National Science Advisory Board for Biosecurity (NSABB)
Meeting Minutes

January 27, 2023
Virtual Meeting

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National Science Advisory Board for Biosecurity (NSABB)
January 27, 2023
Meeting Minutes

NSABB Members Present

Gerald W. Parker, Jr., D.V.M., Ph.D. (Chair)
Shannon Benjamin, M.S., M.B.A.
Kenneth Bernard, M.D.
Mark R. Denison, M.D.
Jacqueline Fletcher, Ph.D.
John D. Grabenstein, R.Ph., Ph.D.
Karmella Haynes, Ph.D.
Rachel Levinson, M.A.
Alex John London, Ph.D.
Syra Madad, D.H.Sc., M.Sc., M.C.P.
Dennis Metzger, Ph.D.
Pamela A. Silver, Ph.D.

NSABB Members Absent

Christina Egan, Ph.D.

Welcome

Lawrence A. Tabak, D.D.S., Ph.D., Performing the Duties of Director, NIH

Lyric Jorgenson, Ph.D., Acting Associate Director for Science Policy, NIH

Gerald W. Parker, Jr., D.V.M., Ph.D., NSABB Chair, Associate Dean for Global One Health, Texas A&M University

Dr. Parker called the meeting to order at 1:00 p.m. ET and explained the role and purpose of the NSABB.

Dr. Tabak welcomed members and others joining the meeting via webcast. He noted that life science research—including studies that aim to understand rapidly evolving pathogens and related countermeasures—has important benefits and risks. NSABB members are recognized experts in their respective fields and help the U.S. government (USG) navigate important questions about safety and security to preserve those benefits and mitigate potential risks.

Dr. Tabak noted his February 2022 charge to the NSABB to review the existing policy frameworks for the oversight of dual use research of concern (DURC) and research involving enhanced potential pandemic pathogens (ePPPs). The frameworks are critical components of a broader system that is designed to help ensure that research is conducted responsibly and that its benefits are realized safely, in ways that mitigate risks. The current meeting followed January 2020 and September 2022 NSABB meetings and 2022 NIH listening sessions on these topics.

Dr. Jorgenson emphasized that NIH and the federal government remain committed to safe and

secure conduct of research for the benefit of American public health and global health security. Because security and transparency issues remain at the forefront of domestic and international science policy, the USG periodically reviews policies to improve and update them as science evolves. The Board's evaluation of the frameworks' function included their effectiveness at achieving their intended purpose and their impact on researchers and institutions and will aid federal efforts to ensure robust oversight in place while supporting scientific progress. The purpose of this meeting is for the NSABB to hear from the working groups who have been deliberating the charge about their draft recommendations and findings, and to receive input from the public. The NSABB will decide whether to accept working groups' findings and recommendations.

Ms. Cari Young reviewed the conflict-of-interest (COI) policy. She reminded NSABB members that they are special government employees and, as such, are subject to specific rules of conduct. Members must disclose personal, professional, and financial COIs at scheduled intervals. Should an issue that could affect—or appear to affect—a member's interests arise, the member is requested to recuse himself or herself from the discussion and leave the meeting.

Draft Findings and Recommendations: Proposed Biosecurity Oversight Framework for the Future of Science

Syra Madad, D.H.Sc., M.Sc., M.C.P., Senior Director, System-wide Special Pathogens Program, NYC Health + Hospitals

Gerald W. Parker, Jr., D.V.M., Ph.D., NSABB Chair, Associate Dean for Global One Health, Texas A&M University

Dennis Metzger, Ph.D., Distinguished Professor Emeritus, Department of Immunology and Microbial Disease, Albany Medical College

Dr. Parker described the NSABB's charge to review the scope and effectiveness of the Potential Pandemic Pathogen Care and Oversight (P3CO) policy and the DURC policy frameworks. The charge's first phase was to review the P3CO framework, including guidance from the White House Office of Science and Technology Policy (OSTP) and the U.S. Department of Health and Human Services' (HHS) implementation of that guidance via its P3CO framework, which guides HHS ePPP research funding decisions.

