SELF GOVERNING SCIENCE?

STCU Responsible Science Webinar
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UNIVERSITY OF CAMBRIDGE

CENTRE FOR THE STUDY OF EXISTENTIAL RISK

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Overview of Talk

1. Governing science?
   a. Governing – directing, shaping, setting limits, making rules
   b. How is biological research governed?
   c. Biological safety and security regimes

Background

2. Dual Use Research of Concern
   a. Problem cases
   b. More rules?

Challenges

3. Self Governing Science
   a. Experiments in building governance in the research community
   b. Independent or collaborative?
   c. We (probably) still need rules
   d. (But we should also "self-govern" better)

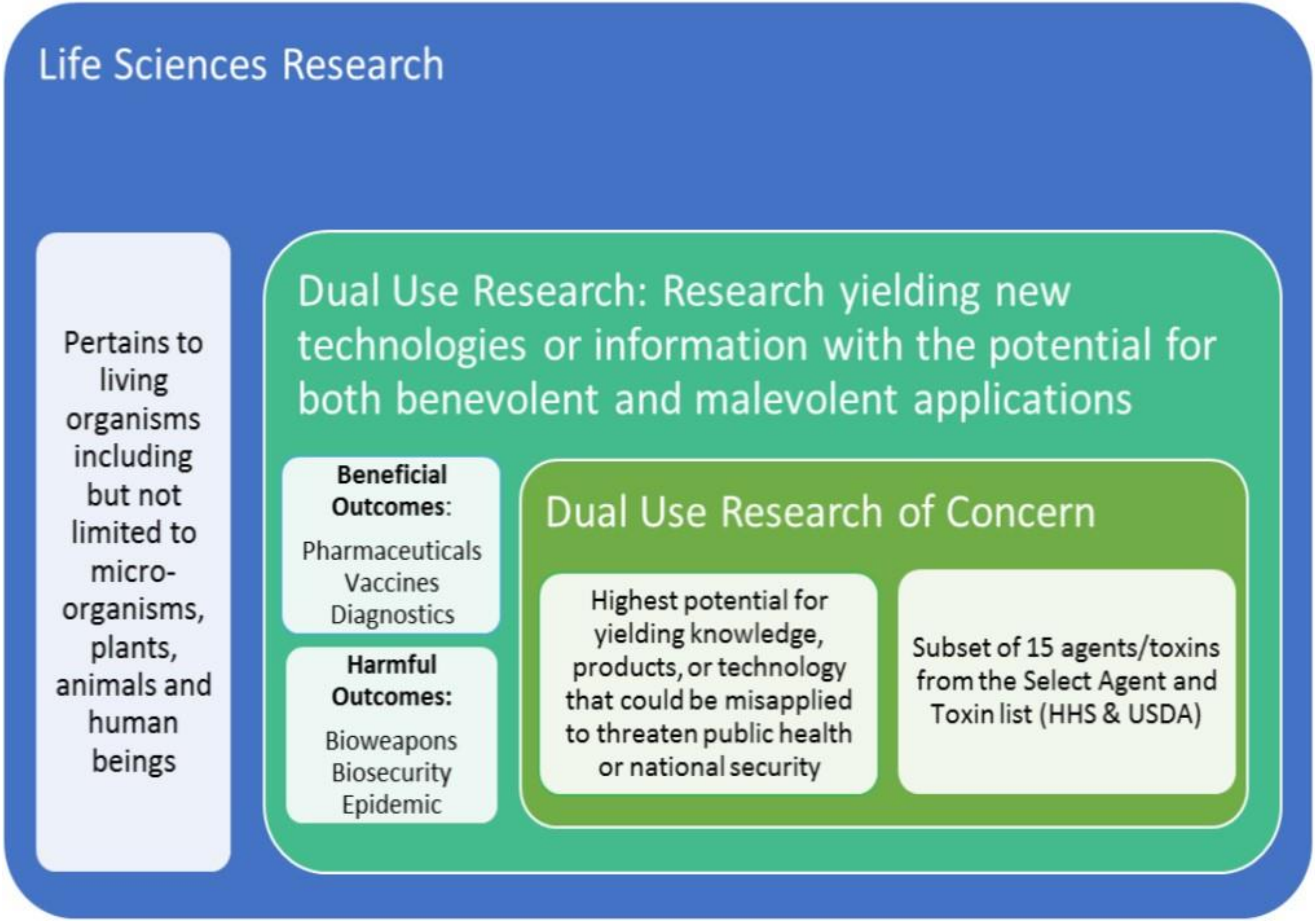
Experiments to find a solution

Governing Science?

- The **governance of science** refers to use of law, or other ruling, by academic or governmental bodies to allow or restrict science from performing certain practices or researching certain scientific areas.
- Science could be regulated by legislation if areas are seen as harmful, immoral, or dangerous.
- There are a huge number of different organizations involved in governing biological research.
- But governance is not just about what we can’t do… It also sets research agendas and directs what we *can* do and what we try to achieve.

Dual Use Research of Concern

- "Dual Use" is the main way we talk about the safety, security (and sometimes ethical) problems posed by certain types of research
- …is life sciences research that**, based on current understanding,**
- **can be reasonably anticipated to provide knowledge, information, products, or technologies**
- **that could be directly misapplied to pose a significant threat**
- with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security



https://www.research.uci.edu/ref/durc/

Dual Use Research of Concern

- When it comes to biological research, there are several definitions, and lots of different organisations and treaties.
- The Biological Weapons Convention, UNSCR 1540, The Australia Group, TheWassenaar Arrangement, The Missile Technology Control Regime
- **Materials linked to weapons development**
- **Technologies connected to weaponization**
