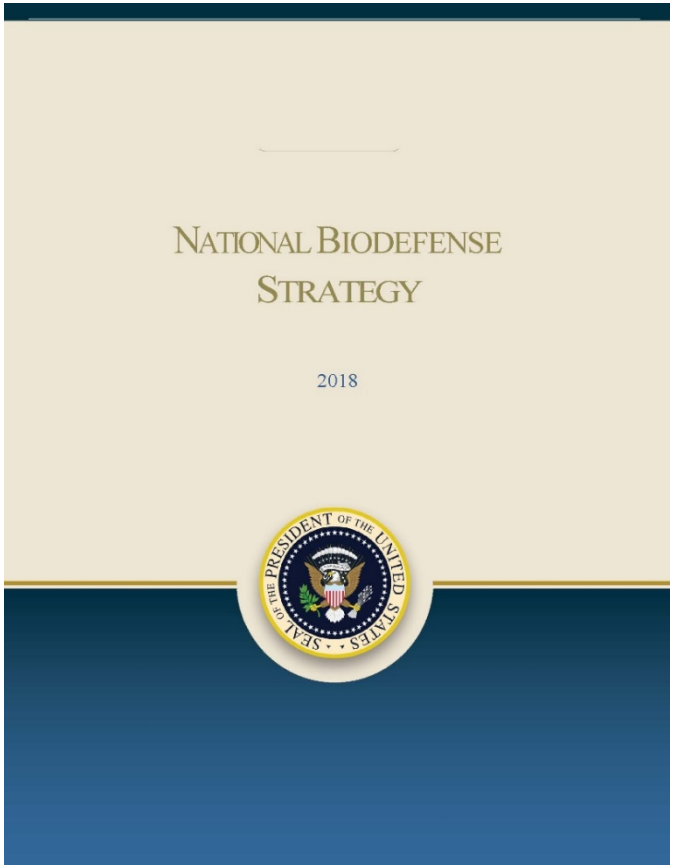
Enhancing Partnerships to Promote Biosafety and Biosecurity

