Presentation to the National Science Advisory Board for Biosecurity

BEYOND DURC
situating policies within larger biosecurity shifts

SAM WEISS EVANS
Senior Research Fellow

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SCIENCE, TECHNOLOGY & SOCIETY
HARVARD Kennedy School

BIOSECURITY IS HAVING A MOMENT

NSABB DURC/P3CO review	
Biotechnology and Biomanufacturing Initiative	Commerce, Energy, Agriculture, HHS, and NSF reports must include "recommendations for actions to enhance biosafety and biosecurity"
National Security Commission on Emerging Biotechnology	Mainly focused on defense
ARPA-H	Lots of room to experiment on integrating social and life sciences

HOW DO WE IMPROVE DUAL USE GOVERNANCE?

Local context: Learning what works in practice, and iterating on it

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Conceptual context: Better understanding the limitations of existing systems

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Future context: Providing institutional support for experiments in novel governance

Local Context

LEARNING WHAT WORKS IN PRACTICE

Little is known about efforts to practically implement high-level biosecurity guidelines

VIRS approached a wide range of organizations (50+) across research lifecycle to learn about biorisk management practices

Many orgs (funders, publishers, universities, etc) hesitant to share, and unsure of the quality or novelty of their practices, despite being as, or more, sophisticated than others we engaged

VIRS Visibility Initiative for Responsible Science

Megan Palmer
Sam Weiss Evans
Dan Greene
Kathryn Brink
Mel Salm
Connor Hoffmann
Jeffrey Landish
Geetha Jeyapragasan

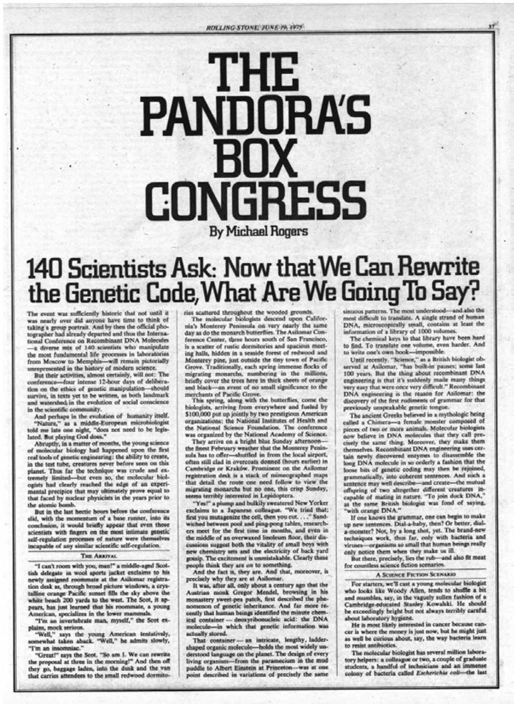
We have a culture of compliance, not collaboration or curiosity

Sam Weiss Evans

Conceptual Context

BIOLOGY IS. . .

Science → Technology → Economy

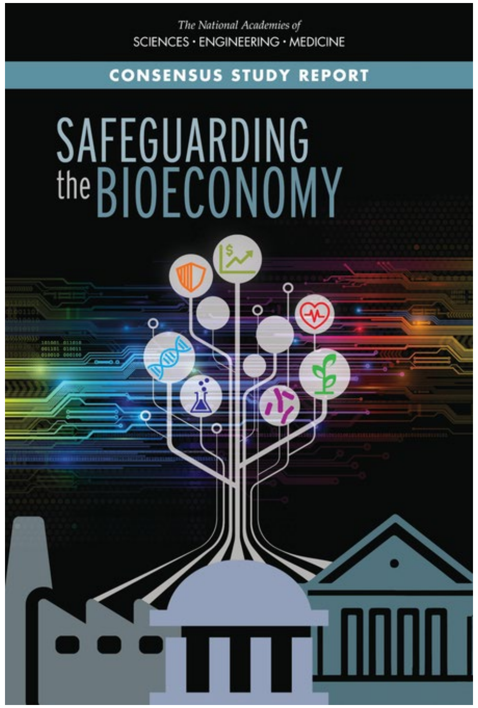


ROLLING STONE, JUNE 19, 1975 37

THE PANDORA'S BOX CONGRESS

By Michael Rogers

140 Scientists Ask: Now that We Can Rewrite the Genetic Code, What Are We Going To Say?



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Conceptual Context

WE HAVE CHOSEN TO DEFINE DURC NARROWLY

Why we did this

Early 2000s (Fink)

