

November 29, 2016

The Honorable Sylvia M. Burwell  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Madam Secretary:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendation pertaining to the Laboratory-Associated Incident Reporting System (LAIRS), developed for United States (US) clinical laboratory reporting of safety-related incidents.

#### BACKGROUND

CLIAC is the federal advisory committee charged with the responsibility of advising HHS on issues related to the Clinical Laboratory Improvement Amendments of 1998 (CLIA), as well as technological advances affecting general clinical laboratory quality and laboratory medicine. This includes issues of clinical laboratory safety that fall under the overarching umbrella of laboratory quality. During the November 5-6, 2014 CLIAC meeting, and at subsequent meetings since that time, the Committee has deliberated on laboratory safety and biosafety in the US, and has provided two related recommendations. The first was made at the April 15-16, 2015 meeting, when CLIAC recommended that HHS provide oversight that ensures the safety of all laboratory practices including decontamination of laboratory instruments, biosafety training, evaluation of the safety of all laboratory practices, and the development of a process for investigating and reporting laboratory-acquired infections. During the April 13-14, 2016 CLIAC meeting, the Committee recommended that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories. At the recent November 2-3, 2016 CLIAC meeting, CDC updated the Committee on progress made in forming the Clinical Biosafety Improvement Taskforce and LAIRS, a system developed jointly by CDC, NIH, and FDA. After deliberation on the issues, the Committee voted to provide the following recommendation to HHS.

## RECOMMENDATION

CLIAC proposes that the voluntary Laboratory-Associated Incident Reporting System (proposed by the CDC Blue Ribbon Panel recommendation in 2012) protect the privacy and confidentiality of reporting individual(s) and larger entities, e.g. via anonymity. The system should borrow from the principles of existing event-reporting systems and focus on incidents, near-misses, and mitigation measures that affect the safety of laboratory professionals. Finally, it should foster a non-punitive culture for reporting.

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to advance laboratory safety and quality in the U.S. CLIAC is committed to providing HHS thoughtful advice in support of this effort. Thank you for your consideration.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via email at [rarnaout@bidmc.harvard.edu](mailto:rarnaout@bidmc.harvard.edu) or by telephone at 617-538-5681.

Sincerely,



Ramy A. Arnaout, M.D, D. Phil  
Chairperson  
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:

Dr. Thomas Frieden  
Director, CDC

Dr. William R. Mac Kenzie CLIAC Designated Federal Official  
Deputy Director for Science, Center for Surveillance, Epidemiology, and  
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Dr. Reynolds M. Salerno, CLIAC Ex-Officio  
Director, Division of Laboratory Systems, CDC

Ms. Karen Dyer, CLIAC Ex-Officio  
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