O.D.260 Inc.

PO Box 534 • Boise • ID 83701 Phone (208)345-7369 • FAX (208)345-7569 E-mail <u>info@od260.com</u> www.od260.com

Adenovirus Registration and Biosafety Form

All use of adenovirus vectors at OD260 Inc must be approved by the Scientific Research Review Committee (SRRC) through the registration process. Please note that the NIH guidelines, to which the SRRC adheres, stipulate that review and approval of any project must be obtained before OD260 Inc. can begin work.

TO REGISTER:

- Please complete ALL sections of the registration form below (ONE FORM PER VIRUS)
- Email the form to info@od260.com.
- OD260 Inc. will evaluate your submission and give you a tentative approval date for your project. If you have any question about this form please contact us at info@od260.com or call us at (855)260-2606 (USA toll-free) or 1-208-345-7369 (worldwide).

AN IMPORTANT NOTE ON HANDLING ADENOVIRUS:

Adenovirus is an infectious respiratory virus and its use as a genetic vector requires the use of adequate containment equipment and practices. Biosafety Level 2 (BL2) is appropriate for most customers; however, for some, use of BL3 or higher level containment facility may be required. Please note that OD260 Inc will not carry out projects that require BL3 (or higher) containment.

1. Contacts

First Name	
Last Name	
Title	
Organization	
Department	
Address	
Phone	
Fax	
Email	

2. The Service

1.1 What service are you interested in? (e.g. virus construction, amplification, titration,)	
1.2 Proposed title for your project (include virus name):	

3. Your Gene of Interest

3.1 What is the gene(s) to
be cloned, including
species from which it is
derived, and nature of the
clone (e.g. genomic,
cDNA, wild-type, mutant)?
, , , , , ,

3.2 Briefly describe the	
biological function of the	
protein(s) you want to	
express. Include its	
(their) normal function(s)	
and your specific goal.	
Please provide details of	
its (their) function	
relevant to Biosafety.	
3.3 Explain what	
element(s) (promoter)	
will control the	
expression of your gene.	
3.4 Is your gene of	
interest involved in cell	
growth control (i.e.	
oncogene, tumor	
suppressor, growth factor,	
cytokine, inducer or	
inhibitor of apoptosis)?	
3.5 Might the expression	
of your gene of interest	
result in tumor	
induction? Note that	
when adenovirus	
replication is blocked, as	
from a deletion of the E1	
region, the viral	
chromosome may	
integrate with a host	
chromosome.	
3.6 Can your gene of	
interest be converted to	
an oncogene or other	
pathogenic form by	
spontaneous mutation,	
e.g., during virus	
propagation?	
3.7 Does your gene of	
interest encode a toxic	
product?	
product:	
3.8 Does your gene of	
interest confer drug-	
resistance?	

3.9 Does your gene of interest contain elements (promoter, coding sequence) from any other virus (e.g. vaccinia, retrovirus, herpes)?
3.10 In which plasmid vector will your gene of interest be provided? (virus construction only)

4. Your virus

4.1 What is the serotype of the adenovirus to be used? (Ad5, Ad2, Ad35, Ad11, other)	
4.2 If you are not using Ad5, state whether it is	
oncogenic and the reason for choosing it instead of	
Ad5. Please note that after reviewing this form	
we may also request from you a detailed map	
showing structures of the vector and the	
recombinant.	
4.3 Please list the adenovirus genes that will be deleted from your	
vector (e.g. E1A, E1B, E3, E2A, E2B, E4).	
4.4 Have you tried, or do you know anybody or any company who has tried to make/amplify the same virus that you are asking us to make/amplify? Was it successful? If not, which method was used?	

5. Your virus and the Environment

The following questions relate to the infectivity of your recombinant virus. Please consider these questions carefully. Remember that although your recombinant virus may not be able to replicate on its own, adenoviruses are common in the environment and are contagious. Co-infection with a wild-type virus may result in the spread of the recombinant through aerosols and/or feces.

5.1 Is the product of your	
gene of interest secreted	
from the cell? If so,	
might systemic	
expression of your gene	
product be hazardous to	
an individual?	
5.2 What adverse effect	
might result from	
inhaling (or other	
exposure to) the	
recombinant virus	
containing your cloned	
gene? Adenovirus can	
infect the respiratory	
tract and the gut. If this	
would result in the	
expression of your gene	
in tissue(s) where it is	
normally not expressed,	
what effects might this	
have?	
5.3 What containment	
level do you propose for	
this work? (BSL2, BSL3,	
other)	
5.4 Does the work you	
are planning involve	
intentional release of	
recombinant organisms	
to the environment?	