National Science Advisory Board for Biosecurity (NSABB)
Meeting Minutes

January 23–24, 2020
Hyatt Regency
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Meeting Minutes

NSABB Members Present

Gerald W. Parker, Jr., D.V.M., Ph.D. (Chair)
Kenneth Bernard, M.D.
Nancy D. Connell, Ph.D.
Mark R. Denison, M.D.
Jacqueline Fletcher, Ph.D.
John D. Grabenstein, R.Ph., Ph.D.
Marie-Louise Hammarskjöld, M.D., Ph.D.
James. W. Le Duc, Ph.D.
Stephen S. Morse, Ph.D.
Jean L. Patterson, Ph.D.
Rozanne M. Sandri-Goldin, Ph.D.
Pamela A. Silver, Ph.D.

Absent

Craig E. Cameron, Ph.D.
Margie D. Lee, D.V.M., Ph.D.

Day 1

Welcome and Call to Order

Gerald W. Parker, Jr., D.V.M., Ph.D., Chair, NSABB

Dr. Parker opened the meeting at 12:32 p.m. and welcomed NSABB members and other participants. He explained that the NSABB provides advice, guidance, and leadership on biosecurity oversight of dual use research (DUR). The NSABB has been a leader in national discussions of DUR and gain-of-function (GOF) research, and its recommendations have played a key role in informing the development of federal policies, some of which would be discussed during this meeting.

Introduction of Committee Members and Conflict-of-Interest Disclosures

Jessica Tucker, Ph.D., Director, Biosafety, Biosecurity, and Emerging Biotechnology Policy Division, NIH

Members of the NSABB introduced themselves and Jessica Tucker, Ph.D., Designated Federal Official for the NSABB, reviewed the conflict-of-interest statement, reminding NSABB members that they are considered temporary employees of U.S. Government (USG) and, as such, are subject to rules of conduct. Members are to disclose personal, professional, and financial

COIs. Should an issue arise that could affect—or appear to affect—a member's interests, the member is requested to recuse himself or herself from the discussion.

Session I: Policy Updates and Charge to the NSABB

U.S. Government Policy Regarding Research Involving Enhanced Potential Pandemic Pathogens (PPPs)—the GOF Deliberative Process

Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH

Research that involves potentially dangerous pathogens has inherent biosafety and biosecurity risks. Mitigating such risks while facilitating beneficial biological research and realizing the benefits is a key challenge that requires effective risk assessment, risk mitigation, policies, practices, and oversight.

DUR is life sciences research that has the potential to be used for both benevolent and harmful purposes. DURC is a subset of DUR that has the greatest potential to generate knowledge, information, or products that could be readily misused to pose a significant threat to public health and national security.

GOF, a cornerstone of molecular biology research, refers to any modification of a biological agent that confers new or enhanced activity. GOF studies that generate PPPs with enhanced ability to cause harm are a type of DURC that has raised public concern. For example, many questions were raised about NIH-funded studies on respiratory transmission of highly pathogenic avian influenza virus H5N1 in 2011-2012. A public debate ensued over whether, and the extent to which, information in manuscripts on these studies could or should be shared, with a range of viewpoints including publish in full, publish with specific redactions, and classification of the research.

In 2014, the U.S. Government paused new funding for certain types of GOF research involving influenza, Middle East Respiratory Syndrome (MERS), or Severe Acute Respiratory Syndrome (SARS) viruses. A robust and transparent deliberative process ensued that included independent assessment of risks and benefits, ethical analysis, and broad stakeholder input and discussion at multiple public meetings convened by the NSABB and the National Academies of Sciences, Engineering, and Medicine (NASEM). In its 2016 report, the NSABB recommended additional, multidisciplinary department-level evaluation prior to a funding decision on GOF research proposals that were reasonably anticipated to create, use, or transfer enhanced PPPs, and appropriate ongoing oversight if funded. The White House Office of Science and Technology Policy (OSTP) issued *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight.* In response to the OSTP policy guidance, the Department of Health and Human Services (HHS) announced the adoption of the *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework).* This allowed HHS agencies to lift the GOF research funding pause. NIH simultaneously announced that it would begin considering relevant research proposals using the new review mechanism established by the *HHS P3CO Framework*.

Discussion

Dr. Bernard highlighted that the NSABB was formed not to stop or restrict DUR but rather to discuss how to mitigate risks and responsibly realize the benefits of such research.

HHS Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced PPPs and Public Transparency Regarding Funded Projects
D. Christian Hassell, Ph.D., Senior Science Advisor, Office of the Assistant Secretary for Preparedness and Response, HHS

Dr. Hassell described the process that HHS uses to review applications for federal funding to conduct research expected to create, transfer, or use enhanced PPPs. PPPs are usually highly transmissible and capable of wide and uncontrollable spread in human populations. They are also likely to be highly virulent and cause significant morbidity, mortality, or both, in humans. PPPs are enhanced when their transmissibility, virulence, or both have been enhanced.

After peer review and before funding decisions are made, HHS convenes the Potential Pandemic Pathogen Care and Oversight (P3CO) Review Committee. Dr. Hassell listed the disciplines represented on the P3CO Review Committee and highlighted rigor of the review.

This committee evaluates the risks and benefits, ethical issues, and risk mitigation plans associated with proposed research that has undergone peer review and has been judged to be scientifically meritorious, but which warrants Department-level review under the *HHS P3CO Framework*. After evaluating the proposed research using the eight criteria outlined in the HHS P3CO Framework, the committee issues its recommendation on whether the research is appropriate for HHS funding. The funding agency then considers the recommendations, makes a funding decision, and reports the decision to HHS and OSTP.

Dr. Hassell acknowledged and addressed several concerns expressed about the P3CO review process including the scope of the framework and requests for increased transparency and timelier posting of committee decisions. He welcomed stakeholders to clarify the definition of "transparency," explained that HHS does not publish committee member names since that could discourage individuals with the necessary expertise from serving, indicated HHS has worked to improve public notification of review outcomes, and noted that, to date, the committee has only completed reviews of two projects involving influenza virus with a third currently underway.

Dr. Hassell suggested that the NSABB could, at some point, consider questions related to the committee's scope and whether the committee, which is made up of federal employees only, should include representatives of academic institutions, industry, or other sectors.

Discussion

Dr. Hassell noted that he chairs the P3CO review committee and clarified that the HHS P3CO review process is for research proposals submitted to HHS only.

Dr. Wolinetz added that the OSTP policy guidance directed departments and agencies to develop their own review processes. HHS was the first federal department to develop a process, and this process applies only to HHS proposals.

In response to a question from NSABB members, Dr. Hassell noted that the committee defines "risks" and "benefits" quite broadly and that the multidisciplinary review is very robust but balanced and is not specifically designed to deny research funding.

Dr. Dennison noted that one reason why only a few proposals have met the criteria for review by the P3CO Review Committee could be that scientists are less likely to submit applications that must undergo extensive additional review.

Charge to the NSABB
Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH

Dr. Wolinetz reviewed the new NSABB charge, which is divided into three phases. In Phase 1 the NSABB will provide recommendations regarding the balance between security and public transparency when sharing information about enhanced PPP research. During Phase 2A the NSABB will evaluate and analyze U.S. DURC policies including their scope, implementation, effectiveness, and impacts on stakeholders; as well as the effectiveness of the pathogen list and experiment type construct. Finally, in Phase 2B the NSABB will evaluate the "Future Commitments" outlined in the OSTP policy guidance and provide recommendation on incorporation of the P3CO policy into the DURC policy framework.

