

## **Bioethics Training: Guiding Principles to Promote a Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences**

Life sciences research is crucial to the development of national capabilities to mitigate the risks posed by infectious diseases and environmental risks, whether naturally occurring, deliberate, or unintentional. As such, life sciences research fosters the long term health, security, and wellness of the public, animals, plants, the environment, and our economy when conducted in a safe and secure manner.

Laboratory incidents may put individuals, communities, and the environment at risk, undermine public confidence in the research enterprise, and must be addressed to help minimize the probability of occurrence and mitigate any potential impacts.

Reinforcing the norms of safe and responsible conduct in life sciences is critical to counteracting the diversion of biological materials, equipment, or technologies for harmful purposes.

Facilities undertaking research or performing diagnostics that involve biological agents and toxins, as well as professional organizations, and academic institutions provide bioethics training and education addressing a broad range of issues including ethical theories, ethical concerns embodied in life sciences' practice, emerging technologies, dual use dilemmas, ethical research, and research integrity.

Such training should also include considerations about how bioethical dilemmas are shaped by life sciences professionals' cultural values and beliefs about the concepts of biosafety, biosecurity, and responsible conduct of research.

Bioethics training should promote responsible, safe, and secure research and diagnostic practices, provide tools and guidance to scientists and institutions that facilitate open discussion and analysis of potential challenges and dilemmas associated with their work, including weighing potential risks and benefits, dual use concerns, and the possibility of accidents or misuse of life sciences research.

Training should be supplemented with primary source materials to further examine the U.S. Government policies regarding life sciences dual use research of concern, the *National Strategy for Countering Biological Threats* (which highlights actions that should be taken to reinforce

**Bioethics:** *The study of the moral principles or values governing, or distinctive of, life sciences research and the moral or societal implications of certain biological research procedures, technologies, or treatments.*

**Culture:** *An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents.*

a culture of responsibility, awareness, and vigilance among all who utilize and benefit from the life sciences), case studies on bioethical dilemmas and historical examples of scientists or biomedical professionals involved in bioterrorism or biocrimes, and guidance and training materials developed by the National Science Advisory Board for Biosecurity and the Federal Experts Security Advisory Panel working group on strengthening the culture of biosafety, biosecurity, and responsible conduct.

When addressing ethical considerations related to laboratory biosafety and biosecurity, bioterrorism or biocrimes perpetrated by biomedical professionals, emerging technologies or dual use research dilemmas, additional questions to be raised may include: is there a difference between common morality and professional ethics?; is there a difference between applied ethics and professional ethics?

Analyzing and providing examples of ethical and decision making frameworks (decision theory, precautionary principle, rights-based approach, deontological ethics, principle-based frameworks, etc.) will serve to promote dialogue and raise awareness on approaches for weighing ethical and societal responsibility issues pertinent to the life sciences.

***Code of conduct: A formal statement of values and professional practices of a group of individuals with a common focus (either an occupation, academic field, or social doctrine) which defines the expectations and directs the actions of the group, and is a persistent reminder of moral and ethical responsibilities.***

Life sciences bioethics training may also include discussions on whether a pan-professional ethics code is needed for the life sciences professions or the equivalent of a Hippocratic oath to "do no harm".

### **Select references:**

1. Federal Experts Security Advisory Panel working group's [training materials on strengthening the culture of biosafety, biosecurity, and responsible conduct](#), American Biosafety Association (ABSA) website.
2. Dual Use Research of Concern (DURC) [information, policies, and training materials](#).
3. [Enhancing Responsible Science: Development of Codes of Conduct for Dual Use Research](#), National Science Advisory Board for Biosecurity 2010.
4. [Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility](#), National Science Advisory Board for Biosecurity 2011.
5. [Responsible life sciences research for global health security: a guidance document](#), World Health Organization, 2010.
6. [Ethics: A Weapon to Counter Bioterrorism](#), Margaret A. Somerville and Ronald M. Atlas, Science, Vol 307, Issue 5717, 1881-1882, 25 March 2005.
7. [Code of ethics](#), American Society of Microbiology (ASM), 2005.
8. [Gain-of-Function Research: Ethical Analysis](#), Michael J Selgelid, 2016, Sci Eng Ethics. 2016; 22(4): 923–964.

9. [New Directions: The Ethics of Synthetic Biology and Emerging Technologies](#), Presidential Commission for the Study of Bioethical Issues, 2010.
10. [Competency Guidelines for Public Health Laboratory Professionals](#), CDC and the Association of Public Health Laboratories, MMWR Supplements May 15, 2015 / 64(01);1-81.
11. [Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories](#), Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel, 2012.
12. [Guidelines for Biosafety Laboratory Competencies](#) (Culture of Safety), CDC and the Association of Public Health Laboratories, 2011.

---

*These guiding principles were developed by the Federal Experts Security Advisory Panel (FESAP) Working Group established to implement FESAP recommendation to strengthen the culture of biosafety, biosecurity, and responsible conduct in the life sciences, with support from experts from professional organizations and academia. For more information, contact the working group co-chairs Dana Perkins [dana.perkins@hhs.gov](mailto:dana.perkins@hhs.gov) and Eilyn Fabregas [eilyn.n.fabregas@aphis.usda.gov](mailto:eilyn.n.fabregas@aphis.usda.gov).*