The primary Phase 1 task was to evaluate the scope and effectiveness of the current P3CO framework regarding preserving the benefits and minimizing the risks of ePPP research, USG funding of ePPP research internationally, balancing transparency and security, and the framework's impact on research and institutions.

Dr. Parker noted that Phase 2 focused on evaluating and analyzing existing federal policies regarding DURC. There are two complementary policies. One requires regular federal review of federally supported research, agencies' identification of DURC within their portfolios, and agencies' identification and appropriate mitigation of risk. The second applies to domestic institutions that receive federal funding for life sciences research and conduct research within the

scope of the policy, even if the research itself is not supported by federal funds, as well as federally-funded international research within the policy's scope.

The NSABB was tasked with determining the DURC policies' effectiveness at achieving their goals, identifying implementation challenges, evaluating the framework's impact on research institutions and the government's ability to support research, and their effectiveness with regards to publication, communication, and dissemination of DURC methodologies and results. The charge also included reevaluation of the definition of DURC, consideration of research advances, and evaluation of the effectiveness of the DURC pathogen list and experimentation type construct at addressing future potential threats. Phase 2 also included consideration of the possible incorporation of P3CO policy into revisions of the DURC oversight framework, with consideration of flexible and adaptive approaches to oversight.

Two working groups reviewed frameworks and heard from an array of subject matter experts involved in implementing and overseeing the policies including federal and non-federal experts in scientific research, institutional research administration, biosafety and biosecurity, and national security. The working groups also received input regarding the impact and challenges of policies.

Dr. Madad presented the draft findings and recommendations of the first working group.

Finding 1. The current definitions of a PPP and ePPP are too narrow. Overemphasis on pathogens that are both likely "highly" transmissible and likely "highly" virulent could result in overlooking some research involving the creation, transfer, or use of pathogens with enhanced potential to cause a pandemic

Recommendation 1. Amend the P3CO policy to require federal department–level review for research that is reasonably expected to enhance transmissibility or virulence of any pathogen that is reasonably anticipated to exhibit characteristics that meet the following PPP definition:

- Likely moderately or highly transmissible and likely capable of wide and uncontrollable spread in human populations; and/or
- Likely moderately or highly virulent and likely to cause significant morbidity and/or mortality in humans; and
- Likely to pose a severe threat to public health, the capacity of public health systems to function, or national security.

Finding 2. Assessments for the identification of ePPP research must be focused on the potential for an activity or a modification to involve or produce a pathogen that meets the characteristics for an ePPP and not on the specific experimental approach or method to be undertaken.

Recommendation 2. Remove current blanket exclusions for research activities associated with surveillance and vaccine development or production but include and implement processes and procedures for urgent federal department–level review and evaluation of ePPP research that is critical for public health or national security.

Finding 3. Current P3CO policy does not adequately include roles for investigators and

institutions in the identification, review, and ongoing oversight of ePPP research.

Recommendation 3. The USG should amend the P3CO framework to include and articulate the roles and responsibilities of investigators and institutions in the identification, evaluation, and review of research for the potential to involve ePPPs. The amendment should be harmonized with existing local oversight processes. Adequate technical and financial assistance should be provided, and an appropriate federal office should be designated to assist investigators and institutions in executing their responsibilities.

Finding 4. The review process outlined in the P3CO framework is generally appropriate. However, implementation directives and guidance to funding agencies, research institutions, and investigators are needed to facilitate implementation and ongoing oversight.

Recommendation 4. Amend the OSTP P3CO Policy Guidance so it is consistent with the *Belmont Report*. Amend the HHS P3CO Framework to clarify that seven categories of research must be given extra care and consideration throughout the research proposal, review, evaluation, and ongoing oversight process. Develop an implementation plan, additional guidance and educational materials, and standard operating procedures for funders, institutions, and investigators. Develop principles and guidelines aimed at ensuring that unnecessary risks have been eliminated, no alternative methods that pose less risk can provide the same benefits as the proposed research, and potential benefits justify the remaining risk.