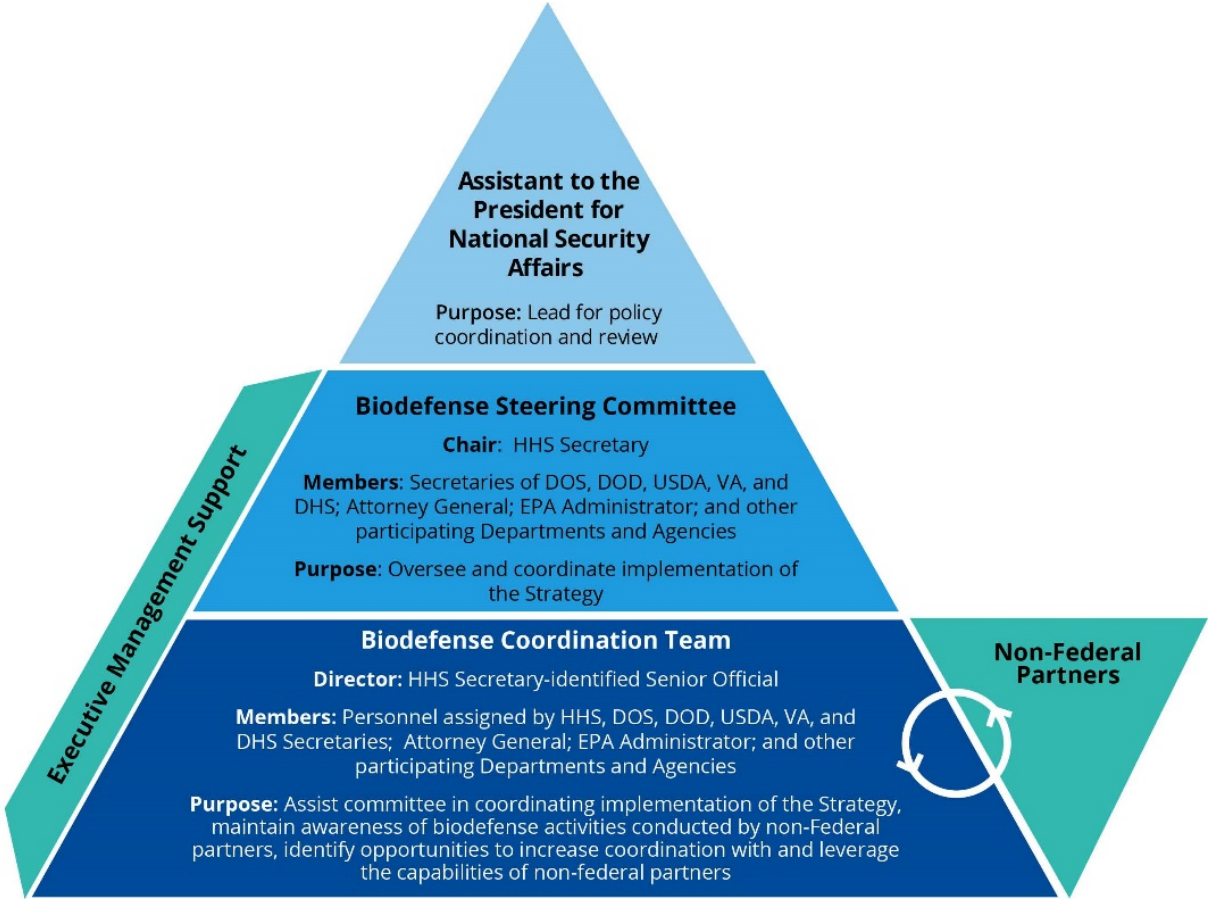
Patricia Delarosa, PhD CBSP RBP

ABSA 62nd Annual Biosafety and Biosecurity Conference
Birmingham, AL
November 19, 2019

