ORD Biomedical Research Laboratory Biosafety and Biosecurity Program: New Initiatives for VHA Research Support



April 28, 2022







- ✓ A recording of this session and the associated handouts will be available on ORPP&E's Education and Training website approximately one-week post-webinar
- ✓ An archive of all ORPP&E webinars can be found here: https://www.research.va.gov/programs/or-ppe/education/webinars/archives.cfm

- ✓ Please use the Q&A feature to submit questions.
 - ✓ Please do not use Chat to send in questions.
 - ✓ Be sure to send questions to "All panelists".
- ✓ We would be ever so grateful if you would complete the post-webinar evaluation survey that pops up once you exit the webinar.
- ✓ Experiencing sound issues you can call in using the number included on the handouts and on your registration confirmation email that you received.

• Call in #: 1 404 397 1596

• Event Number/Access Code: 2762 048 3237

Event Password: ORPP&EWebinars1





Speaker Introductions

Lead Presenter:

John Balog, BS, RBP (ABSA)

ORD National Biosafety Officer, ORPP&E

Co-Presenter:

C. Karen Jeans, PhD, CCRN, CIP

Director of Regulatory Affairs, ORPP&E







Panel Members

Office of Research Oversight

James Trout, PhD

Director, Research Safety & Animal Welfare

TJFACT

William (Bill) Arndt, PhD

Biosafety & Biosecurity Subject Matter Expert

Natasha Griffith, MPH, MS

Biosafety & Biosecurity Subject Matter Expert

Office of Research and Development

Fungchow (Alex) Chiu, PhD

Senior Program Manager Research Facilities

Antonio Laracuente, MBA

Director of Field Operations

George Lathrop, Jr., DVM, MS, DACLAM Chief Veterinary Medical Officer





Webinar Purpose & Objectives

- Describe the purpose of ORD's Biosafety and Biosecurity Program
- Describe current activities regarding data calls supporting the ORD Biosafety and Biosecurity Program
- Identify key components of ORD's Biosafety and Biosecurity assistance visits to VA Facilities
- Describe the educational purpose of the "biosafety toolkit" available for use by VA Facilities
- Gather perspectives from the field on biosafety and biosecurity priorities





Vision Statement

The ORD Biomedical Research Laboratory Biosafety and Biosecurity Program (BRLBBP) provides executive leadership in laboratory biosafety and biosecurity, including standardizing research laboratory biosafety and laboratory biosecurity policies and practices across the Agency

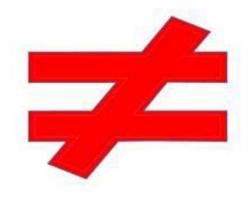
It also ensures VA research laboratories working with biohazards are operated in a safe and secure manner to protect:

- employees,
- the surrounding communities, and
- the environment





Laboratory Biosafety



Laboratory Biosecurity





Lab Biosafety is Not Equivalent to Lab Biosecurity

- Laboratory Biosafety: The consistent application of safety measures to minimize or prevent exposure to the person handling the agent, lab and building occupants, the community and the environment
- <u>Laboratory Biosecurity:</u> The risk- and threat-based control measures established to prevent the unauthorized access, misuse, loss, theft, diversion and intentional release of valuable biological materials, pathogens, toxins, information, expertise, equipment, technology and intellectual property that have the potential to cause harm to humans, animals, plants, the environment, public safety or national security.





ORD Biosafety and Biosecurity Enterprise Implementation

- Collaborate with other national program offices, VISN and VA Facility leadership, VISN and VA Facility safety and scientific subject matter experts, and committee members and staff on the development and implementation of risk management processes and procedures for biomedical research involving biohazardous materials
- Utilize multiple types of communication mechanisms to enhance dissemination of information and networking for the VA research biosafety and biosecurity community:
 - Webinars
 - Dedicated mailbox <u>VHACOORDBiosafety@va.gov</u> for inquiries from the field on biosafety and biosecurity issues
 - Email distribution list for VA research safety staff and research oversight stakeholders





ORD Biosafety and Biosecurity Enterprise Perspective

• Biorisk Management Approach:

- Assess scope of biomedical research activities throughout VA research laboratories
- Apply the risk management approach to VA biomedical research administration and operation
- Define and apply outputs of the biomedical research safety program operations to the administration of biomedical research safety oversight, including Research and Development (R&D) Committee, Subcommittee on Research Safety (SRS), and Institutional Biosafety Committees (IBCs).
- Anticipated timeline to accomplish: 2 to 5 years





ORD Biosafety and Biosecurity Program Components





ORD Biosafety and Biosecurity Program

- Current activities targeted to promote the safety of individuals working in VHA research laboratories and to protect the environment
- Strives to ensure research laboratory safety and security of:
 - Individuals, resources, and information
 - Biological and chemical agents
 - Radiation materials/sources





