POLICY ON RETROVIRAL REPLICATION COMPETENCY TESTING
Institutional Biosafety Committee – Boston/Medford campus

Background

Retroviral vectors have become standard tools in molecular biology in part due to their high transduction efficiency. Based on risk assessment, current biosafety guidelines establish BL2 practices and containment for most applications. Factors considered include, but are not limited to:

- Target cell range
- Nature of the gene insert
- Number of recombinant events needed to generate Replication Competent Virus (RCV)

In order to minimize the risk of generating replication competent virus in target cells or tissues the IBC has adopted the following policy for safety and consistency.

All Principal Investigators and research staff must comply with this policy as required by the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules.

IBC Requirements

Viral testing is not generally required if:

- Experiments are conducted entirely in tissue culture.
- Less than 100 ml of supernatant is produced.
- The transgene is not an oncogene, proto-oncogene or does not code for a potential toxin.
- A third generation SIN (self-inactivating) commercially available lentiviral system is used according to manufacturers specifications.

Testing is required, if:

- Confirmation of the absence of RCV must be documented by the researcher prior to use in animals. Documentation of methodology and results must be available to the BSO. Researchers will destroy all batches in which replication competent virus is detected and notify the BSO within one business day of competent virus detection.
- A current procedure of demonstrated sensitivity and specificity must be used.
• A positive control is required. However, working with infectious HIV-1 when testing for RCL would not be appropriate. A standard p24 ELISA kit with a sensitivity of \( \leq 12.5 \text{ pg/ml} \) is recommended. Acceptable kits can be obtained Cell Biolabs or Perkin Elmer.