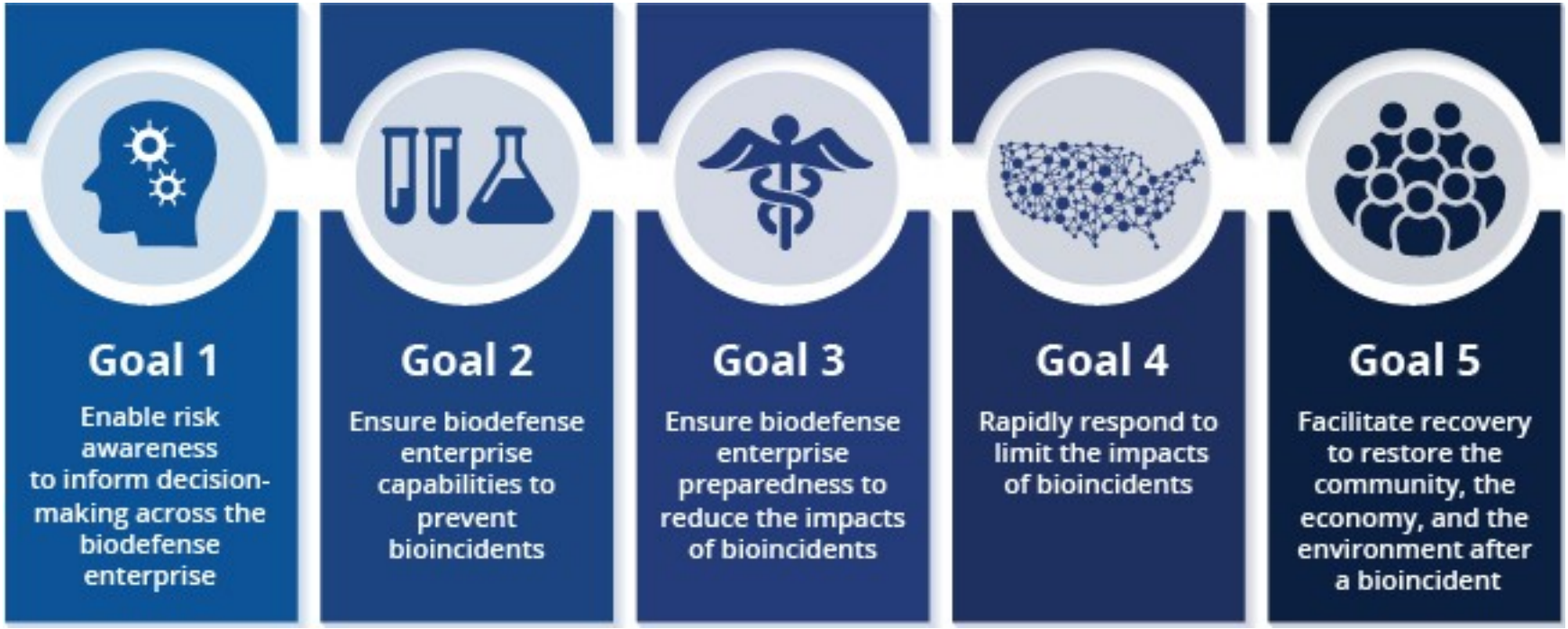


- The National Biodefense Strategy to assess, prevent, protect against, respond to, and recover from biological threats.
- Establishes a leadership structure and approach to coordinate the full range of biodefense activities across the U.S. government
- Recognizes the roles of biosafety and biosecurity in biodefense

Biodefense Enterprise Structure



Goals


Goal 1
Enable risk awareness to inform decision-making across the biodefense enterprise
Goal 2
Ensure biodefense enterprise capabilities to prevent bioincidents
Goal 3
Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents
Goal 4
Rapidly respond to limit the impacts of bioincidents
Goal 5
Facilitate recovery to restore the community, the economy, and the environment after a bioincident

2.4 Strengthen Biosafety and Biosecurity Practices and Oversight to Mitigate Risks of Bioincidents

2.4.1: Strengthen biosafety and biosecurity

2.4.2: Support and Promote the Responsible Conduct of the Life Science and Biotechnology Enterprise

Updates on Select NBS Biosafety and Biosecurity Efforts

1. Applied Biosafety Research
2. Potential Pandemic Pathogens Care and Oversight Committee;
3. Review of the Department of Health and Human Services, *Screening Framework Guidance for Providers of Synthetic Double Stranded DNA* and Efforts to Secure Biotechnology

2019 - Priority 3 Biodefense Research and Development Working Group

Applied Biosafety Research Goals

- Optimizing Evidence-based Biosafety/Biosecurity Practices
- Identify and address research gaps needed to improve laboratory biorisk management with the goal of ensuring that federal guidance and regulations in this focus area are based on the best available science
- Ensure that federal guidance and regulations in biosafety and biosecurity are based on the best available science.

Applied Biosafety Research Tasks

Near Term Tasks:

- Detail priority areas of research of interest to the federal government by articulating known and immediate applied biosafety/biocontainment evidence gaps for life science research facilities.
- Develop a mechanism to strengthen and support existing Applied Biosafety Research.

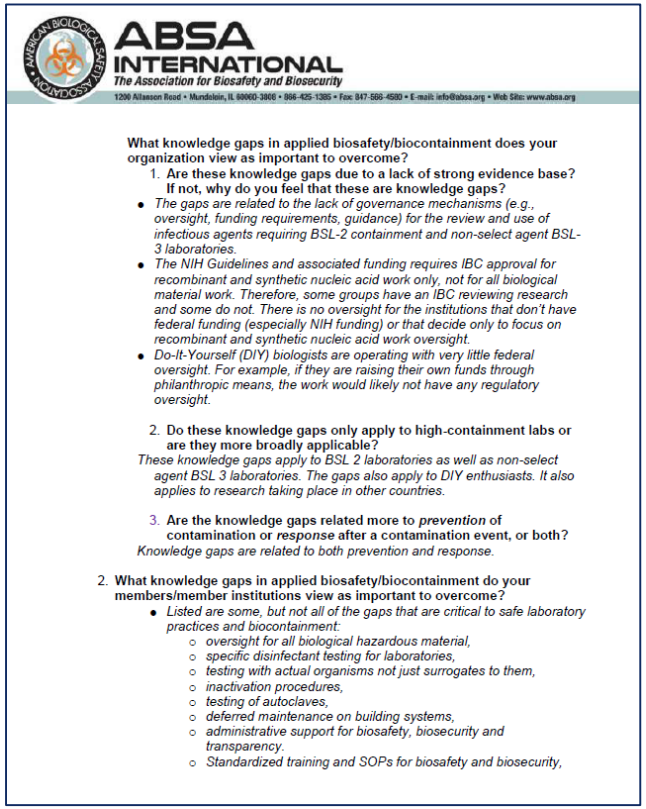
Long Term Tasks:

