

## Dual-Use Technology

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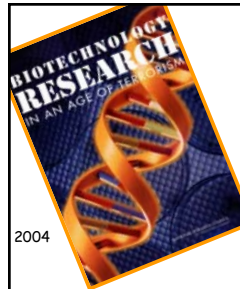


## Case Study

The editor of an American biomedical journal seeks guidance on the handling of a submitted manuscript. The manuscript is co-authored by an interdisciplinary group working in a foreign research institute. The paper reports on recombinant DNA experiments that modify a virulent bacterial pathogen capable of causing fatal infections in humans. The only available preventative measure for this disease is an attenuated whole-cell vaccine. The authors report that the animals infected with this genetically engineered strain died more rapidly than those infected with the wild-type strain. More important, immunization of the animals with the current whole-cell vaccine fails to protect them against lethal infection with the genetically engineered strain. The authors argue that this work will open new doors for the understanding of the disease process and ultimately will lead to the development of more effective vaccines. The pathogen in question is believed to have been stockpiled as a biological weapon by certain countries during the "Cold War" era. The editor is considering rejecting the paper on ethical grounds. What advice will you give her?

## Research and Dual-Use Implications (not just a dilemma for microbiologists)

- Chemistry
- Computer sciences
- Psychology
- Neurosciences
- Nanotechnology



2004

"The Fink Committee Report"

## Recommendations

1. Educating the Scientific Community
2. Review of Plans for Experiments
3. Review at the Publication Stage
4. Creating of a National Science Advisory Board for Biodefense
5. Additional Elements for Protection Against Misuse (containment, training)
6. Role for the Life Sciences in Efforts to Prevent Bioterrorism and Biowarfare
7. Harmonized International Oversight

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## Experiments of Concern

1. Would demonstrate how to render a vaccine ineffective
2. Would confer resistance to therapeutically useful antibiotics or antiviral agents
3. Would enhance the virulence of a pathogen or render a nonpathogen virulent
4. Would increase transmissibility of a pathogen
5. Would alter the host range of a pathogen
6. Would enable the evasion of diagnostic/detection modalities
7. Would enable the weaponization of a biological agent or toxin

## Proposed System of Review

- NIH Recombinant Advisory Committee (RAC)
- Institutional Biosafety Committee (IBC)
- Journal Editors
- National Science Advisory Board for Biodefense (NSABB) 2004--

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**Dual Use Research**

The Dual Use Research Program is a focal point for the development of policies addressing life sciences research that yield information or technologies with the potential to be misused to threaten public health or national security.

OSPA's activities to address such "dual use" research include convening and managing the **National Science Advisory Board for Biosecurity (NSABB)**.

To learn more about the scope of dual use research in the life sciences, please watch the following educational video produced by the NSABB:



<http://www.biosecurityboard.gov/>

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**NSABB Documents**

**NSABB Reports**

- Addressing Biosecurity Concerns Related to Synthetic Biology (April 2010)
- Enhancing Personnel Reliability Among Individuals with Access to Select Agents (May 2009)
- Strategic Plan for Outreach and Education on Dual Use Research Issues (December 18, 2008)
- Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Adverse of Research Information (June 2007)
- Addressing Biosecurity Concerns Related to the Synthesis of Select Agents (December 2006)

**Reports of the International Roundtables on Dual Use Life Sciences Research**

- November 2008 International Roundtable Report
- November 2008 International Roundtable Brief Summary
- October 2007 International Roundtable Summary
- October 2007 International Roundtable Executive Summary
- February 2007 International Roundtable Summary

[http://oba.od.nih.gov/biosecurity/biosecurity\\_documents.html](http://oba.od.nih.gov/biosecurity/biosecurity_documents.html)

NSABB Criteria for Dual Use Research of Concern

BOX 1-3

1. Is it likely that the research could:

- Enhance the harmful consequences of a biological agent or toxin
- Disrupt immunity or the effectiveness of an immunization clinically used or agriculturally useful prophylactic or therapeutic evade detection methods
- Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin
- Alter the host range or tropism of a biological agent or toxin
- Enhance the susceptibility of a host population to a novel pathogenic agent or toxin or recombinant agent

2. Additional Review Assessment


The potential for, and the ways in which, information, technologies, or biological agents from the research could be misused to pose a threat to public health and safety, agricultural crops and other areas, the environment, or national security

The likelihood that the information might be misused

Strategies for mitigating the risks that information from the research could be misused

SOURCE: NSABB (2007).

