

## Fact Sheet on United States Government Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

The United States Government conducts and funds life sciences research which is crucial to the long term health security and wellness of the public, animals, plants, the environment, and our economy. Federal departments and agencies are committed to fostering progress in the life sciences to include responsible research involving biological agents and toxins, conducted in a safe and secure manner. Basic and applied life science research are instrumental in developing national capabilities to mitigate the risks of infectious diseases and environmental risks, whether naturally occurring, deliberate, or accidental.

Reinforcing norms of safe and responsible conduct is one of the objectives of the *National Strategy for Countering Biological Threats* which highlights actions that should be taken to reinforce a culture of responsibility, awareness, and vigilance among all who utilize and benefit from the life sciences. Reinforcing these norms is critical to counteracting diversion of the life sciences for harmful purposes.

The Federal Experts Security Advisory Panel (FESAP) was established by Executive Order 13546 on July 2, 2010 to provide recommendations regarding the security of biological select agents and toxins (BSAT) to the Secretaries of Health and Human Services and Agriculture and the Attorney General. The White House National Security Council staff tasked the FESAP, in September 2014, to undertake a comprehensive review and identify specific recommendations to strengthen the Government's biosafety and biosecurity practices and oversight of federally-funded activities involving (but not limited to) BSAT, consistent with the need to realize such activities' public health and security benefits. While directed at the federal research system, FESAP recommendations have broad applications and may also inform biological risk management practices in non-federal life sciences research.

FESAP recommended several actions to strengthen and sustain the culture of biosafety, biosecurity, and the responsible conduct of science at the federal level such as promoting bioethics training that addresses the fundamental safety and security responsibilities expected of all life scientists; development and incorporation of bioethics modules into laboratory biosafety and laboratory biosecurity training and/or research design; and the development of semi-quantitative methods to evaluate the efficacy of training, education, codes of conduct, and similar interventions to reduce risk and improve safety in domestic research laboratories housing infectious agents and toxins. FESAP also emphasized that training should include discussions of ethical and legal considerations, as well as the social relevance of life science research, and the range of dual-use conundrums and dilemmas that may arise. FESAP's recommended discussions would emphasize the impact of science and technology on society, health, and national security, and highlight efforts that should be undertaken to encourage institutional leadership to support and implement bioethics components within their institution's training programs. FESAP also generated several interagency working groups to address these recommendations.

In order to advance the implementation of FESAP's recommendation on the culture of biosafety, biosecurity, and responsible conduct of life sciences, the United States Government established an interagency working group with representation from 15 offices and organizations across five federal departments and agencies. This interagency working group is co-chaired by the US Department of Health and Human Services / Office of the Assistant Secretary for Preparedness and Response and US Department of Agriculture / Animal and Plant Health Inspection Service. As part of its tasking, this working group refined training goals and objectives; identified the role of "culture" as it relates to biorisk management, emphasizing *principles for guiding decisions and behaviors* as they related to biorisk management (i.e. motivation, leadership, commitment and responsibility, professionalism and competence, learning and improvement, maintaining public trust); conducted an inventory of existing federal and non-federal training and education programs addressing the culture of biosafety, biosecurity and responsible conduct of life sciences; and consulted with experts from academia and professional organizations on best practices and lessons learned. This working group conceptualized training and educational materials to be used by federal departments and agencies in their internal outreach or in conjunction with non-governmental organizations; refined these materials to create, strengthen, and sustain a culture of biosafety, laboratory biosecurity, and responsible conduct in the life sciences research; compiled resources to enhance individual and collective responsibility; and identified resources to reinforce the biological risk management framework of laws, regulations, and policies.