- Develop a mechanism to fund applied biosafety research
- Develop a mechanism for future implementation that includes life science gaps for field research, for biohazard work in low-resource settings, applied laboratory biosecurity gaps, and emerging biotechnologies.

Definition of Applied Biosafety Research

"Research on safety measures, safety equipment, infection control and the sociology of laboratory biorisk management applied to reduce the risk of exposure to laboratory biohazards"

Applied Biosafety Research Workshop Roadmap Gaps



ABSA INTERNATIONAL
The Association for Biosafety and Biosecurity
1200 Allanson Road • Mundelein, IL 60060-3808 • 866-425-1385 • Fax: 847-566-4580 • E-mail: info@absa.org • Web Site: www.absa.org

What knowledge gaps in applied biosafety/biocontainment does your organization view as important to overcome?

1. **Are these knowledge gaps due to a lack of strong evidence base? If not, why do you feel that these are knowledge gaps?**
   - *The gaps are related to the lack of governance mechanisms (e.g., oversight, funding requirements, guidance) for the review and use of infectious agents requiring BSL-2 containment and non-select agent BSL-3 laboratories.*
   - *The NIH Guidelines and associated funding requires IBC approval for recombinant and synthetic nucleic acid work only, not for all biological material work. Therefore, some groups have an IBC reviewing research and some do not. There is no oversight for the institutions that don't have federal funding (especially NIH funding) or that decide only to focus on recombinant and synthetic nucleic acid work oversight.*
   - *Do-It-Yourself (DIY) biologists are operating with very little federal oversight. For example, if they are raising their own funds through philanthropic means, the work would likely not have any regulatory oversight.*
2. **Do these knowledge gaps only apply to high-containment labs or are they more broadly applicable?**

These knowledge gaps apply to BSL 2 laboratories as well as non-select agent BSL 3 laboratories. The gaps also apply to DIY enthusiasts. It also applies to research taking place in other countries.

3. **Are the knowledge gaps related more to *prevention* of contamination or *response* after a contamination event, or both?**

Knowledge gaps are related to both prevention and response.

2. **What knowledge gaps in applied biosafety/biocontainment do your members/member institutions view as important to overcome?**
   - *Listed are some, but not all of the gaps that are critical to safe laboratory practices and biocontainment:*
     - *oversight for all biological hazardous material,*
     - *specific disinfectant testing for laboratories,*
     - *testing with actual organisms not just surrogates to them,*
     - *inactivation procedures,*
     - *testing of autoclaves,*
     - *deferred maintenance on building systems,*
     - *administrative support for biosafety, biosecurity and transparency.*
     - *Standardized training and SOPs for biosafety and biosecurity,*

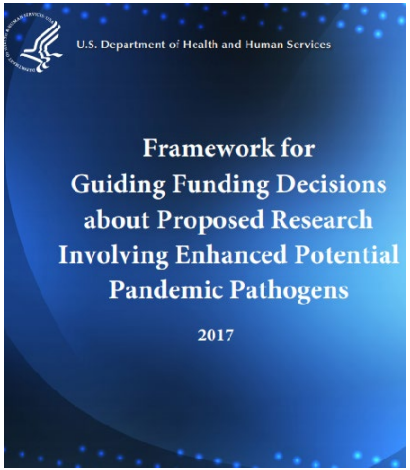
- Sociology of Lab Bio-Risk Management (e.g. Culture of biosafety)
- Agent Exposure and Infection (e.g. Aerosols and Fomites)
- Evaluation of Technology, Procedures and Tools (e.g. Inactivation and decontamination procedures)
- Measuring and Mitigating Risk (e.g. Risk assessment)

P3CO Round Table

Department of Health and Human Services Funding of Enhanced Potential Pandemic Pathogen Research: the P3CO process

HHS P3CO Review Evaluation Criteria

1. Research is scientifically sound;
2. The pathogen is considered to be a credible source of a potential future human pandemic;
3. The potential risks as compared to the potential benefits to society are justified;
4. There is no feasible alternative method to address the same question in a manner that poses less risk;
5. The investigators have demonstrated the capacity and commitment to conduct the research safely and securely;
6. Research results are expected to be responsibly communicated;
7. The research will be subject to ongoing federal oversight; and
8. The research is ethically justifiable.



