**Biohazardous Agent Reference Document (BARD) and**

**Information for Healthcare Providers in the Event of an Exposure**

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| The BARD is an additional guidance tool. It is not a substitute for a risk assessment, biosafety training, lab-specific training, SOP as required by the IBC or a formal [IBC master protocol registration](https://www.uvm.edu/rpo/biosafety-oversight). This document must be readily available in the laboratory, and it is the responsibility of the Laboratory Supervisor or Principal Investigator to ensure that all personnel have read and understood the information. The BARD is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Please bring this IBC-approved BARD with you to the UVMMC Emergency Department if there has been an exposure and someone requires medical assistance. INSTRUCTIONS for BARD Preparation1. Complete the blue Information for Healthcare Providers section.
2. Review the standard information contained in the green section of this document.
3. Add/revise information that is specific to your work in the laboratory (such as strain-specific information). Please be sure that the track changes function is turned on to indicate any changes that you make.
4. Submit the BARD along with your IBC master protocol registration or amendment.
5. Once approved by the IBC, all personnel must review this BARD. The PI will attest during the submission of the registration or amendment to add new personnel that each lab member has read and understands the material.
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| **Information for Healthcare Providers**Dear Healthcare Provider, This individual works in a UVM research laboratory and has been exposed to a pathogen or toxin. Information about the materials this person may have been exposed to is listed below. You may also find useful additional information in subsequent pages of this reference document. |
| **Pathogen Name:** | Adeno-Associated Viral Vectors (AAV) |
| **Pathogen/Toxin Classification:** |  |
| **List All Strains Used in the Laboratory:** |  |
| **List Resistant Genes Known to be Encoded:** |  |
| **Modes of Transmission *(mucous membranes, needle stick, inhalation)*:** | Inhalation of aerosols, droplet exposure to mucous membranes, ingestion, and injection. |
| **Known Medical Precautions and Treatment** |

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| **Prophylaxis** | None available |
| **Vaccines** | None available |
| **Treatment** | No specific treatment |
| **Surveillance** | Monitor for symptoms |
| **Additional Medical Precautions (immunosuppression, pregnancy, allergies)** |  |

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| **Health Hazards** |
| **Host Range** | Humans and some other primates are natural hosts. Other vertebrate animals may be experimentally infected. |
| **Signs and Symptoms** | No known disease association for wild-type virus, although infection may elicit a mild immune response. Recombinant virus may integrate randomly, posing a theoretical risk of insertional mutagenesis. |
| **Infectious Dose** | Unknown |
| **Incubation Period** | Unknown |
| **Exposure Procedures** |
| **Mucous membranes** | Flush eyes, mouth or nose for 15 minutes at eyewash station. |
| **Other exposures** | Wash area with soap and water for 15 minutes |
| **Medical Follow-Up** | Contact UVMMC Infectious Disease Dept. directly at **(802) 847-2700** for immediate assistance. Bring this document with you if seeking medical care. |
| **Reporting** | Report all exposures or near misses to:1. Your immediate Supervisor
2. SOS at 802-656-2560 and ask to have the EH&S team paged
3. Risk Management: <https://www.uvm.edu/riskmanagement/incident-claim-reporting-procedures>
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| **Laboratory Hazards** |
| **Laboratory Acquired Infections** | None reported. Commonly used as a gene therapy delivery system. |
| **Sources** | Respiratory droplets, laboratory cultures |
| **Characteristics** |
| **Morphology** | Non-enveloped, single-strand DNA viruses that can only replicate in the presence of a helper virus (such as Adenovirus, Herpes virus, or Vaccinia). **In the absence of helper virus, wild-type AAV can stably integrate into the host genome (to the AAVS1 region of human chromosome 19) and remain latent until exposed to a helper virus.** Recombinant AAV loses this specificity, but may integrate randomly at a lower rate. **AAV has the ability to infect a broad range of cells.** Eleven serotypes have been identified. |
| **Strain Specific Characteristics**  | The biosafety level of specific AAV will be evaluated on a case-by-case basis, with consideration given to:1. Nature of the transgene
2. Presence of helper virus
3. Type of cell line used for propagation

Verification of purification when propagated in human cell lines or when helper virus is used |
| **Containment Requirements** |
| **BSL - 1** | Transgene *does not* express an oncogene or toxin, viruses generated *without* helper virus, acceptable verification that helper virus is not present, or propagation in insect cell lines |
| **BSL - 2** | Transgene that expresses an oncogene or toxin, viruses that are propagated in human cell lines *without* further purification before use, known presence of helper virus, or lack of acceptable verification of purification |
| **ABSL - 1** | Animals may be housed at ABSL-1 72 hours after administration, once the initial cage change has been completed. |
| **ABSL - 2** | Injection of animals, oropharyngeal or nasal inoculation of virus that requires BSL-2 containment. Animal bedding should be considered biohazardous for 72 hours after exposure. Filter-top cages, hazard ID cage cards, and ABSL-2 door signage must be used. |
| **Aerosol generating activities** | Centrifugation, homogenizing, vortexing or stirring, changing of animal cages, animal surgeries, cell sorting, pipetting, pouring liquids, sonicating, loading syringes |
| **Primary containment device (BSC)** | Use for all BSL-2 virus work, virus propagation, large volumes, or aerosol-generating activities |
| **Personal Protective Equipment (PPE)** |
| ***Minimum PPE Requirements*** | Nitrile gloves, lab coat or gown, appropriate eye/face protection. Wash hands after removing gloves. |
| ***Additional Precautions*** ***(Risk assessment dependent)*** | Open wounds, cuts, and scratches should be covered with waterproof dressings. |
| **Viability** |
| **Disinfection** | Susceptible to 10% bleach, 2% glutaraldehyde, 1% iodine, or 5 % peracetic acid; with 10-minute contact time.  |
| **Inactivation** | Autoclaving for 30 minutes at 121°C |
| **Survival Outside Host** | Can survive on surfaces for several weeks |
| **Spill Clean-Up Procedures** |
| **Small Spill** | Notify others working in the lab. Allow aerosols to settle. Don appropriate PPE. Cover area of the spill with paper towels and apply approved disinfectant, working from the perimeter towards the center. Allow 30 minutes of contact time before clean up and disposal. Dispose in double biowaste bags and biobox. |
| **Large Spill** | **Inside of a lab:** Call UVM Service Operations at 656-2560 and ask to speak to a dispatcher. Ask them to page Risk Management and Safety. **Outside of the lab:** Pull the nearest fire alarm and evacuate the building. Wait out front of the building for emergency responders to arrive. |
| **References** |
| **Addgene AAV Guide** | <https://www.addgene.org/guides/aav/> |
| **BMBL** | <https://www.cdc.gov/biosafety/publications/bmbl5/> |
| **Annual Review of Genetics** | <https://www.annualreviews.org/doi/full/10.1146/annurev.genet.37.110801.143717?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed> |
| **UVM AAV fact sheet** | <https://www.uvm.edu/sites/default/files/UVM-Risk-Management-and-Safety/aav_vectors_fact_sheet.pdf> |
| **Human Gene Therapy Methods** | <https://www.ncbi.nlm.nih.gov/pubmed/28192678> |