**Duke University**

**DURC/PEPP Risk Mitigation Plan (RMP)**

## Instructions: This Risk Mitigation Plan (RMP) template must be utilized as a starting point to develop the RMP for any study determined to fall under the May 2024 [U.S. Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)](https://test-safety.dksctest.dhe.duke.edu/sites/default/files/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf)  (2024 USG Policy). An unedited version of this template is NOT the final document that should be submitted to the Funding Agency. Project and location specific information must be entered into each section below. The Institutional Review Entity (IRE) and the Funding Agency must review and approve the RMP before work can begin. If you have any questions, please contact the Institutional Contact for Dual Use Research (ICDUR) listed below.

## Contact Information:

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| Role: | Name: | Department: | Contact: |
| Principal Investigator (PI) |  |  | Email:Phone number: |
| Institutional Contact for Dual Use Research (ICDUR) | Antony Schwartz, PhD | Occupational and Environmental Safety Office, Biological Safety Division | Email:antony.schwartz@duke.eduPhone number:+1 919 684 8822 |
| Program Officer |  |  | Email:Phone number: |

**Institutional Review Entity (IRE) Review Decision:**

**Institutional Review Entity (IRE) Review Decision Date:**

## SPS Tracking Number:

## Project Title:

## Research Summary:

## Biosafety and Biosecurity Measures

**Biocontainment**

The facilities occupied by Dr. \_\_ laboratory were designed to meet biocontainment standards outlined in Biosafety in Microbiological and Biomedical Laboratories (6th edition [1]; **BMBL6**).

BSL-2 suite includes the following:

* Infectious work is conducted inside of a biosafety cabinet whenever possible
* Inward flowing air without recirculation to spaces outside of the laboratory
* Self-closing and locking doors with controlled access while work is conducted
* An emergency generator in case of a power failure

**Personal Protective Equipment (PPE)**

An essential component of risk mitigation is PPE. The staff follow recommendations in **BMBL6** and the NIH Guidelines for Research Involving Recombinant DNA Molecules (2).

BSL-2 PPE:

* Lab coat
* Safety glasses
* Nitrile gloves

When exiting the BSL-2, PPE is removed in a particular order and hands are washed with soap and water.

**Operational precautions**

In addition to the facility and PPE-mediated risk mitigation practices, standard operating procedures (SOPs) provide risk mitigation. All activities in the \_\_\_ laboratory are described in detailed SOPs including emergency response plans.

**Inventory and tracking**

Select Agents and Toxins are inventoried and tracked from acquisition to destruction, as outlined in our Select Agent Plans and agent-specific SOPs. Biological materials considered to be Category 1 or Category 2 research under the 2024 USG Policy will be inventoried from creation to disposition, as outlined in the laboratory-specific SOP.

**Personnel**

Personnel working with Select Agents and non-exempt amounts of Select Toxins are registered with the Duke Select Agent and Toxin Registration and are subject to all the regulations under 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331. Briefly, this includes initial and ongoing training, a security risk assessment by the FBI, and enhanced requirements for personnel designated as Tier 1 personnel. All personnel working at BSL-3 or ABSL-3 follow a training program that includes initial and annual refresher classroom training, hands-on training, a dedicated mentorship, internal assessment, and an external assessment by OESO Biological Safety Division. Researchers identified as working with Category 1 or Category 2 research have additional training regarding the 2025 USG Policy. All researchers at Duke University working at BSL-2 have annual training requirements and a laboratory-specific SOP that must be reviewed and signed annually by the workers. BSL-2 SOPs are approved by OESO Biological Safety Division for a maximum of three years and reviewed annually during lab evaluations.

**Occupational health plan.**

Each BSL-2 SOP approved by OESO Biological Safety Division outlines the medical surveillance necessary or recommended for the biological material of the SOP. The SOP also outlines actions to take if a spill and/or exposure occurs, namely disinfection and reporting to Employee Occupational Health and Wellness (EOHW). EOHW is also available for questions regarding individual concerns. Personnel who work or enter the BSL-3/ABSL-3 environment have an annual High Containment Health Review that is personalized to the worker and the hazards they may encounter. Specifics are outlined in agent specific SOPs, hazard specific signage, and the Select Agent plans. Duke University also has university-wide exposure control plans for tuberculosis and bloodborne pathogens. All policies and plans require reporting to EOHW for all potential exposures. The laboratory occupational health plan operates in compliance with the institution’s Occupational Medicine Program. The exposure control plan requires reporting to Dr. \_\_\_\_ and the Responsible Official (RO) of all symptoms associated with \_\_\_\_\_\_\_\_ and any instance of a potential exposure. If exposure occurs or symptoms develop, the RO will communicate with the Infectious Disease Physician and Public Health authorities to ensure the individual gets treatment in an extremely timely manner.