ORD Biosafety and Biosecurity Program

- Key Activities include:
 - Collaborate on the development of VHA policy and written guidance;
 - Communicating training requirements;
 - Initiating training programs; and
 - Representing the VA perspective on biomedical research when participating on interagency work groups biosafety, biosecurity and homeland defense
 - Hiring an ORD Research Biosafety Officer
- ORD contracted with TJFACT, LLC to support ORD's BRLBBP





BRLBBP Components: Role of TJFACT

- TJFACT contract supports biosafety and biosecurity practices and procedures at VA field programs as directed by ORD
- Key tasks/activities include:
 - Responding to questions: Coordinate with ORD on the response to VHA field program inquiries/questions
 - Data calls: capture key biosafety and biosecurity data and provide a landscape analysis of VHA field programs
 - On-Site Assistance: Conduct Program Assistance Visits (PAVs) at selected VA Facilities in coordination with ORD
 - Training: Collaborate on the development and delivery of trainings (webinar) and educational tools on biosafety and biosecurity topics





ORD Biosafety and Biosecurity Responding to Questions





BRLBBP: Biosafety Mailbox for Queries

- VA designated email address to submit biosafety and biosecurity questions
- Biosafety subject matter experts (SMEs) will respond with an initial or final response within 7 calendar days
- SMEs will provide responses on biomedical research laboratory topics related to:
 - Biosafety and biosecurity risk assessment practices
 - Handling and management of infectious microorganisms
 - Biohazard and chemical waste management
 - Personal protective equipment (PPE)
 - Biosafety and biosecurity best practices
 - Other biosafety and biosecurity topics

VHACOORDBiosafety@va.gov

NOTE: Biomedical research related biosafety and biosecurity questions should initially be addressed to your local Biosafety POC and/or local Subcommittee on Research Safety (SRS).







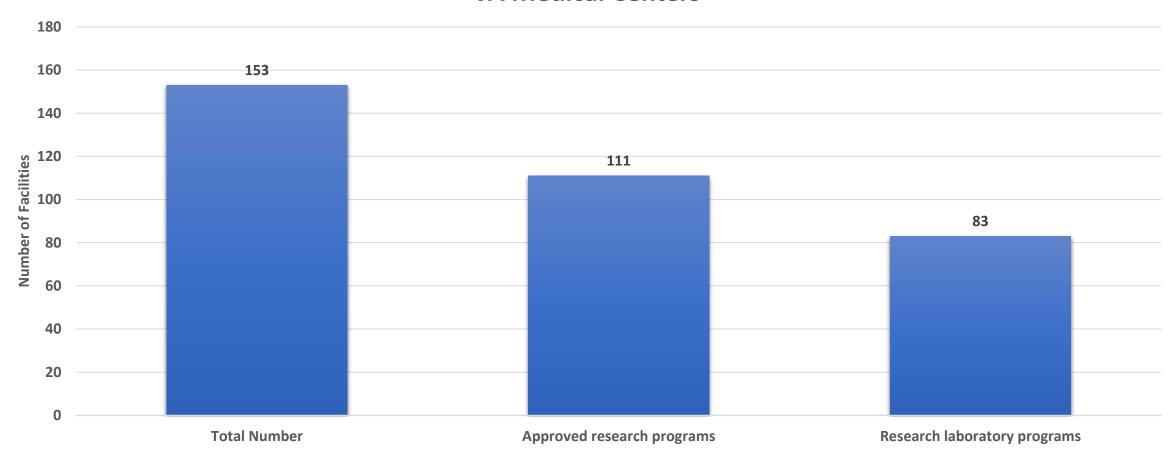
ORD Biosafety and Biosecurity Data Calls





Number of VA Facilities with Research Laboratory Programs

VA Medical Centers







Data Calls (FY21 & FY22)

Objective:

 Conduct an analysis of field data to help inform ORD of biosafety and biosecurity risk management vulnerabilities

Methodology:

- Develop and deploy a data call to support a landscape analysis of relevant and critical biosafety and biosecurity indicators associated with VA field programs
- Evaluate results to determine potential impacts on VA facilities such as staffing, training, and resources
- Identify trends, gaps, and recommendations related to biosafety and biosecurity risk management





ORD Biosafety and Biosecurity Data Call Fiscal Year 2021





- Executed via VA REDCap
 - Sent to 83 VHA medical care facilities
 - 82% response rate (68 facilities)
- Focus Areas:
 - Facility Profile
 - BSL & ABSL Information
 - Availability of Biosafety Support
 - Research Capacity
 - Workforce
 - Biosafety Profile
 - Program Assistance Opportunities