Clandestine bioweapons programs, anthrax, speed of biotech advance

Belief that balance needed was between *science and [national] security*

Why this is a good idea

Clear policy

Implementable with existing governance structures (e.g. IBCs)

Agents and experiments of known concern

Why this is a bad idea

Engenders idea that, if research isn't DURC, it's not a security concern at all (compliance, not curiosity)

Misses novel areas of concern

Balance is now between *science, economics, and [national, environmental, health…] security*

Conceptual Context

WHAT WE MISS BY NOT ATTENDING TO DUR

Health Security
Volume 20, Number 1, 2022 Mary Ann Liebert, Inc.
DOI: 10.1089/hs.2021.0157

Open camera or QR reader and scan code to access this article and other resources online.

CASE STUDY

iGEM and Gene Drives: A Case Study for Governance

Piers Millett, Tessa Alexanian, Megan J. Palmer, Sam Weiss Evans, Todd Kuiken, and Kenneth Oye

Gene drives have already challenged governance systems. In this case study, we explore the International Genetically Engineered Machine (iGEM) competition's experiences in gene drive-related research and lessons in developing, revising, and implementing a governance system. iGEM's experiences and lessons are distilled into 6 key insights for future gene drive policy development in the United States: (1) gene drives deserve special attention because of their potential for widescale impact and remaining uncertainty about how to evaluate intergenerational and transboundary risks; (2) an adaptive risk management approach is logical for gene drives because of the rapidly changing technical environment; (3) review by individual technical experts is limited and may fail to incorporate other forms of expertise and, therefore, must be complemented with a range of alternative governance methods; (4) current laboratory biosafety and biosecurity review processes may not capture gene drive research or its components in practice even if they are covered theoretically; (5) risk management for research and development must incorporate discussions of values and broader implications of the work; and (6) a regular technology horizon scanning capacity is needed for the early identification of advances that could pose governance system challenges.

Keywords: iGEM, Gene drives, Adaptive governance, Risk management, Governance, Adaptive risk management

Check for updates

comment

Dual use of artificial-intelligence-powered drug discovery

An international security conference explored how artificial intelligence (AI) technologies for drug discovery could be misused for de novo design of biochemical weapons. A thought experiment evolved into a computational proof.

Fabio Urbina, Filippa Lentzos, Cédric Invernizzi and Sean Ekins

The Swiss Federal Institute for NBC (nuclear, biological and chemical) Protection —Spiez Laboratory— convenes the 'convergence' conference series[1] set up by the Swiss government to identify developments in chemistry, biology and enabling technologies that may have implications for the Chemical and Biological Weapons Conventions. Meeting every two years, the conferences bring together an international group of scientific and disarmament experts to explore the current state of the art in the chemical and biological fields and their trajectories, to think through potential security implications and to consider how these implications can most effectively be managed internationally. The meeting convenes for three days of discussion on the possibilities of harm, should the intent be there, from cutting-edge chemical and biological technologies. Our drug discovery company received an invitation to contribute a presentation on how AI technologies for drug discovery could potentially be misused.

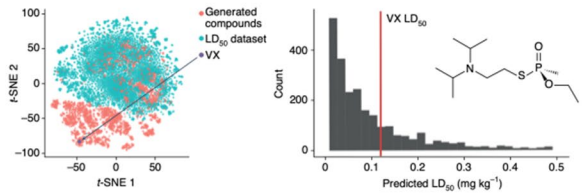


Fig. 1 | A t-SNE plot visualization of the LD_{50} dataset and top 2,000 MegaSyn AI-generated and predicted toxic molecules illustrating VX. Many of the molecules generated are predicted to be more toxic in vivo in the animal model than VX (histogram at right shows cut-off for VX LD_{50}). The 2D chemical structure of VX is shown on the right.

Risk of misuse

The thought had never previously struck us. We were vaguely aware of security concerns around work with pathogens or toxic chemicals, but that did not relate to

Generation of new toxic molecules

We had previously designed a commercial de novo molecule generator that we called

published computational machine learning models for toxicity prediction in different areas, and, in developing our presentation to the Spiez meeting, we opted to explore how AI could be used to design toxic molecules. It was a thought exercise we had not considered before that ultimately evolved into a computational proof of concept for making biochemical weapons.

be used to help derive compounds for the treatment of neurological diseases (details of the approach are withheld but were available during the review process). The underlying generative software is built on, and similar to, other open-source software that is readily available[4]. To narrow the universe of molecules, we chose to drive the generative model towards compounds such as the nerve agent VX, one of the most toxic chemical warfare agents developed during the twentieth century — a few salt-sized grains of VX (6–10 mg)[5] is sufficient to kill

Sam Weiss Evans

Future Context

EMPOWERING PRACTITIONERS TO CONSIDER **DUR** REQUIRES INSTITUTIONAL AND CULTURAL SUPPORT

Red-teaming gene synthesis companies to understand gaps in current DNA screening methodologies

Part of pedagogical development of graduate students/postdocs in EBRC-affiliated institutions

Developed in collaboration with FBI

Shut down by National Security Council 3 days before launch

Organizers didn't even want to write about it until I pushed

EBRC Engineering Biology Research Consortium

Kathryn Brink (Stanford)
Bridget Luckie (Berkeley)

Sam Weiss Evans

Saying the quiet bit out loud: all research is dual use

WHAT SHOULD NSABB DO RIGHT NOW?

Must shift a biosecurity governance system built for science to one that also attends to economics, health, and society

DURC policy should be complemented with a **DUR** policy with guiding principles:

1. All research can be used in a manner that results in harm (Current 3.B)
2. Those harms will likely disproportionately affect already disenfranchised communities
3. Which research is done should be attentive to the concerns of those communities
4. Collectively, we do not [yet] know what types of oversight work well for DUR
5. Institutions that fund, conduct, or support life science research should be empowered to experiment with alternative approaches to identifying and attending to security concerns
6. It is right and good to share, learn from, and iterate upon those experiments

Sam Weiss Evans samuel_evans@harvard.edu

WHAT THE INSTITUTIONAL DURC POLICY SAYS ABOUT DUAL USE RESEARCH

3. Guiding Principles for Oversight of Life Sciences Dual Use Research

- 3.C. "Life sciences research is by nature dynamic and can produce unanticipated results and must be evaluated on an ongoing basis for dual use potential."
- 3.J. "Educating the scientific community about the dual use potential of life sciences research and cultivating a sense of responsibility for dual use research among life scientists is essential for promoting responsible research behavior."

4. Definitions

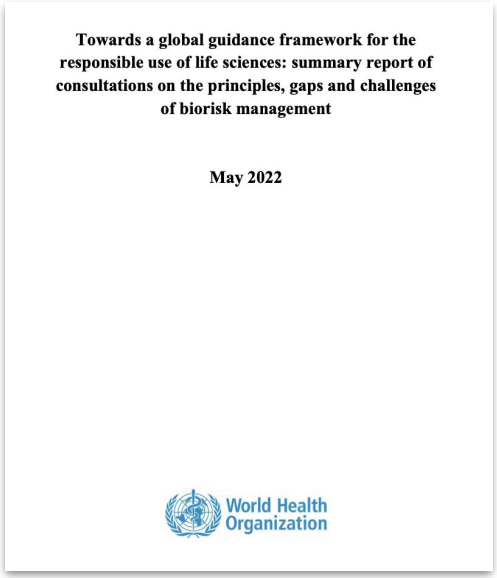
- 4.B. "'Dual use research' is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes."

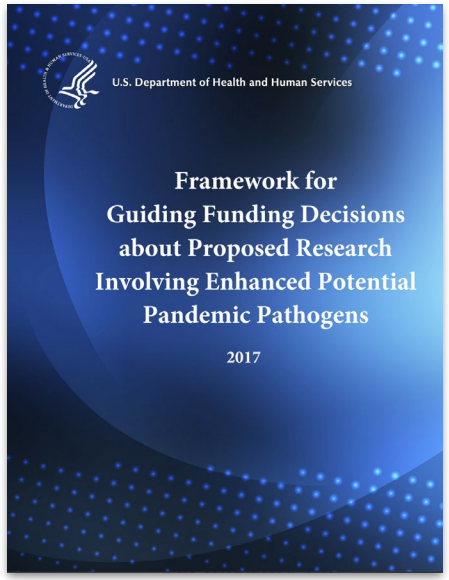
7.2. Responsibilities of USG-funded Research Institutions

