



JAMES MADISON UNIVERSITY®

SOP Title:	Sanctions Following Violations of Biosafety Protocol Registration	SOP No.	8
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Effective Date:	5/18/2022	Page	1 of 1

Purpose: This standard operating procedure (SOP) explains the procedure for handling uncorrected or flagrant violations of a biosafety protocol.

References:

NIH Guidelines: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Ed:
https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

Conditions:

1. The PI or worker must have willfully and repeatedly violated an approved lab safety protocol or the guidelines for safe use of biological hazards as described in NIH guidelines and/or CDC BMBL where applicable.

Procedures:

1. PI will be notified in writing of any violations and have 7 days (or longer if deemed necessary by the IBC) to correct the issue. If the violator is not the PI on the protocol in question, both the PI and the worker will receive written notification.
2. If the deadline is not met, a second written notification will be sent to the PI (and worker) and copied to the appropriate AUH(s) with a deadline for rectifying the issue.
3. A follow-up meeting between the IBC chair (or IBC designee), AUH(s), and PI will also be requested with the goal of identifying and fixing any factors that are preventing compliance.
4. Further failure to follow lab protocol will result in suspension and/or termination of the laboratory protocol and notification of the appropriate Dean(s) and the Vice Provost for Research and Scholarship.

Potential Consequences of Repeated Violations:

- Inability to receive University approval for external funding.
- Removal of University support for scholarly or teaching activities.
- Disciplinary action up to and including termination and expulsion in accordance with relevant University policies.
- Non-compliance may be subject to enforcement and penalties as defined by Code of Virginia § 40.1-51.22 and § 40.1-51.39.
- Non-compliance with Occupational Safety and Health Administration (OSHA) requirements may be subject to enforcement and penalties as defined by the United States Department of Labor (DOL) Federal Civil Penalties.