National Science Advisory Board for Biosecurity

National Institutes of Health
May 11, 2017
Teleconference
Meeting Summary

Purpose of Meeting

The members of the National Science Advisory Board for Biosecurity (NSABB) met to receive and discuss relevant policy updates, an update on the progress of the Working Group on Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) Policy Stakeholder Engagement, and the draft report of the Blue Ribbon Panel (BRP) reviewing the 2014 variola virus incident on the National Institutes of Health Bethesda campus.

Voting Members

Samuel L. Stanley, M.D. (Chair)
Craig E. Cameron, Ph.D.
Marie-Louise Hammarskjöld, M.D., Ph.D.
Joseph Kanabrocki, Ph.D., NRCM(SM)
Theresa M. Koehler, Ph.D.
Marcelle C. Layton, M.D.
Jan Leach, Ph.D.
James W. LeDuc, Ph.D.
Margie D. Lee, D.V.M., Ph.D.
Francis L. Macrina, Ph.D.
Joseph E. McDade, Ph.D.
Stephen S. Morse, Ph.D.
Jean L. Patterson, Ph.D.
David L. Woodland, Ph.D.

Ad hoc Members

Kenneth Bernard, M.D.
Mark R. Denison, M.D.
John D. Grabenstein, R.Ph., Ph.D.

Welcome and Introduction

Samuel L. Stanley, M.D., welcomed attendees and members of the public. He welcomed the people who currently have ad hoc status but who will soon join NSABB. He acknowledged Susan Wolf, J.D., University of Minnesota, who left NSABB after the November 2016 NSABB meeting, and thanked Jan

Leach, Ph.D., and Drew Endy, Ph.D., who will be stepping down in June 2017, for their service and contributions to the board before reviewing the agenda for the teleconference.

Jessica Tucker, Ph.D., Executive Director, NSABB, called the roll of NSABB voting and ex officio members and reviewed the rules governing conduct and conflict of interest. The minutes of the previous board meeting were unanimously approved.

Policy Updates

Carrie D. Wolinetz, Ph.D., National Institutes of Health (NIH), reviewed recent federal policy activities related to NSABB's work on gain-of-function research.

In May 2016, NSABB released a report whose central finding was that studies that were anticipated to enhance a potential pandemic pathogen (PPP) have potential public health benefits but also entail significant risks. NSABB recommended that federal departments carry out additional multidisciplinary evaluations prior to making funding decisions, as well as appropriate ongoing oversight if research is funded.

In January 2017, the White House Office of Science and Technology Policy (OSTP) released *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight,* directing federal departments and agencies that are considering funding projects anticipated to involve the creation, transfer, or use of enhanced PPP to adopt a department-level, multidisciplinary, pre-funding review mechanism that considers:

- Potential risks and benefits of the research
- Alternative approaches to address the same question in a manner that poses less risk than the approach proposed
- Capacity of the investigators and institutions to conduct the work safely and mitigate potential risks
- Ongoing oversight throughout research conduct and communication of results
- Ethical issues

A PPP is a pathogen that is both (1) likely highly transmissible and capable of wide and uncontrollable spread in human populations and (2) likely highly virulent and likely to cause significant morbidity or mortality in humans. The policy will require review of studies anticipated to involve the creation, transfer, or use of enhanced PPP, which is a PPP resulting from the enhancement of a pathogen's transmissibility or virulence. The policy does not include wild-type pathogens that exist in or have been recovered from nature. The policy also excludes surveillance activities and activities associated with developing or producing vaccines.

The principles to be considered by each department's review mechanism are:

1. The proposal or plan for such a project has been evaluated by an independent expert review process (whether internal or external) and has been determined to be scientifically sound;

2. The pathogen that is anticipated to be generated by the project must be reasonably judged to be a credible source of a potential future human pandemic;

3. An assessment of the overall potential risks and benefits associated with the project determines that the potential risks as compared to the potential benefits to society are justified;

4. There are no feasible, equally efficacious alternative methods to address the same question in a manner that poses less risk than does the proposed approach;

5. The investigator and the institution where the project would be carried out have the demonstrated capacity and commitment to conduct it safely and securely and have the ability to respond rapidly, mitigate potential risks, and take corrective actions in response to laboratory accidents, lapses in protocol and procedures, and potential security breaches;

6. The project's results are anticipated to be responsibly communicated, in compliance with applicable laws, regulations, and policies and any terms and conditions of funding, in order to realize their potential benefit;

7. The project will be supported through funding mechanisms that allow for appropriate management of risks and ongoing federal and institutional oversight of all aspects of the research throughout the course of the project;

8. The project is ethically justifiable. Non-maleficence, beneficence, justice, respect for persons, scientific freedom, and responsible stewardship are among the ethical values that should be considered by a multidisciplinary review process making decisions about whether to fund research involving PPPs.

Adoption of a review process by a federal department in accordance with the OSTP guidance will result in an end to the funding pause announced in 2014 for that department. The Department of Health and Human Services (HHS) is putting together its review mechanism, which is expected soon.

Discussion

Margie Lee, D.V.M., Ph.D., asked how principle seven will be applied to projects that are funded outside of NIH. Dr. Wolinetz said that, in general, federal agencies place similar terms and conditions for acceptance of research awards to help ensure compliance with applicable laws, regulations, and policies. While most of this type of research is currently funded by HHS, it is expected that other agencies will closely consider HHS procedures as they develop their own review mechanisms.

Marie-Louise Hammarskjöld, M.D., Ph.D., asked about the process for educating institutions and investigators on how to better identify and plan such research long before they submit proposals. Dr. Wolinetz said that the policy development process, including NSABB's public discussions, has contributed to awareness-building and education, particularly among the small community of

researchers and institutions who conduct this type of research. The release of the OSTP policy guidance, as well as future rollout and communication efforts regarding a final HHS review mechanism, will also help foster awareness and education.

