







"RESPONSIBLE CONDUCT OF RESEARCH"

SESSION OF THE

AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE (AAAS)-KUWAIT INSTITUTE OF SCIENTIFIC RESEARCH (KISR) WORKSHOP

AAAS INTERNATIONAL ENGAGEMENT: RESPONSIBLE BIOSCIENCE FOR A SAFE AND SECURE SOCIETY

Video Teleconference Kuwait City, Kuwait and Washington, D.C. March 16, 2011

SUMMARY

The "Responsible Conduct of Research" (RCR) video teleconference was held as a session of the AAAS-KISR workshop, AAAS International Engagement: Responsible Bioscience for a Safe and Secure Society. This AAAS-KISR workshop was the second in a series of workshops organized by AAAS to better understand critical issues that underlie international collaboration and scientific engagement in the biological sciences and that focuses on the Broader Middle East and North Africa (BMENA) region. An AAAS-KISR report on the full workshop can be found at:

http://cstsp.aaas.org/InternationalMeeting/Kuwait/InternationalEngagementWS2.pdf

The following summary describes the "Responsible Conduct of Research" videoteleconference session, held as a joint effort by the organizers of the workshop (AAAS and the KISR) and the National Institutes of Health / National Science Advisory Board for Biosecurity (NSABB). The purpose of this session was to engage life scientists and policymakers from the BMENA region, focusing on bioethics, biosafety, and biosecurity as a suite of areas to consider in addressing risks associated with biological research. The session included perspectives from scientists across the BMENA region and the United States on topics related to core ethical and safety considerations, which include concerns about biological research issues and the misuse of research results (the "dual use dilemma").

The session included reports from an earlier breakout session, brief presentations by panelists in Kuwait, and a general discussion involving the panelists, workshop participants in Kuwait, and the AAAS / NSABB biosecurity/DUR panel at the AAAS headquarters in Washington, D.C.

The panel in Kuwait consisted of:

- Moderator:
 - Ara Tahmassian, PhD, Boston University, USA
- Panelists:
 - Ethics and responsible conduct of research: Zabta Shinwari, PhD,
 Quaid-i-Azam University, Pakistan
 - Biorisk management and responsible conduct of research: James (Jim) M.
 Welch, Elizabeth R. Griffin Research Foundation, USA
 - Security concerns and responsible conduct of science: dual use research:
 Michael J. Imperiale, PhD, NSABB, University of Michigan, USA

About 70 scientists and policymakers from across the BMENA region participated in this session.

The Washington Discussant Panel included:

- Kavita Berger, PhD, AAAS, Washington, District of Columbia, USA
- Paul Keim, PhD, NSABB, Northern Arizona University, Flagstaff, Arizona, USA
- Stuart Levy, MD, NSABB Tufts University School of Medicine, Boston, Massachusetts, USA

The Washington audience included another NSABB member, NSABB ex officio members, the Executive Director of the Presidential Commission for the Study of Bioethical Issues, staff from the U.S. National Academy of Sciences, and NIH staff.

SESSION SUMMARY

The session began with reports from the rapporteurs of the breakout sessions held earlier in the afternoon with the Kuwait workshop participants. The questions that had been discussed by breakout session participants included:

 What are the existing infrastructure and instruments (i.e. policy, training, reporting mechanism) already in place in your country to facilitate a culture of safety, security, and ethics? How would you compare the programs in your country to those in neighboring countries, in the entire region, and internationally?

- Have you received training on the responsible conduct of research? Who was in charge of the training (institutions, country)? What were the basic concepts taught?
- Whose responsibility is it to create a responsible research environment that allows scientists to conduct their research ethically and safely (both from a biosafety and biosecurity point of view)?
- What experience do you have with the concept of dual use research and dual use research of concern? What do you think about these issues? Where did you learn about them (i.e. websites, literature, training, etc.)?
- Is it ethical to report "concerning behavior" when you see it in a lab environment? Does your institution have a reporting mechanism in place to deal with such behavior? Are you comfortable in reporting on a colleague or supervisor, if necessary?

A number of the points made by the rapporteurs are incorporated into the summary of the discussion below, following the presentations by panelists.

The three Kuwait-based panelists then each made presentations on one of the different areas of risk in biological research: bioethics, biosafety, and biosecurity.