Finding 5. The HHS review group appears to have the appropriate expertise, and the process protects potentially sensitive personal and proprietary information and facilitates open discussion. However, the review process needs more transparency to engender public trust.

Recommendation 5. Take more steps to increase transparency in the review process at the federal and local levels. Share a summary of determinants that inform ePPP research funding decisions.

Finding 6. The focus of the current P3CO framework on pathogens that are likely to cause disease in humans is appropriate. However, an analogous oversight framework is lacking for research involving enhanced animal or plant pathogens.

Recommendation 6. Consider development of an analogous oversight framework for research involving enhanced animal or plant pathogens.

Finding 7. Global collaboration is vital to U.S. pandemic preparedness and response and broader global health security. USG support for international ePPP research should be coupled with processes equivalent to the requirements that govern domestic research in the United States.

Recommendation 7. ePPP research at international institutions that receive USG support should be subject to review and oversight equivalent to U.S. policies and procedures.

Dr. Metzger presented working group findings and recommendations regarding the DURC policies.

Finding 8. The DURC policies appear to have achieved their original intent, but the scope of the framework limits its success to a small fraction of the life sciences research enterprise.

Recommendation 8. Continue to facilitate sharing of experiences and best practices regarding implementation. Any updates to USG DURC policies, particularly regarding the scope of research subject to review and/or the relevant entities to which the policies apply, must involve relevant stakeholders and be accompanied by robust USG outreach and education and an adequate implementation period.

Finding 9. Determining whether research meets the definition of DURC requires assessments based on the best available information at the time but entails uncertainty.

The current definition of DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Recommendation 9. Remove the term "directly misapplied" from the definition. The wording might limit identification and oversight of research that may pose significant threats, whether deliberate or accidental.

Finding 10. The current scope of the DURC policies is limited and the list-based approach to oversight is inherently less adaptive than other potential approaches. Some institutions have voluntarily expanded the scope of research reviewed for potential DURC to include the entirety of their pathogen research portfolios. However, this entails an additional burden that varies based on the nature and size of the institution's or funding agency's pathogen research portfolio.

Recommendation 10. Include within the policy's scope all research that involves any human, animal, or plant pathogen or toxin reasonably anticipated to result in one or more of the seven experimental effects. Establish mechanisms to ensure that investigators and institutions execute their responsibilities effectively. Reviewing bioinformatics, modeling, and other *in silico* experimental approaches and research involving genes from or encoding pathogens, toxins, or other agents for potential DURC is currently not recommended. However, investigators and institutions should be aware of the potential risks of such research. Continued assessment of the risks and benefits associated with advances and applications of such approaches must inform the ongoing evaluation of the scope of these policies.

Finding 11. Responsible communication of research methods and results is a central component of mitigating risks associated with DURC. Most research subject to DURC policies is fundamental research and the findings are intended to and can be communicated responsibly if identified early in the research life cycle and if adequate consideration is given to the timing, modes, and venues of communication, among other risk mitigation measures.

Recommendation 11. Engage relevant stakeholder and publishing groups in developing and

adopting more uniform editorial policies, review processes, and best practices for identifying material that may raise significant biosecurity and biosafety concerns. Facilitate sharing of best practices and guidelines for assessing options for mitigating risks.

Finding 12. The potential biosafety and biosecurity risks associated with ePPP research and DURC justify USG efforts to introduce oversight of relevant research activities, regardless of the funding source.

Recommendation 12. In line with the NSABB's 2016 recommendation regarding ePPP research, promote and ensure that all research meeting the scope of these policy frameworks conducted within the United States and/or supported by the USG be subject to equivalent oversight regardless of funding source.

Finding 13. Overlaps in DURC and ePPP oversight frameworks lend themselves to a single framework, but differences in timing of assessments and roles of investigators and institutions must be reconciled.

Recommendation 13. Develop an integrated approach to oversight of research that raises significant biosafety and biosecurity concerns, including ePPP research and DURC. Clearly articulate federal, institutional, and investigator responsibilities in the assessment and identification of proposed and ongoing research and minimize the potential for duplicative or parallel institutional or federal review processes.

