

Biosecurity and the Bioeconomy



PRESENTED BY

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Definitions

Biosecurity

Measures designed to prevent loss, theft, or deliberate misuse of biological material, technology, or research-related information from laboratories or laboratory-associated facilities.¹

Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion, or release. removes emphasis on intentional release to focus on unauthorized element.²

Bioeconomy

The U.S. bioeconomy is economic activity that is driven by research and innovation in the life sciences and biotechnology, and that is enabled by technological advances in engineering and in computing and information sciences.³

The bioeconomy represents the infrastructure, innovation, products, technology, and data derived from biologically-related processes and science that drive economic growth, improve public health, agricultural, and security benefits.⁴

1. Mesorhiz, D., Fritts, J., eds. 2020. *Biosecurity in Microbiology and Biomedical Laboratories*. 4th Edition. U.S. Department of Health and Human Services. HHS Publication No. (CDC) 300859. June 2020.
2. World Health Organization. 2020. Laboratory biosafety manual, fourth edition. Geneva: World Health Organization. (Laboratory biosafety manual, fourth edition and associated monographs). Licence: CC BY-NC-SA 3.0 IGO.
3. National Academies of Sciences, Engineering, and Medicine. 2020. *Safeguarding the Bioeconomy*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25525>.
4. U.S. OSTP. 2019. Summary of the 2019 White House summit on America's bioeconomy. <https://trumpwhitehouse.archives.gov/wp-content/uploads/2019/10/Summary-of-White-House-Summit-on-Americas-Bioeconomy-October-2019.pdf>





Biosecurity Significance—WHO ARE THE THREAT ACTORS?

Actors may include:

- States
- Groups
- Individuals

Motivations may include:

- Financial gain
- Competitive advantage (in research or industry)
- Filling knowledge gaps in research

Actor may target:

- Public research institutions
- Private research institutions & industry
- Academic institutions

Economic and National Security Risks Pertaining to the Bioeconomy

Operational Risks

Insufficient funding for research and development,

Asymmetric research constraints,

An inadequate workforce,

An ineffective or inefficient intellectual property and regulatory environment.

Biosecurity Relevance

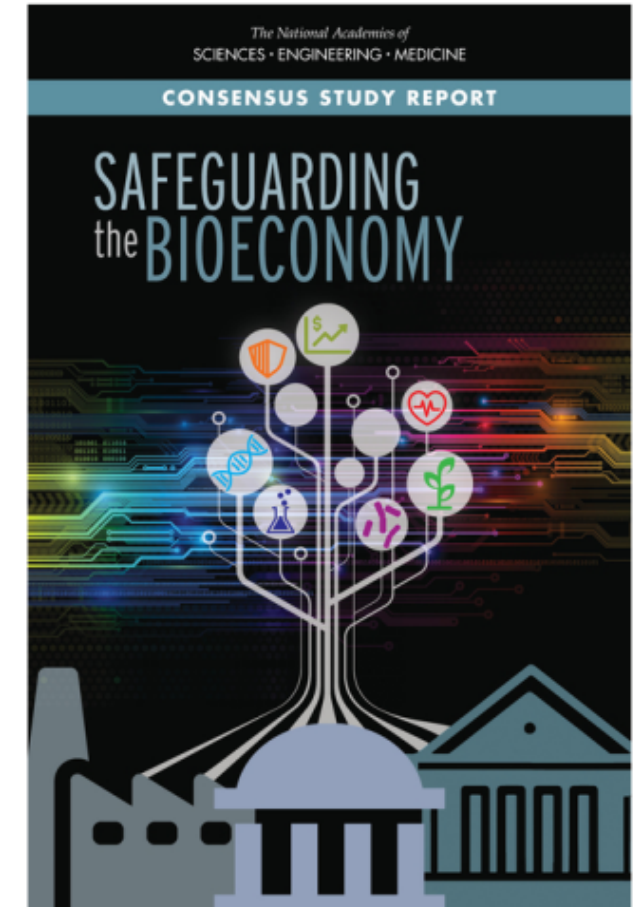
Biosecurity and biosafety are “cost centers” and not typically incorporated into funding proposals

Technology convergence driving innovation outpace regulations

Increase in multi-country and cross-institutional collaboration

Increase focus on talent development including undergraduate, graduate, and early career foundational research training for scientists, engineers, and other disciplines

Excessive or poorly designed regulations could impede innovation by constraining the choices available to innovators or imposing on them requirements that would tend to increase cost or uncertainty



