

Duke University Policy for Working with Exempt Quantities of Select Toxins

Purpose: Select Toxins are toxins determined to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. The inclusion criteria are reviewed and maintained by the [Federal Select Agent Program](#). While the Federal Select Agent Program has many regulations, the select toxins are exempt from most of the federal select agent regulations if the amount under the control of a principal investigator does not exceed, at any time, the amounts indicated in the [Permissible Toxin Amounts table](#), as listed on the Federal Select Agent website. While these toxins are exempt from most of the regulations, laboratories that use permissible levels of the select toxins must still follow due diligence and institutional policies (42 CFR Part 73.3 Section 16). It is Duke University policy to ensure that these toxins with potential for severe consequence are kept securely and are used safely.

Oversight: At Duke University, Occupational & Environmental Safety Office (OESO) Biological Safety Division has oversight of all biological materials in the workplace that are hazardous to humans, animals, or plants. It is ultimately the responsibility of the Principal Investigator and researchers working with the permissible amount of select toxins to review this policy document and inform the OESO Biological Safety Division prior to ordering and possessing any amount of select toxins.

Work Practice Controls: Due to the potential of these toxins to pose a severe threat to public health and safety, Duke University requires the following work practices:

- A toxin-specific Standard Operating Procedure (SOP) must be approved by OESO Biological Safety Division prior to ordering select toxin. Contact biosafety@duke.edu for the SOP template.
- All orders of select toxins must be done through the [Select Agent Ordering website](#) (link will open the Select Agents & Toxins page on OESO's website. Access to the ordering website is requested by contacting OESO Biological Safety Division (biosafety@duke.edu). The Select Agent Ordering portal requires a sign-in with your NetID and password).
- All toxins will be shipped directly to the OESO Biological Safety Division office. A member of the Biological Safety Division will deliver the toxin to your laboratory when the toxin is received. A person named in the SOP as working with the toxin must be in the lab to receive it.
- Toxin must be kept in a secure location, such that unauthorized laboratory members and/or visitors to the lab could not find the location upon casual entry and gain access to the toxin.
- Access to toxins should be restricted to only the authorized personnel listed in the SOP.
- An inventory logbook, hardcopy or electronic, must be maintained with the running total amount in mg, purpose of each use/manipulation, date on which the material was used, name and initials or signature of the authorized user. The logbook should be kept in a location where unauthorized users cannot gain access and manipulate the information in the logbook. The logbook should be maintained in such a way that the authenticity of the information in the logbook can be verified.
- Annually, using the Biological Material Reporting System (BMRS), a report, including the amount of toxin currently in the lab, must be submitted. This is usually done around the time of the annual Lab Safety Evaluation.
- If you plan to create recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules, the work may be regulated under the NIH Guidelines and the

Federal Select Agent Program. Please reach out to OESO Biological Safety at biosafety@duke.edu for further guidance.

- Any transfer of select toxin to another user outside of the laboratory must be approved by the Responsible Official of the Duke Select Agent Program. Contact OESO Biological Safety at biosafety@duke.edu for approval. Please provide as much information as possible regarding this request. At minimum, the information provided should include, recipient's name, institution name, address, telephone number, email address; name of the toxin and the total amount transferred; and the legitimate need claimed by the recipient. If the select toxin is being transferred to an outside institution, a Material Transfer Agreement (MTA; executed by the Office of Research Contracts) and an approval from the receiving entity's Biosafety Office will be required.
- If the Principal Investigator or authorized users of the exempt quantities of select toxins detect a known or suspected violation of Federal law or become aware of suspicious activity related to the toxin, it must be reported immediately to the Responsible Official of the Duke Select Agent Program at biosafety@duke.edu or 919-684-8822.