Dr. Parker noted that DURC and P3CO policies were intended to balance progress, transparency, and security. Stakeholders told the NSABB that additional guidance and clear expectations are required for effective, timely oversight and that long review delays must be avoided. The draft report includes recommendations for dividing roles, responsibilities, expectations, and resources that are intended to strengthen timely review and oversight at the local and federal levels, with additional ePPP review required at the federal level.

He described a conceptual approach for this oversight which would require the assessment of risks for research that involves a human, animal, or plant pathogen, toxin, or other agent that is also reasonably anticipated to involve one of the seven categories of experiments listed in the current DURC policies. Under the draft report's recommendations, investigators and institutions would be responsible for identifying proposed and ongoing pathogen research anticipated to involve one of the seven experimental effects and for notifying institution and federal officials of the need for federal review, including that which may warrant additional federal review for its potential to create, transfer, or use enhanced PPPs. Recommendations are intended to promote consistent implementation and more timely execution of investigator, institutional, and federal responsibilities on an ongoing basis.

Dr. Parker thanked the working group members.

Public Comments

Noting the staggering death toll of the COVID-19 pandemic, David LoVecchio said that some pharmaceutical companies conduct studies without regulatory oversight, sometimes in labs

located in cities, near public transportation or airports. Technical difficulties cut his comments short.

Nir Eyal, D.Phil., professor of bioethics and director of the Center for Population-Level Bioethics at Rutgers University, read draft recommendation 12, which is in line with a 2016 recommendation for ePPP research that was never implemented. Currently, external review for this type of research is required only if the research is federally funded. Dr. Eyal said that such research should always be subject to external review.

Kari Debbink, Ph.D., a virologist at Johns Hopkins University, said that virologists understand the potential risks of their research and take them seriously. These researchers already follow HHS, U.S. Food and Drug Administration, and institution rules, which call for layers of protection and reporting. Any changes should be made in collaboration with working scientists. Because PPP research is international, Dr. Debbink warned against any requirements that would result in cutting ties with international researchers who do not operate under U.S. standards, warning that such breaks would diminish the ability to respond to global outbreaks.

Tom Inglesby, M.D., director of the Johns Hopkins Center for Health Security, said that moving forward on the recommendations would be a welcome step. In particular, he supports modification of the ePPP definition and the focus on the anticipated end state of work, articulation of research institution roles and responsibilities, transparency of the decision-making process, and devoting sufficient financial and policy support to make the policy work. The recommendations should cover both publicly and privately funded research and should apply to all federal agencies. Additionally, the USG should engage with other governments on shared approaches. The NSABB should better explain how reviews should be conducted and recorded and review the rest of the written comments they submitted.

Jeremy Kamil, Ph.D., associate professor at Louisiana State University Science Center in Shreveport, said that the largest new viral threats to human health come from nature, not experiments in labs. Noting that oversight frameworks have been effective, Dr. Kamil urged caution regarding unintended delays that impede the development of new antiviral drugs. Recommendation 2 should be considered with great caution, because of the importance of effective surveillance systems for new variants and viruses.

J. Kenneth Wickiser, Ph.D., M.Phil., associate professor at Columbia Mailman School of Public Health, called for rigorous standards for biosafety level 3 (BSL-3) labs, which themselves lack an internationally accepted definition. Dr. Wickiser said a national board should evaluate gain-of-function experiments, regardless of funding source. He proposed mandatory training and use of protective equipment for those who get samples from wildlife internationally. Dr. Wickiser also proposed enhanced ethics and history training for bioscience and medical science students and professionals.

Seema Lakdawala, Ph.D., associate professor of microbiology and immunology at Emory University, asked the NSABB to reconsider recommendation 1, because predicting viral

transmission in a human population is difficult. She suggested that federal oversight agencies partner with scientists, especially virologists. Dr. Lakdawala suggested reconsidering removing exemptions for surveillance in recommendation 2. Currently, surveillance systems are overtaxed in their oversight of influenza A virus subtype H5N1. More regulatory review will impede surveillance of outbreaks and efforts to understand the risks to humans.