The anticipated timeline involves the NSABB forming a working group focused on Phase 1 activities in February. By the spring or early summer of 2020, the NSABB will develop recommendations on the Phase 1 charge and shortly thereafter, form working groups to address Phases 2a and 2b. with a goal to deliver recommendation on Phase 2 in spring 2021.

Discussion

NSABB members suggested that the Board's deliberations include consultation with the Federal Select Agent Program (FSAP) to help ensure that the government does not issue conflicting policies or regulations.

Dr. Bernard conveyed that P3CO policy is a branch of DURC and not a new issue even though it was developed separate from DURC policy.

In response to a question from Dr. Silver, Dr. Hassell indicated that precedent exists regarding the decision not to disclose the names of individual P3CO review committee members, which is intended to help protect their safety, security, and privacy.

Dr. Wolinetz stated that during its deliberations on the review process, the NSABB heard about an existing HHS review process for research on certain avian influenza viruses. The NSABB modeled some aspects of the recommended review process on this HHS process, for which individual reviewers were not publicly identified.

Session II. Transparency and Security in Research—Policies and Perspectives

Balancing Transparency and Security—Ethical Considerations

David B. Resnik, J.D., Ph.D., Bioethicist, National Institute of Environmental Health Sciences

Dr. Resnik defined "transparency" as the process of making information that is shared meaningful and useful to the person who is receiving that information. For example, transparent information for the public might not include scientific details, which are less useful for this audience, but it might cover the implications of a discovery for society. The information shared in a transparent process might include details of completed, ongoing, or proposed research projects; summaries of peer-review deliberations on grant applications; or information used to make peer-review decisions. Different audiences have different needs or expectations for information, and a process that is transparent to one group might not be to another.

Among the benefits of transparency are that it promotes openness and honesty, supports peer review and scientific debate, and benefits the public. The risks of transparency include its potential to harm public health, society, or national security; violate the confidentiality of the peer-review process; result in retaliation against reviewers or theft of applicants' research ideas; prevent reviewers from being candid about their opinions; or disrupt ongoing research. Transparency about ongoing research could be disruptive if it jeopardizes the scientific priority of the research.

Policies can require full disclosure (complete transparency), no disclosure (no transparency), or partial disclosure (sharing of some but not all details, perhaps on a need-to-know basis). A challenge with partial transparency is how to determine who can receive which types of information and how to keep the information secure.

Discussion

Information can no longer be buried, because Google searches can find information regardless of where or how it is published. Ultimately, NIH is likely to require the publication of original data.

Balancing Transparency and Security—Policy Considerations

Gigi Gronvall, Ph.D., Senior Scholar and Associate Professor, Center for Health Security, Bloomberg School of Public Health, Johns Hopkins University

Dr. Gronvall reviewed international and domestic policies and agreements that are relevant to security and communication about scientific research. International policies include the Biological Weapons Convention and United Nations Security Council Resolution 1540. Key U.S. policies and regulations include National Security Decision Directive 189 and Export Administration Regulations.

Fundamental Research Security, developed by the JASON science advisory group as part of a National Science Foundation-commissioned study, is part of an ongoing effort to keep international research collaboration both open and secure. A NASEM report, *Biodefense in the*

Age of Synthetic Biology, provides an objective review of the impact of synthetic biology capabilities on biodefense threats and the capabilities that pose the greatest concern. The companion guide to U.S. DURC policies, *Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide* addresses and provides guidance about responsible communication of scientific research amongst other things.

Dr. Gronvall encouraged the NSABB to discuss research safety separately from research security and noted that while a framework that can be broadly disseminated would be helpful, who makes decisions will always be controversial.

Discussion

NSABB members discussed the notion that institutions, companies, and foreign entities might have little reason to adopt any of the NSABB's recommendations about DURC research if they do not receive money from the U.S. government but noted that, despite a general decrease in the percentage of research and development that is federally funded, the U.S. government is probably the main source of funding for GOF research in the U.S.

Dr. James Le Duc highlighted that at most universities, institutional committees closely review and monitor research that is conducted, including DURC. However, other members recalled the research involving horsepox virus conducted in Canada, noting that it was privately funded and none of the U.S. regulations applied.

In response to questions about the competitiveness and ability of the United States to continue to attract the best and brightest researchers, Dr. Gronvall explained that the JASON report covers primarily the economic implications of multinational research collaborations. Problems arise when research is misused for economic benefit or is stolen but framed this mainly as a research integrity issue.

Dr. Denison suggested that iterative reviews could allow important research to move forward, as long as processes are in place to stop research if a demonstrable risk arises. Dr. Gronvall pointed out that iterative reviews are sometimes included in clinical trials' frameworks, which require a clinical trial to be stopped if an issue develops. A challenge for assessing the risk of these types of events is the lack of data on laboratory accidents or deliberate releases.

Perspectives on Transparency and Security Regarding Enhanced PPP Research
Moderator: *Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH*

Jessica Belser, Ph.D., Influenza Division, Centers for Disease Control and Prevention (CDC)

Dr. Belser has spent more than 15 years working in high-containment laboratories with virulent and transmissible human and zoonotic influenza viruses and viruses classified as select agents by the U.S. government. This period spans NSABB deliberations on DURC and the pausing and subsequent lifting of HHS funding for GOF research.

Dr. Belser expressed that she feels safe when she conducts her research and is confident that she has the necessary training and experience to work safely with viruses that pose a threat to human health. The numerous and overlapping layers of security and engineering controls and the presence of well-trained colleagues and coworkers collectively result in the conduct of research at the highest standard in an environment that protects both scientists in the laboratory and the world outside the laboratory's airlocked doors.

At the departmental and institutional levels, biosafety and biosecurity review boards assess the merit of proposed research and the likelihood that research is DURC. If a DURC study is proposed, an HHS review is initiated by a multidisciplinary panel of federal employees who assess the merits of the research, its risks and benefits, and risk-mitigation measures that must be implemented before the research can be approved or funded.

This system ensures that funders support sound and ethically justified research and provides confidence for researchers that all required safety and security benchmarks are met for this research to proceed responsibly. These oversight activities are subject to the same level of confidentiality as all other decisions pertaining to research funding requests. Applications for research funding in general, as well as the additional documents required for DURC studies, contain a substantial amount of confidential and sensitive information. Release of this information could compromise the safety and security of the research, those who conduct it, and the facilities where it is conducted.

This system could benefit from some improvements, such as more clearly identifying publicly funded projects that have passed such reviews or periodic reassessment and review of relevant policies and practices.

Tom Inglesby, M.D., Director, Center for Health Security, Bloomberg School of Public Health, Johns Hopkins University

Dr. Inglesby summarized the first half of a commentary that he and Marc Lipsitch, D.Phil., published in *mSphere* the previous day. In this article, Drs. Inglesby and Lipsitch point out that although the P3CO guidance from OSTP calls on agencies to make their review mechanisms for research that uses enhanced PPPs transparent to the public, HHS has not published the names of the P3CO Review Committee members. Furthermore, the resumption of enhanced PPP research in 2017 after the moratorium ended was disclosed to the public only after a reporter asked the government about this research.

