

Dual-Use Technology

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VCU

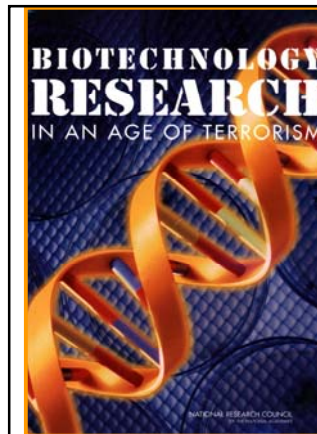
Case Study

The editor of an American biomedical journal arranges a teleconference call with you and seven other associate editors on the editorial board. She seeks guidance on the handling of a submitted manuscript. The paper in question was submitted 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. In their paper, the authors demonstrate 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

Examples?



<http://www.nap.edu>

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

Proposed System of Review

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

<http://oba.od.nih.gov>

- ## 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

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information

A Report of the National Science Advisory Board for Biosecurity (NSABB)
June 2007

BOX 1-3
NSABB Criteria for Dual Use Research of Concern

1. Is it likely that the research could:
 - a. Enhance the harmful consequences of a biological agent or toxin
 - b. Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification
 - c. Confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies
 - d. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin
 - e. Alter the host range or tropism of a biological agent or toxin
 - f. Enhance the susceptibility of a host population
 - g. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent
2. Additional Review Assessment
 - a. 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 plants, animals, the environment, or material
 - b. The likelihood that the information might be misused
 - c. The potential impacts of misuse
 - d. Strategies for mitigating the risks that information from the research could be misused

SOURCE: NSABB (2007).

Experiments of concern? To be vetted online

UNIVERSITY OF CALIFORNIA, BERKELEY
GOLDMAN SCHOOL OF PUBLIC POLICY

FACULTY PROJECTS

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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 Science,^[1] and UK Royal Society^[2] have repeatedly stressed the importance of addressing this problem. While genuine "experiments of concern" are rare,^[3] 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.^[4] Surveys of working biologists^[5] show widespread 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. NIH's National Science Advisory Board for Biosecurity (NSABB) called on the biology community to take the lead in managing the experiments of concern.^[6] Researchers and their institutions will need fast, convenient, and authoritative advice to meet this challenge.

SUBMIT AN EXPERIMENT FOR REVIEW
E-mail the Portal Administrator
[mailto:foa@publicpolicy.berkeley.edu]

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APR 15 10:00 AM '08
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POLICY FORUM
ETHICS:
Genetics: A Weapon to Counter Bioterrorism
Margaret A. Somerville and Ronald B. 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 biowarfare.
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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POLICY FORUM
ETHICS: A Weapon to Counter Bioterrorism
 A. Saverille and Ronald M. Atlas*

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 Revill & Makoto R. Daoudo

What Others Think

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 biowarfare 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.

http://www.nap.edu/catalog.php?record_id=12460

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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