CHILDREN'S MEDICAL RESEARCH INSTITUTE
Jeans for Genes®

Internal Notes:
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Shipped/picked up on:_____

# Vector and Genome Engineering Facility (VGEF) Recombinant viral vector Request Form – External Academic / For-Profit Organisation

Use this form if there is no collaboration arrangement between CMRI and the Recipient(s), or if the Recipient(s) is a company or other for-profit organisation. To place an order, email this completed form to Dr Predrag Kalajdzic, Staff Scientist at **pkalajdzic@cmri.org.au**.

Before placing an order, please review the checklist below to ensure you have supplied or can supply all requisite information and materials.

**The Requesting Investigator must provide VGEF with the following:**

- □ verified expression plasmid compatible with the vector system being ordered;
- □ 200ug plasmid DNA for standard AAV production or LV production;
- □ 1mg of plasmid DNA for large scale AAV production;
- □ all plasmids provided must be produced using Endotoxin-free DNA kit (<0.1 EU/ µg), such as Qiagen Endo-Free Maxi or Megaprep or equivalent. *Note: VGEF does not accept miniprep purified DNA to be used directly for production.*
- □ picture of control digest to verify plasmid integrity and DNA quality;
- □ evidence that plasmid DNA has been checked for purity and has an A260/280 of >1.8.
- □ for AAV constructs, VGEF requires three separate enzyme (XmaI or SmaI, AhdI and MscI) digest to verify ITR integrity. *Note: excessive amounts of linearized full-length plasmid indicate recombination has occurred.*
- □ Vector map and Sequence file – VGEF encourages you to submit your plasmids to our vector library. *Note: CMRI will be happy to work with you on establishing Material Transfer Agreements for your reagents.*
- □ Information about your gene of interest or insert and any special requirements for handling and storage e.g. Toxicity, oncogenic, pro-apoptotic etc.

*Additional information:*

*(i) Completed order forms remain subject to acceptance by CMRI and the Requesting Investigator and/or Recipient(s) of the accompanying material transfer agreement which sets out limitations on the permitted use of the biological materials to be supplied by CMRI.*

*(ii) The Requesting Investigator is required to provide details of any collaborating investigators/institutes to be given access to the vectors and/or any additional sites the vectors will be transferred to (see Section 4 of the order form).*

Please contact the VGEF team to discuss any concerns regarding these criteria and to review your specific requirements and determine the most suitable approach:
**Dr Predrag Kalajdzic, Staff Scientist at pkalajdzic@cmri.org.au**
**https://www.cmrijeansforgenes.org.au/research/research-facilities/vector-and-genome-engineering-facility**

**Ethical approval:** _____ **NHREC number**: _____
By signing here I, _____ (*print name*), confirm that I have received appropriate human ethics approval allowing human material reprogramming into induced pluripotent stem (iPS) cells.

Signature of Principal investigator:_____

## 1. Billing information (to be completed by the Principal Investigator):

| | |
|---|---|
| **Principal Investigator (PI):** | **Requesting Investigator / Lab contact:** |
| **Order Date:** | **Contact Phone:** |
| **By signing here I,……, confirm that the activity involving the use of reagents ordered from CMRI's VGEF has been approved by appropriate Institutional Biosafety Committee (IBC).**<br><br>**(signature of the PI)**<br><br>**Your institution IBC approval number:** | |
| **Fund number or Purchase Order Number:** | **Contact E-mail:** |
| **Billing address:** | **Shipping address (if different to Billing Address):** |

## 2. CONSTRUCT INFORMATION

**CONSTRUCT NAME:**

**INFORMATON REGARDING PLASMID PROVIDED TO CMRI's VGEF:**

| Insert (bp): | Plasmid (bp): | Volume (ul): | Concentration (ug/ul): | A260/A280: |
|---|---|---|---|---|
| | | | | |

**INFORMATION NEEDED FOR VSV-g PSEUDOTYPED LENTIVIRAL ORDERS**

**TRANSFER PLASMID TYPE**

- ☐ 3rd gen SIN HIV-1 5'LTR
- ☐ 3rd gen SIN RSV 5'LTR
- ☐ 3rd gen SIN CMV 5'LTR
- ☐ OTHER (PLEASE DESCRIBE):

**TITRATION ONLY:**

- ☐ Transduction + QPCR
- ☐ FACS

☐ Crude LV production (without purification). Each crude LV production gives 15ml (up to 30ml) final volume per single plate. Number of plates requested: _____

☐ **Concentrated LV production (with purification). Each concentrated LV production gives final volume between 100ul and 250ul which is aliquoted in specified volumes (between 5ul and 50ul). If you would like the prep to be concentrated, please indicate the final volume and volume of the aliquots requested:_ _____**

**INFORMATION NEEDED FOR AAV ORDERS:**

☐ **Crude AAV production (without purification). Number of plates requested:_____**

☐ **Small scale production – Iodixanol purification. Final Volume Requested:* _____ ul**

☐ **Large scale production – CsCl purification. Final Volume Requested:* ~1000ul**

**SEROTYPE NEEDED (Please describe the requested rAAV variant below):**

Alternatively, contact the VGEF team to discuss your specific requirements and determine the most suitable rAAV variant:
Dr Predrag Kalajdzic, Staff Scientist (pkalajdzic@cmri.org.au)
https://www.cmrijeansforgenes.org.au/research/research-facilities/vector-and-genome-engineering-facility

**TITRATION ONLY:**

☐ **QPCR** ☐ **ddPCR**

* - **Iodixanol purification** protocol gives 500ul final product, while **CsCl purification** protocol gives 1mL final product. Volumes of both production protocols can be further concentrated to as little as 100ul, which will increase the concentration/ul, but not the total number of particles. Please indicate the final volume you want your preparation to be concentrated to **prior** to titration.

**INFORMATION NEEDED FOR ADENOVIRAL ORDERS:**

☐ **E1 deleted Ad5 amplified from Pac1 digested DNA**

☐ **E1 deleted Ad5 amplified from viral stock**

☐ **OTHER (PLEASE DESCRIBE):**

**Attach picture of restriction digest confirming plasmid integrity:**

## 3. PROJECT DESCRIPTION:

**To be completed by Recipient**

**Give a brief overview of the Project and its aims and how vectors will be used:**

## 4. PERMITTED SITES

### a. REQUESTING SITE

| **Please provide details of Requesting Investigator's laboratory or institute:** |
|---|
| |

### b. ADDITIONAL PERMITTED SITES

**If the Project requires the vectors supplied by VGEF to be transferred to any laboratory or institute other than the Requesting Investigator's laboratory or institute and/or to be shared with or distributed to any external collaborators or to any researchers other than researchers working under the direct supervision of the Requesting Investigator, please provide details:**

| | |
|---|---|
| **Organisation Name(s):** | |
| **Address Details:** | |
| **Contact person(s):** | |
| **Telephone No:** | |
| **Email Address:** | |
| **Planned activities:** | |
| **Name and contact details of the responsible person(s):** | |
| **IBC approval for Additional Permitted Site(s):** Please provide details or attach evidence of IBC approval | |

**Note:**

1. CMRI reserves the right to enter into a separate material transfer agreement with any external collaborators or researchers identified in this section 0 for the permitted use of the biological materials to be supplied by CMRI.
2. Following the execution of this request form, if the Project requires the vectors supplied by VGEF to be transferred to an additional laboratory or institute (other than those identified in this section 4), please contact VGEF and supply the details of any additional site(s).

## 5. BIOHAZARD DETAILS

**Describe any potential or expected toxicity or additional biohazardous concerns, in particular expression/knockdown of oncogenes or tumor suppressor genes, and expression of inserts that may induce apoptosis:**

## 6. PERMITTED USE DESCRIPTION

**To be completed by VGEF**

**Give a brief description of the Project and use of the vectors based on the Project Description (section 3 above) and any other changes or special terms to the Project as agreed with the Principal Investigator and/or Requesting Investigator.**

## 7. SUPPLIED TRANSFER PLASMID

**Attach a map for the supplied transfer plasmid:**

# TERMS AND CONDITIONS OF SALE AND LIMITED USE AGREEMENT BETWEEN THE CHILDREN'S MEDICAL RESEARCH INSTITUTE AND RECIPIENT OF MATERIALS

This agreement is made and entered into by and between the **Children's Medical Research Institute (ABN 47 002 684 737)** of 214 Hawkesbury Road, Westmead, NSW 2145 (**CMRI**) and the entity named in the accompanying CMRI recombinant viral vector request form for the provision of CMRI's proprietary materials to Recipient on the terms set out below.