- **Banned biological or pathogenic materials**
- **Linked technologies**
- **Information, academic publications or knowledge**

A (partial) list of biological research regulations

Biosecurity & Bioethics

Governance & Regulations Master Sheet

Arms Control

International Bodies	Treaties and Standards	National Regimes	Community Regimes
Australia Group	Biological and Toxin Weapons Convention		
Organisation for the Prohibition of Chemical Weapons	Chemical Weapons Convention		
	Draft Convention on the Criminalisation of Chemical and Biological Weapons		
	Environmental Modification Convention		
	Geneva Protocol		
	Working Paper I - International Arms Control Agreements of Relevance to the Control of the Biotechnology Revolution		

Health & Disease Control

International Bodies	Treaties and Standards	National Regimes	Community Regimes
Food and Agriculture Organisation	WHO Guidance on Regulations for the Transport of Infectious Substances		
Office International des Epizooties (World Anim	WHO Laboratory Biosafety Manual		
World Health Organisation	WHO Laboratory Biosecurity Guidance		
	Codex Alimentarius		
	International Health Regulations		
	International Plant Protection Convention		
	Terrestrial and Aquatic Animal Health Codes		
	UN 3700		
	UN2900		
	UN2814		
	Terrestrial and Aquatic Manuals		

Environmental Protection

International Bodies	Treaties and Standards	National Regimes	Community Regimes
Convention on Biodiversity Secretariat	Aarhus Convention		
	Cartagena Biosafety Protocol		
	Convention on Biodiversity		

Trade

International Bodies	Treaties and Standards	National Regimes	Community Regimes
World Intellectual Property Organisation	Bonn Guidelines on Access to Genetic Resources		
World Trade Organisation	International Treaty on Plant Genetic Resources		
	International Convention for the Protection of New Varieties of Plants		
	Rotterdam Convention on Prior Informed Consent		
	Sanitary and Phytosanitary Agreement		
	Technical Barriers to Trade Agreement		
	Trade Related Aspects of Intellectual Property Agreement		
	Nagoya Protocol on Access to Genetic & Benefit Sharing		
	Sanitary and Phytosanitary Agreement		
	United Nations Environment Programme International Biosafety Guidelines		

