

SUBJECT: IBC Lentiviral Exposure Plan

1. PURPOSE: Establish the Standard Operating Procedures for post-exposure guidance on lentivirus.

2. DEFINITIONS:

BBP	Bloodborne Pathogen
ECOMP	Employees' Compensation Operations & Management Portal
EOH	Employee Occupational Health
ERP	Exposure Response Plan
IBC	Institutional Biosafety Committee
NIH-OSP	National Institute of Health – Office of Science Policy
PEP	Post-Exposure Prophylaxis
PI	Principal Investigator
SRS	Subcommittee on Research Safety
VAMC	Veterans Affairs Medical Center

3. OVERVIEW:

- a) Every research protocol involving the use of lentiviral vector, must have a laboratory-specific Exposure Response Plan (ERP) developed by the PI and reviewed by Employee Occupational Health (EOH) before work begins.
- b) Following exposure personnel should seek medical attention immediately through EOH (4M-123) or in the Emergency Department if EOH is closed. If possible, the exposed person should bring a copy of the ERP when seeking medical care.
- c) Lentiviruses are retroviruses that are part of the same family that includes the Human Immunodeficiency Virus (HIV), but they have been modified for research and therapeutic purposes.
- d) In research lentiviruses are used as a carrier vehicle (lentiviral vector) to introduce genetic material (transgenes) into target cell genomes. The lentiviral vectors that are commonly used today are considered to be replication incompetent.
- e) Despite being replication incompetent, there is a potential insertional risk if a transgene is inserted into a genetically sensitive area and may induce mutational changes.
- f) Exposure is a concern under these conditions:
 - i) Direct parenteral inoculation
 - ii) Contact with mucous membranes on non-intact skin
 - iii) Contact with droplets from an aerosol-generating procedure

4. POST-EXPOSURE:

- a) **Perform First Aid:**
 - i) Thoroughly wash the affected area with soap and water for a minimum of 5 minutes.

- ii) If eyes or mucous membranes were exposed they should be flushed a minimum of 15 minutes.
- iii) Do not squeeze or massage the area of injury, do not use harsh chemicals like bleach as that risks compromising the skin's barrier function.

b) Document the Exposure:

- i) The lab specific Exposure Response Plan must include information on the exact type of lentiviral vector, its generation, replication competence, transgenes of concern (e.g., oncogenes), knockdown/knockout genes, or any other toxins carried by the vector.
- ii) Check what type of cells or tissues are being manipulated.
- iii) Confirm the route of exposure, amount of exposure, and when it occurred
- iv) Document all of the above in a written report (can be on paper originally, but will need to be converted to electronic record).
- v) Alert the PI so they're aware there's been a potential exposure.
- vi) Report the exposure incident to the National Institute of Health – Office of Science Policy (NIH-OSP) to NIHGuidelines@od.nih.gov. More details on NIH-OSP incident reporting can be found [here](#).

c) Medication:

- i) Benefits or risk of post-exposure prophylaxis for insertional risks is an unstudied area, however the recommendation is for the affected individual to receive medical evaluation **as quickly as possible** (within 0-72 hours).
- ii) Exposed individual should discuss nature of exposure, potential post-exposure prophylaxis (PEP), and antiviral therapy with the employee occupational health or emergency department physician. These medical providers may contact the on-call infectious disease specialist.
- iii) If indicated, PEP should be initiated as soon as possible to prevent insertional risks, especially if the lentiviral vector carried hazardous transgenes. The window for successful PEP may close after 72 hours.
- iv) Antiretroviral medication regimen (ex: Raltegravir with or without Tenofovir, or Isentress and Emtricitabine) should be given for 7 days (or as directed by medical provider). Protease inhibitors have no effect on lentiviral vector transduction/integration and are not recommended for insertional risks. If recommended by the medical provider, PEP will be ordered through the Minneapolis VAMC outpatient pharmacy.
- v) Be sure to tell your medical provider about all your medications so they can evaluate any potential drug-drug interactions.

d) Follow-Up:

- i) Baseline and follow-up lab blood tests are suggested for those receiving PEP.
- ii) Generally testing for lentiviral exposure is not useful. Documentation of the exposure is the key to assessing any future related issues.

5. Next Steps:

- a) Both the PI and the exposed individual should enter written reports into Employees' Compensation Operations & Management Portal (ECOMP) within 5 days. If PEP is administered that should be documented.
- b) The PI must submit a written report to the IBC and SRS Coordinator(s) within 30 business days.

- c) [SRS-012 Medical and Security Incident Plan](#) for more information on reporting and follow-up
- d) Exposure follow-up will be performed by Minneapolis VAMC Occupational Health.

6. REFERENCES:

1. “Risks Associated With Lentiviral Vector Exposures and Prevention Strategies,” National Library of Medicine (30 December 2016). <https://pmc.ncbi.nlm.nih.gov/articles/PMC5152689/>
2. [Incident Reporting – December 2023 \(December 2023\)](#). <https://osp.od.nih.gov/policies/incident-reporting-december-2023/>
3. “Lentiviral Vector post-exposure prophylaxis guidance,” Columbia University Environmental Health and Safety (3 October 2023). <https://research.columbia.edu/sites/default/files/content/EHS/Homepage/LentivirusPostExposureProphylaxisPrintAndGo.pdf>
4. “Print-And-Go Sheets: Lentiviral Vector Post-Exposure Guidance,” Weill Cornell Medicine Environmental Health and Safety (February 2021) https://ehs.weill.cornell.edu/sites/default/files/lentivirus_print_and_go_sheet.pdf
5. “Risks Associated With Lentiviral Vector Exposures and Prevention Strategies” Shlimgen, et. al. [Journal of Occupational and Environmental Medicine \(December 2016\)](#)

7. IBC Committee Approval: December 23, 2024

8. REVISIONS: N/A

9. EXPIRATION DATE: N/A

FOLLOW-UP RESPONSIBILITY: Institutional Biosafety Committees (IBC)