Gigi Gronvall, Ph.D., associate professor at the Bloomberg School of Public Health at Johns Hopkins University and senior scientist at the Johns Hopkins Center for Health Security, said that the recommended scope of work subject to extra review is too broad. Reasonable expectation of transmissibility is too subjective and presupposes an unrealistic amount of knowledge to be used as a standard. Dr. Gronvall predicted that much more research would be subject to review, resulting in a slowing or ceasing of necessary work, and urged the NSABB to take a careful look at what will make the community the most safe and productive.

Felicia Goodrum, Ph.D., professor of immunobiology at Arizona State University, spoke after the public comment period ended. She said the existing oversight framework is highly effective. If oversight is expanded, it should be balanced. She worried that increased oversight will delay or prevent some research, especially by young researchers, putting U.S. leadership of science at risk. Dr. Goodrum noted that the response to the COVID-19 pandemic was built on past research that was conducted safely and effectively.

Dr. Parker thanked those who provided both spoken and written public comments.

Deliberation of Draft Findings and Recommendations

Dr. Parker began deliberation of the draft findings and recommendations.

Dr. Metzger said that the "bottom-up" review is an important component of the report that needs to be further emphasized. He described concerns that the federal government reviews cause delays and stated that recommendations should clarify that investigators take the first step in identifying research of concern. Investigators would determine whether their research will involve one of the seven areas of concern in applications and as research occurs. The purpose of the dedicated federal office being recommended is to help mitigate risks, not ban experiments.

Dr. Parker agreed that researchers and institutions have the best understanding of the risks and benefits of their own research, noting that the draft framework pairs a bottom-up and top-down approach. The institutional oversight could be similar to an IACUC or IRB. All levels of review will require resources to implement oversight.

Dr. Denison said commenters were anxious about overreach. A draft framework goal was to note that the current DURC pathogens list does not include other potentially dangerous ones, but the current recommendation may be too broad. As written, the framework conflates issues such as zoonotic risk, surveillance, and vaccine discovery with gain-of-function. Dr. Denison added that the draft framework has neither a mechanism for rapid exclusion from oversight nor a process that allows examination of all experiments of concern rather than programs of concern.

Dr. Bernard said that the NSABB's purpose was not to provide egregious oversight but rather to support science. He noted that there have been questions regarding adequacy of current oversight scope and procedures. The recommendations raise issues for the government to consider in a more specific manner, and he called for ensuring a period in which policies could be changed if implementation does not work. He added that funding institutional oversight bodies is mandatory.

Dr. Silver also noted researcher anxiety about the draft recommendations' potential to limit research and emphasized that they provide mitigation strategies and that many good practices already exist that can be leveraged.

Dr. London suggested combining recommendations 7 and 12 into a single recommendation that says that all domestic research should fall under the purview of the policy, regardless of funding source. The single recommendation should also say that international research funded by the USG should be overseen the same way that domestic USG-funded research is and would call for harmonized international oversight.

Ms. Levinson reiterated that the recommendations call for starting with a bottom-up review, first by investigators who perform the pertinent experiments and are most knowledgeable about them which would provide a simple way to implement the oversight. Investigators would have a role to alert institutions. This would accelerate the entire review process, even though the recommendations' scope expands beyond the 15 current DURC agents. The increased scope should trigger assessments of community impact and provision of appropriate resources to institutions and relevant federal entities.

Dr. Metzger noted that discussions leading to the draft recommendations made clear that institutional biosafety committees (IBCs) oversaw their research portfolios with different levels of scrutiny, and the USG should give IBCs clear guidance, especially regarding the seven research areas of concern. IBCs should communicate with PIs regarding concerns, work with investigators to mitigate them, and consult the dedicated USG office for advice, if needed.

Dr. Denison stressed the value and effectiveness of IBCs and noted that the separation of P3CO and DURC is artificial. Addressing each in separate processes could be overwhelming, especially for young investigators.

