B without the binding commitment to provide this assistance.

3. Definition:

An emergency situation can be declared by Laboratory B when laboratory testing of human-source specimens for Variola virus resulting from a real or perceived terrorist attack is needed. The emergency may not meet the federal or state definitions of a widespread emergency, and may arise out of a situation external to either the state of Laboratory B or the state of Laboratory A or the United States.

4. Responsibilities:

4.1 Laboratory A agrees to:

4.1.1 Maintain all requirements necessary to retain status as a LRN Member at the confirmatory B/C level.

4.1.2 Comply with the Federal Acquisition Regulations that require the laboratory to prioritize surge capacity testing of the selected bioterrorism agents over standard Laboratory Activities in the Biosafety Level 3 (BSL3) laboratory.

4.1.3 Conform to Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition facility and practice criteria and provide vaccination of employees when appropriate.

4.1.4 Conform to existing requirements of the Select Agent Rule, USA PATRIOT Act of 2001, and BMBL 5th Edition Appendix F for facility and personnel security.

4.1.5 Meet the Health Insurance Portability and Accountability Act (HIPAA) requirements in managing clinical specimens and results (this may require a Laboratory B provided link (such as a PHIX up link).

4.1.6 Participate in CDC-sponsored proficiency testing for Variola, Vaccinia and Varicella-Zoster viruses.

4.1.7 Use only CDC LRN protocols and reagents when conducting PCR-based confirmation testing of Variola, Vaccinia and Varicella-Zoster viruses.

4.1.8 Immediately report positive confirmation results to Laboratory B and the CDC.

4.1.9 Provide 24/7 services when requested by Laboratory B.

4.1.10 Interact with the FBI Weapons of Mass Destruction Coordinator and provide expert witness testimony if required.

4.1.11 Surrender any and all LRN reagent stocks received directly from Laboratory B
immediately in the event the MOA is terminated under Section 5.2 herein.

4.2 Kansas Department of Health and Environment agrees to:

4.2.1 Provide the appropriate specimens to the Laboratory A for determination of the presence or absence of Variola virus nucleic acid from patients presenting with symptoms suggestive of smallpox following the CDC LRN rule-out procedures for Varicella-Zoster and Vaccinia virus at Laboratory B.

4.2.2 Provide for disposal of medical waste and maintain itemized list of costs incurred for reimbursement by Laboratory A.

4.2.3 Provide for transportation of the specimens to and from Laboratory A and pay for all costs related to such specimen(s) transportation.

4.2.4 Provide results of laboratory tests in an electronic or paper version in a confidential manner determined by Laboratory A.

5. Effective Date:

5.1 This MOA will become effective on the date all parties have affixed their signature hereto. This MOA supersedes any previous agreements.

5.2 This MOA will remain in effect indefinitely unless either the leading party at Laboratory B or the leading party at Laboratory A requests termination of this agreement. A 30-day written notice is expected to be given by either party to terminate this agreement. The 30 day notice may be waived if it is determined necessary by the leading party at Laboratory B at any time to be in the interests of the Laboratory B mission requirements to terminate the agreement without notice. The 30 day notice may be waived if it is determined necessary by the Laboratory A leading party, at any time, to be in the interests of the Laboratory A mission requirements to terminate the agreement without notice.

5.3 This MOA shall not be altered, changed, modified or amended except by written consent of all the parties.

5.4 When all signatures have been affixed, Laboratory B will duplicate the document, maintain the original, and provide copies to the Laboratory A leading party and any other identified individuals within BOTH organizations.

5.5 This MOA has been reviewed and agreed upon by all responsible parties indicated by the authorized representatives of Laboratory B and Laboratory A.

Authorized Signatures: