HARVARD MEDICAL SCHOOL | MASSACHUSETTS EYE AND EAR INFIRMARY

DEPARTMENT OF OPHTHALMOLOGY

SCHEPENS EYE RESEARCH INSTITUTE | OCULAR GENOMICS INSTITUTE

**GENE TRANSFER VECTOR CORE**

Custom AAV request form

**Vector core use only**

Date Received

ID# assigned

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Purchaser Contact Information | | | |
| Principal Investigator | **Martin Marsala, MD** | Lab contact |  |
| Division/Institute | **UCSD** | Division/Institute |  |
| Phone | **858 232 3081** | Phone |  |
| Fax |  | Fax |  |
| Email | **mmarsala@ucsd.edu** | Email |  |

|  |  |
| --- | --- |
| 2. Purchaser Billing and Shipping Information | |
| Quote requested | **X Yes No** |
| PO  or fund number  (for SERI researchers) |  |
| Billing address |  |
| Shipping address |  |

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| 3. Vectors |
| a. Project Description |
| Give a brief overview of the project and its aims  Testing Anc80 after spinal subpial delivery in pigs and NHP. |

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| b. Custom rAAV production | | |
| For vector core use ID# | | |
| a) Plasmid/clone name: | | **pscAAV-UBC-eGFP** |
| b) Expression cassette  (promoter + transgene + regulatory elements) | | **UBC promoter-eGFP-SV40 PolyA** |
| c) Transgene expression size (ITR – ITR, ITR included)(max. capacity is 4.75kb)\* | | **2.5kb** |
| d) Are you providing helper plasmid? | | **Yes No No** |
| e) Serotype | | **Anc80L65** |
| f) Application (in vitro/in vivo) | | **in vivo** |
| g) Requested scale (mini, midi, maxi – or absolute particle requirement) | |  |
| c. Supporting plasmid DNA services | | |
| 1. Basic cloning (AAV-cis or other) |  | |
| 1. AAV prep quality control (Titer, Purity, Clonality) | **AAV prep, Titer** | |
| 1. DNA sequence analysis (ITR to ITR sequencing) |  | |
| d. Please complete the following if source material will be provided | | |
| a) DNA volume (µl) | **N/A** | |
| b) DNA concentration (µg/ul) | **N/A** | |
| c) OD 260/280nm | **N/A** | |
| d) Purification method (Qiagen Endotoxin free kit required) | **N/A** | |
| e) Quality control N/A |  | |
| Diagnostic restriction digest to confirm integrity of ITR region and insert need to be provided.  Note: MSCI, XmaI or AhdI digest are the default enzymes for intact ITR confirmation.   1. Attach picture and map of restriction digest confirming digest plasmid integrity (ITR and insert) 2. Please provide sequence in attachment (vector nti format preferred)   Submission incomplete without sequence and digest information. Incomplete information will delay production. | | |
| f). Additional requirements | | |
| We request and appreciate that the investigators inform and acknowledge us in any publication using an rAAV derived from the Core. | | |

**\* Note that our standard release criteria will not apply for vectors with over-size genomes (>4.75kb)**

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| 4. Compliance | | | |
| To comply with federal, state and local guidelines, approval is required at the institutional level to be able to possess or work with Biohazardous materials. Materials produced by GTVC require BL1 level biocontainment for plasmids and rAAV. | | | |
| Does the product your vector produces toxic or oncogenic? Yes X No  X | | | |
|  | COMS/IBC protocol must be approved before vector can be delivered. Protocol may be submitted/pending at the time of request. | COMS/IBC protocol # |  |
| Approval date |  |
|  | I have been informed that the materials requested are bio hazardous and I have consulted the applicable federal, state and local guidelines (initial and date) | | **\_\_\_\_\_\_/\_\_\_\_\_** |
| Note: If you are requesting viral vectors for in vivo use, you must have approval from your Institutional Animal studies Committee (IACUC). | | | |

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| 5. Signature of Principal Investigator | | | | | |
| By signing this document, I acknowledge that I have read the form and all the information provided is correct | | | | | |
| Name | **Martin Marsala, MD** | Signature |  | Date | **1/9/2019** |

**Appendix A**

Terms and Conditions for Custom AAV Request Form

1. Massachusetts Eye and Ear Infirmary and The Schepens Eye Research Institute, Inc. (hereinafter “MEE”) hereby grant to the Purchaser a non-exclusive, internal research use license to Anc80 for the purpose of evaluating the Vectors purchased under this Custom AAV Request Form and Terms and Conditions (the Purpose”). This license pertains to the Vectors purchased through the MEE Vector Core and does not include the right to grant sublicenses to Anc80. Should the Purchaser desire to use the Vectors for any other purpose other than the Purpose, such use will be governed under the terms of a separate agreement. The Vectors are intended for research purposes only and are not intended for use in humans.

2. Purchaser agrees to give credit to GTVC, as appropriate, in any abstract or manuscript resulting from the use of the Reagents in the following way: “AAV vectors were produced by the Gene Transfer Vector Core, Grousbeck Gene Therapy Center at the Massachusetts Eye and Ear Infirmary (Boston, MA) (http://vector.meei.harvard.edu/)”

3. Except for Section 6, these Terms and Conditions, unless terminated as provided herein, shall remain in effect for ninety (90) days from the delivery of the Vectors to Purchaser.

4. MEE has made no investigation and makes no representations whatsoever that the Vectors and other biological materials supplied under this Custom AAV Request Form and Terms and Conditions, or the methods used in making or the use of the materials do not infringe the patents of others.

5. MEE EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE VECTORS AND OTHER BIOLOGICAL MATERIALS, OR INFORMATION SUPPLIED BY MEE, CONTEMPLATED BY THIS CUSTOM AAV REQUEST FORM AND TERMS AND CONDITIONS.

6. Indemnification

a) Purchaser shall indemnify, defend and hold harmless MEE and its trustees, officers, medical and professional staff, employees and agents and their respective successors, heirs and assigns (the “Indemnitees”), against any liability, damage, loss or expense (including reasonable attorney’s fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments: arising out of any theory of product liability (including, but not limited to, actions in the form of contract, tort, warranty, or strict liability) concerning any product, process or service made, used or sold or any right or license granted under the Custom AAV Request Form and Terms and Conditions.

b) Purchaser’s indemnification under this Section 6 shall not apply to liability, damage, loss or expense to the extent that it is directly attributable to the negligent activities, reckless misconduct or intentional misconduct of the Indemnitees.

c) Purchaser agrees, at its own expense, to provide attorneys reasonably acceptable to MEE to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

d) This Section 6 shall survive expiration or termination of the Terms and Conditions.

7. Purchaser shall not distribute or release the Vectors to others without the written permission of MEE. Purchaser shall protect the Vectors at least as well as it protects its own valuable tangible personal property and shall take measures to protect the Vectors from any claims by third parties including creditors and trustees in bankruptcy.

8. Purchaser shall comply with all applicable laws and regulations. In particular, it is understood and acknowledged that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations among other things, prohibit or require a license for the export of certain types of technical data to certain specified countries. Purchaser hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by Purchaser or its affiliates, and that it will defend and hold MEE harmless in the event of any legal action of any nature occasioned by such violation.

9. The Custom AAV Request Form and the Terms and Conditions constitute the entire understanding between the parties and neither party shall be obligated by any condition or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

10. The interpretation and application of the provisions of the Terms and Conditions shall be governed by the laws of the Commonwealth of Massachusetts.