## 1. DEFINITIONS

**Commercial Purposes** means the sale, lease, licence or other transfer of the Materials or Modifications to a for-profit organisation, or use of the Materials or Modifications by any organisation (including Recipient) to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, licence, or transfer of the Materials or Modifications to a for-profit organisation (including the grant of an option to do any of the foregoing).

**Confidential Information** all know-how, technical and financial information, materials and any other commercially valuable or sensitive information in whatever form, including inventions (whether or not reduced to practice), trade secrets, formulae, graphs, drawings, samples, devices, models and any other materials or information of whatever description, which CMRI regards as confidential, proprietary or of a commercially sensitive nature. The following are exceptions to such information (and Recipient bears the burden of establishing the existence of such exceptions):

(a) information which is lawfully in the public domain prior to its disclosure by CMRI;

(b) information which enters the public domain otherwise than as a result of an unauthorised disclosure;

(c) information which is or becomes lawfully available to Recipient from a third party who has the lawful power to disclose such information to Recipient on a non-confidential basis; and

(d) information which is rightfully known or independently developed by Recipient prior to the date of disclosure.

**Intellectual Property** means statutory and other proprietary rights in respect of copyright and neighbouring rights; all rights in relation to inventions, patents, know-how, plant varieties, registered and unregistered trademarks, registered and unregistered designs, circuit layouts and rights to maintain the confidentiality of information, but does not include moral rights that are not transferable.

**Liabilities** means any and all, losses, claims, damages, liabilities, obligations, penalties, judgments, awards, costs, expenses, and disbursements, including, the costs, expenses and disbursements, as and when incurred, of investigating, preparing, or defending any action, suit, proceeding, or investigation asserted by a third party (including reasonable and expenses).

**Material** means the lentiviral vectors, adeno-associated viral vectors and adenoviral vectors, generated by the CMRI Vector and Genome Engineering Facility. Unless the context requires otherwise, the Material also includes all Progeny and Unmodified Derivatives any related information or material supplied in connection therewith by CMRI.

**Modifications** mean substances created by Recipient which contain or incorporate any of the Materials, other than Progeny and Unmodified Derivatives.

**Permitted Site(s)** means (a) the Requesting Investigator's laboratory or institute, or (b) a laboratory or institute other than the Requesting Investigator's laboratory or institute identified as an Additional Permitted Site in the CMRI Recombinant viral vector request form and which CMRI has provided written consent for the distribution, handling, storage, and use of Material.

**Permitted Use** means for the research purposes as agreed and outlined in the Permitted Use Description (Section 6) in the CMRI Recombinant viral vector request form, and excludes Commercial Purposes.

**Personnel** means a party's employees, officers, directors or other authorized representatives, and in the case of Recipient includes the Recipient Scientist.

**Progeny** means an unmodified descendant of the Materials, including virus from virus, cell from cell, or organism from organism.

**Proposed Use** means the research project and aims outlined in the Project Description (Section 3) in the CMRI Recombinant viral vector request form.

**Recipient** means the organisation, laboratory or institute identified as Recipient in the CMRI Recombinant viral vector request form.

**Requesting Investigator** means the Requesting Investigator identified in the CMRI Recombinant viral vector request form.

**Results** means the data, results, output and methodology of or arising out of Recipient's use of the Materials, as well as any accompanying reports, feedback and other deliverables and materials. The Results do not include any proprietary methods forming part of Recipient's pre-existing Intellectual Property.

