Safe Work Practice

Animal Projects with Genetic Vectors

1.0 Hazard Description

Many recent eukaryotic cell transformation vector and transduction particle technologies are based on a genetic backbone from pathogenic viruses including adenoviruses, lentiviruses, herpesviruses, baculoviruses, retroviruses and adeno-associated viruses. These technologies (hereafter referred to as viral vectors) are considered Risk Group 2 (RG-2) due to the possibility that they may recombine with genetic sequences from related lysogenic viruses present in the eukaryotic cells or animal being transformed and create viable copies of the original parent virus. Therefore, any animal research, teaching or testing activities involving the transformation of animals with viral vectors, the initial implantation must be conducted in Containment Level 2 (CL-2) facilities while following appropriate containment standard operating procedures (SOPs).

In addition, Environment and Climate Change Canada is developing a regulatory program under the New Substances Notification Regulations (Organisms) (NSNR(O)) for genetically modified animals produced with viral vectors or other modern genetic technologies including CRISPR/Cas9 systems. The resultant genetically modified animals do not necessarily need to be housed in biocontainment facilities but their housing location does need to be assessed to ensure against accidental release of the animals to the environment.

1.1 Hazard Assessment Considerations

1. The generation designation and replication competency of viral vectors utilized with animal models at the University of Alberta (U of A) must be determined by the Principal Investigator (PI). Note, only viral vectors which are replication deficient, and designated third generation or greater may be used at the U of A.
   - If using a commercial viral vector, the supplying company typically provides safety information through their website.
   - If the PI cannot locate information on the viral vector they are employing, they should contact the Biosafety Officers at biosafety@ualberta.ca for assistance.
2.0 Minimum Hazard Controls

2.1 Elimination/Substitution

1. The PI should consider if substitution of the viral vector with an alternative non-viral based vector system could be used to attain the same outcome.

2.2 Engineering Controls

1. Animals inoculated with viral vectors must be housed in CL-2 animal facilities for at least 72 hours following inoculation.
2. After 72 hours, the inoculated animals may be moved to a clean cage and transferred to conventional animal housing facilities.
   - After the initial 72 hours, the inoculated viral vectors are unlikely to leak out of the incision site which has begun to heal and the cells will not be excreted in the animal’s urine, feces or saliva.
3. Animal facilities housing genetically modified animals (whether the animal was modified at the University of Alberta or was obtained from an external supplier/collaborator) must be registered with the appropriate NSNR(O) Designated Official. Contact the Biosafety Officers for assistance in connecting to the appropriate NSNR(O) Designated Official. Animal housing facilities may be inspected by the NSNR(O) Designated Official to ensure proper containment of the genetically modified species.

2.3 Administrative Controls

1. Following transfer of the animals to a clean cage, the cage that housed the animals for the first 72 hours after inoculation of the viral vector must be processed as biohazard waste as per Item 2.4.7 of the Animal Projects with Biological Materials Safe Work Practice (EHS-SWP-130).
2. If using CRiSP/Cas9 technologies:
   - The PI’s Biosafety Registry must include CRISPR/Cas9 on their biological materials list,
   - Sequence tags must be checked to confirm they are unique to the intended target location within the animal’s genome with no identical target sequence present in the human genome, and,
   - CRISPR/Cas9 material may not be administered via aerosol delivery.

2.4 Personal Protective Equipment (PPE)

1. No additional minimal PPE controls beyond those outlined in the Animal Research, Teaching and Testing Projects (EHS-SWP-101), and Animal Projects with Biological Hazards SWPs are required.
3.0 Emergency Preparedness/Response

1. No additional minimal Emergency Preparedness/Management controls beyond those outlined in the Animal Research, Teaching and Testing Projects, and Animal Projects with Biological Hazards SWPs are required.

4.0 Applicable Legislation and Regulations

1. Canadian Biosafety Standard, Public Health Agency of Canada
2. Human Pathogens and Toxins Act, Public Health Agency of Canada
3. Human Pathogens and Toxins Regulations, Public Health Agency of Canada
4. New Substances Notification Regulations (Organisms), Environment and Climate Change Canada
5. Occupational Health and Safety Act, Government of Alberta
7. Occupational Health and Safety Regulations, Government of Alberta

5.0 Related Resources

1. Biosafety Guidelines, Environment, Health & Safety, University of Alberta
2. Safe Work Practice: How to Use Animal Safe Work Practices (EHS-SWP-100), Environment, Health & Safety, University of Alberta
4. Safe Work Practice: Animal Projects with Biological Materials (EHS-SWP-130), Environment, Health & Safety, University of Alberta

6.0 Document Management

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