It was discussed that the final presentation slide depicting a simplified road map should be amplified in the report by placing it before the other recommendations.

Dr. Parker noted that implementing the recommendations will require significant education, training, funding, and a rollout period.

There was some discussion of transparency issues. It was noted that some members of the public inaccurately thought decisions are made in secret, probably because decisions were announced after the fact and related public records kept names secret.

Dr. London noted a need for clear rules and processes that are public and transparent. He also

expressed a reservation about how much oversight work should be transferred to institutions, because the potential impacts of this research are not limited locally. Having federal level of review would reassure the public about research done in its name.

Dr. Parker said that an implementation plan would aid transparency.

Dr. London stated that the ultimate goal is to make sure that what is done has societal value, and thinks it is important to think about criteria for considering risks, benefits, and potential alternative methods for possible research. The scientific community should discuss valuable methods and ways to find social value in research while reducing risk.

Dr. Denison described the importance and limitations of practical implementation considerations regarding the recommendations. Dr. Bernard said that the NSABB's role is advisory. Oversight must be better but not more intrusive.

Dr. Parker said that NIH, the Department of Defense, and other government agencies have expert virologists who can be consulted as part of the policy process. He suggested noting in the recommendations that the NSABB also stands ready to assist. Others agreed with the importance of experts across the disciplines and the USG.

Ms. Levinson called for studying impact of any new policy on institutions and funding agencies to clarify confusion, ensure adequate resources, and avoid inadvertently inhibiting important research.

Dr. Parker noted public comments that said society cannot afford delays.

Vote to Approve

Noting that NIH Office of Science Policy staff have been taking notes on changes suggested during the discussion, Dr. Parker pointed out two major ones. The bottom-up responsibility at the institutional level is intended to improve and speed the review process, coupled with top-down guidance. Recommendations 7 and 12 could be combined.

Dr. Parker asked if there was a motion for the Board to vote to finalize the draft findings and recommendations with the agreed-upon modifications. There was a motion to finalize the draft findings and recommendations with modifications.

Dr. Jorgenson explained that if the vote passes, the Board would be endorsing the findings and recommendations with clarifications to the report that would not change the spirit and intent of the recommendations. The report would be transmitted to the government.

Members offered second and third motions, and the members voted unanimously to accept the report with modifications.

Dr. Parker said he would ask NIH staff to incorporate the modifications that the Board discussed and send the new version of the report for review.

Dr. Denison commended the government employees and investigators for their hard work over the years in oversight and conduct of research. Dr. Parker thanked Dr. Tabak and the NIH Office of Science Policy for their support.

Dr. Parker said that discussion of biosecurity, biosafety, P3CO, and DURC precedes the Board's recommendations and will continue. Related issues are challenging but important to the future of science. The NSABB is happy to assist.

Closing Remarks and Adjournment

Dr. Tabak thanked NSABB members for their work on the draft report, noting that he would accept the NSABB's offer to be engaged in future discussions.

Dr. Parker adjourned the meeting at 3:15 p.m.

Certification

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.

Caroline E. Young -S Digitally signed by Caroline E. Young -S Date: 2023.04.24 19:30:05 -04'00' 4/24/23

Caroline E. Young, Sc.M. Date
Executive Secretary
National Science Advisory Board for Biosecurity

Gerald W Parker, Jr. 4/25/23

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

Attachment 1: NSABB Voting Member Roster

Chair

Gerald W. Parker, Jr., D.V.M., Ph.D.
Associate Dean for Global One Health
College of Veterinary Medicine & Biomedical Sciences
Texas A&M University

Voting Members

Shannon Benjamin, M.S., M.B.A.
Associate Director, Environmental Health & Safety
Ginkgo Bioworks

Kenneth Bernard, M.D.
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, National Security Council

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

Christina Egan, Ph.D.
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Chief, Biodefense and Mycology Laboratories
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Jacqueline Fletcher, Ph.D.
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Wallace H. Coulter Department of Biomedical Engineering
Georgia Institute of Technology and Emory University

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