Update from the Working Group on Institutional Oversight of Life Sciences Dual Use Research of Concern Policy Stakeholder Engagement

Joseph McDade, Ph.D., chair of the stakeholder engagement working group, provided an overview of the group's progress regarding the NSABB's charge to help the U.S. government plan and host one or more meetings to solicit stakeholder feedback about their experiences implementing the United States Government Policy for Institutional Oversight of Life Sciences DURC. The group has been working on identifying a suitable meeting location, appropriate participants and panelists, and topics to be addressed, and it is developing the meeting format and draft agenda.

The purpose of the meeting is to engage people who are involved in day-to-day implementation of institutional DURC policies and to get their feedback on key issues such as:

- Actions taken to implement the policy
- Experiences and challenges associated with policy implementation
- Procedures for reviewing research subject to the policy
- Best practices and novel strategies for managing DURC
- Effective education strategies

The workshop will be held in Chicago, Illinois on September 25-26, 2017; a date that coincides with the second anniversary of the institutional DURC policy going into effect. The meeting will consist mainly of panel discussions, followed by audience interaction. Attendees will include senior research administrators, institutional review entity chairs and members, institutional contacts for dual use research who serve as points of contact between institutions and the government, researchers, biological safety officers, and U.S. government officials.

The working group envisions that the meeting will be helpful towards future policy evaluations and will also help the stakeholder community share best practices.

Dr. McDade thanked the working group members for their time and welcomed input from board members and the public.

Report from the Blue Ribbon Panel Reviewing the 2014 Variola Virus Incident

Dr. Stanley introduced RADM Kenneth Bernard, M.D., U.S. Public Health Service (Retired), chair of the BRP appointed by the NIH Director to review the 2014 incident in which several vials of smallpox were

found on the NIH campus. Dr. Stanley informed NSABB members that their task was to discuss the panel's draft report and decide whether it was ready to be finalized and conveyed to NIH leadership and asked NSABB members to focus on factual errors or unclear statements. Dr. Bernard thanked NIH staff for their support in preparing the report and provided an overview of the panel's findings and recommendations.

In 2014, U.S. Food and Drug Administration (FDA) staff were in the process of cleaning out laboratory space leased from the NIH for a move to the FDA campus in White Oak, Maryland. While clearing a cold room, a researcher found several boxes containing more than 300 vials of abandoned biological materials, six of which contained samples of smallpox virus (variola). The cold room was not locked and was accessible to anyone who could get into the building. The report includes a timeline of events. The panel spoke with most of the people involved.

The BRP's tasks were to look at how the smallpox vials came to be improperly stored, identify any systemic issues and factors that had contributed to the lapse, and evaluate whether NIH had taken adequate actions to minimize similar incidents in the future. The panel focused on the last of these aspects, because the others had already been well covered by the Centers for Disease Control (CDC), FDA, the Federal Bureau of Investigation (FBI), the Government Accountability Office (GAO), and the House Energy and Commerce Committee.

In the report, the BRP summarizes the contributing factors such as a lack of designation of responsibility for infectious materials in shared spaces, failure to find all variola samples in the 1980s when the World Health Organization (WHO) requested samples be destroyed or transferred to WHO, and lack of a policy for what to do with materials when someone retires or leaves. There was also a lack of clarity on how responsibilities were shared between NIH and FDA.

While noting problem issues with the immediate response, such as inadequate chain-of-custody records, the panel concludes that the overall incident response was appropriate, thorough, and characterized by excellent cooperation among NIH and several other federal agencies. They also note that NIH rapidly responded to address the underlying causes of the incident and responded to the issues raised by internal and external reviews—in so doing, NIH has reduced the probability of future incidents of this nature.

The report contains specific recommendations to NIH that focus on revisions to NIH biosafety policies and procedures. Dr. Bernard noted that NIH has addressed or is addressing most of the issues identified.

The report also conveys general approaches to improving biosafety and biosecurity, including the importance of emphasizing individual responsibility among researchers and continuous prioritization by institutional leadership.

Discussion

Dr. Hammarskjöld asked whether any recommendations will be conveyed to institutions that receive government funding. Dr. Joseph Kanabrocki, Ph.D., NRCM(SM) said that NIH encouraged extramural research institutions to carry out a sample inventory process similar to that undertaken by federal labs

following the 2014 discovery and biosafety outreach efforts continue, including during an annual national biosafety stewardship month.

Public Comment

Samuel Evans, D.Phil., M.Sc., Harvard University, asked whether the September DURC policy stakeholder workshop will be open to the public. Dr. Wolinetz confirmed that it will. Information about registration will be available soon on the NSABB website.

Brooke Pearson, Ph.D., Department of Defense, asked whether there has been an effort to collect the lessons learned and use them to discuss new consolidation efforts, such as for polio. Dr. Bernard said that the principles to follow are outlined in the report, and the Department of Defense could apply them. He thinks it would be better for the whole government to have a common system.

NSABB Discussion and Recommendation

The Board unanimously recommended that the BRP's report be forwarded to NIH leadership. Dr. Stanley thanked the panel for their efforts.

Closing Remarks and Adjournment

Dr. Stanley thanked the participants on the call and adjourned the meeting.

03/29/18

Jessica Tucker, Ph.D.
Executive Secretary, National Science Advisory Board for Biosecurity

I hereby acknowledge that, to the best of my knowledge, the foregoing Minutes are accurate and complete.

This Minutes document will be considered formally by the NSABB at a subsequent meeting; any corrections or notations will be incorporated into the Minutes after that meeting.

Date: 4/2/18

Samuel L. Stanley Jr., M.D.
Chair, National Science Advisory Board for Biosecurity