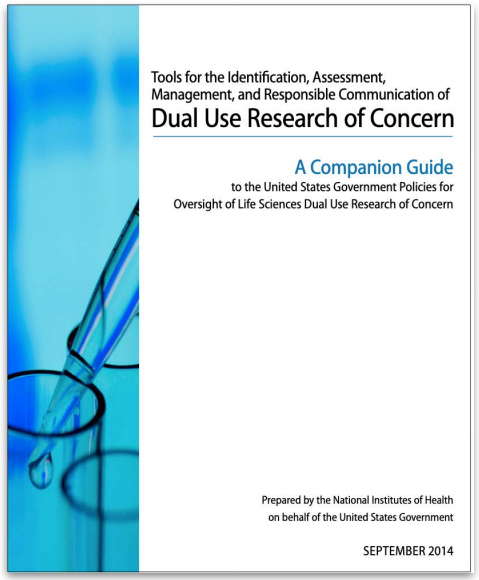
- 7.2.G. "…Institutions may also wish to address dual use topics in existing courses on research ethics or the responsible conduct of research."

Background

Many **high-level guidelines and strategies** have been developed to help life science research stakeholders identify, assess, and mitigate biosafety and biosecurity concerns.







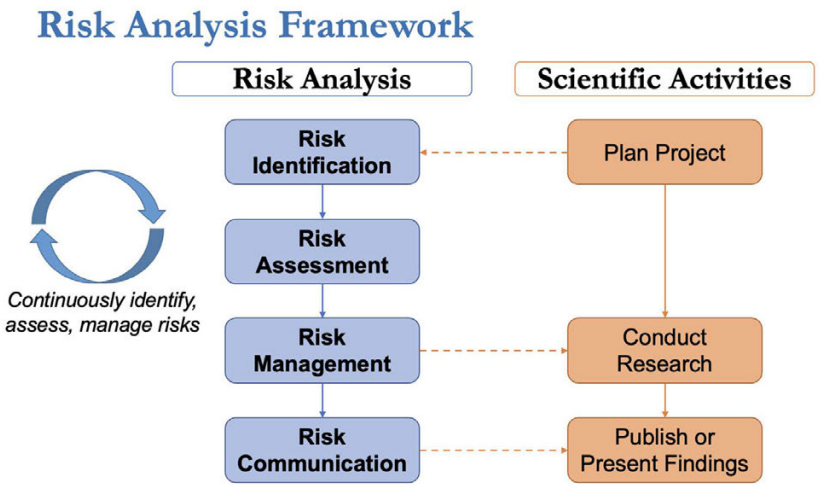


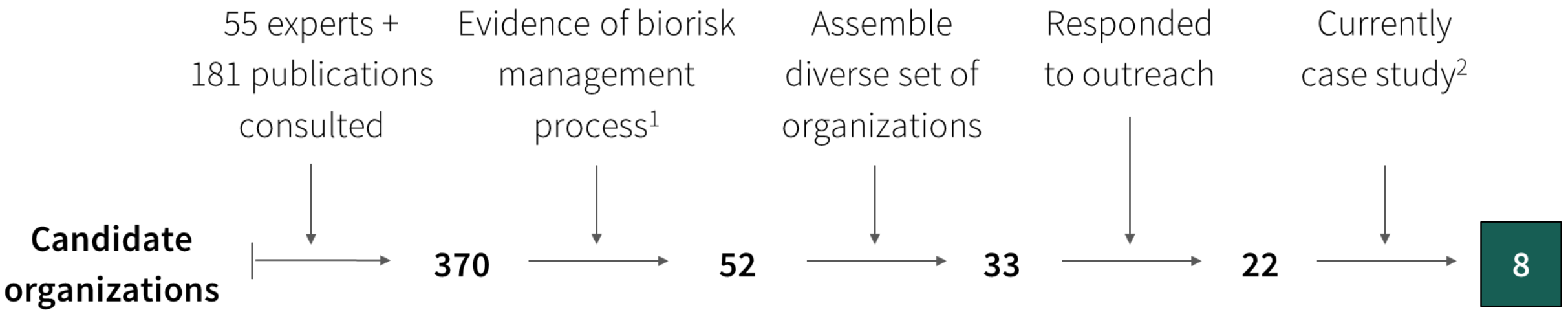
Image Citation: Gryphon Scientific. Dual Use Risk Analysis Training Materials for Malaysian Life Scientists

Background

However, **little is known about the practical implementation** of these guidelines.

Many life-science research stakeholders do not publicly share their practices for managing biosafety and biosecurity risks, **hampering the ability of stakeholder groups to learn from each other**.

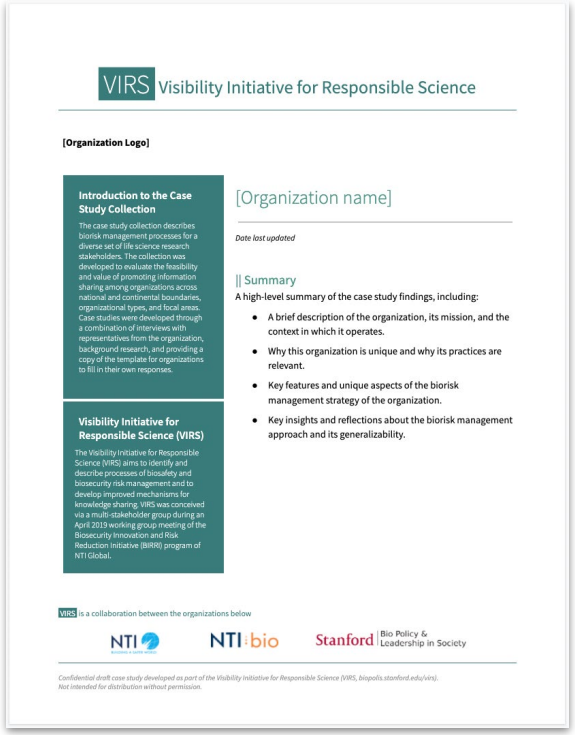
Case Study Selections



1 - Initial focus on funders and publishers; research organizations largely excluded to avoid redundancy
2 - Some organizations on hold because of internal approval timelines, unclear fit, etc.

Case Study Pilot

Developed a **case study format** for describing risk management practices



VIRS Visibility Initiative for Responsible Science

[Organization Logo]

Introduction to the Case Study Collection

The case study collection describes biorisk management processes for a diverse set of life science research stakeholders. The collection was developed to evaluate the feasibility and value of promoting information sharing among organizations across national and continental boundaries, organizational types, and focal areas. Case studies were developed through a combination of interviews with representatives from the organization, background research, and providing a copy of the template for organizations to fill in their own responses.

Visibility Initiative for Responsible Science (VIRS)

The Visibility Initiative for Responsible Science (VIRS) aims to identify and describe processes of biosafety and biosecurity risk management and to develop improved mechanisms for knowledge sharing. VIRS was conceived via a multi-stakeholder group during an April 2019 working group meeting of the Biosecurity Innovation and Risk Reduction Initiative (BIIRR) program of NTI Global.

[Organization name]

Date last updated

|| Summary

A high-level summary of the case study findings, including:

- A brief description of the organization, its mission, and the context in which it operates.
- Why this organization is unique and why its practices are relevant.
- Key features and unique aspects of the biorisk management strategy of the organization.
- Key insights and reflections about the biorisk management approach and its generalizability.

VIRS is a collaboration between the organizations below

NTI | NTI:bio | Stanford Bio Policy & Leadership in Society

Confidential draft case study developed as part of the Visibility Initiative for Responsible Science (VIRS, biopolis.stanford.edu/virs). Not intended for distribution without permission.

2 government organizations (Center for Biosecurity and Biopreparedness - Denmark, National Institute for Public Health and the Environment - Netherlands)

1* service provider (DoE Joint Genome Institute)

2 research organization (MIT-Broad Foundry, Colorado State University)

1 biotechnology competition (iGEM Foundation)

2 publishers (*Science* magazine, ASM Journals)

Many organizations cautious - **also conducting short interviews with optional attribution**