

MEMORANDUM OF AGREEMENT
Cooperative Services Agreement during Emergency Situations

BETWEEN

The Board of Regents of the University of Nebraska,
a public body corporate for and on behalf of
the University of Nebraska Medical Center,
Nebraska Public Health Laboratory
University of Nebraska Medical Center
986495 Nebraska Medical Center
Omaha, NE 68198-6495

AND

Kansas Department of Health and Environment (KDHE)
6700 SW Topeka Blvd. Forbes Field Bldg 740
Topeka, KS. 66620

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:

The Nebraska Public Health Laboratory (NPHL) located at the University of Nebraska Medical Center (UNMC), in Omaha, NE is responsible for providing laboratory services to Nebraska Department of Health and Human Services. The NPHL, 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 NPHL 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 the Kansas Department of Health and Environment (KDHE) with a resource laboratory (the NPHL) for testing human-source specimen(s) for Variola virus following completion of Varicella-Zoster and Vaccinia virus testing by the KDHE. There may be occasion, based on the CDC's patient symptoms/risk criteria, that initial PCR (Polymerase Chain Reaction) analysis may be required to be performed at the NPHL.

This agreement addresses the willingness of the NPHL to provide laboratory testing capabilities for the KDHE during an emergency situation involving testing required for Variola virus. There is presently no laboratory diagnostic capability at KDHE for Variola virus in Kansas.

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 the KDHE without the binding commitment to provide this assistance.

3. Definition:

An emergency situation can be declared by KDHE 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 wide-spread emergency, and may arise out of a situation external to Kansas, Nebraska or the United States.

4. Responsibilities:

4.1 Nebraska Public Health Laboratory 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 KDHE 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 KDHE and the CDC.

4.1.9 Provide 24/7 services when requested by KDHE.

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 the KDHE 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 NPHL 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 KDHE.

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

4.2.3 Provide for transportation of the specimens to and from the NPHL 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 the NPHL.

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 Secretary of the KDHE or the Director of the NPHL at UNMC 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 Secretary of the KDHE at any time, to be in the interests of the KDHE mission requirements to terminate the agreement without notice. The 30 day notice may be waived if it is determined necessary by the NPHL Laboratory Director, at any time, to be in the interests of the NPHL 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, the KDHE will duplicate the document, maintain the original, and provide copies to the NPHL Director 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 the KDHE and the NPHL at UNMC.

KDHE:

[Redacted]

Leo G. Henning
Interim Laboratory Director
Kansas Department of Health and Environment

4-30-12
(Date)

[Redacted]

Dr. Robert Moser
Secretary,
Kansas Department of Health and Environment

5/21/12
(Date)

For the Board of Regents:

[Redacted]

Deborah Thomas
Associate Vice Chancellor
For Business and Finance

4-3-12
(Date)

NPHL Laboratory Director:

[Redacted]

Dr. Steven Hinrichs
Director,
Nebraska Public Health Laboratory

4/9/12
(Date)