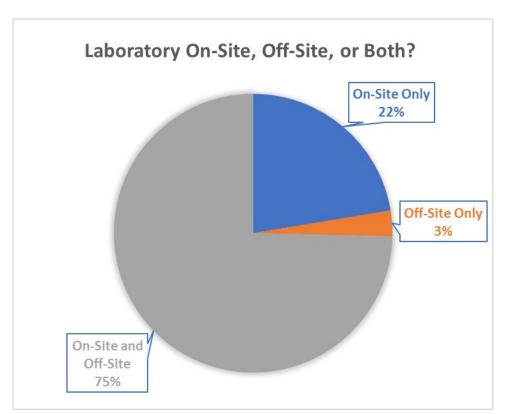
fidential Fage I	
VHA ORD Biosafety and Biosecurity Data Call Survey	
The VHA Office of Research and Development (ORD) is labiosecurity across the VA research enterprise. Through the challenges facing R&D officers and investigators, focused or agents.	VA REDCap tool, information will be collected about the
We request that you complete this data call by June 15, 202	21.
This survey link is unique to you, and cannot be forwarded. someone else needs to receive this survey instead, please er appropriate email address to forward a data call unique to the	mail bobbie.peterson@va.gov and provide the
Thank you in advance for your timely response.	
Please enter your VA email address	
Facility Profile	
Facility Name	
	()
Facility Location	
	(Please provide the address, city and state.)
Laboratory on-site, off-site, or both?	On-Site Off-Site Off-Site On-site=VA Operated or Contractor Operated; Off-site = University affiliates, research foundations, or medical centers.)
If off-site, please specify the type of facility:	Contractor Operated Medical Center University Affiliates Private Research Foundations
Facility Square Footage	
Approximate Total Square Footage of Laboratory Space	
	()
Approximate Square Footage of Wet Laboratory Space	
	(Wet laboratory space is defined as laboratory space where benchtop research occurs. This excludes support spaces, such as administrative spaces.)
Approximate Square Footage of Animal Space	
	()
	_
09/09/2021 9:49am	projectredcap.org REDCa

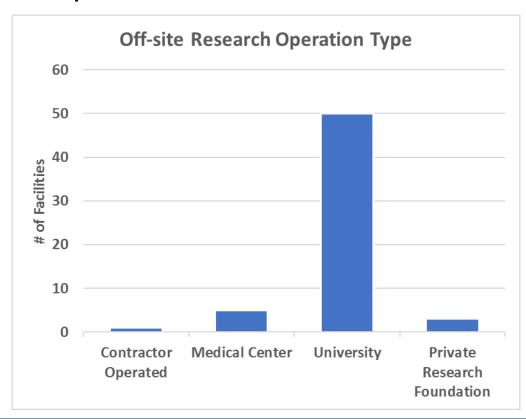




Facility Profile

- 74.6% of the VA research facilities perform research both on-site and at off-site facilities
- 94.3% of off-site research is conducted at University Affiliates



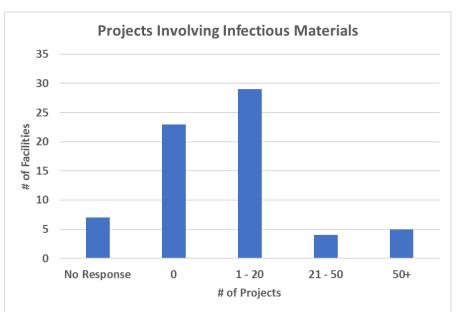


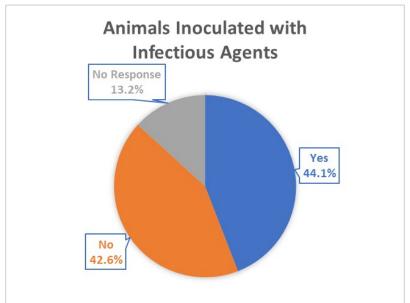


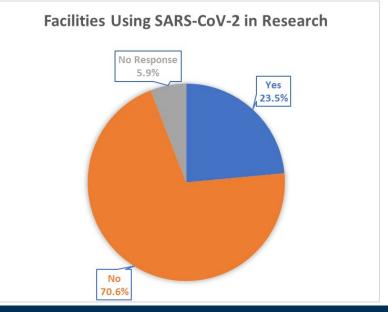


Biosafety Profile

- 55.9% of the research facilities use infectious materials
 - 44.1% stated they use infectious materials in animal experiments
 - 23.6% stated they use SARS-CoV-2 as part of their research activities
- 33.8% of the research facilities do not use infectious materials