Dr. Inglesby called for the release of the names of the review panel members, similar to regular study sections. He also recommended that the review panel include nongovernment scientists who have relevant expertise. He also questioned whether research on these pathogens has really benefited human health.

Details on the HHS decision process, such as the criteria used to assess the proposals, and on the qualitative or quantitative risk assessments conducted, have not been publicly released. No information is available to the public on the potential risks and benefits of the research that was reviewed and approved.

Dr. Inglesby recommended that HHS publish such information and give the public a chance to comment on the findings of each review before HHS funds the research. Another recommendation is to establish a common international approach to enhanced PPP research, in accordance with the *HHS P3CO Framework*. Given that it funds this type of research, the U.S. government has a responsibility to establish strong standards as an example for other countries.

Vincent R. Racaniello, Ph.D., Higgins Professor of Microbiology & Immunology, Vagelos College of Physicians and Surgeons, Columbia University

Dr. Racaniello shared his opinion that scientists should not be told what experiments they cannot do; instead, they should be required to do their experiments safely. Dr. Racaniello uses blogs, videos, and social media to communicate scientific issues to the public. Many members of his audience lack a science background but are interested in microbes and their impact on human health.

An example of what not to do comes from two studies that adapted the avian H5N1 virus for respiratory transmission in ferrets. H5N1 infection in humans, while rare, can be deadly, but the virus cannot be transmitted effectively by aerosol. However, because the popular press and scientists used doomsday language to convey the studies' results, they were not published in a scientific journal or transmitted accurately to scientists and the public. A key finding—that the adaptations to the virus eliminated its lethality—was therefore ignored by many scientists. This experience shows the need for transparency about the research so that the public understands it.

One question raised at the time was whether the benefits of these experiments justified the risk. Dr. Racaniello shared that the real value of the results was not in helping predict the timing of the next pandemic or making a vaccine, but the important information on requirements for viral transmission.

The decisions about the GOF research moratorium and resumption as well as the procedures established to review these studies have been transparent. Although the deliberations of the P3CO Review Committee have not been transparent, that is true of all study section deliberations.

Marc Lipsitch, D.Phil., Director and Professor of Epidemiology, Center for Communicable Disease Dynamics, Harvard University

Dr. Lipsitch summarized the second half of the *mSphere* commentary that he and Dr. Inglesby published. Like other scientists, Dr. Lipsitch is a strong proponent of open science and sharing data, which is supported by NIH, other funders, and many journals. However, this concept can conflict with biosafety and biosecurity. For example, open science policies might require an investigator to share her reagents with anyone who requests them, even if the requestor might not use these reagents safely.

Drs. Lipsitch and Inglesby propose that journals and funders include special provisions in their access policies for studies that use enhanced PPPs or other agents that pose a risk of accidental

transmission or dual use risks. They also note that the *HHS P3CO Framework* does not apply to funders other than the federal government and that journal and preprint publishers have spotty policies on biosecurity requirements and almost no policies regarding population-level biosafety risks.

A proposed solution is for the federal government to recommend best practices for journal publishers and funders outside the federal government. Funders would be asked to adopt similar policies to those of HHS, and publishers would be asked to publish manuscripts describing enhanced PPP research only if the funder provides documentation attesting that a review has been conducted and listing the risks and benefits identified in this review.

Luciana Borio, M.D., Vice President, In-Q-Tel

Enhanced PPP research should not be done to answer a question posed out of curiosity. This type of research requires a strong rationale, and its potential benefits must outweigh its risks. Every possible effort must be made to minimize these risks, and these risky experiments must be conducted carefully and transparently by experts.

Dr. Borio shared her experience with a U.S. Food and Drug Administration (FDA) review process. FDA publishes its scientific rationales to support its approvals of products once the approval decisions are made. These reviews are expected to be conducted by experts in the field who are free of conflicts of interest pertaining to the decision.

Dr. Borio argued that less transparency leads to less security. In practice, sharing fundamental scientific knowledge is critical and leads to scientific progress. Not sharing information on materials and methods can increase the risks of the research if others try to replicate these experiments. Sharing scientific information is fundamental to our society's values and to the scientific enterprise, and transparency is linked to scientific success and innovation.

Discussion

Process to Ensure Safety and Security of Enhanced PPP Research
Dr. Wolinetz prompted panelists to elaborate on what aspects of the review process, as opposed to the research itself, could benefit from improved transparency. Dr. Belser pointed out that many of the concerns raised by this panel are addressed to at least some extent in many risk-mitigation plans, which are considered during HHS P3CO reviews. These plans call, for example, for monitoring pathogens for dual use potential, responsible communication, review of documents before they are submitted to journals, applicability of existing countermeasures, and use of attenuated strains when possible. Publicly sharing more information about the scope of the issues discussed during the review process might reassure scientists and the public about the efforts made to ensure that this research is conducted safely and securely.

Role of Journals
Rozanne M. Sandri-Goldin, Ph.D., an NSABB member and editor-in-chief of the *Journal of Virology*, reported that the American Society for Microbiology requires editors-in-chief of its journals to indicate whether any studies reported in manuscripts meet any of the DURC

conditions. Ten years ago, most submissions to the journal were from U.S. laboratories. Today 60% of submissions come from overseas researchers, mostly from China. Teams sometimes state that they have met the Chinese biosafety review conditions, but Dr. Sandri-Goldin does not know what those conditions are.

Dr. Inglesby noted that an outcome of HHS P3CO review may be a required development of a plan for responsible communication, but the framework does not describe the components of such a plan. Censoring or not allowing enhanced PPP research to be published is the wrong way to conduct oversight and control. Dr. Wolinetz noted that over the past 16 years, the NSABB has engaged in a substantial amount of responsible communication and has developed important guidance. She believes that this guidance is being implemented, including by journals. Dr. Inglesby indicated that the type of communication that the *HHS P3CO Framework* requires does not describe the process used to mitigate safety and security concerns.

One concern is that journals are becoming the first and not the last line of defense. Furthermore, if a manuscript does not meet the publication criteria for one journal, the authors can submit it to a less prestigious journal that lacks strict requirements. The submission of manuscripts with a certification that the research was reviewed and approved by a preapproval review committee might make publication decisions easier for journal editors.

Dr. Inglesby suggested that the NSABB or another advisory committee could help journal editors by reviewing manuscripts on research that might involve enhanced PPP and noted that the NSABB has been charged in the past to review manuscripts.

Many journals formulated their policies at a time when the focus was more on biosecurity than on population-level biosafety, such as accidental release of an enhanced PPP. These policies could be improved because, for example, not all reviewers or all journal editors know how to identify this type of research.

Benefits and Risks of Confidentiality

NIH typically must keep pre-funding deliberations confidential, but it does make peer-review decisions publicly available. One reason for keeping the peer-review process confidential is to protect intellectual property, which is necessary for the scientific ecosystem. In most areas of science, considerations about scientific careers and trade secrets are important. However, it was suggested by Dr. Lipsitch that it would be reasonable for the small body of enhanced PPP research to require disclosure to the people who might be affected by that research if, for example, an accident was to occur. Dr. Borio and others noted the challenges and potentially negative effects of trying to restrict or control unclassified research information, noting that such actions can increase risk.

Requests for More Transparency

Dr. Lipsitch argued against the claim that disclosure of prefunding decisions might not be feasible or legal by pointing out that the recommendations in the *mSphere* commentary pertain to a very limited amount of research. For most proposals reviewed by NIH, the public wants to know whether NIH is spending taxpayer money wisely on promising research. But their questions are very different when they live near facilities that conduct enhanced PPP research

that could threaten their health and well-being. Research that raises these types of questions requires a higher level of transparency than studies that address ordinary scientific questions.

Dr. Racaniello posited that the public probably does not want to know about the deliberations of the review committee. Transparency is not worthwhile if only a few people will use the information that is disclosed.

Dr. Wolinetz clarified that NIH did disclose the projects that underwent P3CO review. NIH shares information on these projects with the public in the same way that it shares details on all of the research it funds.

Dr. Inglesby again called for release of the names of P3CO Review Committee members and the content of their deliberations. In the past, enhanced PPP experiments have been approved without full disclosure of this information, and some of the people involved in approving these studies might have had conflicts of interest. Furthermore, the public needs to understand why the federal government has determined that the benefits of the research it has approved outweigh the risks.

Dr. Belser conveyed satisfaction with the *HHS P3CO Framework*. However, sensational headlines must not alarm people or prevent them from understanding why this research is necessary and that it is done safely and securely.

Accident Reporting

Accidents happen, even in some of the country's best laboratories and although accidents involving enhanced PPPs are probably rare, they can have serious consequences for many people. Panelists acknowledged that some safety and required reporting of laboratory accidents already exist for some types of research, including select agent research. Some panelists questioned whether all laboratory accidents are reported and said a central repository for biosafety data on accidents could aid risk assessments. Others noted that in their experience, incident reporting was very thorough, especially if a high-consequence pathogen was involved. Dr. Inglesby reiterated that the issue was not whether or not GOF research was carried out outside of required regulations or oversight, but rather that they were not properly disclosed to the public.

International Outreach

Dr. Bernard highlighted prior work done by NIH and the NSABB to share information about dual use research and promote international best practices for oversight and suggested it may be worth revisiting in the context of P3CO.

Other Issues

NSABB members and panelists discussed the scope of research that might warrant review under the P3CO process. Dr. Belser noted that many studies that do not involve enhanced PPPs are treated as if they do. Not everyone understands that only a small number of enhanced viruses develop both pathogenicity and transmissibility.

The panel clarified that an enhanced PPP is a pathogen that is artificially enhanced resulting in a pathogen that is both highly transmissible and highly virulent in humans and does not include pathogens that are naturally circulating pathogens that may also be transmissible and virulent, such as the coronavirus responsible for the current outbreak.

Adjournment - Day 1
Dr. Parker thanked the participants for their contributions and insightful discussions before adjourning proceedings at 4:41 p.m.

Day 2

Welcome and Call to Order
Gerald W. Parker, Jr., D.V.M., Ph.D., Chair, NSABB

Dr. Parker called the meeting to order at 9:01 a.m., welcomed participants to the second day of the NSABB meeting, and reviewed the agenda for the day.

Session III: Transparency, Security, and Confidentiality—Procedures and Practices

Scientific Peer Review

NIH Peer-Review Process
Jodi B. Black, Ph.D., Deputy Director, Office of Extramural Research, NIH

The peer-review policy officer at the NIH Office of Extramural Research makes sure that the peer-review process is harmonized across NIH. All but three of the 27 NIH institutes and centers (ICs) have funding authority. The Center for Scientific Review (CSR) conducts peer review for approximately 75% of the applications to NIH, and the ICs conduct peer review for more complex research applications, such as those for research centers.

NIH is legally required to use a two-stage peer-review system. When applications arrive at the CSR, they are assigned to the appropriate IC and to the unit that will conduct the peer review. An NIH study section (peer-review panel) conducts the initial review, which is followed by a second review by the council of the IC that funds the research. The ICs make the final funding decisions. NIH makes information about awarded applications available to the public but peer review meetings, according to regulations, are closed to the public and any associated review material is exempt from disclosure.

NIH draws from a pool of approximately 26,000 peer reviewers, most of whom are members of standing study sections. Reviewer qualifications include expertise and stature in the field, mature judgment, impartiality, and managed conflicts of interest. NIH publishes the study section rosters and meeting schedules on a searchable website.

A core value of peer review at NIH is confidentiality, which allows free exchange of scientific information and helps protect trade secrets as well as commercial, financial, privileged, and confidential information. Information shared is used for the evaluation process only and materials, discussions, and documents are deleted or destroyed after each review. Each reviewer and council member is required to sign a confidentiality agreement. At every peer-review meeting, peer reviewers are reminded not to share applications, proposals, or confidential meeting materials with anyone not officially participating in the peer-review process. Penalties can be applied to anyone who breaches the confidentiality rules of the peer-review process.

National Science Foundation Peer-Review Process
Theresa Good, Ph.D., M.Sc., Deputy Director, Division of Molecular and Cellular Biosciences, National Science Foundation (NSF)

NSF receives approximately 50,000 proposals and makes 12,000 new awards each year. Several of NSF's eight directorates, including the Biological Science Directorate, fund biomedical research. To receive approval for funding, proposals must receive a high score on two merit review criteria:

1. Intellectual merit: potential to advance knowledge and understanding within and across scientific fields
2. Broader impacts: potential to benefit society or advance desired societal outcomes

The program director chooses the reviewers for each proposal on the basis of reviewers' expertise and lack of conflicts of interest. When they meet to discuss the proposals, the reviewers categorize each proposal as high, medium, or low priority or as noncompetitive. The reviewers then give their recommendations to the division director or deputy division director, who makes a recommendation about whether to fund the awards. After a business review, information on the successful proposals becomes publicly available.

Although transparency of processes is a core NSF value, reviews and reviewer identity are kept confidential, a longstanding practice in accordance with the Privacy Act. NSF releases the titles and abstracts of applications and notices of review panel meetings to the public, but the proposal and review content are not disclosed publicly, whether awarded or declined. Only the principal investigator receives unattributed individual reviews, panel summaries, and context statements. The NSF confidentiality policies ensure the protection of research ideas and allow peer reviewers to discuss ideas openly without fear of retribution.

Balancing Security and Transparency for Research Involving Biological Select Agents and Toxins
Samuel S. Edwin, Ph.D., Director, Division of Select Agents and Toxins (DSAT), CDC

The Federal Select Agent Program (FSAP), administered by CDC and the U.S. Department of Agriculture (USDA), regulates the possession, use, and transfer of biological select agents and toxins that could pose a severe threat to public, animal, or plant health or to animal or plant products. The HHS and USDA lists have 67 select agents and toxins, 14 of which are designated

as Tier 1 (those that present the greatest risk of deliberate misuse and potential for devastating effects).

FSAP provides oversight over possession, use, and transfers and can conduct inspections without prior notification and before issuing a certificate of registration. Inspections help ensure a facility has adequate safety and security measures in place to work with select agents and toxins and can include evaluations of registered laboratories, shipping and receiving processes, documents, and security procedures. The electronic FSAP information system offers a secure Web-based user interface to provide real-time information on who holds select agents, what types of agents they hold and where, and how they are using those agents.

The Federal Bureau of Investigation (FBI) conducts security risk assessments (SRAs), which are required for access to any select agent or toxin. FSAP receives the SRA results and, based on the determination of the Criminal Information Services Division, approves or denies requests for access. FSAP enforces select agent regulations through voluntary or administrative actions or through civil or criminal penalties. In 2018, three entities were required to implement a corrective action plan, nine matters were shared with the FBI for potential investigation (although FBI determined that no action was needed in any of these cases), and four matters were referred to the HHS Office of Inspector General or USDA's Investigative and Enforcement Services.

The select agent program publishes an aggregate annual report that includes program parameters such as the number of registered entities and inspections but does not include entity-specific information. Information about registered labs is, however, shared with relevant state public health officials.

Discussion

When asked about the ability of hackers to breach the security of the FSAP database, Dr. Edwin explained that CDC hosts the database in a highly secure system, and access to the real-time data requires special permission. Every year, the division hires a team to try to hack into the system; to date, no one has crossed the security barriers.

Dr. Le Duc and Dr. Connell suggested using the data collected by FSAP on laboratory thefts, losses, and releases along with other institutional data to help quantify the risk of research involving select agents and toxins according to biosafety level. Dr. Edwin noted that while more than 250 registered laboratories are required to report issues related to select agents, and other unregistered laboratories report these issues as well, FSAP cannot require registered laboratories to report certain details that may be required to carry out detailed assessments and get a complete picture of incidents.

Dr. Edwin explained that every year, FSAP sends a report to Congress that does not identify the entities that are using select agents and toxins, although FSAP does have this information. For the most part, entities working with select agents and toxins make sure that their personnel have the needed training and know how to prevent avoidable incidents. Early recognition and action have been a hallmark of the program. FSAP reports every loss to the FBI, but none of the losses

that the FBI has investigated has had criminal involvement. No thefts have been identified since the program began.

Dr. Edwin clarified that CDC and USDA have a joint inspection system, and they choose individuals who have relevant expertise to conduct each inspection. He is working with USDA leaders to ensure that FSAP has a single voice and uses a single inspection team for each facility.

A key difference between research involving enhanced PPPs and research involving select agents is that FSAP lacks the authority to oversee enhanced PPP research activity if the PPP is not a select agent. However, Dr. Edwin noted that agents can be added to the list of select agents and toxins at any time, but making these determinations takes time.

Community Engagement on Pathogen Research
Moderator: *James W. Le Duc, Ph.D., Director, Galveston National Laboratory*

Ann Masel, CPA, Former Chair, Community Liaison Committee (CLC), Galveston National Laboratory (GNL)

The GNL has a similar appearance to other University of Texas Medical Branch buildings, and while many people are unaware of the work done in the facility, its location and unobtrusive appearance may help combat misperceptions and negativity about the work conducted there. That said, the GNL is surrounded by small concrete barriers, has a single entrance and there is 24-hour security. Everyone who enters must have a badge and proof of identity, be on the expected visitor list, and be escorted from the lobby to pass through the security check.

The CLC has nine members, who serve three-year terms and provide advice on community concerns. The CLC meets six times a year to hear presentations about research, use of research animals, and emergency preparedness in the GNL. Whenever an incident occurs, the scientific director contacts the CLC chair to discuss whether to inform the rest of the committee at that time, depending on the severity of the incident. The CLC also helps the facility's leader communicate with the public and reviews policies and procedures with elected officials.

The public does not necessarily want to know the details about who's working on what pathogen, but genuine public outreach efforts and building trust are important.

Caree Vander Linden, Public Affairs Officer, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

USAMRIID is the only Department of Defense (DoD) laboratory equipped to safely study highly hazardous viruses requiring maximum containment at biosafety level 4 (BSL4). In 2010, USAMRIID established the Containment Laboratory Community Advisory Committee, made up of representatives of the city of Frederick and Frederick County, as well as citizen volunteers, who meet about four times a year. Many are subject matter experts, microbiologists, and people with backgrounds in biosafety. The committee gives USAMRIID another way to hear from and share information with the public.

Over the past 18 months, there were a number of incidents at USAMRIID including the May 2018 failure of the steam sterilization plant that led to containment laboratory operations being shut down, and the July 2019 suspension of the facility's FSAP registration. USAMRIID has since revised its training, mentorship, and compliance programs; installed a new thermal system; and developed a plan for a limited number of studies with newly trained personnel. In November 2019, CDC authorized the facility to resume some of its research. The committee was fully informed of these developments at the time they occurred.

With oversight from regulatory agencies, the U.S. Army, and the DoD, USAMRIID must balance the need for transparency with operational security. The facility needs to coordinate a series of notifications and send them quickly to the right people in the right order. USAMRIID also posts summary information on its website about the types of incidents in BSL3 and BSL4 laboratories each year, but it does not post the raw data or actual incident reports.

It is important to engage respectfully, keep the message simple in plain English, and provide appropriate context. The committee has been an integral part of USAMRIID's information sharing process.

Rebecca Moritz M.S., CBSP, SM(NRCM), Responsible Official and Institutional Contact for Dual Use Research, University of Wisconsin–Madison

Before constructing its influenza research laboratory, the University of Wisconsin–Madison held a town hall meeting with neighbors, local business community members, and local officials to describe the facility, the research to be conducted, and the planning process. The facility now offers invitation-only tours during each annual shutdown which have been very well received. Researchers pretend to conduct experiments using colorful liquid and participants learn about the facility's scientific and research priorities, research oversight, biosafety and biosecurity, and other topics. The university also used an Ebola drill that involved hospital and city emergency response workers to educate the entire health network in Madison about the facility's activities. Other outreach activities include presentations and question-and-answer sessions with laboratory leaders and researchers on various topics.

The public has shown only limited interest in the university's influenza research, and most inquiries about the facility's work come from the media. A scientific communications team vets every request to the university for an interview and decides who is best suited to respond and how. The university spends a significant amount of resources to offer this level of engagement, especially for media inquiries.

This type of proactive outreach requires a significant amount of resources but is important because it helps frame what is happening, potentially helps correct misinformation, and allows the institution to potentially have a say in any story. It is essential to find common language to help prevent sensationalism and heightened fear of this work because of a lack of understanding of the science and the biosecurity measures that are in place. Ms. Moritz shared that she has received several written threats and was personally identified by name in an editorial published in the largest newspaper in the state written by an animal rights activist who has previously

glorified harming researchers. As a result, Ms. Moritz has worked with law enforcement agencies to ensure that her personal security and job are not affected.

Ms. Moritz asked the NSABB to consider the following questions when it discusses transparency:

- Who is the intended audience?
- What is the method for delivering the information?
- How will risks to an institution that conducts this work be minimized?

Shannon Benjamin, M.S., M.B.A., RBP, CBSP, SM(NRCM), Associate Director for Research Safety, National Emerging Infectious Diseases Laboratories (NEIDL), Boston University

The foundation of research transparency at Boston University rests on a decision that the university will never engage in classified research, so all research at the NEIDL must be publishable and able to be shared with the community. One input to this decision was meetings with community members who wanted to know what was happening at the facility.