Economic and National Security Risks Pertaining to the Bioeconomy

Potential misuse or intentional acts

Constrained access to international data,

Use of bioeconomy datasets to the detriment of individual privacy or national security,

Cyber risks associated with the bioeconomy,

Economic attack through theft and infiltration,

Exploit critical infrastructure vulnerabilities,

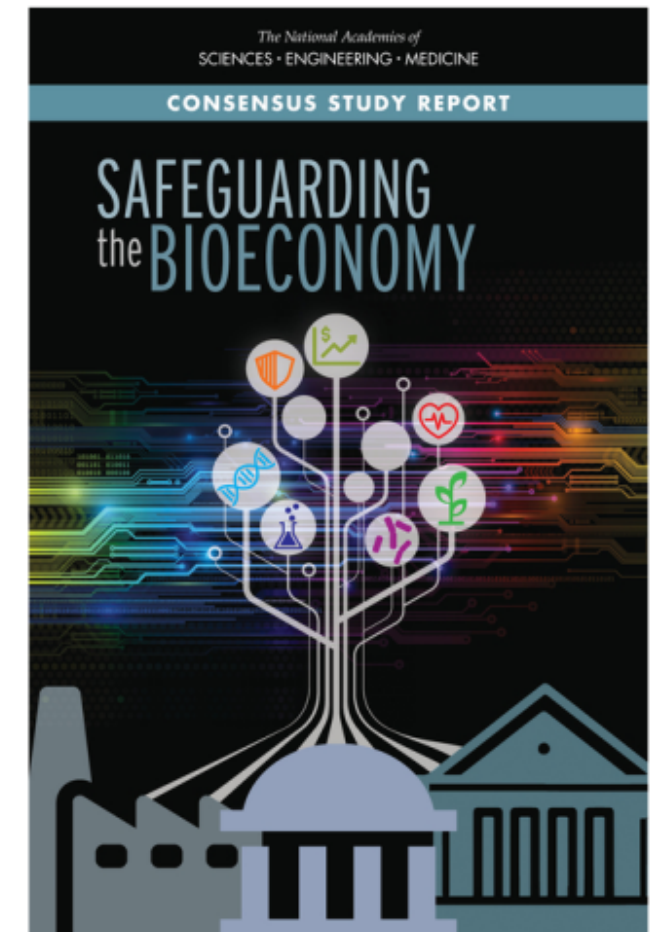
Exploit traditional biosecurity vulnerabilities.

Biosecurity Relevance

Illicit acquisition of dual-use materials and technology (i.e., research products) is an ongoing threat perpetuated by actors that operate outside of global nonproliferation norms and agreements.

Actors can seek information and materials which cannot be produced or acquired on their own.

Researchers and research institutions remain attractive targets for actors seeking to acquire dual-use materials, technology, and expertise.



Biosecurity Significance—Workforce Development

Research Funding and Training Needs

Sufficient funding is appropriated so institutions can allocate resources toward trainees and early career scientists in academic settings dedicated to basic research

Inclusive and diverse workforce

Training programs at undergraduate and graduate levels

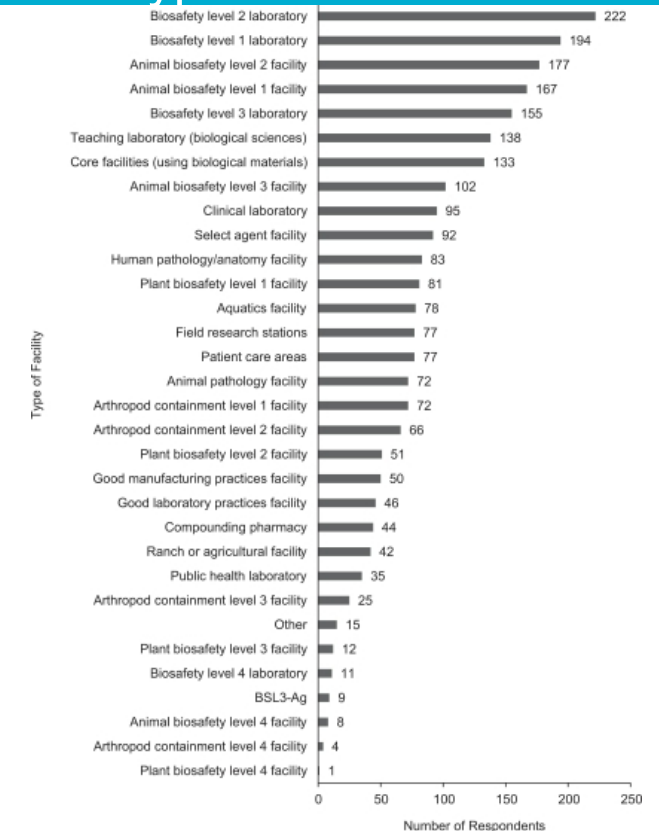
Support for multidisciplinary teams

Where do Biosafety Professionals work?