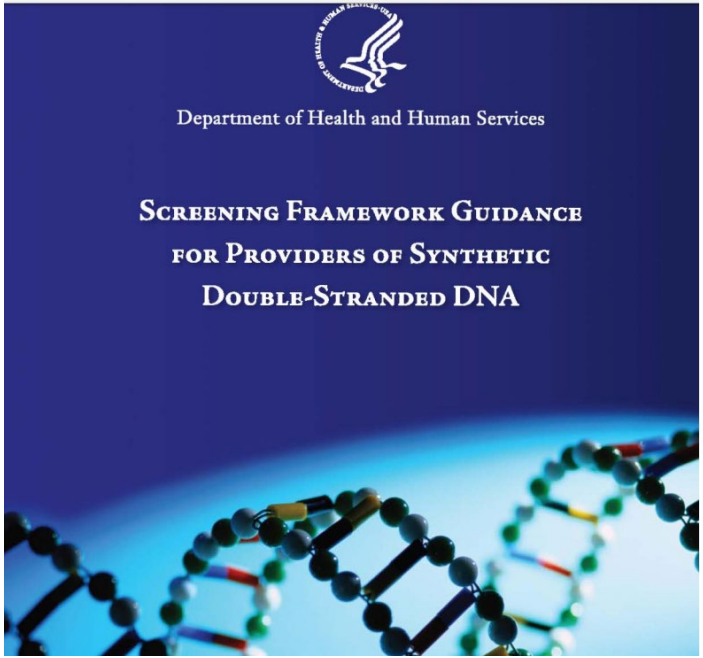
BLUF
Two research projects involving potential pandemic pathogens (PPP) were reviewed

- **December 2017:** HHS adopts the *HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (*HHS P3CO Framework) lifting the pause on HHS funding of certain research that involves enhanced Potential Pandemic Pathogens (PPP) and providing a method for department-level review.
- **June–December 2018:** The HHS P3CO review group reviews two PPP research proposals and determines that both are acceptable for HHS funding based on defined criteria, including ethical considerations, detailed in the HHS P3CO Framework.
- **January 30 and February 14, 2019:** The funding agency applies terms and conditions of award, funding the research.

Review of the 2010 Screening Framework Guidance (*Guidance*) and Efforts to Secure Biotechnology

- 2010. Department of Health and Human Services, *Screening Framework Guidance for Providers of Synthetic Double-stranded DNA*;

