Facility for Life Science Automation

LISA

Conditions of use of the Open Biosystems Lentivirus pGIPZ-shRNAmir libraries

(1) License Agreement with Open Biosystems

The Biological Materials provided by Open Biosystems and any Biological Materials derived from them are for the sole and exclusive use of the Principal Investigators listed in the license agreement (*attached*). The transfer of Biological Materials to any Non-Licensee, whether For-Profit or not, whether in Collaboration or not, is prohibited by the agreement. Any confidential information obtained from OpenBiosystems or through the use or application of the Biological Materials is to be held confidential until 3 years after the expiry of the license agreement in June 2013.

The following two exemptions apply.

1.1 Transfer of cell lines and animal models derived from the Biological Materials for the sole and exclusive use in Collaboration is permitted (Clause 2.3). Cost recovery for such provision is permitted (Clause 2.3.3).

These cell lines and animal models must be accompanied by a printed copy of the Limited Label License (attached), and the Principal Investigator receiving the materials shall sign and return a copy of the Limited Label License which shall be held on file by LISA. You are required to inform LISA of any redistribution of biological materials. LISA is liable to make available that information to Open Biosystems upon reasonable request.

1.2 Screening Services through the use or application of Biological Materials are permitted to Collaboration Non-Institute investigators provided that the resulting deliverables are limited to data (Clause 2.5). Costs recovery is permitted. Screening Services for For-Profit Entities are strictly prohibited.

Open Biosystems does not intend to put any limits on the use of the pGIPZ-shRNAmir system as long as it stays within the IMB.

(2) OGTR DNIR 452

OpenBiosystems' Translentiviral Packaging System does currently not qualify as a 3rd generation system under Australian law. Work with this system is granted by the Office of the Gene Technology Regulator to the University under license OGTR DNIR452 (Teasdale / Gonda) (*attached*) within the rooms and facilities listed in the license only. Authorization to work under this license is subject to your group leader having signed an independent form. Any work potentially producing viral particles with the Translentiviral System must adhere to the limitations and regulations stated within OGTR DNIR452.

Keypoints:

2.1 License holder is the University of Queensland, and all users are required to undergo an introduction session to be informed of the condition of the license. Individuals should organise this directly with UQ Biosafety Officer Peter Leeton (p.leeton@uq.edu.au). LISA keeps a record of this and will restrict access to viral reagents.

2.2 The license is restricted to the pGIPZ Open Biosystems platform. All other systems will require an alternative OGTR license.

2.3 The license covers cell based work only (*e.g.* no whole animal or introduction of transduced cells into animals. Contact Peter Koopman or Melissa Little for alternative existing licenses.)

2.4 The license covers the PC2 lab areas on all seven floors within the IMB. However, it is your sole responsibility to ensure your work area is listed and to work with and store virus exclusively in these areas. Further limitations due to IMB Lentivirus guidelines may apply.

2.5 All viral materials and their disposal needs to be recorded in the IMB Freezer Database with virus stocks stored in *Remarkables*, which will be located on Level 1 XXX. All information including record or disposal needs to be entered. This will be audited and non-compliance will result in removal of permission to use the license.

2.6 The use of pGIPZ-shRNAmir without the generation of viral particles, *i.e.* in transient transfections, is unaffected by this license. Normal regulations apply. However, if you later change to producing virus without proper induction, you are in breach with Australian law.

2.7 OGTR DNIR 452 is effective 22/12/2008 - 31/01/2014. Continued use or storage after the expiry is subject to renewed approval by the OGTR. In the absence of a new license, it will be your responsibility to dispose of any viral materials according to Australian law. It is your responsibility to inform your group leader about any viral materials left behind before you leave the IMB.

For your information:

The Translentiviral Packaging System developed by Kappes *et al* is <u>not</u> a 2nd generation system. It is a new 5 plasmid system designed to enhance safety even further than 3rd generation systems and widely acknowledged as as safe or safer than conventional 3rd generation systems. Its most important new feature is the provision of the reverse transcriptase (RT) and integrase (IN) in trans, producing a class of vectors that contain split gag-pol components on separate vectors. The *trans*-vector was evaluated in side-by-side experiments with conventional 3rd generation and SIN vectors for its ability to recombine and mobilize DNA. In contrast to conventional 3rd generation and SIN vectors, *trans*-vector design prevented the generation of recombinant lentivirus containing a functional gag-pol structure, which is absolutely required for retroviral DNA mobilization and the emergence of replication competent retrovirus. It is due to these safety enhancements that the *trans*-lentiviral system does not fulfil the specifications required by Australian law and could not be classified as a 3rd generation system. It is very likely to be included in the relevant Australian law during its next revision. Literature and more detailed information about the system's safety features is available from LISA upon request.

(3) IMB Lentivirus Guidelines

All work using Lentivirus including the pGIPZ Open Biosystems Platform needs to be performed according to the IMB guidelines (*attached*). Currently, you may be required to conduct all individual viral work in the IMB Lenti Virus Suite located in Room 1.109. Access to this communal space is regulated by Jill Bradley. Make sure you have current PC2 training, read the Lenti Suite Guidelines (*attached*), arrange for an induction with Jill, prepare and/or sign off on all relevant risk assessments, and pass a buddy test with a fellow Lenti Suite user. Please contact Jill Bradley (j.bradley@imb.uq.edu.au) for any further questions regarding these guidelines.

If you are unsure about any issue covered in this document do not hesitate to contact LISA for assistance and clarification and use the expertise of your floor manager, Jill Bradley, or Paul Lovelock.

Attachments:

Limited Label License OBS shRNAmir.pdf
OGTR DNIR 452 License.pdf
UQ IBC Recommendations for working with retroviral vectors
Lenti suite guideline 4.4.pdf

Version:	Date:	Author:	Approved:
1.0	18 June 2009	Michael Hanzal-Bayer	Rohan Teasdale