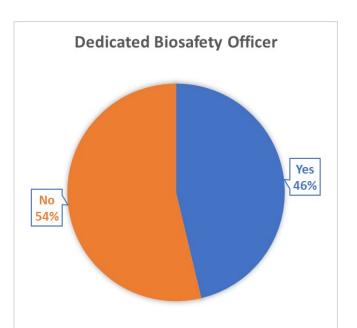


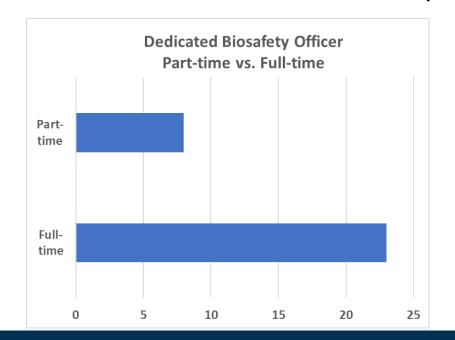




Availability of Biosafety Support

- 46% of the research facilities had dedicated Biosafety Officer (BSO) positions
 - 74% of the BSOs are full-time staff
 - 26% of the BSOs are part-time positions
- 54% of the research facilities did not have dedicated BSO positions



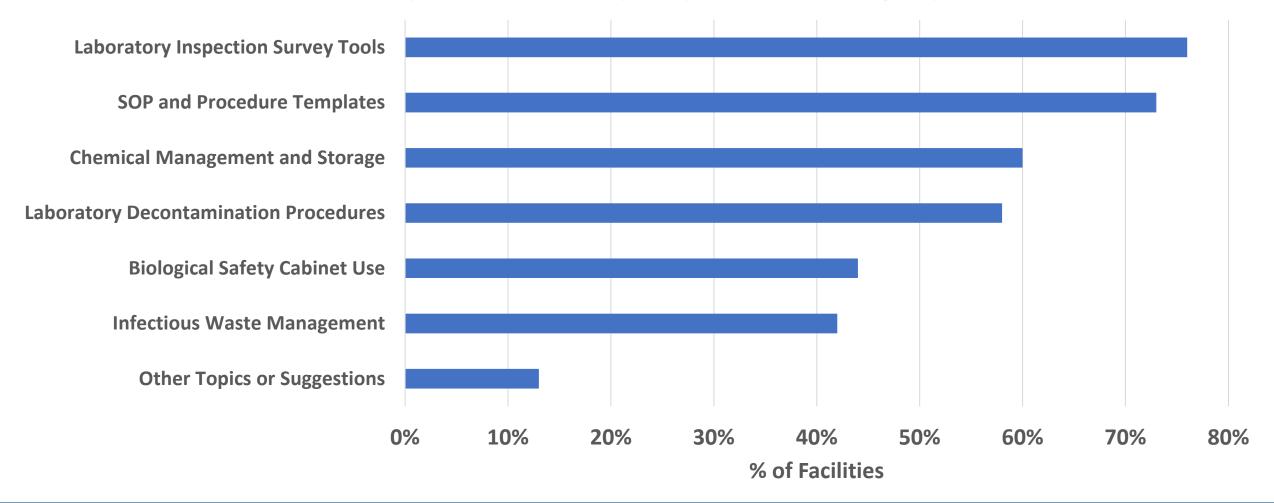








Biosafety and Biosecurity Requested Training Topics





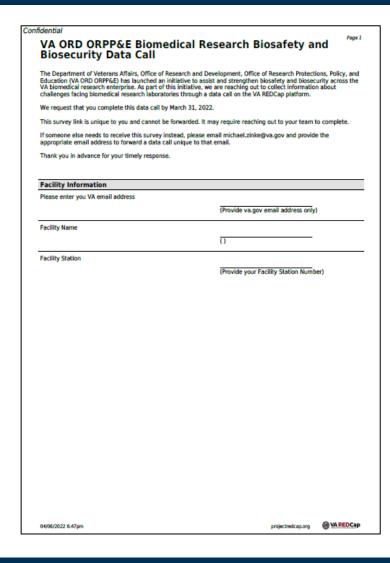


ORD Biosafety and Biosecurity Data Call Fiscal Year 2022





- Executed via VA REDCap
 - Will send to 83 VHA medical care facilities
 - Sent to 53 VHA medical care facilities (to date)
 - 24% response rate (20 facilities) (to date)
- Focus Areas:
 - Research Biosafety Point of Contact (POC)
 - SARS-CoV-2 Research
 - SARS-COV-2 Basic Research
 - COVID-19 Clinical/Epidemiology Research
 - SRS Activities
 - IBC Activities
 - Biosafety POCs Contact Information