Drug Control

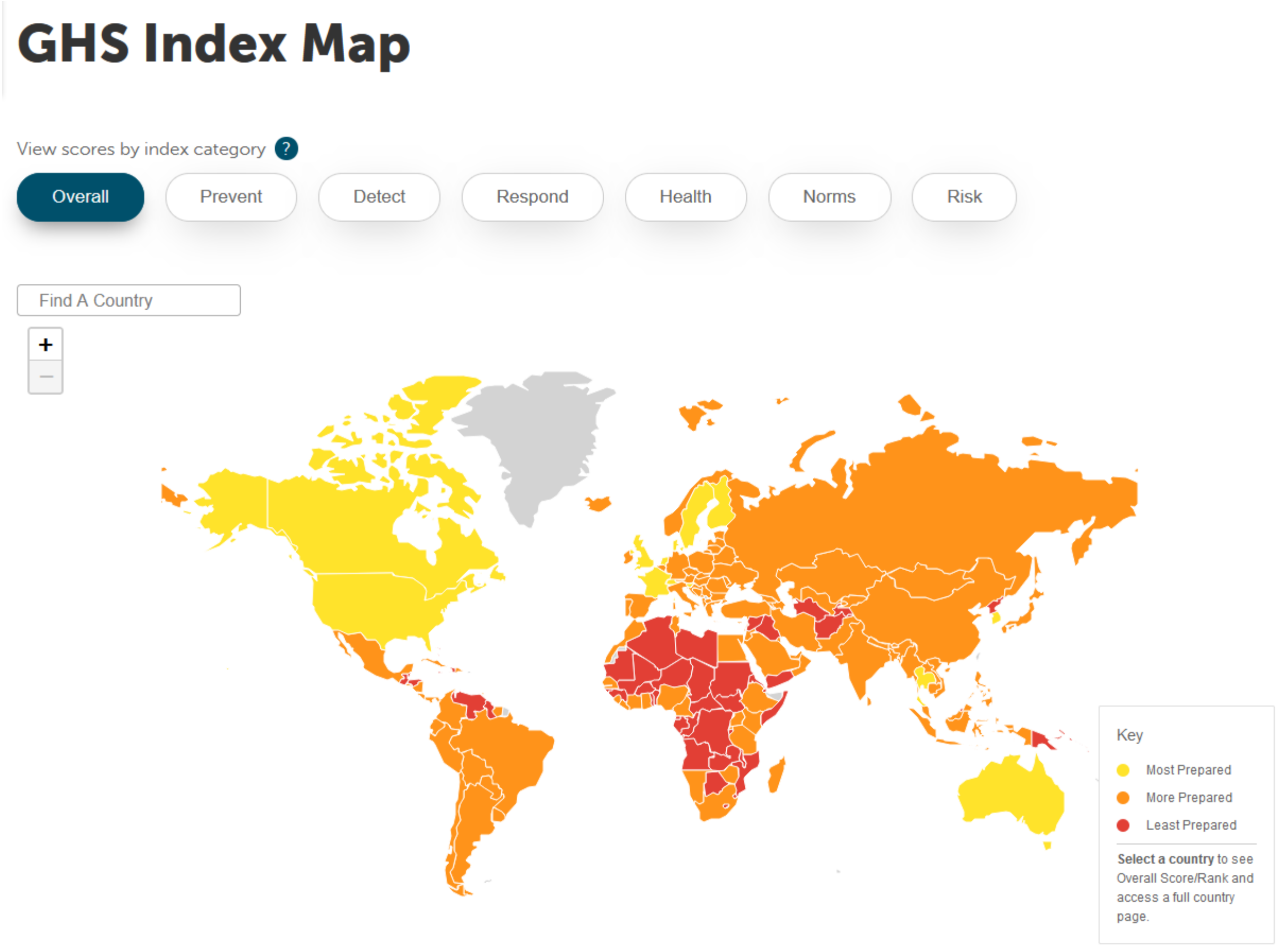
International Bodies	Treaties and Standards	National Regimes	Community Regimes
	UN Drug Conventions		
	World Anti-Doping Code		
	Copenhagen Declaration on Anti-Doping in Sport		
	International Convention Against Doping in Sport		

