Case Western Reserve University
Institutional Biosafety Committee
Policy on the Use of Adeno-Associated Viral Vectors

Adeno-associated viral vectors (AAV) provide a relatively safe and effective means of delivering genetic material into a target cell or tissue. The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* classifies AAV as RG-1, as it is not associated with disease in healthy human adults. However, the inserted gene(s) and additional plasmids/viruses can increase the risks associated with exposure. As a result, the CWRU Institutional Biosafety Committee has created the following policy in an effort to provide consistency for our investigators utilizing AAV in their research.

Required information on the IBC Protocol Form:

1. Packaging cell line, AAV vector backbone, insert and co-transfected plasmids that provide packaging proteins in trans.

Virus Risk Group and Containment requirements:

Viral Vector	Produced with Helper Virus?	Express oncogene or toxin molecule?	RG/BL ABSL
AAV	Yes	Yes or No	RG-2/BL-2 ABSL-2
	No	Yes	RG-1/BL-2 ABSL-2 for 24hrs
	No	No	RG-1/BL-1 ABSL-1

1) Any research utilizing AAV, produced using a helper virus (such as adenovirus or herpes virus), shall follow guidelines set out for adenovirus/herpes virus and shall be designated as RG-2/BL-2 for the duration of the experiments or until appropriate testing for replication competent virus has been completed. Infected animals should be maintained at BL-2 in the animal facility.

2) Any research utilizing AAV, produced without a helper virus, shall be designated as RG-1/BL-1 as long as the transgene does not encode a potentially oncogenic protein or a toxin molecule. Infected animals can be maintained at BL-1 in the animal facility.

    a. If the recombinant AAV encodes for a potentially oncogenic protein or toxin molecule, then the experiments must be conducted at RG-1/BL-2. Infected animals should be maintained under BL-2 containment for 24 hours after infection. Afterwards, the animals can be moved to a BL-1 facility but potentially contaminated

cages, bedding and food should be decontaminated and treated as biohazardous waste.

b. Cells in culture infected with AAV should be maintained under BL-2 containment. If an experiment needs to be performed under BL-1 conditions, medium can be removed 24 hours after infection, cells washed, and then moved to BL-1. Potentially infected medium and plasticware should be decontaminated and treated as biohazardous waste.

Viral Preparation and handling:

1. Viral preparation should be performed in a certified hood in a BL2 room and cells must be maintained under BL2 conditions while the virus is being packaged and secreted into the medium.

2. Whether in animals or cell lines, the handling of AAV should be done under BL2 containment conditions and in a hood if possible.