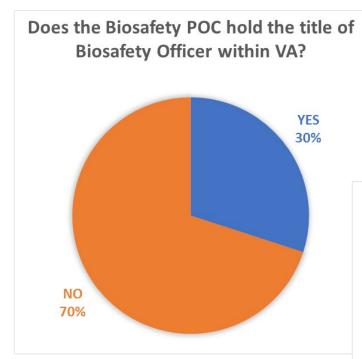


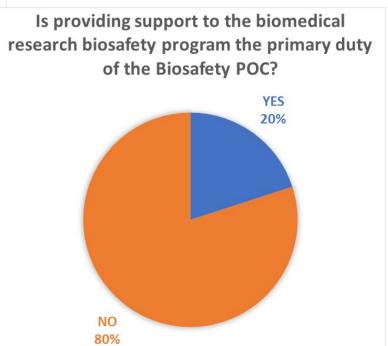




Research Biosafety POC

- 70% reported the biosafety POC do not hold the official position of Biosafety Officer within the VHA
- 80% reported the primary duties of the biosafety POC is not dedicated to the research biosafety program



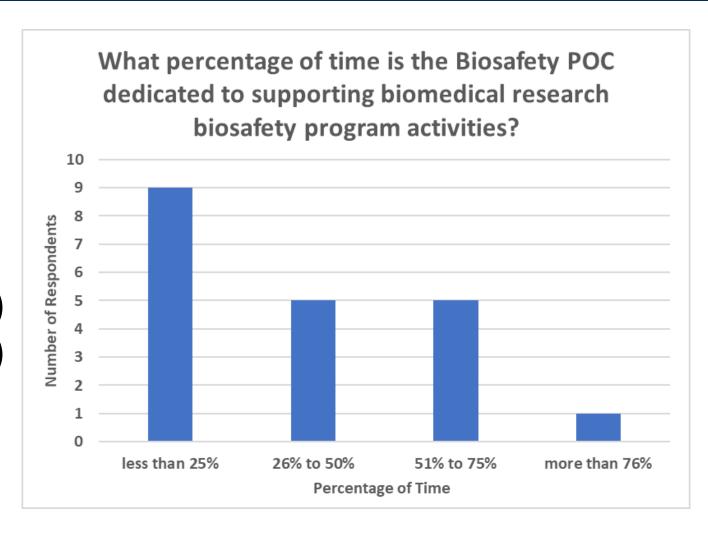






Time the biosafety POC dedicates to the biosafety program ranged from:

- less than 25% (9 respondents)
- 26% to 50% (5 respondents)
- 51% to 75% (5 respondents)
- more than 76% (1 respondent)

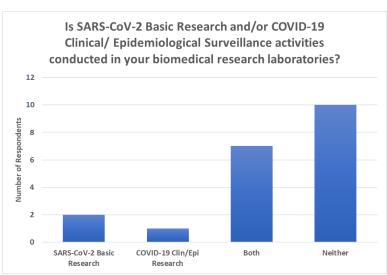


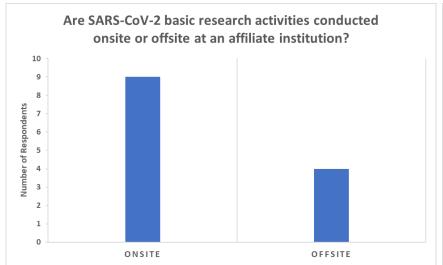


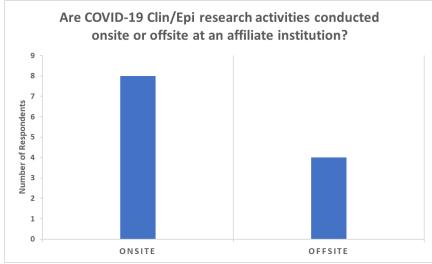


SARS-CoV-2 Research

- 10% SARS-CoV-2 basic research
- 5% COVID-19 clinical/epidemiological surveillance
- 35% Both SARS-CoV-2 basic research and COVID-19 clinical/epidemiological surveillance
- 50% No SARS-CoV-2 basic research or COVID-19 clinical/epidemiological surveillance