Social and Ethical Impacts

International Bodies	Treaties and Standards	National Regimes	Community Regimes
	Universal Declaration on the Human Genome and Human Rights		
	International Declaration on Human Genetic Data		
	Universal Declaration on Bioethics and Human Rights		
	United Nations Declaration on Human Cloning		

Differences in regulation and capacity

https://www.ghsindex.org/



The present-day challenge…

- As biological research and its applications evolve, new attempts at the governance of biology are emerging
- They challenge traditional assumptions about how science works and who is responsible for governing.

Evans, S.W et al (2020). *Embrace experimentation in biosecurity governance*

The present-day challenge…

- fears about DIY-bio are often manifestations of fears about synthetic biology itself.
- Some critics claim – falsely – that synthetic biology is "virtually unregulated", and DIY-bio spaces would be simply an even riskier, less regulated extension.
- On top of this, DIY-bio has been seen philosophically as having "a streak of anti-establishment at heart" (Wall, 2015).

Sundaram, S. (2021). *Biosafety in DIY-bio laboratories: from hype to policy*

The challenge for governance

- What we can do with biological science is changing remarkably
- More people in more different settings are doing this than before
- Many of the ways we think about governing biological research are based on older assumptions

The challenge for governance

both of which were contrary to the public's image of the FBI and how it operates (6). Moreover, these efforts called on scientists to take responsibility for identifying and addressing potential security concerns.

The American Biological Safety Association (ABSA) International observed that biosafety professionals have been increasingly asked to assess security in addition to safety aspects of research, but do not know how to assess security concerns, and, perhaps more important, how to think about malicious intent and intentional release. ABSA concluded that further training would improve security and promote common biosecurity practices throughout the scientific community through educational opportunities and development of a global biosecurity credential (7).

We do not have perfect knowledge of the ways that biology might be used by malicious actors, or of the best ways to prevent such uses. No a priori reason exists to believe that our original assumptions and hypotheses are optimal. The consequences of getting assumptions wrong, such as a pandemic caused by a laboratory-derived pathogen, are among the strongest arguments for testing a wide range of assumptions in ways that can provide signals of effectiveness prior to catastrophic events.

The "gold standard" needs evaluation

Whether through application of the legal standard or through deeply ingrained habit, many DIY-bio practitioners behave, or seek to behave, very similarly in community spaces as they do or used to in institutional labs. However, this may not always be the appropriate standard, either in practice or in theory. How well laboratory biosafety is practised in institutional settings clearly varies. This can result from the national regulatory context but is often a matter of culture in individual labs or departments. The pressures of academia or industry (to obtain results fast, and to publish; pressures that likely do not apply to DIY biologists in the same way) can result in corners being cut. Moreover, the knowledge that experiments are being done in a "sanctioned" space can bring about a certain complacency towards biosafety. In

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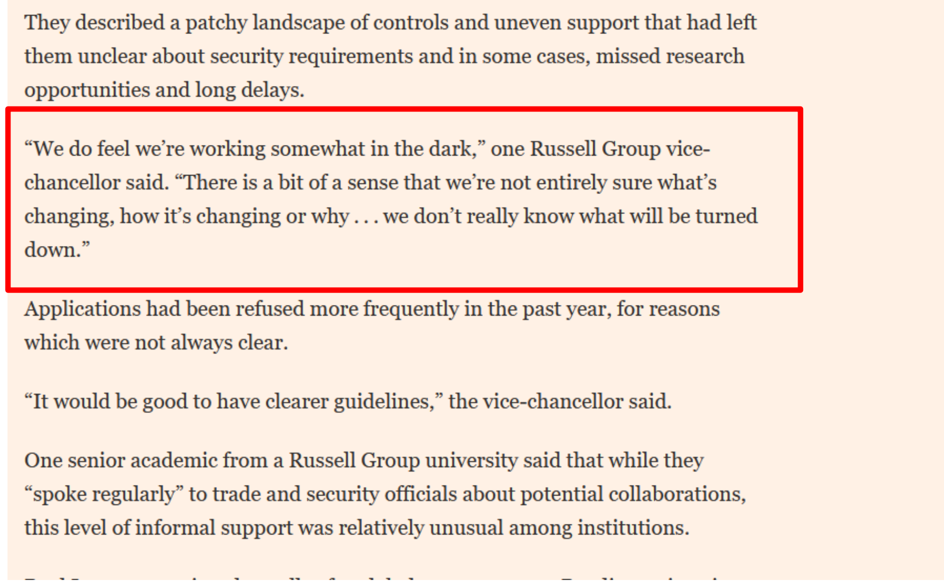
Problem cases

