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JUL 08 2009

DHB

MEMORANDUM FOR: ELLEN P. EMBREY, DEPUTY ASSISTANT SECRETARY OF DEFENSE (FHP&R), PERFORMING THE DUTIES OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

SUBJECT: Recommendations Pertaining to the Transfer, Storage, and Oversight of the Warren Air Force Base Cohort Serum Repository and Data Assets

1. References:

   a. Kolata, G. Old Blood Samples Offer New Clues to a Medical Mystery. The New York Times, 11 April 2000.

   b. Memorandum of Recommendation, Armed Forces Epidemiological Board, Warren Air Force Base Serum Repository, 25 March 2005.

   c. Memorandum from Assistant Secretary of Defense for Health Affairs (ASD(HA)), Transfer of Warren Air Force Base Serum Repository to the Department of Defense, 8 September 2005.

   d. Status Briefing to the Defense Health Board: The Warren Air Force Serum Collection, by Edward L. Kaplan, M.D., Professor of Pediatrics, University of Minnesota Medical School, 7 May 2009.

BACKGROUND

2. Sera in the Warren Air Force Base serum repository were collected from more than 30,000 Air Force recruits during the Korean Conflict. The sera were obtained as a part of the extensive studies of streptococcal infections and rheumatic fever carried out by Dr. Charles Rammelkamp, Dr. Lewis Wannamaker, Dr. Floyd Denny, Dr. Harold Houser and others. These studies and the on-base laboratory were established and funded by the Department of Defense (DoD) based on the recommendation of the Armed Forces Epidemiological Board (AFEB).

3. Much of what is known about the epidemiology, natural history and treatment of group A streptococcal infections as well as prevention of complications was learned during the Warren studies between 1949 and 1952. The Warren laboratory and group of investigators were awarded a Lasker Prize for these sentinel studies in 1954.

4. Shortly before his retirement in the late 1970s, Dr. Rammelkamp entrusted the entire collection to Dr. Edward Kaplan (Department of Pediatrics, University of Minnesota Medical

School, Minneapolis) with the proviso that he serve as guardian of the collection and to make certain that only deserving scientific studies would be selected for future use of the sera.

5. The collection consists of approximately 45,000 vials. The mean amount of serum in each vial is greater than 4.0 ml. The samples have always been frozen and have been maintained for the past five decades at -20 degrees Celsius. The collection is carefully catalogued in a computer database at the University of Minnesota and a partial database at the Medical Follow up Agency at the Institute of Medicine (for collaborative studies).

6. In December 2004, Dr. Kaplan was requested to brief the AFEB about the collection and its significance. This briefing resulted in a unanimous recommendation by the Board to the then Assistant Secretary of Defense for Health Affairs (ASD (HA)), Dr. William Winkenwerder, that the collection be returned to the guardianship of the DoD because of its value to the Department and because it has always been the property of the DoD. (See attached memorandum of March 2005.)

7. As a consequence, in September 2005 the ASD (HA), Dr. Winkenwerder, agreed with the Board's recommendation regarding the value of the collection to the DoD, and agreed that the collection should be retained by DoD. He directed that the collection be taken charge of by the Armed Forces Institute of Pathology (AFIP) (See attached memorandum by Dr. Winkenwerder dated September 2005.). However, soon thereafter the Base Realignment and Closure (BRAC) Commission announced the future closure of the AFIP, thus requiring the identification of an alternative location to receive and store the Warren serum collection.

8. Since that time, Dr. Kaplan has maintained guardianship of the repository without any external financial support to do so.

9. In November 2008, a proposed plan was formulated by the involved parties to relocate the collection to Wright-Patterson Air Force Base, (where there are facilities to store the frozen collection) and to include a role for the Medical Follow up Agency of the Institute of Medicine to be accorded a significant responsibility in oversight of the maintenance and utilization of sera in the repository. A tentative agreement was reached that this change be funded by the DoD.

10. The successor to the AFEB, the Defense Health Board (DHB), received a second and updated briefing from Dr. Kaplan at its May 2009 meeting. (See attached power point presentation from Dr. Kaplan's briefing).

FINDINGS

11. During its meeting held on 7 May 2009, the DHB reaffirmed the previous recommendation issued by the AFEB which emphasized the irreplaceable scientific value of the Warren Air

Force Base serum collection and accompanying data assets for the DoD, and more generally, for the medical, scientific, and public health communities at large.

12. The DHB also reaffirmed that the DoD rightfully has ownership of this unique resource, as it has since the collection was created between 1949 and 1953.

CONCLUSION

13. In summary, this unique collection of more than 45,000 sera gathered as a part of AFEB initiated, directed and funded studies more than fifty years ago has the documented potential for innovative scientific, medical and public health related studies to benefit DoD directly as well as the scientific and medical communities outside of the DoD.

14. The recommendations below represent the unanimous opinion of the Members of the Infectious Disease Subcommittee of the DHB, including those several members of the Infectious Disease Subcommittee present at the 7 May 2009 DHB meeting.

RECOMMENDATIONS

15. The DHB recognizes that the transfer of this serum collection is a matter of urgency. It is recommended that DoD take immediate steps to transfer the serum collection to a facility in which DoD (in collaboration with the Medical Follow-Up Agency (MFUA) of the Institute of Medicine) can provide storage facilities, maintain control and regulate access to the collection for future use to answer questions of importance to the DoD as well as to the wider medical and scientific community.

16. The DHB recommends that the DoD, through the Office of the ASD (HA), establish a governance structure to continue to maintain scientific oversight of this serum collection and the associated medical information. The governance structure should include DoD personnel with infectious disease expertise (including expertise in clinical laboratory science and surveillance for emerging infectious diseases threats to force health protection), representative(s) of the MFUA (as manager of the medical information associated with the serum collection), and representative(s) from the Infectious Disease Control Subcommittee of the Defense Health Board as well as representatives with appropriate expertise from outside of the DoD sub-committee

17. The above recommendations were unanimously approved.

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FOR THE DEFENSE HEALTH BOARD:

Gail Wilensky, PhD
President, Defense Health Board

Gregory A. Poland, MD
Chair, Infectious Disease Control Subcommittee

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