2009



Guiding Principles

- Research on select agents and toxins is essential
- Such research carries potential security and safety concerns
- Select Agent Program should focus on agents and toxins that might be used as biotreatments
- Policies and Practices for research with select agents and toxins should promote both science and security
- Not all labs and not all agents are the same
- Misuse of biological materials is taboo in every scientific community

[http://www.nap.edu/catalog.php?record\\_id=12774](http://www.nap.edu/catalog.php?record_id=12774)

FROM THE ACADEMY EDITORIAL BOARD

Modeling attacks on the food supply

The potential of the attack on the food supply is a topic that has received significant attention in the scientific community. This article discusses the challenges of modeling such attacks and the implications for food security.

The authors explore the complexities of modeling food supply attacks, including the need for interdisciplinary approaches and the importance of data collection and analysis. They discuss the potential for such attacks to disrupt food production and distribution, and the need for robust systems to prevent and respond to such threats.

The article concludes by highlighting the need for continued research and collaboration between scientists, policymakers, and the public to ensure the resilience of our food supply.

EDITORIAL

1918 Flu and Responsible Science

The influenza pandemic of 1918 is revisited in this special issue. The influenza pandemic of 1918 is revisited in this special issue. The influenza pandemic of 1918 is revisited in this special issue.

This special issue features a collection of articles that explore the historical, scientific, and public health aspects of the 1918 influenza pandemic. The authors discuss the challenges of understanding the origins and spread of the virus, the impact of the pandemic on society, and the lessons learned for future pandemic preparedness.

The issue also includes a historical photograph of a crowded street during the 1918 pandemic, illustrating the scale of the outbreak and the public health measures implemented at the time.

Science 7 October 2005

**Experiments of concern to be vetted online**



**UNIVERSITY OF CALIFORNIA, BERKELEY**  
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**The Problem.** Advances in the life sciences offer important new ways of understanding and organizing DNA for human use. In practice, however, this same research could extend science in directions that make it easier for would-be weapons designers to produce dangerous new pathogens and toxins. The US National Academies of Sciences,<sup>[1]</sup> and UK Royal Society<sup>[2]</sup> have repeatedly stressed the importance of addressing the problem. While genuine "experiments of concern" are rare,<sup>[3]</sup> it is important to evaluate instances that do occur in a careful and responsible manner.

**The problem, for now, is that most researchers have no quick, practical, and convenient way to get this advice.** Existing institutions (e.g. Institutional Biosafety Committees) are usually overworked, focus mainly on safety and compliance with federal guidelines and regulations, and some have little or no expertise for analyzing biosecurity problems. Informal channels are no better. The average researcher seldom knows anyone in the biosecurity community or, indeed, has any way of deciding which discipline(s) are even relevant.

**The Opportunity.** Researchers have discussed the experiments of concern problem extensively in recent years. One result is an emerging norm that researchers should seek informal outside review before publishing controversial results.<sup>[4]</sup> Scores of working biologists<sup>[5]</sup> have endorsed support for extending this norm so that researchers would feel an obligation to obtain competent, outside advice before performing experiments in the first place. For their part, many biosecurity experts have said that they are ready, willing, and able to give this advice. Developing a review mechanism that taps the requisite expertise is a logical next step. Here, National Scientific Advisory Board for Biosecurity (NSABB) called on the biology community to take the lead in managing the experiments of concern.<sup>[6]</sup> Researchers and their institutions will need fast, convenient, and authoritative advice to meet this challenge.

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 E-mail the Portal Administrator:  
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March 24 March 2008  
 Vol. 307, No. 6171, pp. 1881 - 1882  
 DOI 10.1126/science.1150279