- Dr. Shinwari discussed bioethics, beginning with the position that scientists have an obligation to do no harm, intentionally or unintentionally. He described Pakistan's efforts to promote responsible conduct of research through the establishment of a task force to examine education, legislation, and develop a code of conduct. A commission on higher education hosted workshops on responsible conduct of research and dual use research (DUR), including workshops specifically intended for biological researchers, and distributed surveys on awareness of these topics. They found that, similar to results from European surveys, a majority of respondents were unfamiliar with key concepts of DUR. Pakistan continues to work with organizations such as the AAAS, the US Department of State's Bioengagement Program (BEP), and the International Council for the Life Sciences (ICLS) to promote responsible conduct of research.
- Mr. James Welch discussed biosafety. He stated his belief that scientific research holds great promise for mankind, and that he and the Elizabeth R. Griffin Research Foundation advocate the strengthening of global research capacity. He noted, however, that research must be safe in order to minimize the risk of collateral damage to researchers, the public, and research itself. He and his foundation advocate using risk management to determine which best local,

practical, and sustainable practices and procedures can be implemented to minimize this risk.

• Dr. Michael Imperiale discussed biosecurity. He began with a brief history of the NSABB and its international outreach efforts. The NSABB created an International Engagement Working Group to raise awareness about dual use life sciences research issues across the globe; gain perspectives from the global community on DUR and DURC and identify and monitor the strategies for managing DUR and DURC in different countries and identify gaps; expand the NIH network of those individuals and organizations interested and/or engaged in activities related to DURC; and to make the reports and recommendations of the NSABB available internationally. Dr. Imperiale discussed the link between science and society, the continuum of risk associated with biological research, the importance of transparency of research activities and review processes, the use of existing frameworks to address security concerns, the ever-expanding efforts for awareness raising and education of "dual use" concerns, and the importance of engaging the public and policymakers on science and security issues.

Dr. Katherine Bowman, National Academies, USA, presented a brief overview of the activities of the Inter-Academy Panel Biosecurity Working Group, and other scientific organizations' international outreach programs in this area.

The panelists in Kuwait City, Washington, and members of the audience then posed and responded to questions based on the presentations and the earlier breakout session reports.

The following major points were made during the meeting:

- While there was a general acknowledgement in BMENA countries of the ethical issues relating to plagiarism, there was significant variation among countries in systems for reporting other ethical violations, national policies on animal use, and standards for collaboration and data sharing among researchers across the region.
- Several researchers reported that their scientific organizations or countries were actively developing codes of conduct for research.

For summaries of the NSABB's international roundtables and videos of webcasts, webinars, and video-teleconferences:

http://oba.od.nih.gov/biosecurity/internationalwebcast.html

More information on NSABB's approach to DUR/C and biosecurity can be found at: http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807 Sept07.pdf

- The level of biosafety training, including requirements for routine refresher courses, varied widely across the BMENA region. Several researchers expressed their interest in globally-accessible biosafety training tools.
- Many participants reported different definitions of "dual use" across the region. Furthermore, these definitions differed from the NSABB definition of "dual use research" and "dual use research of concern." Especially confusing was the fact that "dual use research" was often understood in the region to be research that resulted in benefits for two or more parties, for example a researcher and their colleague at a partner institution, and did not refer to potentially harmful outcomes. Due to the difficulty in determining whether DURC was occurring in BMENA countries, several participants noted the important role that this series of AAAS workshops played in assessing risks in the region. It was also proposed that NSABB's materials should be made available in regionally relevant languages and terminology.
- There was widespread acknowledgement of the importance of reviewing research from the proposal stage through the entire research process to publication.
- It was observed that the degree of risk in research is in part determined by the local context, as certain research may hold greater risks for some countries than others. Greater understanding of local concerns was considered important for assessing risk and promoting responsible conduct.
- Several researchers emphasized the importance of educating scientists, policymakers and the public about risks, including those related to dual use research. There was agreement that research is conducted for public benefit and that securing the public trust is essential. A review process which was as transparent as possible was suggested.
- Several researchers emphasized the need for developing models for risk identification, assessment, monitoring, and management of research within their institutions.
- Several researchers from the BMENA region expressed concern that focusing on biosecurity, export controls and the transfer of knowledge and samples would disproportionately hinder the progress of increasing research capacity in the region, particularly in developing countries.

It was clear that awareness of bioethical, biosafety, and biosecurity issues is growing among researchers in the BMENA region. The session also revealed common principles between researchers in the region and the U.S. Many researchers expressed interest in the activities of the AAAS and NSABB, and in promoting greater awareness and dialogue within their institutions, countries, and region.

The AAAS, KISR, and NSABB found the insight yielded by the session to be both important and helpful in planning future events.