1. COVID19
2. UK Scientists Dual Use research with China?



They described a patchy landscape of controls and uneven support that had left them unclear about security requirements and in some cases, missed research opportunities and long delays.

"We do feel we're working somewhat in the dark," one Russell Group vice-chancellor said. "There is a bit of a sense that we're not entirely sure what's changing, how it's changing or why . . . we don't really know what will be turned down."

Applications had been refused more frequently in the past year, for reasons which were not always clear.

"It would be good to have clearer guidelines," the vice-chancellor said.

One senior academic from a Russell Group university said that while they "spoke regularly" to trade and security officials about potential collaborations, this level of informal support was relatively unusual among institutions.

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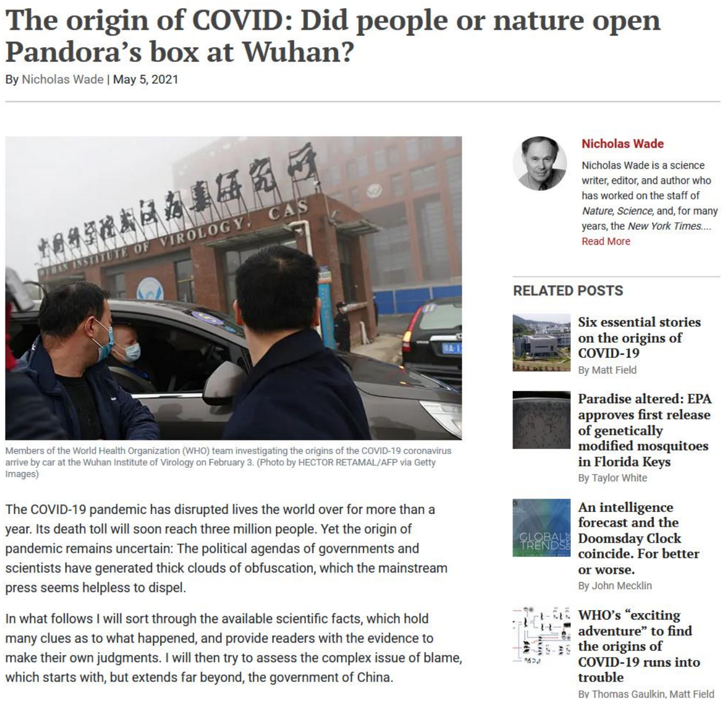

The origin of COVID: Did people or nature open Pandora's box at Wuhan?

By Nicholas Wade | May 5, 2021

Members of the World Health Organization (WHO) team investigating the origins of the COVID-19 coronavirus arrive by car at the Wuhan Institute of Virology on February 3. (Photo by HECTOR RETAMAL/AFP via Getty Images)

The COVID-19 pandemic has disrupted lives the world over for more than a year. Its death toll will soon reach three million people. Yet the origin of pandemic remains uncertain: The political agendas of governments and scientists have generated thick clouds of obfuscation, which the mainstream press seems helpless to dispel.

In what follows I will sort through the available scientific facts, which hold many clues as to what happened, and provide readers with the evidence to make their own judgments. I will then try to assess the complex issue of blame, which starts with, but extends far beyond, the government of China.