The NEIDL's approach to transparency begins with its people and culture. The Personnel Suitability and Reliability Policy which details how personnel are managed, supports a safe environment by, for example, offering opportunities to opt out of work, giving direction on reporting safety and behavioral concerns, and requiring several types of clearance every year. This policy is shared with the public, city officials, and the NEIDL's CLC, whose 14 members meet monthly to discuss the NEIDL's operations, scientific direction, and safety. The committee plays a vital role in ensuring the transparency of NEIDL operations and activities.

Oversight and compliance activities include reviews and approvals of protocols by the Institutional Biosafety Committee (IBC), which includes members of the public. IBC minutes are posted on the Boston University website. The Boston Public Health Commission (BPHC) reviews protocols for high- or maximum-containment research, and the university gives 30-day notice of its intention to start a research project to the BPHC executive director and the Boston City Council.

Operational safety is assured through internal daily safety checks and announced and unannounced inspections and monitoring from BPHC, the CDC Select Agent Program, and other authorities having jurisdiction, including the city's fire department and its water and sewer commission. NEIDL incident reports and annual reports are posted online, as is agent-specific information. Ms. Benjamin and other research safety managers share the results of all inspections during their monthly meetings with BPHC and with the CLC, which plays a vital role in promoting transparency by facilitating outreach and public participation.

The Comprehensive Emergency Management Plan describes a commitment to provide training to internal and external responders and to conduct three drills each year in conjunction with first responders and city officials. The surrounding community receives advance notice of all drills. Send Word Now is an emergency communication platform that can transmit messages quickly and in real time to various devices. Messages about certain types of incidents are sent out automatically with this service, and others are initiated by and sent to relevant individuals.

Research transparency has been more beneficial than detrimental, and the facility's relationship with city officials and the surrounding community have improved significantly as a result. However, the facility does not share certain types of information, such as details on its building automation system monitoring, protective measures, transportation and shipping, specific locations (room/floor numbers), or agent inventory.

Discussion

Federal vs. Institutional Roles
Dr. Wolinetz asked the panelists to comment on federal and institutional roles in transparency. Ms. Moritz explained that the University of Wisconsin–Madison is conducting the first project that received funding after the P3CO review process, and that review process went well. She suggested more unified communication mechanisms so that joint messages can be issued by the institution and funder when new projects are being reviewed or are approved.

Resources Required
When asked about the costs of maintaining the programs described by the panelists, Ms. Vander Linden replied that she is the only person at USAMRIID who works on media and community relations. Ms. Masel said that the efforts of the GNL CLC are not costly. The GNL has a single public relations officer who has other responsibilities, and the scientists serve as the laboratory's public faces. Any major needs are covered by the communications team in the president's office.

Ms. Benjamin and her colleagues keep most of the online information up to date. They post quarterly reports on incidents and share this information with several committees and city officials. Journalists who have questions are typically directed to the NEIDL website, which seems to answer their questions.

The NEIDL engages in research projects only after ensuring that no restrictions will be placed on the potential to publish the findings. In addition, whenever a shipment is expected, first responders are asked about streets that the delivery vehicle must avoid. Shipments involve the university's emergency management and public safety personnel, researchers, and BPHC, so these activities are associated with some costs.

Ms. Moritz has four colleagues, and she often works on weekends. Researchers spend a significant amount of time preparing the laboratory for each tour. For example, they secure certain items and clear space so that people on the tour can easily walk through the building.

Dr. Hammarskjöld commented that the work of the panelists is extremely important, and she was grateful that individuals like Ms. Moritz are willing to withstand personal threats to do this critical work.

Media Relations
Dr. Hammarskjöld asked whether the panelists work with trusted members of the media to issue stories proactively or after an incident. Ms. Moritz said that she works with a strong science communications division in the university relations office. This team helps researchers translate

major research information into lay language, and the team has taught Ms. Moritz how to express herself in language that the public can understand. Many institutions are reluctant to share information on their enhanced PPP or select agent research out of fear that FSAP will penalize them for informing the public of their work. This fear must be eliminated to make proactive national and international conversations possible.

Ms. Masel emphasized the importance of identifying and tailoring the message to the audience. Members of the public might not want every detail, but they do want to know that laboratories take all the appropriate precautions.

Sharing Best Practices
Dr. Hammarskjöld asked how to share the best practices described by the panelists. The panel members reported that none of them had ever been part of a panel like this one. Dr. Parker encouraged the panelists to consider ways to hold similar discussions more often because the panelists have developed best practices that should be circulated. Ms. Vander Linden pointed out that such discussions could help participants learn from one another.

Information Shared with the Public
When asked whether their laboratories publish research agendas in advance that list the agents the laboratories will work with, Ms. Masel and Ms. Benjamin said that investigators give presentations about upcoming research at CLC meetings. In Boston, notices of the approval of a new project and of planned shipments are sent to BPHC and the mayor's office. Ms. Moritz stated that influenza research at the University of Wisconsin–Madison is ongoing, and researchers rarely receive new agents.

Dr. Le Duc asked the panelists how to engage the community, how much information they share with the community, and how they use feedback from the community. Ms. Masel said that when everything is going well, very few members of the public comment on the GNL's research. The question is what to do when a set of negative comments comes in. Ms. Moritz said that the local community around the university does not have many concerns about high-consequence pathogen research. For example, only 10 people attended the Ebola town hall, all of their questions were about the science, and no one expressed any concerns. According to Ms. Benjamin, transparency is the foundation of research at the NEIDL. Ms. Vander Linden said that USAMRIID publishes the results of all of its research. The direction for its research comes from the DoD, so the facility does not solicit public input on this topic.

Session IV: Responsible Engagement/Communication for Enhanced PPP Research—Considerations and Strategies

Responsible Public Communication/Engagement—Risks, Benefits, and Uncertainty
Moderator: *Joseph Kanabrocki, Ph.D., CBSP, Associate Vice President for Research Safety and Professor of Microbiology, University of Chicago*

Baruch Fischhoff, Ph.D., Howard Heinz University Professor, Institute for Politics and Strategy, and Engineering & Public Policy, Carnegie Mellon University

Dr. Fischhoff shared a few high-level observations and practical implications. First, intuitions are unreliable, and people overestimate how well they understand and communicate with one another. Therefore, people should rely on evidence, not intuition, when designing their communications processes.

He noted that the basic science regarding this area of communication is mature. The first NASEM report on risk communication was published in 1989, and NASEM has since issued several reports on related topics, including the potential risks and benefits of GOF research and communication capacity to counter infectious disease threats. Several scientific journals have published articles on science and risk communication as well.

Content design builds trust by addressing the following topics:

- Analysis: What specific decisions do people face?
- Description: How do they make them intuitively?
- Intervention: How can they be helped in making them?
- Evaluation: Are current efforts good enough?

Communications teams should have members with the needed expertise. Science communication requires subject matter experts who can make sure that the information is accurate, decision scientists who can ensure that the information is relevant, social and behavioral scientists who can confirm mutual understanding, and practitioners who can implement follow-up activities. All opinions should be welcome, but those who know each topic best should have authority to make decisions.

When and how an organization communicates (or stays silent) shapes the interpretation of its messages and how much it is trusted. A policy to manage emerging events should require the dissemination of timely and useful information. The messages must use standard formats and address risks and benefits, uncertainty, and personal actions.