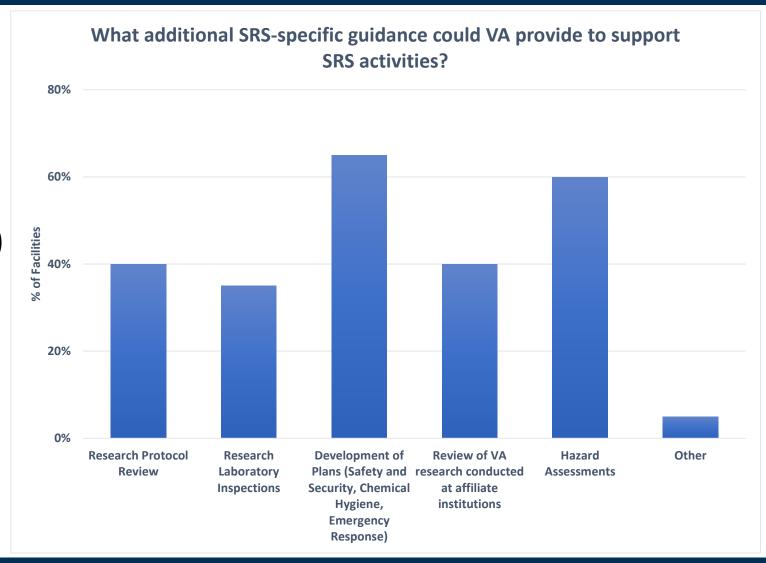






Additional SRS Guidance Requested

- Development of Plans (65%)
- Hazard Assessments (60%)
- Research Protocol Review (40%)
- Review of VA Research Conducted at Affiliate Institutions (40%)
- Research Laboratory Inspections (35%)
- Other (5%)

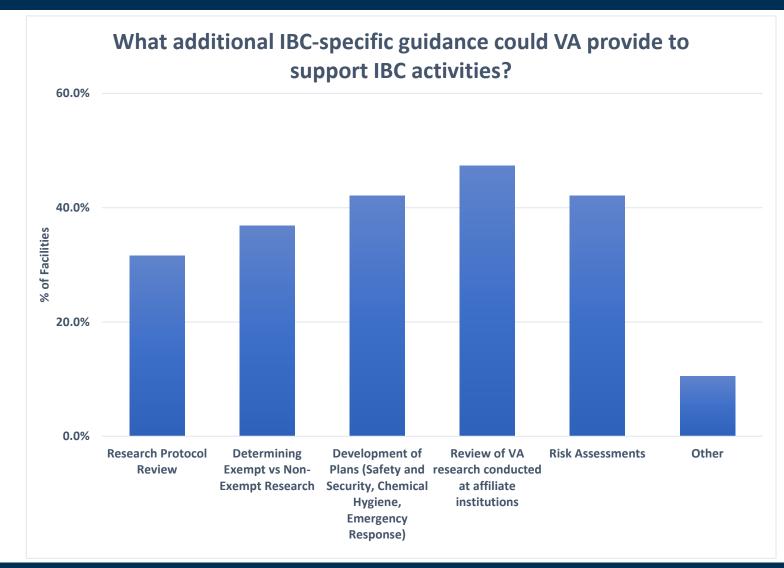






Additional IBC Guidance Requested

- Review of VA Research Conducted at Affiliate Institutions (47.4%)
- Risk Assessments (42.1%)
- Development of Plans (42.1%)
- Determining Exempt vs Non-Exempt Research (36.8%)
- Research Protocol Review (31.6%)
- Other (10.5%)

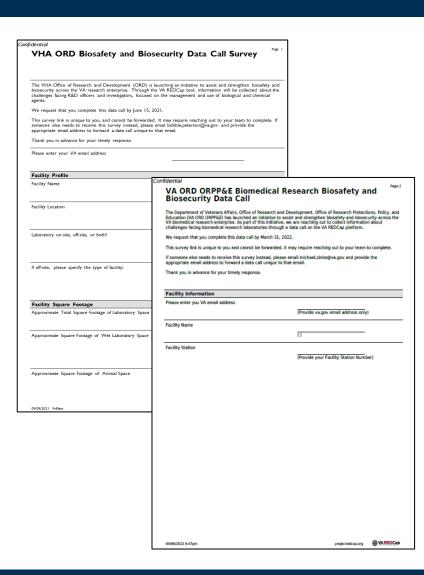






Data Call (FY21 & FY22) Outcomes

- Identified areas for improvement and standardization across VA facilities
- Defined opportunities/needs for additional support to enhance biosafety and biosecurity program development and implementation
- Informed and prioritized biosafety and biosecurity educational initiatives and activities
 - Biosafety Toolkit
 - ORD Biosafety Webinar Series
 - Additional educational tools
- Supported the development and identification of topics for the FY22 BRLBBP Data Call







ORD Biosafety and Biosecurity Program Assistance Visits (PAVs)

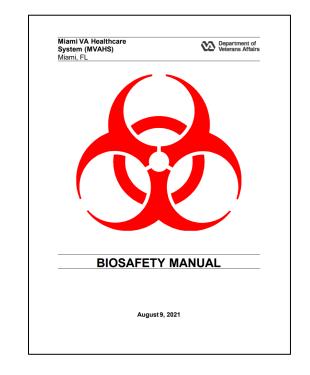




Program Assistance Visits (FY21 & FY22)

- Identify the various biosafety and biosecurity program elements associated with the research activities conducted at VHA field sites
- Gather information related to a facility's biosafety and biosecurity program
- Information will be used by ORD to:
 - Improve support for the management of the biosafety and biosecurity risks in VHA research laboratories
 - Support the development national biosafety policies and guidance
 - Prioritize biosafety and biosecurity educational initiatives and activities

NOT A COMPLIANCE VISIT!