Nicholas Wade

Nicholas Wade is a science writer, editor, and author who has worked on the staff of *Nature*, *Science*, and, for many years, the *New York Times*....
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https://thebulletin.org/2021/05/the-origin-of-covid-did-people-or-nature-open-pandoras-box-at-wuhan/

Experiments with "self-governance"

- Several groups of researchers have been working towards better models of self-regulation, oversight and governance
- iGEM
- The "DIY Bio" community
- Johns Hopkins Center for Health Security (Emerging Leaders in Biosecurity Initiative)
- Stanford University [Synthetic Biology Leadership Excellence Accelerator Program (LEAP)],
- BioSecurity Commons
- (also…) Biological and Toxin Weapons Convention Meeting of Experts,
- (and…) ABSA International Biosecurity Symposium

Few-to-no governments have laws in place specifically concerning DIY-bio; this is part of why it is often assumed that the field is unregulated. Similar criticisms have been levelled at synthetic biology as a whole. In fact, “regulation need not be specific to a particular scientific field in order to be applicable to it” (Rhodes, 2014) and there are frequently several layers of regulatory and legal oversight that are already ‘on the books’ (Bar et al, 2012).

Of course, there are numerous governance mechanisms beyond biosafety and biosecurity legislation that effectively regulate biotechnology, and many of these have implications for DIY biologists. For instance, intellectual property rights, trade agreements and export controls may restrict or allow the flow of materials and knowledge.

In the EU, DIY-bio practitioners must adhere to the “blanket” EU Directive 2009/41/EC on the contained use of genetically modified micro-organisms if they wish to perform such work legally, no matter their institutional or commercial context. Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work is also relevant, dealing with non-GM uses. These Directives are implemented in each Member State through national legislation. In the UK, for instance, these processes are administered by the Health and Safety Executive, and this continues to be the case post-Brexit. Importantly, and unlike the situation in the USA, this legislation applies regardless of whether the activity occurs in the context of employment or not.

Sundaram, S. (2021). *Biosafety in DIY-bio laboratories: from hype to policy*

tainty, lack of control, and systematic learning (10). This approach places the concept closer to a design-build-test cycle, but with the focus on governing in a complex adaptive space, not on controlling the system.

GOVERNANCE AS AN EXPERIMENT

One current experimental governance approach is the International Genetically Engineered Machine (iGEM) Foundation's Safety and Security Program. iGEM runs a yearly competition for around 6000 students and community biolab members from more than 40 countries. Each year, iGEM generates a set of hypotheses about how proposed changes in safety and security governance of the competition might affect teams and lead to better oversight, and reviews cases that tested—or previously were not caught by—its system. Through these reviews, iGEM recognized that processes for screening teams' genetic sequences

PHOTO: JUSTIN KNIGHT/IGEM FOUNDATION

sumptions we make in the process of governing, most notably about the structure of science, governing authorities, and their relations to specific security conceptions. These assumptions tend to come in packages. For example, the use of a system of export controls relies on an assumption that science consists of discrete knowledge entities (e.g., published articles or biological specimens), restricting the export of which enhances security. It also relies on seeing threats as likely originating abroad, as opposed to, say, within labs in a country (i.e., an insider threat).

Another example is the assumption that scientists are best placed to govern themselves, which is at the heart of the DURC policies, despite scientists not necessarily having training to identify security risks. This assumption is so firmly rooted in biosecurity governance that questioning it is difficult, and even when it is questioned,

Evans, S.W et al (2020). *Embrace experimentation in biosecurity governance*

Integrating an increasingly adaptive risk management approach has allowed iGEM's biosafety and biosecurity program to become comprehensive, be cross-cutting, and cover the competition's life cycle.

Each year, around 6000 students and community lab members form over 300 teams from over 40 countries to compete against each other for medals and prizes based on their advances in synthetic biology design, implementation, and integration into society. This is the world's largest international synthetic biology competition, known as iGEM (the international Genetically Engineered Machines competition), and it has a dedicated Biosafety and Biosecurity Program.[1] Integrating an increasingly adaptive risk management approach has allowed iGEM's program to become comprehensive, be cross-cutting, and cover activities throughout the competition life cycle.

iGEM's program is forward-leaning, in that it addresses both traditional (pathogen-based) and emerging risks both in terms of new technologies and new risks. It is integrated into the technical work of the competition—with clearly described roles and responsibilities for all members of the community. It operates throughout the life cycle of projects—from project design to future application. It makes use of specific tools to gather and review biosafety and biosecurity information, making it easier for those planning and conducting science and engineering to recognize potential risks and match them with appropriate risk management approaches, as well as for specialists to review this information to identify gaps and strengthen plans. The program makes use of both incentives (such as through a Safety and Security Award for excellence and human practices components of its medals) and penalties for noncompliance (up to and including disqualification).[2]

iGEM has an inherently adaptive approach to safety and security, integrating the engineering design-build-test cycle into its own program, as well as the teams that compete.[3] This has yielded a series of concrete examples of how experiences in implementation have helped improve policy, including an increasing diversity of sources for genetic parts and organisms, keeping pace with technical developments, considering pathways toward future environmental release, addressing antimicrobial resistance, and testing the efficacy of current biosecurity arrangements. We review each of these aspects of iGEM's safety and security program below.

Millet, P. et al (2019). *Developing a Comprehensive, Adaptive, and International Biosafety and Biosecurity Program for Advanced Biotechnology*

Safety and Security

We expect everyone involved with iGEM to **act responsibly** throughout the competition. Considering safety and security is an important component of responsible research and innovation.

Working safely and securely

Find our more about safety and security in project design, laboratory work, and transfer practices.

WORKING SAFELY

Safety and Security Rules

Find out the safety and security rules all teams must follow.

SAFETY & SECURITY RULES

Safety and Security Policies

Find out about iGEM's policies on the use of humans, animals, anti-microbial resistance, gene drives, and more

SAFETY & SECURITY POLICIES

Keep it in the lab

Find out more about keeping modified organisms in the lab and how you might take their products outside.

DO NOT RELEASE

What I have to do

Everyone has a role to play. Find out more what is expected from team members, instructors and our Committee.

ROLES

Safety and Security Committee

Find out more about the experts from around the world that helps keep iGEM safe and secure.

COMMITTEE

- Historically, scientists have instead favored methods of self-governance.
- This has often proven to be successful, however for biosecurity, complete self-governance is impractical on a large-scale international level.
- It seems likely that some formal regulations and policies will be needed.
- To be ready to adapt to future changes in policies and regulations, the formulation of the regulations need to take into account the nature of the scientific community.
- Biosecurity education can help establish an environment where scientists can effectively collaborate with the security community in the development of polices and regulations that will promote security, without impeding scientific freedom.

Experiments with “self-governance”

Positives:

- More understanding of the security, safety and ethical implications of work
- Practicing researchers and labs work collaboratively to monitor practices
- Assessment and accountability are distributed widely among people who are doing the work
- Encourages a culture of caring about “what is being done and why”

Negatives:

- **Danger of “marking your own homework”**
- **Too much reliance on technical expertise, when the problem might require different knowledge to identify security or ethics issues**
- **Will it really make a difference when so much research is funded by militaries?**

Experiments with “self-governance”

In reality:

- Means building more governance capacity within scientific communities and…
- Working in collaboration with governing bodies and…
- With ongoing reference to existing and new regulations
- Working more collaboratively with governing bodies to keep regulation relevant and fit for purpose

Experiments with “self-governance”

In reality:

- Better thought of as increasing and distributing capabilities in order to better ensure that scientific research does least harm and achieves the most good.
- Involves a serious engagement with the risks and benefits of biological (or other) research – shaping the future and what we aim for
- Scientists might not have expertise to identify security risks *but* they do have technical knowledge to identify measures for assessing and reducing identified risks.