Jo L. Husbands, Ph.D., Scholar and Senior Project Director, Board on Life Sciences, NASEM

Dr. Husbands noted that this conversation has been going on since at least the early 2000s, and began with controversies over several articles that, according to some, had raised security risks. Since that time, NASEM and other experts have made clear that the publication stage is too late to make decisions, for all the reasons discussed at this meeting. Assessments of and decisions about potential risks, benefits, and risk mitigation strategies must be made at a much earlier stage. In addition, interventions must be feasible throughout the research cycle.

Responsible communication and engagement are central components of the *HHS P3CO Framework* and are important throughout the research cycle. However, this framework does not resolve all the issues, and its implementation raises other questions, such as those about the appropriate mix of transparency and security for research that poses risks of misuse or biosafety hazards.

Both the local and science communities must be engaged. Dr. Husbands suggested that the NSABB consider the following issues:

- Lessons learned from unsuccessful engagement with communities
- Lessons learned about interactions between the local and scientific communities
- The division of responsibility between NIH and the institution conducting the research, especially when decisions at the local level could produce national reactions
- Opportunities for institutions to share experiences and learn from one another
- Qualitative frameworks to assess risk by identifying unstated assumptions
- Adaptations of frameworks from other fields to assess potential benefits of a line of research or a capability (but not a specific experiment)

Sam Lipson, M.S., REHS, Director, Environmental Health, Public Health Department, Cambridge, Massachusetts

As an advisor to the Boston Biosafety Committee, Mr. Lipson helped the city write regulations before the NEIDL was approved. In this capacity, he worked with groups that were outraged by the decision process and believed that Boston University was not listening to community groups representing local residents. That early error had major consequences, including how long it took to obtain approval for constructing the NEIDL. This delay could have been avoided with genuine, early outreach. The university has learned its lesson, but at great cost.

Cambridge pursued local control and developed a process that is enforceable by law. The academic sector is well covered by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), so Cambridge's process pertains primarily to private-sector research and to research not funded by NIH at Harvard University and the Massachusetts Institute of Technology. The city's role is to protect the safety of those who work in and live near the laboratories, but the city's ordinances do not address all of its residents' ethical and policy concerns.

Mr. Lipson indicated his comments were framed based on his specific experiences in Boston and Cambridge. The public's perception of motive is important. For example, the public might perceive that the motive for research is profit in the private sector and personal ambition in academia. The community might therefore regard rules requiring secrecy as not serving their best interests. Many members of the public do not understand the mechanisms of biological risk from pathogen research and are more likely to believe that they are at risk because they live near a laboratory. In his community, DURC issues are not likely to be the prominent issue for the public, which is more concerned about environmental releases and laboratory-acquired infections. Although a few people care about global biosecurity issues, most people's main focus is the impact on their daily lives.

Earning credibility and trust takes time. Listening, finding the right range and level of technical detail, and early input are important. The Boston University experience showed that spending time now is better than dealing with a situation later that requires credibility the university has not yet earned. Although Boston residents paid a great deal of attention to the NEIDL during its construction because of the negative attention, they paid much less attention once the NEIDL was built. Developing a good communications strategy requires early input from the community, demonstrated knowledge of the subject, candor about past mistakes, and reinforcement of the public's role and right to know.

Carole R. Baskin, D.V.M., M.Sc., CPIA, Director, Communicable Disease Control Services, Saint Louis County Department of Public Health

Dr. Baskin asserted that no sustainable and effective alternative to self-regulation by scientists of their activities is available, including dissemination of research information. Self-regulation does not mean that scientists can do whatever they want whenever they want or that their work can escape public scrutiny. Self-regulation does mean avoiding the use of legal instruments that could cripple research or become ineffective as technology advances.

Public trust lets scientists write guidelines and best practices. Public distrust leads to laws, regulations, and government policies that are difficult to amend when technology and the state of knowledge evolve. Scientists at all career levels therefore need to be more engaged in science policy and with the public. Committees with anonymous members can lead to public perceptions of conflicts of interest. Engagement with the public is a two-way form of communication that includes not only providing information and education but also listening and responding to concerns and misinformation.

The new generation of scientists needs training in scientific communications and must engage the public through social media, public lectures, presentations, and city and county council meetings. If they are properly engaged, elected officials can help the scientific community by, for example, pushing back on alarmist headlines or at least not being swayed by them. Public health agencies must also be engaged because they must respond if a dangerous pathogen escapes the laboratory.

Global biosecurity is the only one that counts, because GOF research has global consequences. More international engagement is needed to promote harmonization of GOF research governance, and the culture of responsible research and research dissemination must be global. Global engagement in biosecurity could involve citizen scientist programs, better syndromic surveillance, a greater focus on common values than on differences, communication of risks and unknowns, expression of empathy and respect, and promotion of action.

Dr. Baskin recommended that those communicating about GOF research and biosecurity underpromise, overstate positive news, and give factual arguments. Scientists and institutions should focus on people instead of biological agents, minimize list-based rules, promote an international code of conduct and research security guidelines, establish a voluntary accreditation system for institutions, collaborate with other institutions and develop common codes, and track high-containment laboratories more effectively. For countries, global biosecurity could involve treaties to formalize agreements, signal political will, and provide a mandate for funding and effective communications and collaborations among countries by remembering the impact of culture on risk tolerance. Education exchange programs can ensure that the next generation of scientists is part of the global community.

Achieving global biosecurity will require common standards and technical language, common software and databases for surveillance, common food safety policies and policies for antibiotic use, common laboratory method standards, complementary research among countries to

minimize duplication of effort and maximize sharing of findings, and mobilization of multidisciplinary expertise within and across countries.

Discussion

Mr. Lipson explained that anyone who starts a company in Cambridge must inform a biosafety council that includes community members, and this approach has been very effective. Companies learn a great deal by engaging the community and understanding the risks and potential benefits of their research.

It was noted that science competitions for students bring people from different parts of the globe together, increase understanding, and help form global communities. Younger scientists seem to be interested in the broader social context of their work, and this interest could be leveraged for outreach on biosecurity and biosafety. Some universities have a white-coat ceremony for graduate students who take a scientific oath that is similar to the Hippocratic Oath. This oath makes these young scientists think more carefully about their responsibilities.

According to Mr. Lipson, approximately 18 or 20 communities in Massachusetts have rules based on those of Cambridge. Not all of these communities enforce these rules, and some of the rules are not relevant because these communities have no companies conducting relevant research. Some communities in other states have rules for both private and academic laboratories, and some of these rules are less stringent than those of Cambridge and Boston.

The Cambridge approach to the private sector works well and aligns with emerging industry best practices. Cambridge has navigated intellectual property for a long time without any problems, because most of the information the city needs as a regulator or overseer of biosafety practice is not proprietary. However, the rules of different cities, even within the same state, are different, which does not make sense. Cities that have strong rules and want to keep them should be permitted to do so. The sector would benefit from consistent rules and reporting requirements, but no formal regulations at the state or federal level have emerged. Mr. Lipson believes that these regulations should be at the state level.

NSABB members reiterated the importance of communicating risk and scientific information effectively. Finding a spokesperson who can effectively communicate science is easier than finding someone to communicate information on public policy, because policy is less objective. Dr. Fischhoff's research might be particularly relevant to this issue. People view proximity as the risk, rather than the worker as the vector.