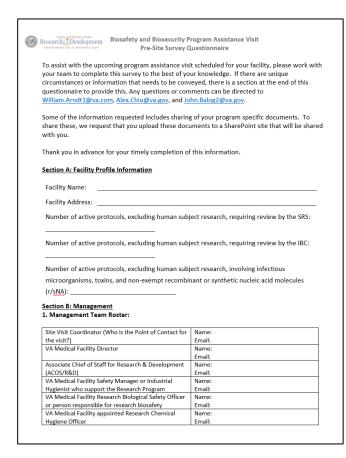






Program Assistance Visits (FY21 & FY22)

- Initial outreach is coordinated through ORD
 - Introductory emails, official memos, and pre-site questionnaires
- TJFACT biosafety and biosecurity SMEs conduct the visits in partnership with ORD and the facilities' Executive Leadership Teams
- Activities consist of:
 - Biomedical research laboratory tours
 - Discussions with biomedical research personnel/staff
 - Review of biosafety and biosecurity related documents
- Duration varies from 1 4 days depending on the size of the facility







Program Assistance Visits (FY21 & FY22): Role of ORO

- ORO is collaborating in the planning of this effort at the invitation of ORD
- ORO's participation is not for purposes of identifying noncompliance, and no member of ORO attends the PAVs
- ORD evaluates data provided by ORO regarding frequent safety findings and other compliance challenges
 - Data is summarized and sites are not identified
 - Information helps to inform ORD decisions regarding training topics, etc.





Program Assistance Visits (FY21 & FY22)

- Team typically consist of:
 - Two (2) members from ORD
 - Two (2) TJFACT SMEs
- TJFACT SMEs responsible for coordinating logistics with field sites
 - Agenda/Itinerary
 - On-site meeting accommodations (conference room, parking, etc.)
 - In-brief and Exit-brief with the Executive Leadership Team
 - Documentation requests/uploads (SharePoint)
 - Coordinating staff interviews
- Drafts reports are provided to the sites for review and comment prior to being finalized
- Final reports are provided to the sites and ORD





Program Assistance Visits (FY21 & FY22)

PAVs Conducted in FY 2021

- Atlanta January 11-14, 2021
- Omaha February 8-10, 2021
- Portland April 6-9, 2021
- Cleveland May 4-7, 2021
- White River Junction June 29-30, 2021
- Syracuse August 17-19, 2021

Information obtained was/is used to:

- Provide suggestions to the site on biosafety and biosecurity best practices
- Identify and prioritize biosafety and biosecurity development opportunities related to:
 - Existing gaps and challenges
 - Additional policies and guidance
 - New training and educational initiatives/tools

PAVs Conducted in FY 2022

- Columbia* March 2 3, 2022
- Miami April 5 8, 2022
- Denver May 24 26, 2022





ORD Biosafety and Biosecurity Educational Tools and Trainings





Educational Tools and Trainings

- Provide resources and guidance to VHA staff enhance biomedical research biosafety and biosecurity programs at VHA facilities
- Leverage information obtained from data calls, PAVs, and questions obtained from the field to prioritize tool development activities
- Develop and publish a Biosafety Toolkit that:
 - Provides resources for general biosafety and biosecurity information
 - Provides field programs with guidance and best practices
 - Serves as a training supplement for VHA staff
 - Assists in the development of Biomedical Research Laboratory Safety Manuals





Tools from the ORD BRLBBP Toolkit

Available Educational Tools:

- Compressed Gas Cylinders
- Anesthetic Gases
- Biological Safety Cabinets (BSCs)
- Waste Segregation and Disposal
- Laboratory Biosafety Sign Narrative and Template
- Laboratory Biological Risk Assessment Narrative and Template





Updated ORD/ORPPE Program Webpage

The ORD Biomedical Research Laboratory Biosafety and Biosecurity Program weblink:

https://www.research.va.gov/programs/biosafety/default.cfm

Toolkit: Research Laboratory Biosafety and Biosecurity weblink:

https://www.research.va.gov/programs/orppe/education/toolkits/biosafety.cfm





Sample Tool from the ORD BRL BBP Toolkit

Compressed Gas Cylinders

Objective

 Provide a training supplement and a printable sign to be posted in spaces where gas cylinders are used and stored

Intended Usage

- Training supplement for VHA staff on the proper use and storage of compressed gas cylinders
- Printable signage is to be laminated and posted in spaces where compressed gas cylinders are used and stored



COMPRESSED GAS CYLINDERS

Storage and Handling Reminder -ISECURE

Inspect cylinders for leaks.