59.7% of respondents report working in a public or private academic institution

37.1% of non-US members operate in government non-academic settings

Responses Indicating Facility Type at Institutions



Biotechnology Example: Gene Therapy Research (Eisenman, Debold, & Riddle)

Article conclusion

“Biosafety professionals responsible for clinical research oversight must be aware of emerging technologies and their associated risks to support the safe and ethical conduct of research.”

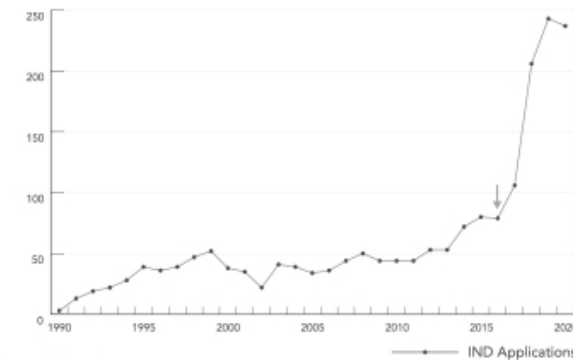
Biosecurity considerations

Is the IBC the correct role to check for biosecurity protocols included in study protocols?

With the increase in multi-site studies and clinical trials outside of academic institutions how can biosafety professionals support commercial IBCs to consider biosecurity risks when evaluating research proposals

Biosecurity risk focused training for IBC members

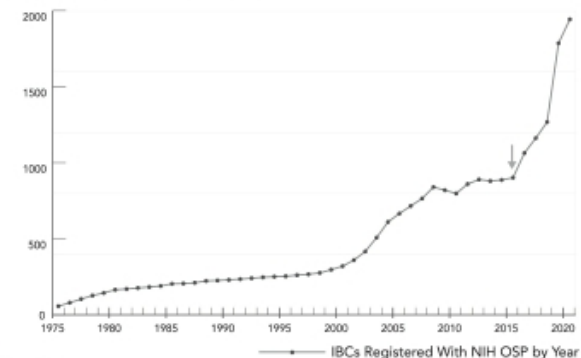
A Gene Therapy IND Applications Per Year



Gene therapy research caused a growth in IBCs registered with the NIH.

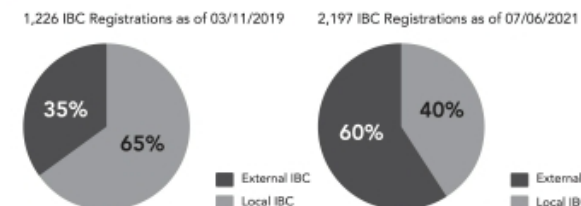
(A) Gene therapy IND applications submitted per year to the FDA. Data adapted with permission from Peter Marks, Director, FDA CBER.

B IBCs Registered With NIH OSP



(B) IBC registrations approved by the NIH OSP per year. Data adapted with permission from Kathryn Harris, NIH OSP.

C IBC Landscape



(C) Change in local versus externally administered IBCs registered with NIH OSP.

CBER, Center for Biologics Evaluation and Research; FDA, Food and Drug Administration; IBCs, Institutional Biosafety Committees; IND, investigational new drug; NIH, National Institutes of Health; OSP, Office of Science Policy.



Bioeconomy as surge capacity

Additive manufacturing to address supply chain shortfalls

Increase in laboratories conducting research and diagnostic activities



Conclusions

Biosecurity risks faced from biotechnology development reflect a declining role of governments in control and regulations in an increasingly more globalized and interconnected world.

Increased global interest in furthering the bioeconomy presents a risk of proliferation of both technology and expertise in countries given the lack of information regarding biosafety for synthetic biology and limited scientific knowledge of the unintended consequences of these technologies.

A focus of biosecurity only on containment laboratories or to address current regulatory requirements is short-sighted.

Opportunities for ABSA