Discussants shared their opinions that during an epidemic or potential event, the best approach is to focus communication on the science and when policy questions arise, honest answers should be given. Honesty is the bottom line, including regarding what we don't know. Scientists can explain that science will evolve and promise to update the public as this evolution occurs.

Dr. Denison noted that not doing research can be risky, and this risk should be incorporated into risk-assessment matrices. Dr. Fischhoff said that one judgmental bias is ignoring the opportunity

cost, or the cost of not conducting the research. People naturally focus on one aspect of the issue and ignore the other.

One challenge is how to make important decisions when information is not available or when waiting until the information is available is not an option. Public health agencies encounter this problem frequently, such as when they must decide whether to close schools, airports, or both. Cost–benefit analyses are as important as risk–benefit analyses. Schools should not be closed if closure is unnecessary for scientific reasons, because closed schools can alarm the public and affect the community's economy when parents must stay home to care for their children. People must become comfortable making decisions based on educated guesses alone in the absence of information.

Two audiences for messages about policy are people in the local community and those who could be affected in surrounding communities. The local community might be concerned about pandemic potential, and others might be concerned about global biosecurity and the management and protection of intellectual property. Members of the public have concerns about policy as well as public health impact.

Public Comment
Gerald W. Parker, Jr., D.V.M., Ph.D., Chair, NSABB

Dr. Parker welcomed verbal public comment from those present and informed all participants that written public comments should be sent to Dr. Jessica Tucker within 10 days of the meeting.

Wendy Hall, Ph.D., Special Senior Advisor for Biological Threats, Office of Chemical, Biological, and Nuclear Policy, Department of Homeland Security, noted that Dr. Black had mentioned security as a peer-review core value. Dr. Hall wondered whether this value refers to security considerations, such as guards and guns, or national security considerations. Another question is how decisions about enhanced PPP research that imposes risk on the nation or the world could incorporate a national security risk calculation if such a calculation is not part of the peer-review process. Integrating these considerations into the peer-review process is one way to disseminate these issues to the scientific community, including researchers who do not receive government funding.

Nicholas Evans, Ph.D., Assistant Professor of Philosophy, University of Massachusetts Lowell, congratulated the NEIDL staff for their willingness to share information. He wondered about the value of this information and how many people pay attention to it. Experiments on genomic testing have shown that people do not mind this type of testing, but they want to know that it is being done and that it benefits them. If IBC records are only released when bad things happen, people might think that many bad things are happening. Sharing information on biosafety incidents would allow research on prevention and mitigation strategies for these types of incidents. An NIH representative pointed out that the *NIH Guidelines* require IBC minutes to be shared with the public.

NSABB Discussion and Next Steps
Gerald W. Parker, Jr., D.V.M., Ph.D., Chair, NSABB

Jessica Tucker, Ph.D., Director, Biosafety, Biosecurity, and Emerging Biotechnology Policy Division, NIH

Dr. Parker outlined the approach to addressing the NSABB's charge. The NSABB will form a working group to address the Phase 1 objectives.

Dr. Tucker will contact the NSABB seeking volunteers to join the Phase 1 working group. She clarified that members of the panels at this meeting and other experts who are not NSABB members can serve as ad hoc members of working groups. She explained that one of the initial tasks of the working group will be outlining what is needed to accomplish the task. Once the working group develops draft recommendations, the NSABB will hold a public meeting to consider this document. At that time, the NSABB can begin working on its Phase 2 tasks. Phase 2 will be a more substantial undertaking that will require meetings with various stakeholders. When the Phase 2 working group is formed, its members can similarly discuss what activities and support are needed, including whether any external contracts would be needed to complete the work.

Dr. Denison suggested a series of scenarios could be designed for risk–benefit analyses and best practices. Experts could be asked to review these scenarios. Dr. Parker noted that the Phase 1 working group can decide whether to use this approach. The Federal Advisory Committee Act rules govern the functions of the NSABB, and close coordination with Dr. Tucker will be necessary to make sure that the working group and the Board continue to comply with these rules.

Closing Remarks and Adjournment
Gerald W. Parker, Jr., D.V.M., Ph.D., Chair, NSABB

Dr. Parker closed the meeting at 2:23 p.m. by thanking the NSABB members and others who participated. He said he looked forward to working with the NSABB on the complex issues discussed at this meeting so that the scientific engine can continue to advance rapidly.

Jessica M. Tucker -S

Digitally signed by Jessica M. Tucker -S
Date: 2020.04.22 14:12:38 -04'00'

Date: _____

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

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

This Minutes document will be considered formally by the NSABB; any corrections or notations will be incorporated into the Minutes.

Date: 30 April 2020

Gerald W Parker

Gerald W. Parker, Jr., D.V.M., Ph.D.
Chair, National Science Advisory Board for Biosecurity

Attachment I

National Science Advisory Board for Biosecurity
Voting Member Roster

Chair

Gerald W. Parker, Jr., DVM, PhD
Associate Dean for Global One Health
College of Veterinary Medicine and Biomedical Sciences
Texas A&M University

Voting Members

Kenneth Bernard, MD
RADM, U.S. Public Health Service (Retired)
Former Special Assistant to the President for Biodefense, Homeland Security Council, White House
Former Special Adviser for Health and Security on the National Security Council

Craig E. Cameron, PhD
Jeffrey Houpt Distinguished Investigator
Chair, Department of Microbiology and Immunology
University of North Carolina School of Medicine

Nancy D. Connell, PhD
Senior Scholar and Professor
Department of Environmental Health and Engineering
Johns Hopkins Bloomberg School of Public Health

Mark R. Denison, MD
Edward Stahlman Professor of Pediatrics
Professor of Pathology, Microbiology and Immunology
Director of the Division of Pediatric Infectious Diseases
Vanderbilt University Medical Center

Jacqueline Fletcher, PhD
Regents Professor Emerita
National Institute for Microbial Forensics and Food and Agricultural Biosecurity
Oklahoma State University

John D. Grabenstein, RPh, PhD
Executive Director (Retired)
Global Medical Affairs
Merck Vaccine Division
Merck & Co., Inc.

Marie-Louise Hammarskjöld, MD, PhD
Charles H. Ross Jr. Chair and Professor of Microbiology, Immunology, and Cancer Biology
Associate Director, Myles H. Thaler Center
University of Virginia School of Medicine

James W. LeDuc, PhD
Director, Galveston National Laboratory
Professor, Department of Microbiology and Immunology
University of Texas Medical Branch

Margie D. Lee, DVM, PhD
Professor and Head, Department of Biomedical Sciences and Pathobiology
Virginia-Maryland College of Veterinary Medicine
Virginia Tech

Stephen S. Morse, PhD
Professor of Epidemiology
Mailman School of Public Health
Columbia University

Jean L. Patterson, PhD
Professor
Texas Biomedical Research Institute

Rozanne M. Sandri-Goldin, PhD
Chancellor's Professor and Chair, Department of Microbiology and Molecular Genetics
University of California Irvine School of Medicine

Pamela A. Silver, PhD
Elliot T. and Onie H. Adams Professor of Biochemistry and Systems Biology
Member, Harvard University Wyss Institute of Biologically Inspired Engineering
Department of Systems Biology
Harvard Medical School