Store cylinder in cool, well-ventilated, fire-resistant areas in compliance with local, state, and federal regulations and secure cylinders properly at all times.

Ensure valves are secured and/or caps are tightened when not in use.

Check support brackets regularly for strength and integrity.

Use carts when moving cylinders designated for this purpose.

Report any leaks or damages to your supervisor immediately.

Ensure cylinders are placed where they will not be damaged, knocked over, or hit by falling objects.





Sample Tool from the ORD BRLBBP Toolkit

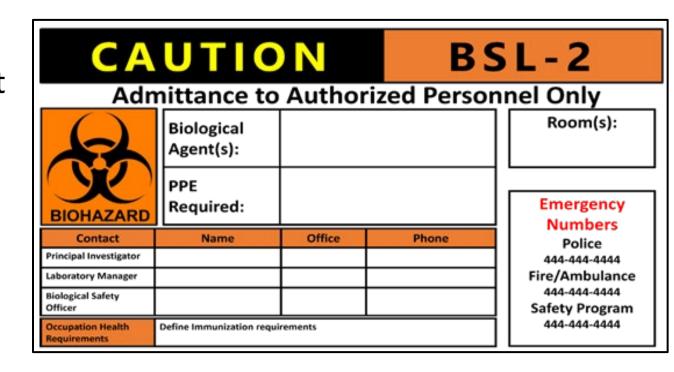
Laboratory Biosafety Signs

Objective

 Provide guidance on the appropriate signage to be posted at the entrances of biosafety level (BSL) 1 - 3 research laboratories

Intended Usage

- Support VHA staff on posting the appropriate biosafety-related signage to be included at the entrances of research laboratories
- Serve as an aid in the development of facility-specific Biosafety Signs







Educational Tools and Trainings TBD

Personal Protective Equipment (PPE)

 Provide guidance and support to VHA staff on the identification, selection, and proper use of personal protective equipment (PPE) to serve as a training supplement

Biosafety Frequently Asked Questions (FAQs)

- Provide a resource and guidance to VHA staff on general biosafety and biosecurity FAQs
- Questions obtained through ORD biosafety email address, program assistance visits, and common questions within the biosafety community

General Biosafety and Biosecurity Definitions

 To provide a list of common terms and definitions about general laboratory biosafety and biosecurity to support clear and concise communication

Other Tools

Additional tools to be identified based on feedback





Educational Tools and Trainings

Webinars

- ORD Biosafety and Biosecurity Webinar Series (3 Webinars to be Conducted as Part of Initial Launch of New Initiatives)
 - Webinar #1 Biosafety and Biosecurity Program: New Initiatives for VHA Facility Support
 - Webinar #2 TBD
 - Webinar #3 TBD
- Information from multiple sources, including feedback from today's webinars, will help determine the focus of the next two webinars.





Next Steps





Next Steps

- Updating or Development of Memorandum of Understandings:
 - Update: Use of BLS-3 Laboratory Space at University
 - Development: Use of BLS-2 Laboratory Space at University
 - Update: Use of Institutional Biosafety Committee at University or VA Facility
- Policy Revision
 - Identification of gaps/needs in VHA Directive 1200.08.
- Forms
 - Begin redesign of VA Form 10-0398: Research Protocol Safety Survey.
- Research Biosafety Committee Infrastructure
 - Guidance on administrating VA IBC meetings and standardizing the format of meeting documents (agenda, minutes, roster of members)
- Prioritize development of addition biosafety "toolkit" content





References

- VHA Directive 1200.08. Safety of Personnel and Security of Laboratories Involved in VA Research, Veterans Health Administration, January 8, 2021.
- Toolkit: Research Laboratory Biosafety and Biosecurity
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Ed.,
 Centers for Disease Control and Prevention and National Institutes of Health,
 2020.
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), National Institutes of Health, 2019.
- ABSA International The Association for Biosafety and Biosecurity, (www.absa.org).





Please Note

A recording of this session and the associated handouts will be available on ORPP&E's Education and Training website approximately one-week post-webinar.

An archive of all ORPP&E-hosted webinars can be found here: https://www.research.va.gov/programs/orppe/education/webinars/archives.cfm





Availability of Recording

- A recording of this session and the associated handouts will be available on ORPP&E's Education and Training website approximately one-week post-webinar
- An archive of all ORPP&E webinars can be found here: https://www.research.va.gov/programs/orppe/education/webi nars/archives.cfm.



Questions and Answers





Please Complete the Survey!

Thank you!