**POLICY FORUM**

**ETHICS:**  
**EBiCS: A Weapon to Counter Bioterrorism**  
 Margaret A. Somerville and Ronald M. Adair

**Your thoughts on a code of ethics?**

**CODE OF ETHICS FOR THE LIFE SCIENCES**

**All persons and institutions engaged in any aspect of the life sciences must**

1. Work to ensure that their discoveries and knowledge do no harm (i) by refusing to engage in any research that is intended to facilitate or that has a high probability of being used to facilitate bioterrorism or bio warfare; and (ii) by never knowingly or recklessly contributing to development, production, or acquisition of microbial or other biological agents or toxins, whatever their origin or method of production, of types or in quantities that cannot be justified on the basis that they are necessary for prophylactic, protective, therapeutic, or other peaceful purposes.
2. Work for ethical and beneficent advancement, development, and use of scientific knowledge.
3. Call to the attention of the public, or appropriate authorities, activities (including unethical research) that there are reasonable grounds to believe are likely to contribute to bioterrorism or bio warfare.
4. Seek to allow access to biological agents that could be used as biological weapons only to individuals for whom there are reasonable grounds to believe that they will not misuse them.

5. Seek to restrict dissemination of dual-use information and knowledge to those who need to know in cases where there are reasonable grounds to believe that the information or knowledge could be readily misused through bioterrorism or bio warfare.
6. Subject research activities to ethics and safety reviews and monitoring to ensure that (i) legitimate benefits are being sought and that they outweigh the risks and harms; and (ii) involvement of human or animal subjects is ethical and essential for carrying out highly important research.
7. Abide by laws and regulations that apply to the conduct of science unless to do so would be unethical and recognize a responsibility to work through societal institutions to change laws and regulations that conflict with ethics.
8. Recognize, without penalty, all persons' rights of conscientious objection to participation in research that they consider ethically or morally objectionable.
9. Faithfully transmit this code and the ethical principles upon which it is based to all who are or may become engaged in the conduct of science.

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**Your thoughts on a oath?**

**EMBO reports**

*science & society*

**A Hippocratic Oath for life scientists**

A Hippocratic-style oath in the life sciences could help to educate researchers about the dangers of dual-use research

James Revell & Malcolm R. Dando

**A Survey of Attitudes and Actions on Dual Use Research in the Life Sciences**

**A Collaborative Effort of the National Research Council and the American Association for the Advancement of Science**



Dual use research represents a dilemma in the life sciences in which the same technologies that fuel scientific advances could also be misused for bio warfare or bioterrorism. Reducing the risks posed by dual use research without slowing scientific progress is a critical goal, in which the scientific community plays an essential role. A survey conducted by the National Research Council and AAAS (the American Association for the Advancement of Science) provides baseline data to better understand current attitudes and levels of awareness among life scientists about dual use concerns and policies to address these risks. Overall, the survey findings suggest that there may be considerable support for mechanisms for research oversight that are developed and implemented by the scientific community itself.

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Measures of Personal or Institutional Responsibility	% Saying Strongly Agree or Agree (or Yes*)
Principal investigators should be responsible for the initial evaluation of the dual use potential of their life sciences research.	87
Principal investigators should be responsible for training lab staff, students and visiting scientists about dual use research.	86
Should professional science societies have codes for the responsible conduct of dual use life sciences research?	82*
University and college students should receive educational lectures and materials on dual use life sciences research.	68
Scientists should provide formal assurance to their institution that they are assessing their work for dual use potential.	67
Funding agencies should require grantees to attest on grant applications that they have considered dual use implications of their proposed research.	60
Should scientific journals have policies regarding publication of dual-use research?	57*
Institutions should provide mandatory training for scientists regarding dual use life sciences research.	55

**Table 1.** Summary of results regarding support for measures of personal and institutional responsibility. NOTE: The results reported cannot be generalized beyond the scientists who responded to this survey. Not all respondents answered every question; the number of responses for each question ranges between 1,633 and 1,755.

Measures of Personal or Institutional Responsibility	% Saying Strongly Agree or Agree (or Yes*)
Greater restrictions should be placed on access to specific biological agents or toxins.	47
Researchers conducting dual use research should be certified.	42
All grant proposals for life sciences research with dual use potential should be reviewed by a researcher's institution prior to submission for funding.	41
Scientists conducting or managing research should take an oath.	38
Research findings should be classified based on their dual use potential.	28
Dual use research needs greater federal oversight.	26
Certain experimental methods or findings should be altered or removed prior to publication or presentation.	22
Certain biological equipment that is commonly used in life science research should be licensed.	21
There should be restrictions on disclosure of details about the research or its findings through personal communication.	21
There should be restrictions on publication of findings based on their dual use potential.	21

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## Oversight of dual use life sciences research

What's necessary?

What's reasonable?

What's likely?