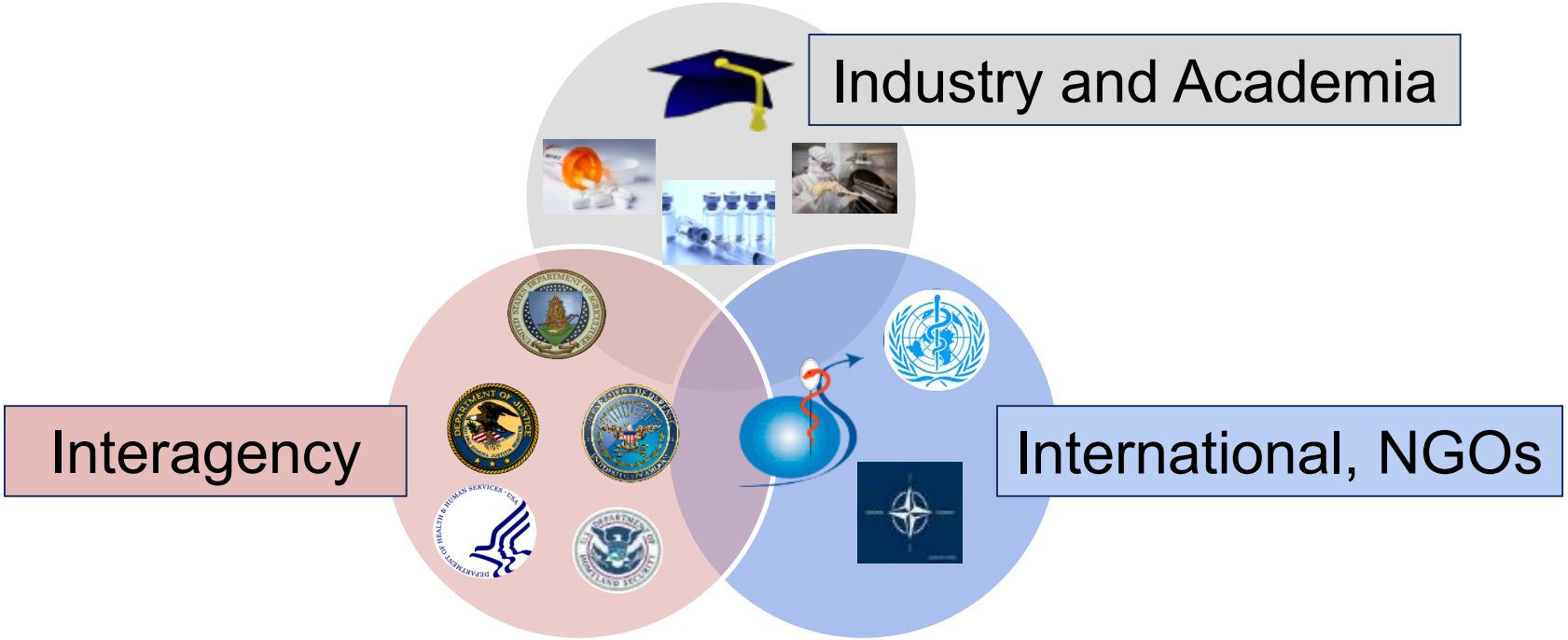
- USG is conducting a review of the *Guidance*.



Background - 2010 *Guidance* Document

- Goals of the *Guidance:*
  - Minimize the risk that unauthorized individuals or individuals with malicious intent will obtain “toxins and agents of concern” through the use of nucleic acid synthesis technologies, and:
  - Simultaneously minimize any negative impacts on the conduct of research and business operations that use these technologies;

Synthetic Biology Whole-of-Society Engagement



EBRC: Engineering Biology Research Consortium

The Engineering Biology Research Consortium is the leading **U.S.-based non-profit, public-private partnership** dedicated to bringing together an inclusive community committed to advancing engineering biology to address national and global needs. We showcase **cutting-edge research** in engineering biology, identify pressing challenges and opportunities in research and application, articulate compelling **research roadmaps and programs** to address these challenges and opportunities, and **provide timely access** to other key developments in engineering biology.

Roadmapping **Security** **Policy** **Education**

Institutions & Government

INSTITUTIONAL MEMBERS

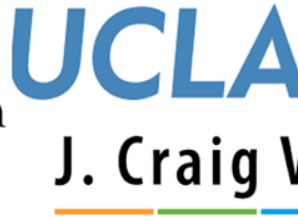
Institutional Members range from small start-ups to larger, well-established biotechnology research and manufacturing companies. These organizations play a critical role in helping guide the field of engineering biology by working in a community of scientists and engineers committed to rapid advancement in the field.

Agilent Technologies
ASIMOV
BASF
CORTEVA agriscience
DSM
HITACHI
INSCRIPTA
teselagen BIOTECHNOLOGY
TWIST BIOSCIENCE
VTT
zymergen

GOVERNMENT ENGAGEMENT

NSF
U.S. DEPARTMENT OF HOMELAND SECURITY
DEPARTMENT OF DEFENSE UNITED STATES OF AMERICA

Individual Member Affiliations



As of 1/30/19

www.ebrc.org

For More Information

Visit our website:

www.phe.gov/biodefense