## Program oversight

## The research program, procedures, occupational health plan, documentation, security and facilities are reviewed annually by the RO and the Alternate Responsible Officials (AROs) and at regular intervals by the CDC as part of the institution’s Select Agent Program. Duke RO and ICDUR is Dr. Antony Schwartz. All biosafety protocols are approved by the Duke Institutional Biosafety Committee (IBC) after risk assessments were conducted by the OESO Biological Safety Division. In addition, the Biological Safety Division regularly reviews the research program and ongoing activities of the laboratory. The Biological Safety Division has a diverse skill set and provides support in the areas of biosafety, communications, facilities, compliance, legal, security and health. Members of the Biological Safety Division are in regular contact with the principal investigator and laboratory personnel to provide oversight and assure biosecurity. At Duke the IRE is the Institutional Biosafety Review Committee and is managed by the Occupational and Environmental Safety Office Biological Safety Division.

**Evaluation of medical countermeasures** (this section will be customized based on the agent/toxin)

Agent- or laboratory-specific SOPs contain a section for information regarding vaccination, prophylaxis, or antibiotics/antiviral regimens, if available. This information is reviewed by a committee including OESO Biological Safety, EOHW, Duke Infectious Disease Physicians, and laboratory safety representatives, as needed. SOPs, as explained above, are approved by OESO Biological Safety for a maximum of three years and reviewed annually by OESO and lab personnel. Information for select agents is also included in the Select Agent Biosafety Plan.

The only medical intervention currently available is \_\_\_\_\_\_\_. Vaccination is no longer available to personnel working in laboratories. Treatment for a \_\_\_\_\_ exposure will consist of \_\_\_\_\_\_\_.

## Notification of funding agency

## If additional DURC/PEPP data is identified, the ICDUR will notify Dr. \_\_\_’s Program Officer through appropriate and established institutional mechanisms. Additional modifications to the risk mitigation plan will be made as necessary. All manuscripts potentially containing DURC/PEPP will be sent to the ICDUR and IRE for review. The ICDUR will ensure the May 2024 DURC/PEPP Policy (3) is followed, and the appropriate US Government agency is notified.

**Determining the venue and mode of communication**

## To advance the scientific mission, it is important for research results to be shared via peer-reviewed publications. However, if the research is considered DURC/PEPP, additional discussions are necessary before sharing the information. When publication of DURC/PEPP is planned, the ICDUR and IRE will work with Dr. \_\_\_\_\_ and the Director of Research Communications to:

## Evaluate the benefits of publishing the manuscript (significance in the field, etc.)

## Consider the risk that publishing the results could pose a serious threat in a reasonable timeframe

## Determine how best to explain the value of the work to the scientific community and general public

## Develop a description of the biosafety and biosecurity measures in place to be included in the manuscript (4)

## Seek advice from NIH and others regarding the risk of publishing the research

## Develop press conference and talking point tools to put the work in context and to minimize sensationalism

## Dr. \_\_\_\_ and collaborators on the project will adhere to responsible communications guidelines in written (emails, letters, publications, etc) and spoken (scientific presentations, informal talks, lectures, interviews, and informal discussions) communications.

## Dual Use Research of Concern (DURC/PEPP) Risk Mitigation

## DURC/PEPP training

## The PI is responsible for ensuring that all staff are appropriately trained in all biological safety protocols. Currently, the training is comprised of an online training session that describes the May 2024 DURC/PEPP policy. The successful completion of the training and associated quiz is required for Dr. \_\_\_\_ and their researchers. The training will be renewed every three years or as needed if there are changes to the program or additional risk mitigation measures are warranted.

## DURC/PEPP Institutional Review

## Dr. \_\_\_\_ conducts an assessment of a research project and sends that information to the ICDUR. The ICDUR, who is also the chair of the IRE, receives the assessment and gathers any additional materials pertaining to the project from Dr. \_\_\_\_\_\_. Members of the IRE independently review the materials and then discuss whether the research is DUR, DURC/PEPP, or neither using the criteria set in U.S. Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern. If the research is deemed to be DURC/PEPP, appropriate notifications will be made. In addition, the ICDUR will work with Dr. \_\_\_\_\_ and the IRE to determine which risk mitigation measures are appropriate. Dr. \_\_\_\_\_\_ will provide the ICDUR with regular research updates and all manuscripts and presentations for review.

**References**

1. <https://www.cdc.gov/labs/bmbl/index.html>
2. <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>
3. <https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf>
4. <https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf>