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May 4, 2015

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

Dear Madam Secretary:

The Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC), met on Thursday, April 23, 2015, to consider the following report: Recommendations of the Advisory Committee to the Director, CDC Concerning the National Institutes of Health Intramural Laboratory Safety Program.

The Advisory Committee to the Director unanimously approved forwarding the enclosed report to you for distribution as appropriate.

If you have any questions about the report, please feel free to contact me via email at aeg1@gwu.edu or by telephone at (202) 994-0612.

Sincerely,



Alan E. Greenberg, M.D., M.P.H.
Chair

Enclosure

Recommendations of the Advisory Committee to the Director, CDC
Concerning the National Institutes of Health Intramural Laboratory Safety Program
23 April 2015

In July 2014, CDC announced the formation of the External Laboratory Safety Workgroup (ELSW) of the Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention. Although the ELSW was established as a workgroup of the ACD, CDC, HHS Secretary Burwell charged ELSW to review laboratory safety practices at the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), in addition to CDC. As a workgroup of the ACD, the ELSW reports directly to the ACD. ELSW proposals are presented to the ACD, and, if adopted, they are provided to the CDC Director and then to the HHS Secretary. At the April 23, 2015, meeting of the ACD, the ELSW presented its observations and proposals regarding the NIH's intramural laboratory safety program. The ELSW met with NIH occupational health and safety leadership and staff via teleconference since September 2014, and they had a four-day on-site meeting at NIH's facilities in Bethesda and Frederick, Maryland, in February 2015. The proposals were drawn from information gathered from these discussions in staff engagement sessions, in-person observations of laboratories, and a review of protocols, policies, and procedures related to laboratory safety at the agency. Below are the recommendations of the ACD, CDC, that were adopted at the April 2015 meeting.

1. **Observation:** The research community world-wide looks to the NIH for leadership in the realm of research and laboratory safety. The NIH Intramural DOHS Program is a model program for institutions supporting extramural NIH research as well as for other institutions and agencies. The commitment of NIH leadership toward laboratory safety is evident and is demonstrated at all levels examined by the ELSW. Safety awareness is viewed as an expectation and this philosophy is exemplified via the involvement of senior NIH leadership in the safety infrastructure supporting the NIH Intramural Programs. For example, the NIH Deputy Director of Intramural Research serves as chair of the Dual-Use Research of Concern (DURC) Review Committee. Education and training, including in the realm of laboratory safety, are viewed as fundamental missions of the NIH and this message is communicated with clarity throughout the NIH campus. A good example of the commitment of leadership to safety and security can be found in a review of the incident involving the discovery of the previously unaccounted-for vial of smallpox in a freezer on the NIH campus. This finding was promptly communicated to the NIH Director, who responded by providing a clear, unambiguous and decisive response that resulted in the highly publicized "biosafety stand-down" which was REQUIRED for all labs affiliated with the NIH Intramural Program and strongly encouraged for all extramural grantee institutions. This incident and the response to it are demonstrative of clear and prompt reporting of incidents and local responsibility to respond appropriately. The Division of Occupational Health and Safety staff facilitated and executed the NIH Director response mandate and the NIH community seemed to be cooperative and committed to this response. Another clear demonstration of NIH leadership commitment to research safety was the sentiment we heard from numerous persons that when additional financial resources are needed for an unanticipated challenges in the realm of safety, the resources are identified and provided. Again, the discovery of the small pox vial led to the hiring of

additional staff to exhaustively inventory every freezer, refrigerator and cold room on the NIH campus during the “biosafety stand-down.”

2. Observation: Governance structures and committees (e.g. Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Institute Safety Committees) are supportive in maintaining a culture of shared responsibility and accountability across the Institutes. An electronic database system (PI Dashboard) has been established and is seen by the NIH intramural research community as a useful tool to communicate around issues of research safety and compliance. Support staff who are assigned to administer these safety governance structures take ownership and responsibility toward safety. The scope of protocols reviewed by the Institutional Biosafety Committee (IBC) appears to include recombinant microorganisms as well as work involving non-recombinant pathogenic microorganisms (Risk Group 2, 3 and 4), although there was some inconsistency noted as to whether research involving non-recombinant organisms was reviewed by the IBC. This inconsistency may stem from the IBC’s practice to delegate approval authority to the Institutional Biosafety Officer (BSO) for protocols involving non-recombinant Risk Group 2 pathogens. In addition, under the current system, the IBC protocols have no term limits or expiration dates.
 - Recommendation: The Institutional BSO is an extremely competent, dedicated biosafety professional who does an exemplary job in conducting the preliminary review of all protocols submitted to the IBC and in approving those protocols involving non-recombinant Risk Group (RG) 2 pathogens. We believe that the resources devoted to this effort should be expanded to include at least one additional staff person appropriately trained to serve in this review function. We recommend further that the IBC participate at some level in the review of these RG 2 protocols.
 - Recommendation: IBC protocols are kept current by submission of protocol amendments via an electronic protocol submission and approval system. However, we recommend that the NIH IBC consider assigning an expiration date for each protocol such that these protocols are periodically reviewed in their entirety. We recommend that the tenure of an IBC protocol not exceed five (5) years.
 - Recommendation: Dedicated NIH scientists serve on the NIH IBC and other safety committees. We recommend that these scientists be acknowledged for their service and that incentives for such committee service be considered.
3. Observation: Risk assessment of research proposals are performed in a collaborative effort that involves the Principal Investigator (PI), the Institutional Biosafety Committee, and the Biosafety Officer (BSO) and other DOHS staff. As stated above, the IBC considers all rDNA protocols, but review of protocols involving non-recombinant RG 2 pathogens are delegated to the BSO for review. It is not clear that the protocol- driven risk assessment process is a full risk assessment. While it

does systematically try to identify risks, it does not always ask PIs to consider alternative processes that would further mitigate the risk.

- Recommendation: As stated above, we recommend that the IBC participate at some level in the review of protocols involving RG2 pathogens. We believe that the manner in which the NIH chooses to involve the IBC in the review of non-recombinant RG2 protocols is best determined by NIH.
 - Recommendation: The IBC review process be augmented so as to build in questions throughout the assessment process that continually ask PIs whether and how they have considered ways to approach an experiment in ways that would further mitigate risks associated with the proposed research activity.
 - Recommendation: DOHS should consider amending the risk assessment questions that are asked of the PI about DURC (i.e. the questions derived from the Fink Committee report). The PI should be asked not just about the potential for harm if the research were used deliberately and maliciously, but also about the potential for harm to the public if an accident were to occur in the course of this research.
4. Observation: The Division of Occupational Health and Safety (DOHS) is recognized across the NIH as the central authority in support and promotion of laboratory and research safety programs at the NIH. The Director of DOHS demonstrates strong leadership and command for service-oriented, risk-based safety programs. DOHS focus is research safety and demonstrates an appropriate balance between regulatory compliance and facilitation of research activities. DOHS staff are professional, competent and dedicated and are recognized as such by the NIH Intramural community they serve. DOHS staff serve as safety specialists who are assigned to Institutes and who serve as the liaison between laboratory staff, DOHS and safety committees. Under the unified direction of DOHS, safety programs are consistent, respected and standardized across the Institutes of the NIH. The DOHS work force is stable and home grown, responsive and supportive. DOHS communications are frequent and promote strong relationships with research staff.
- Recommendation: Building on the excellent relationship and communication that DOHS has with NIH investigators, we recommend that the NIH consider developing a “Culture of Safety” survey tool similar to that developed by the CDC in an effort to accurately gauge areas for improvement in laboratory and research safety programs currently and over time.
5. Observation: Laboratory safety training is offered centrally through the DOHS via a variety of methods, including on-line training as well as classroom and laboratory-based training sessions. All persons, including visiting scientists and students, are required to take laboratory safety training. NIH Campus identification cards, and thus access to the NIH campus, are provided ONLY upon completion of training.

Verification of competency for hands-on laboratory activities is currently limited to containment laboratories (BSL3 and BSL4).

- Recommendation: We recommend that competency verification and associated documentation be expanded and strengthened.
6. Observation: The NIH Intramural Occupational Medicine Program is a very strong, comprehensive occupational medicine program that serves as a model occupational health program for any biomedical research entity. Collaboration with other DOHS staff is clear. The Occupational Health Director is an enthusiastic and dedicated health care practitioner that the NIH is lucky to have as part of its research community.
 7. Observation: During our visit to NIH laboratories, it was noted that the design of several of the BSL2 labs visited were not optimal in providing separation of laboratory/research materials from desk and personal space assigned to investigators.
 - Recommendation: We propose that DOHS staff have an opportunity to comment and provide input on the design of new lab space and the remodeling of old lab space.
 8. Observation: NIH staff conveys comfort in reporting of incidents, no fear of reprisals. This observation was consistently observed in interviews with staff at all levels of the NIH. The immediate reporting and the NIH response to the discovery of the previously unidentified vial of small pox is an excellent example of this culture of responsible reporting.
 9. Observation: The NIH community includes a large number of contract employees. The process of providing access to the closed NIH campus provides a mechanism to ensure that persons are granted access to NIH labs only following an appropriate "on-boarding" process, which includes training as needed for their work. We recognize that the use of contract employees can be a challenge, particularly from the perspective of occupational health and safety and applaud the process that the NIH has established to address this challenge.
 10. Observation: Through discussions with lab managers we learned that they welcomed opportunities for increased communication between the managers of different labs. It was suggested that in instances where a principal investigator may not be a supporter of basic biosafety practices (e.g. wearing of lab coats) a forum for sharing experiences through lessons learned as well as strategies for improvement of the safety culture at the NIH would be helpful in supporting a culture of safety.
 - Recommendation: We propose that the NIH establish regular opportunities and mechanisms to improve communications between lab managers across the NIH.



Memorandum

Date: 5/27/2015

To: Jennifer M. Cannistra, Executive Secretary
U. S. Department of Health and Human Services (DHHS)

From: Acting Chief, Federal Advisory Committee Management Branch
Management Analysis and Services Office
Centers for Disease Control and Prevention

Subject: Advisory Committee to the Director, CDC—Advisory Committee Recommendations

Attached is a letter to Secretary Burwell from the Advisory Committee to the Director, CDC regarding recommendations concerning the National Institutes of Health Intramural Laboratory Safety Program.

If there are any questions, please contact me.



Catherine Ramadei