**Unmodified Derivatives** means substances created by Recipient which constitute an unmodified functional subunit or product expressed by the Material. Unmodified Derivatives include:

(a) purified or fractionated subsets of the Materials;

(b) proteins expressed by DNA/RNA supplied by CMRI; or

(c) monoclonal antibodies secreted by a hybridoma cell line.

**2. THE RECIPIENT AND REQUESTING INVESTIGATOR WILL:**

(a) Use the Materials and CMRI's Confidential Information only for the Permitted Use.

(b) Use, handle, store, transport and dispose of the Materials safely and in compliance with all laws, regulations, and OGTR's guidelines.

(c) Be responsible for any injury or damages that your use may cause.

(d) Keep the Materials secure and prevent unauthorized use of or access to the Material;

(e) Ensure that the Materials are only used at the Permitted Sites and only for the Permitted Use, and under the direction and/or supervision of the Requesting Investigator;

(f) Keep CMRI's Confidential Information confidential, not disclose it to third parties without CMRI's consent and only use the Confidential Information exclusively for the Permitted Use and no other purpose.

(g) Immediately notify CMRI on becoming aware of:

(i) any unauthorised person coming into possession of any part of the Materials or any Confidential Information;

(ii) any unauthorised person doing anything in contravention of rights that attach to and arise from the Materials or Confidential Information,

and report full particulars to CMRI and provide all reasonable assistance and information CMRI may request with respect to that unauthorised act.

(h) Notify CMRI and obtain CMRI's written consent prior to using the Materials or Confidential Information beyond the Permitted Use or using, transferring to, or storing the Materials at a location other than a Permitted Site.

(i) Acknowledge CMRI's Vector and Genome Engineering Facility as the source of the Materials in any publications, oral presentation or other public disclosure referring to the Materials, Modifications or Results.

(j) Return or destroy the Materials at the end of the Permitted Use.

(k) Retain ownership of: (i) Modifications (except that CMRI retains ownership of Material incorporated therein) and (ii) those substances created through the use of Material, but which do not contain or constitute Material.

(l) Indemnify CMRI and its Personnel and keep them indemnified from and against Liabilities arising out of or in connection with Recipient's or its Personnel's use, handling, storage, transport or disposition of the Materials or Modifications or breach of this agreement, unless such Liabilities (if any) directly result from CMRI's gross negligence, or breach of this agreement.

(m) Pay CMRI for actual shipping costs or provide courier account number.

**3. THE RECIPIENT AND REQUESTING INVESTIGATOR WILL NOT:**

(a) Sell, transfer, disclose or otherwise provide access to the Materials to any third party other than at a Permitted Site(s), and only for the Permitted Use, and under the supervision of the Requesting Investigator, unless CMRI has given its express written consent beforehand.

(b) Use the Materials or any products containing or derived from the Materials in humans, or use them in human diagnosis or treatment.

(c) Use the Materials for Commercial Purposes.

(d) Have a license to CMRI's Intellectual Property and Confidential Information beyond use of Materials for the Permitted Use.

(e) Have a right, claim, or interest in CMRI's Confidential Information.

(f) Use the name of the Materials in any media release or promotional materials without the written consent of CMRI.

(g) Assign, novate or sub-contract this agreement to any other party without CMRI's prior written consent.

**4. LEGAL LIMITATIONS:**

(a) CMRI PROVIDES THE MATERIALS "AS IS," AND CMRI DISCLAIMS AND PROVIDES NO REPRESENTATION OR WARRANTY WHATSOEVER.

(b) WITHOUT LIMITING (a) ABOVE, CMRI DISCLAIMS AND PROVIDES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, EXPRESS OR IMPLIED.

(c) WITHOUT LIMITING (a) ABOVE, CMRI DISCLAIMS AND PROVIDES NO REPRESENTATION OR WARRANTY THAT USE OF THE MATERIALS WILL NOT INFRINGE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

(d) CMRI IS TO HAVE NO LIABILITY TO RECIPIENT, HOWEVER ARISING UNDER ANY CAUSE OF ACTION OR THEORY OF LIABILITY, IN RESPECT OF SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, LOSS OF PROFIT OR LOSS OF BUSINESS OPPORTUNITY.

(e) This is the whole agreement, and it can only be amended in writing.